STATUTORY INSTRUMENTS
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STATUTORY INSTRUMENTS SUPPLEMENT

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S T A T U T O R Y I N S T R U M E N T S

2014 No. 29.

THE NATIONAL DRUG POLICY AND AUTHORITY (REGISTRATION) REGULATIONS, 2014

ARRANGEMENT OF REGULATIONS

Regulation.

Regulation.

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S T A T U T O R Y I N S T R U M E N T S

2014 No. 29.

The National Drug Policy And Authority (Registration) Regulations, 2014

(Made under Sections 35 and 64 of the National Drug Policy and Authority Act, Cap. 206)

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 64 of the National Drug Policy and Authority Act and on the advice of the National Drug Authority, these Regulations are made this 24th day of March, 2014.

PART I—PRELIMINARY

1. Title.

These Regulations may be cited as the National Drug Policy and Authority (Registration) Regulations, 2014.

2. Application.

These Regulations apply to the registration of—

(a) human and veterinary drugs and preparations including herbal medicine products for human and veterinary use;

(b) vaccines and other immunological products for human and veterinary use; and

(c) surgical instruments.

3. Interpretation.

In these Regulations, unless the context otherwise requires—

"Act" means the National Drug Policy and Authority Act, Cap. 206;

"active ingredient" means the antigenic substance or compound of an antigenic substance that induce specific responses in humans and animals against an infectious agent, its antigens or toxins;

"active pharmaceutical ingredient" means any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of a human being or animals;

"antigen" means a substance that when introduced into the body stimulates the production of an antibody and includes toxins, bacteria, foreign blood cells, and the cells of transplanted organs;

"Authority" means the National Drug Authority;

"batch" means a defined quantity of starting material, packaging material, or product processed in a single process or series of processes and in the case of continuous manufacture, means a defined fraction of the production, characterised by its intended homogeneity and includes lot;

"batch number" means a distinctive combination of numbers or letters which specifically identifies a batch, on the labels, the batch records and the certificates of analysis of a manufactured product and includes lot number;

"bulk product" means any product that completes all processing stages including the final packaging;

"commitment batch" means the production batches of an active pharmaceutical ingredient or finished pharmaceutical product for which the stability studies are initiated or completed post-approval through a commitment made in a regulatory application;

"diagnostic antigen" means a crude or purified fraction isolated from the microbial culture and intended for in vitro detection of an existing specific immune response or antibodies;

"dosage form" means the physical form in which a product is prepared for administration to the recipient;

"drug" includes a herbal medicine product which is packaged for commercial purposes;

"generic product" means a drug which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference drug , and whose bioequivalence with the reference drug has been demonstrated by appropriate bioavailability studies;

"herbal medicine product" means a finished, labeled herbal medicine product that contain as active ingredients aerial or underground parts of plants, or other plant materials, or a combination of these, whether in the crude state or as plant preparations and which may contain conventional excipients in addition to the active ingredients and may also contain by tradition, natural organic or inorganic ingredients which are not of plant origin;

"immunological product" includes vaccines, immunoglobulins and antisera and in vitro diagnostic antigens;

"indication" means the intended use of the product;

"in-process control" means checks performed during production in order to monitor and if necessary, to adjust the process to ensure that a product conforms to its specifications and includes the control of the environment or equipment;

"licensed person" means a person licensed under the Act;

"manufacturer" means a person licensed to manufacture drugs or active pharmaceutical ingredients;

"manufacturing process" means the transformation of starting materials into finished products including drug substances or pharmaceutical dosage forms through a single operation or a sequence of operations;

"master cell seed" means a collection of aliquots of a preparation of cells, for use in the preparation of a product, distributed into containers in a single operation and processed together in a manner that ensures uniformity and processed and stored in a manner that ensures stability;

"master formula" means a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a manufactured product as well as the processing instructions, including the in-process controls;

"ongoing stability study" means the study carried out by a manufacturer on production batches according to a predetermined schedule in order to monitor, confirm and extend the projected re-test period or shelf-life of the active pharmaceutical ingredient, or to confirm or extend the shelf-life of the finished pharmaceutical product;

"patent holder" means an owner of a patent for a particular product seeking to register the product;

"pharmaceutical form" means the form stating—

(a) the presentation of a product including solution, suspension, eye drops, emulsion, ointment, suppository, tablet, capsule;

(b) in case of injections, the type of presentation including vial and ampoule; and

(c) the dental cartridge and the type of content including powder for reconstitution, solution, suspension, oily solution;

"pharmaceutical product" means any medicine intended for human use and a veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in the dosage form;

"primary batch" means a batch of an active pharmaceutical ingredient or finished pharmaceutical product used in a stability study, from which stability data is submitted in an application for registration for the purpose of establishing a re-test period or shelf-life;

"product" means a drug or preparation for human or veterinary use or a vaccine or other immunological product;

"production" means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the product;

"production batch" means a batch of an active pharmaceutical ingredient or finished pharmaceutical product, manufactured at production scale by using production equipment in a production facility as specified in the application;

"proprietary name" means the trade or brand name which is unique to a particular product and by which the product is generally identified and registered in the country of manufacture;

"reprocessing" means the reworking of all or part of a batch of a product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations;

"shelf life" means the time during which the quality of the product remains acceptable for its intended use, established based on stability studies;

"starting material" means any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials;

"validation protocol" means a document describing the activities to be performed in a validation exercise;

"validation report" means a document in which the records, results and evaluation of a completed validation program and proposals for the improvement of processes or equipment are assembled.

4. Registration of drugs, preparations, vaccines and other immunological products.

(1) All products shall be registered in Uganda before sale or distribution.

(2) A person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product.

5. Register of drugs, preparations, vaccines and other immunological products.

The Authority shall maintain a register of the drug or preparation, vaccine or other immunological products registered under these Regulations, in the format specified in Schedule 1 to these Regulations.

6. Application for registration.

(1) An application for registration of a product shall be made to the Authority in the prescribed Form 1 of Schedule 2 to these Regulations for human or veterinary drugs and preparations and Form 2 of Schedule 2 for vaccines and other immunological products.

(2) An application for registration of a product may be made by—

(a) the patent holder;

(b) a licensed person;

(c) the manufacturer; or

(d) an agent authorised by the manufacturer or patent holder.

(3) The application shall state—

(a) the name, physical address, email address, the telephone and fax number of the applicant;

(b) the proprietary name of the product;

(c) the approved generic name of the product;

(d) the particulars of the product;

(e) the strength of the product in per unit form such as mg, mL, IU/G or IU/M, where applicable;

(f) the indication of the intended use of the product;

(g) the description of the product;

(h) the packaging specifications specified in regulation 10;

(i) the studies undertaken in respect of the product, if any;

(j) the safety and efficacy properties of the product;

(k) the chemistry and pharmaceutical form and aspects of the product;

(l) the registration and licensing status of the product in other countries including the country of manufacture;

(m) the particulars relating to the toxicology and pharmacology of the product; and

(n) any other information as may be determined by the Authority.

(4) The application shall be in writing, in the English language and shall in addition to the requirements referred to under subregulation (3) be accompanied by—

(a) two samples of the product;

(b) all the general and specific information and documents relating to the product;

(c) a complete index to the various appendices; and

(d) the prescribed fees.

(5) Where the original documents required under subregulation (4) are in a language other than English, the original documents shall be presented together with certified English translations.

(6) Where an applicant wishes to amend any part of a submitted application, the applicant shall pay the prescribed fees for each proposed amendment.

7. Particulars and activities of manufacturer.

(1) Where the applicant is not the manufacturer of the product, the applicant shall provide in relation to the manufacturer—

(a) the name, physical address, email address, telephone and fax number of the manufacturer; and

(b) a copy of the manufacturing licence.

(2) Where different activities of manufacturing are carried out at more than one site, the applicant shall provide the particulars specified in subregulation (1) in respect of each site, clearly specifying the activity which is carried out at each site.

(3) The applicant shall provide details of—

(a) the procedures used at the various stages of manufacture in the form of a flow diagram accompanied by a list of the equipment used at each stage; and

(b) the analytical, microbiological and other process control procedures and the frequency and sequence in which they are carried out during the manufacturing process.

(4) The applicant shall provide the characteristics of a manufactured product by—

(a) stating the details of the product including—

(i) the name, dosage form and strength of the product;

(ii) the approved generic name of the product, if any;

(iii) the visual description of the manufactured product; and

(iv) the visual description of the packaging for the product; and

(b) stating the regulatory status of the product in other countries including the country of origin.

(5) In addition to the requirements under subregulation (4), the application shall also contain the details of the active pharmaceutical ingredient including—

(a) the nomenclature of the active pharmaceutical ingredients;

(b) the properties of the active pharmaceutical ingredients used;

(c) the site of manufacture for the active pharmaceutical ingredients;

(d) the route of synthesis of the active pharmaceutical ingredients used;

(e) the specifications of the active pharmaceutical ingredients bearing the justification for such specifications;

(f) the container closure system including the description and identification of the components; and

(g) the results of the stability testing.

(6) An applicant for registration of a manufactured product shall in the application furnish the Authority with the following—

(a) a valid licence or other form of authorisation for manufacturing the product;

(b) the pharmaceutical development detailing the studies conducted in relation to the product;

(c) the formulation for a typical batch of the product;

(d) the site of manufacture, where any aspect of manufacture occurs, and the activity performed at the site;

(e) the manufacturing process giving steps of the process and showing where the respective materials are introduced in the manufacturing process;

(f) a copy of the master formula and a copy of a manufacturing record for a real batch;

(g) the documented evaluation of at least three production scale batches to provide assurance that the manufacturing process will reliably meet predetermined specifications;

(h) the manufacturing process controls of critical steps and intermediates;

(i) the manufacturing process validation and evaluation;

(j) the specifications for excipients;

(k) the control of the finished product listing the general characteristics, specific standards, tests and limits for results;

(l) the analytical procedures;

(m) the suitability of the container or closure system and other packaging used for storage and transportation; and

(n) the container labelling sample for the product.

(7) Stability testing and the design of the formal stability testing shall be based on the behaviour and properties of the active pharmaceutical ingredients and the dosage form.

(8) The Authority may, upon application exempt applicants for research based innovation products from the requirement to submit batch manufacturing records.

8. Raw material specifications and details of their analytical methods.

(1) The applicant shall provide the specifications of the raw material to be used and details of the analytical methods used for the raw materials.

(2) Where World Health Organisation Technical Report Series or pharmacopoeial references to specifications and analytical methods are given, photocopies of the references or monographs shall be supplied.

(3) For non World Health Organisation Technical Report Series, non-pharmacopoeial raw materials, the following information shall be provided—

(a) a description of the active immunogenic raw materials;

(b) the pysico-chemical tests conducted;

(c) the biological activity tests conducted;

(d) comprehensive details of the procedures involved in the various stages of the manufacture of the products;

(e) summarised specifications of the manufactured products including the acceptable limits of all the physical and other control procedures carried out to ascertain the specifications of the final product;

(f) the specifications and test methods for all dosage forms;

(g) the batch manufacturing records;

(h) stability studies on the manufactured products; and

(i) test samples.

9. Manufacture of active raw material.

(1) The applicant shall state the details of the manufacturer of the active raw material and the description of the methods of manufacture of the active raw material.

(2) The description referred to under subregulation (1) shall include—

(a) a description of the source of the raw material and the specifications and the test methods of the starting materials such as—

(i) the animal sources;

(ii) the virus sources;

(iii) the cellular sources including microbial cells, animal cells, primary cells, and cell lines;

(iv) the genetic constructs and recombinant cell lines including host cells, gene construct, vector, final gene construct and cloning and establishment of recombinant cell lines; and

(v) the cell bank system including master cell bank, working cell bank, end of production cells and characterisation and testing of cell banks;

(b) a description of the growth and harvesting process including propagation and harvesting;

(c) the purification and downstream processing including inactivation, where appropriate, purification, where appropriate, stability processing and detoxification;

(d) the details of the manufacture of synthetic raw material including synthetic peptides and conjugates and modified active raw materials; and

(e) a description of in process control specifications and tests at each stage of manufacture of active raw materials.

10. Requirements for sample of packaging.

(1) The applicant shall at the time of applying for registration of a product provide a sample of the labelling and packaging for the product which shall contain—

(a) the brand name, where applicable;

(b) the international non-proprietary name or generic name of the product;

(c) the quantity of active ingredient per dosage unit;

(d) the pharmaceutical form and the quantity of active ingredient per dosage unit;

(e) the total contents of the primary, secondary and tertiary container;

(f) the date of manufacture of the product;

(g) the date of expiry of the product;

(h) the batch number of the product;

(i) the storage conditions;

(j) the product information for health professionals;

(k) the patient information and package leaflet; and

(l) the name and address of the manufacturer of the product.

(2) The Authority shall not consider an application for registration of a product unless the words used in the labelling and packaging of the product are in English.

(3) The name and address of the manufacturer, the date of manufacture or the conditions of storage may be omitted from the primary packaging if the primary packaging is a blister, strip pack or a vial or an ampoule of less than ten millilitres.

(4) The name of the manufacturer may be substituted with a trade mark or other symbol associated with the manufacturer.

(5) Where the name and address of the manufacturer, the date of manufacture or the conditions of storage are omitted from the primary packaging under subregulation (3), they shall appear in full on the secondary packaging.

(6) The application shall also contain—

(a) justification for any differences to the product in the country issuing the submitted World Health Organisation Type Certificate such as a certificate issued in terms of the World Health Organisation Certification Scheme for Pharmaceutical Products Moving in International Commerce or the Certificate of a Pharmaceutical Product;

(b) data on the interchangeability for generic products as may be determined by the Authority; and

(c) a summary of the pharmacology, toxicology and efficacy of the product, when the product contains new active ingredients and new combinations of active ingredients.

(7) The Authority shall only register a product with a clear, easily legible and comprehensible label.

11. Therapeutic effects and indications.
The applicant shall state—

(a) the proposed therapeutic use of the product;

(b) the evidence of the potential benefit of using the product in Uganda; and

(c) the potential side effects of the product.

12. Information leaflet.

(1) The product packaging shall include a prescribing information leaflet in the case of prescription medicines or a patient information leaflet in the case of non-prescription medicine.

(2) The leaflet shall include the following information—

(a) the international non-proprietary or botanical name, where appropriate;

(b) a brief description of the mechanism of action and pharmacological effects;

(c) clinical information on the product including—

(i) not more than three indications;

(ii) the dosage regimens for the different age groups, including for children;

(iii) the contraindications;

(iv) precautions in pregnancy;

(v) lactation, renal and hepatic failure, if any;

(vi) the adverse reactions including their frequency;

(vii) clinically significant drug interactions; and

(viii) the symptoms and treatment of over dosage; and

(d) pharmaceutical information on the product including-

(i) the dosage form of the product;

(ii) the strength of the product;

(iii) the excipients of the product;

(iv) the conditions under which the product is to be stored;

(v) the shelf-life of the product;

(vi) the pack size of the product;

(vii) a description of the product and package; and

(viii) the name and physical address of the manufacturer of the product.

(3) Inappropriate claims shall not be included in the information leaflet.

13. Registration of product manufactured outside Uganda.

(1) Where the product to be registered by the Authority is manufactured outside Uganda, the product shall be registered in the country of manufacture, prior to registration in Uganda.

(2) The applicant for registration of a product manufactured outside Uganda shall furnish the Authority with a certified copy of the certificate of registration issued by the country of manufacture and the conditions of registration, if any.

(3) Notwithstanding the requirements of this regulation, the applicant may submit a certificate of pharmaceutical product issued under the World Health Organisation Certification Scheme or any other scheme approved by the Authority, on the quality of a pharmaceutical product moving in international commerce instead of the certificate of registration.

(4) Where the applicant submits a certificate under subregulation (3), the exporting country shall be deemed to be the country of manufacture.

14. Certificate of registration.

(1) The Authority shall issue a certificate of registration of a product registered under these Regulations, in the prescribed Form 3 of Schedule 3 to these Regulations.

(2) The Authority shall issue a certificate of registration where the Authority is satisfied that—

(a) the product dossier is submitted with evidence of—

(i) the safety, efficacy and quality of the product;

(ii) the stability of the data regarding the product; and

(iii) two samples of the drug or preparation;

(b) for an ectoparasiticides, a field trial, to prove the claims of efficacy of the preparation in animals and the safety of the people and environment exposed to these products, was carried out in Uganda;

(c) the applicant has complied with internationally accepted Good Manufacturing Practices, adopted by the Authority; and

(d) the applicant has paid the prescribed fees.

15. Suspension or cancellation of certificate of registration.

(1) The certificate of registration of a product shall be suspended for failure of the holder of the certificate of registration—

(a) to meet the quality specifications and standards of the registered product; or

(b) to renew the certificate of Good Manufacturing Practice.

(2) A certificate of registration a product shall be cancelled where—

(a) the holder of the certificate of registration fails to meet the quality specifications and standards required of the registered products;

(b) the holder of the certificate of registration fails to renew the certificate of Good Manufacturing Practice;

(c) the registered product is banned or is declared obsolete by the Authority;

(d) the registered product has serious adverse reactions as may be determined by the Authority;

(e) the risk of using the drug or preparation outweighs the benefit as may be determined by the Authority; or

(f) the Authority establishes that the information presented in the application for registration was false.

16. Additional requirements for veterinary drugs and preparations.

(1) The applicant shall provide for each veterinary drug or preparation to be registered—

(a) a list of the active ingredients or immunogens and their amount per unit dose;

(b) a list of all excipients, adjuvants and preservatives, their amount per unit dose and the reason for their inclusion in the formulation; and

(c) details of the adverse effects of the drug or preparation to animals and precautions to be taken before or during use in certain animals.

(2) Where a drug or preparation has adverse effects, the drug shall not be registered.

17. Toxicity to animals, animal product consumers and handlers.

The applicant shall provide information on the residue studies carried out on the product where it is administered to food producing animals to enable the Authority to investigate—

(a) the summary of the pharmacokinetics of the drug and its residues;

(b) how long the drug or its metabolites persists in animal tissue;

(c) the practical withdrawal periods that should be observed before slaughtering the animals for consumption or consumption of other food products from live animals;

(d) the analytical methods suitable for verifying the appropriateness of the withdrawal period; and

(e) the potential of the veterinary product to cause drug resistance in human beings exposed to animal products that were treated with the veterinary drug or preparation.

18. Toxicity to the environment.

(1) The applicant shall provide information relating to the assessment of the potential of exposure of the drug or preparation and its active metabolites to the environment taking into account—

(a) the target species and the likelihood of and method of excretion of the drug or preparation and its active metabolites into the environment;

(b) the pattern of use and quantity of the drug or preparation used for herd or flock medication or individual medication;

(c) the method of administration and whether it may lead to direct entry of the drug or preparation into the environment; and

(d) the method of disposal of the unused drug or preparation.

(2) The applicant shall provide information on the studies carried out on the potentially harmful effects of the drug or preparation to the environment and the measures proposed to minimise the risks during the use of the product including—

(a) the fate and behaviour of the drug or preparation in the soil;

(b) the effects of the drug or preparation on soil organisms;

(c) fate and behaviour of the drug or preparation in water;

(d) the effect of the drug or preparation on aquatic organisms; and

(e) the effect of the drug or preparation on other non-target organisms.

Additional Requirements for Herbal Medicine Products

19. Application for registration.

(1) An application for the registration of an imported herbal medicine product shall be made to the Authority, in the prescribed Form 4 for imported herbal medicine product for human use or Form 5 for imported herbal medicine product for veterinary use, as the case may be, of Schedule 4 to these Regulations.

(2) An application for the registration of a local herbal medicine product shall be made to the Authority in prescribed Form 6 of Schedule 4 to these Regulations.

(3) An application for registration under subregulation (1) or (2) shall be made by—

(a) the patent holder or the owner of the formulation of the herbal medicine product;

(b) a licensed person;

(c) the manufacturer of the herbal medicine product; or

(d) an agent authorised by the manufacturer or the patent holder.

(4) The application shall contain—

(a) the name, physical address, telephone number, fax number, and e-mail address of the applicant;

(b) the name of the herbal medicine product;

(c) the name of the active or main constituent of the herbal medicine product;

(d) the indications of the herbal medicine product;

(e) the form of preparation of the herbal medicine product, such as belladonna leaf, opium tincture, yeast tablets or convallaria tonic;

(f) the dosage forms of the herbal medicine product, such as tablet, powder, ointment or capsules;

(g) where applicable, the strength of dosage form of the herbal medicine product;

(h) the excipients of the herbal medicine product, such as starch, or honey;

(i) the major adverse effects of the herbal medicine product;

(j) two samples of the packaging of the herbal medicine product;

(k) the storage conditions, shelf life and expiry date of the herbal medicine product;

(l) the pack sizes or weight of the herbal medicine product;

(m) where the applicant is not the manufacturer of the herbal medicine product, the name and address of manufacturer; and

(n) where the herbal medicine product is reputed to have adverse effects or where the history of use of the medicine is not well known in Uganda or where the active or main constituent of the product is known, a monograph on the herbal medicine product.

(5) The packaging required under subregulation (2) (j) shall have a label which shall indicate—

(a) the name of the herbal medicine product;

(b) a list of the main active ingredients the herbal medicine product and their quantities;

(c) the common English and botanical names of the plants used in the herbal medicine product;

(d) the dosage form for the herbal medicine product;

(e) the therapeutic indications of the herbal medicine product, which shall not be more than three;

(f) the minimum and maximum dosages and the dosages for children and the elderly and where appropriate, the average dosage levels;

(g) information on over-dosage;

(h) where available, the contraindications, warning, precautions and major drug interactions of the herbal medicine product;

(i) the date of manufacture of the herbal medicine product;

(j) the expiry date of the herbal medicine product, which shall not be more than one year from date of manufacture except where justification is given;

(k) the lot or batch number of the herbal medicine product;

(l) where the applicant is not the manufacturer, the name and address of the manufacturer; and

(m) the conditions for the storage of the herbal medicine.

20. Specifications for the herbal medicine product.
For the purposes of determining the active ingredients of a herbal medicine product an applicant shall provide the following specifications—

(a) the microbiological contamination tests and tests for other toxins, if any;

(b) the uniformity of weight for tablets, single-dose powders, suppositories, sachets and capsules, the disintegration time for tablets, capsules, suppositories and pills, the hardness and friability such as of uncoated tablets, the viscosity for internal and external fluids, the consistency or semisolid preparations, and dissolution tablets or capsules, if applicable;

(c) the physical appearance of the herbal medicine product, such as colour, odour, form, shape, size and texture;

(d) the loss on drying or water content of the herbal medicine product;

(e) identity tests and qualitative determination of the relevant substances of the plants used in the herbal medicine product including finger-print chromatograms;

(f) the quantification of the relevant active ingredients of the herbal medicine product, where these are identified and where the analytical methods are adequate ; and

(g) limit tests for the residual solvent in the herbal medicine product.

21. Good manufacturing practices not to apply to herbal medicine products.

The requirements of good manufacturing practices shall not apply to herbal medicine products.

22. Certificate of registration for herbal medicine products.

The Authority shall issue a certificate of registration for a herbal medicine product in the prescribed Form 3 of Schedule 3 to these Regulations.

23. Suspension of certificate of registration.

A certificate of registration of a herbal medicine product shall be suspended for failure of the holder of the certificate to meet the quality specifications and standards of the registered herbal medicine product.

PART III—REGISTRATION OF SURGICAL INSTRUMENTS

24. Definitions.

For purposes of this Part—

"adverse event" means a problem that can or does result in permanent impairment, injury or death to the patient or the user;

"*in vitro* diagnostic device" means a surgical instrument that is intended to be used *in vitro* for the examination of specimens taken from the body of a human being or of an animal;

"significant change" means a change that could reasonably be expected to affect the safety or effectiveness of a surgical instrument;

"surgical instrument" means any instrument, apparatus, implement, machine, implant, *in vitro* reagent or calibrator, software, material or other similar or related article and includes an appliance which is intended by the manufacturer to be used, alone or in combination, for human beings or animals for one or more of the specific purposes of-

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(d) supporting or sustaining life;

(e) disinfection of a surgical instrument; or

(f) providing information for medical purposes by means of *in vitro* examination of specimens derived from the body of a human being or of an animal and which does not achieve its primary intended action in or on the body of a human being or of an animal by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

"test kit" means an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.

25. Registration of surgical instruments.

(1) All surgical instruments shall be registered by the Authority before sale or distribution in Uganda.

(2) The Authority shall register the surgical instruments which meet the safety and efficacy standards determined by the Authority.

26. Register of surgical instruments.

The Authority shall maintain a register of the surgical instruments registered under these Regulations, in the format specified in Schedule 5 to these Regulations.

27. Application for registration of surgical instruments.

(1) A person who intends to manufacture, import or export a surgical instrument shall, prior to the manufacture, importation or exportation of the surgical instrument, apply to the Authority for registration of the surgical instrument.

(2) An application for registration of a surgical instrument shall be made to the Authority in the prescribed Form 7 of Schedule 6 to these Regulations.

(3) An application for registration of a product in Uganda may be made by—

(a) the patent holder;

(b) a licensed person;

(c) the manufacturer of the surgical instrument; or

(d) an agent authorised by the manufacturer or patent holder.

(4) An application shall contain—

(a) the name, physical address, email address, the telephone and fax number of the applicant;

(b) the brand name of the surgical instrument;

(c) a brief description of the surgical instrument;

(d) the category of the surgical instrument;

(e) where the applicant is not the manufacturer, the name, physical address, telephone number, fax number and e-mail of the manufacturer as it appears on the label of the surgical instrument;

(f) the intended use and method of use of the surgical instrument;

(g) the contraindications, warnings, precautions, potential adverse events of the surgical instrument;

(h) the list of accessories and other devices or equipment to be used in combination with the surgical instrument;

(i) the variations in shapes, style or size of the surgical instrument, if applicable;

(j) the labelling details of the surgical instrument;

(k) the packaging descriptions including the pack sizes of the surgical instrument; and

(l) the storage conditions recommended for the surgical instrument.

28. Surgical instruments deemed registered.

(1) Where a surgical instrument or a group of surgical instruments is registered and the instrument or group of surgical instruments, as the case may be, forms part of another surgical instrument or of another group of surgical instruments, as the case may be, all the surgical instruments or the group shall be deemed to be registered.

(2) Where a test kit is licensed or registered outside Uganda, all the reagents or articles of the test kit that are manufactured by the manufacturer of the test kit are deemed, for the purposes of its importation, sale or advertisement, to have been registered in Uganda.

29. Labeling requirements.

(1) The applicant shall submit with the application for registration of a surgical instrument, a label which shall have—

(a) the name of the surgical instrument;

(b) the name and address of the manufacturer of the surgical instrument;

(c) the identifier of the surgical instrument, including the identifier of any surgical instrument or appliance that is part of a system, test kit or group;

(d) where the contents of the package of the surgical instrument are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the surgical instrument, such as the size, net weight, length, volume or number of units;

(e) the word “Sterile”, if the manufacturer intends the device to be sold in a sterile condition;

(f) the expiry date of the surgical instrument, where applicable, to be determined by the manufacturer on the basis of the component of the surgical instrument, as the case may be, that has the shortest projected useful life;

(g) unless self-evident to the intended user, the medical conditions, purposes and uses for which the surgical instrument is manufactured, sold or represented, including the performance specifications of the surgical instrument, where those specifications are necessary for proper use;

(h) the directions for safe and effective use of the surgical instrument, unless directions are not required; and

(i) any special storage conditions applicable to the surgical instrument.

(2) The information required under subregulation (1) shall be provided in English, and shall be in a permanent and prominent manner, in terms that are easily understood by the intended user.

30. Certificate of registration for surgical instrument.

(1) The Authority shall issue a certificate of registration for a surgical instrument which is registered under these Regulations.

(2) The certificate of registration shall be in the prescribed Form 8 of Schedule 7 to these Regulations.

(3) The Authority may set out in the certificate of registration the terms and conditions for registration including—

(a) the tests to be performed on a surgical instrument to maintain the safety and efficacy requirements; and

(b) the requirement to submit the results of any tests performed on the surgical instrument.

(4) The Authority may, taking into account new development with respect to a surgical instrument, amend the terms and conditions of the registration of a surgical instrument.

(5) The holder of the surgical instrument certificate shall comply with the terms and conditions of the certificate of registration.

31. Suspension of certificate of registration.

(1) The Authority may suspend the registration of a surgical instrument by giving the holder of the certificate of registration a notice of the suspension, in writing, that states the reason for the suspension.

(2) The Authority shall suspend a registration where the Authority determines that—

(a) the holder of the certificate of registration has contravened these Regulations or any provision of the Act;

(b) the holder of the certificate of registration made a false or misleading statement in the application for registration;

(c) the holder of the certificate of registration has not complied with the terms and conditions of the certificate of registration; or

(d) the surgical instrument no longer meets the safety and efficacy standards determined by the Authority.

(3) Before suspending the registration of a surgical instrument under this regulation, the Authority shall—

(a) consider the record of the holder of the certificate of registration, of compliance with the Act and these Regulations;

(b) consider whether maintaining the registration would cause injury to the health or safety of patients, the users of the surgical instrument or any other persons; and

(c) give written notice of the intention to suspend a registration to the holder of the certificate of registration, which shall set out the reason for the proposed suspension, any corrective action required to be taken to avoid the suspension and the time within which the corrective action is to be taken.

(4) The Authority shall not suspend the registration of a surgical instrument—

(a) where corrective action is required by the Authority under subregulation (3) (c) and the time which the corrective action is to be taken has not elapsed; and

(b) without giving the holder of the certificate of registration an opportunity to be heard by the Authority.

32. Suspension for the health and safety of patients, users and other persons.

Notwithstanding regulation 31 (4) (b), the Authority may suspend the registration of a surgical instrument without giving the holder of the certificate of registration an opportunity to be heard, where it is necessary to do so to prevent injury to the health or safety of patients, users or any other persons.

33. Reinstatement of registration of surgical instrument.

The Authority may reinstate the registration of a surgical instrument where the situation that caused the suspension is corrected or where the reason for the suspension was unfounded.

34. Surgical instrument not to have adverse effects.

A surgical instrument shall not, when used for the medical conditions and purpose for which it was manufactured, adversely affect the health or safety of a patient, user or any other persons.

35. Sale of surgical instrument to the general public.

(1) Subject to subregualtion (2), where a surgical instrument or appliance is intended to be sold to the general public, the information required under regulation 29 (1) shall—

(a) be set out on the outside of the package that contains the surgical instrument or appliance; and

(b) be visible under the normal conditions of sale of the surgical instrument or appliance.

(2) Where the package that contains the surgical instrument or appliance is too small to display all the information required under regulation 29 on the outside of the package, the directions for the use of the surgical instrument or appliance shall accompany the surgical instrument or appliance.

PART IV—GENERAL PROVISIONS RELATING TO REGISTRATION.

36. Responsibility of applicant for accuracy of information submitted.

The applicant for registration under these Regulations shall be responsible for the accuracy of the information submitted in support of the application for registration and for any alterations to the information supplied.

37. Additional information and samples.

(1) Where the information or documents submitted in respect of an application for registration or an application for amendment or alteration of a registration under these Regulations, are not sufficient for the Authority to

determine whether the human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument to be registered meets the safety and efficacy requirements determined by the Authority, the Authority may request the applicant to submit additional information necessary for the registration.

(2) In the course of examining an application, the Authority may request an applicant to provide a sample of the human or veterinary drug or preparation, vaccine or other immunological or surgical instrument to be registered.

38. Receipt and consideration of application by the Authority.

(1) The Authority shall determine an application for registration under these Regulations, within sixty days from the date of receipt of the application.

(2) Where the Authority is satisfied with an application, it shall approve the application and register the human or veterinary drug or preparation, vaccine or other immunological or surgical instrument, as the case may be.

(3) Where the Authority is not satisfied with the information provided in an application, the Authority shall require the applicant to provide further information as may be necessary to complete the application.

(4) Where the Authority does not accept an application, the Authority shall communicate its decision and the reasons for refusal to the applicant.

39. Application for amendment or alteration of registration.

(1) Whenever a holder of a certificate of registration wishes to make an amendment or an alteration to the particulars provided in the application for registration made under these Regulations, the holder of the certificate of registration shall apply to the Authority for amendment or alteration of the registration.

(2) An application for amendment or alteration of registration shall be shall be accompanied by—

(a) a detailed description of the amendment or alteration to be effected with reasons for the amendment or alteration;

(b) where applicable, samples of the altered human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be; and

(c) the prescribed fee.

40. Validity of registration.

(1) The Authority shall issue for the first registration, a certificate of registration which shall be valid for five years.

(2) The holder of a certificate of registration issued under subregulation (1) shall pay an annual retention fee prescribed by the Authority for maintaining the registered human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, on the Register.

(3) A certificate for renewal of registration shall be valid for one year from the date of issue.

(4) The certificate of registration issued under these Regulations shall be kept at the premises of the holder of the certificate of registration.

(5) The holder of a certificate of registration shall monitor the safety and effectiveness of the registered human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument while on the market in Uganda and shall submit periodic reports as may be prescribed by the Authority.

(6) The registration of a human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument under these Regulations shall be valid except where the registration is suspended or cancelled by the Authority or is terminated by the holder of the certificate of registration.

41. Refusal to issue certificate of registration.

(1) The Authority may refuse to issue, amend or alter a certificate of registration where—

(a) the applicant does not comply with these Regulations or any provisions of the Act;

(b) the human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, does not meet the safety and efficacy standards determined by the Authority;

(c) the information or samples submitted are not sufficient to enable the Authority to determine whether the human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, meets those requirements and the applicant does not comply with a request to submit additional information or samples;

(d) the applicant makes a false or misleading statement in the application;

(e) the human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, or its sample label does not comply with the labelling requirements specified in these Regulations.

(2) Where the Authority refuses to issue, amend or alter the registration of a drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, the Authority shall—

(a) notify the applicant in writing of the reasons for the refusal; and

(b) give the applicant an opportunity to be heard.

42. Application for renewal of registration.

(1) A holder of a certificate of registration who wishes to renew the registration shall submit an application for renewal of registration, to the Authority at least 90 days before the expiry of the registration.

(2) An application for renewal of registration shall be in writing to the Authority and shall be accompanied by—

(a) a consolidated report of the changes, if any, whether reported to the Authority or not, which are made with respect to the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, during the validity of its registration;

(b) a report of additional adverse drug reactions, if any, detected during the lifetime of the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be;

(c) five samples of the packaging of the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, for which renewal of registration is sought, in the form in which it is to be marketed;

(d) the prescribed fee.

43. Fees.

The fees to be paid under these Regulations shall be prescribed by the Authority.

44. Offences and penalties.

A person contravening a provision of these Regulations commits an offence and shall be liable to any of the penalties set out under the Act.

SCHEDULES

SCHEDULE 1

FORMAT

Regulation 5

FORMAT FOR REGISTER FOR DRUGS AND PREPARATION FOR HUMAN OR VETERINARY USE AND FOR VACCINES AND OTHER IMMUNOLOGICAL PRODUCTS

PART A- REGISTER FOR DRUGS AND PREPARATION FOR HUMAN OR VETERINARY USE

Name of particulars of applicant (patent holder, licensed person, manufacturer or agent)	*Manufacturer*	*Name of drug*	*Generic name of drug*	*Strength of drug*	*Dosage form*	*Pack sizes*	*Country of manufacture*	*NDA Registration No.*

PART B- REGISTER FOR FOR VACCINES AND OTHER IMMUNOLOGICAL PRODUCTS

Name and particulars of applicant (patent holder, licensed person, manufacturer or agent)	*Manufacturer*	*Name of drug*	*Generic name of drug*	*Strength of drug*	*Dosage form*	*Pack sizes*	*Country of manufacture*	*NDA Registration No.*

SCHEDULE 2

FORM 1

Regulation 6 (1)

APPLICATION FOR REGISTRATION OF HUMAN AND VETERINARY DRUGS AND PREPARATIONS

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

PART I- QUALITY OVERALL SUMMARY – PRODUCT DOSSIER

INTRODUCTION

(a) Summary of product information:

Non-proprietary name of the finished pharmaceutical product (FPP)			
Proprietary name of the finished pharmaceutical product (FPP)			
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph)			
Applicant name and address			
Dosage form			
Reference Number(s)			
Strength(s)			
Route of administration			
Proposed indication(s)			
Contact information	Name: Phone: Fax: Email:		

Publication(s)	Most recent edition/ volume in which API/FPP appears	Most recent edition/volume consulted
API status in pharmacopoeia and forum:		
Ph.Int.		
Ph.Int. monograph development (through www.who.int)	<e.g. monograph under development or draft/final published>	
USP		
Pharmacopeial Forum		
Ph.Eur.		
Pharmeuropa		
BP		
Other (e.g. JP)		
FPP status in pharmacopoeia and forum:		
Ph.Int.		
Ph.Int monograph development (through www.who.int)	<e.g. monograph under development or draft/final published>	
USP		
Pharmacopeial Forum		
BP		
Other (e.g. JP)		
Other reference texts (e.g. public access reports):		

(b) Other Introductory information:
Related dossiers (e.g. FPP(s) with the same API(s) submitted to NDA by the applicant):

Reference number (e.g. A001)	**Prequalified (Y/N)**	**API, strength, dosage form** (e.g. Abacavir (as sulphate) 300 mg tablets)	**API manufacturer** (including address)

Identify available literature references for the API and FPP:

SUMMARY OF QUALITY ASSESSMENT OF LABELLING AND SAMPLES *(NDA Use Only)*
Discussion/comments on the quality components of:
Summary of product characteristics <insert assessment observations, comments, etc.>
Labelling (outer and inner labels) <insert assessment observations, comments, etc.>
Package leaflet (patient information leaflet) <insert assessment observations, comments, etc.>
Samples (e.g. FPP, device) <insert assessment observations, comments, etc.>

2.3. S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API)) (NAME, MANUFACTURER)

Complete the following table for the option that applies for the submission of API information:

Name of API:	
Name of API manufacturer:	
☐	Certificate of suitability to the European Pharmacopoeia (CEP): is a written commitment provided that the applicant will inform NDA in the event that the CEP is withdrawn and has acknowledged that withdrawal of the CEP will require additional consideration of the API data requirements to support the dossier: ? yes, ? no; provide a copy of the most current CEP (with annexes) and written commitment in *Module 1*; the declaration of access should be filled out by the CEP holder on behalf of the FPP manufacturer or applicant to the Prequalification Programme who refers to the CEP; and provide summaries of the relevant information under the appropriate sections (e.g. S.1.3, S.3.1, S.4.1 through S.4.4, S.6 and S.7; see Quality guideline).
☐	Active pharmaceutical ingredient master file (APIMF) procedure: APIMF number assigned by WHO (if known): _____ ; version number (and/or date) of the open part: _____ ; version number (and/or date) of the closed part: _____ ; a copy of the letter of access should be provided in *Module 1*; and summaries of the relevant information from the Open part should be provided under the appropriate sections; see Section 3.2.S in the Quality guideline.
☐	Full details in the PD: summaries of the full information should be provided under the appropriate sections; see Section 3.2.S in the Quality guideline.

2.3. S.1 General Information (name, manufacturer)

2.3. S.1.1 Nomenclature (name, manufacturer)

(a) (recommended) International Non-proprietary name (INN):
(b) compendial name, if relevant:
(c) chemical name(s):
(d) company or laboratory code:
(e) other non-proprietary name(s) (e.g. national name, USAN, BAN):
(f) chemical Abstracts Service (CAS) registry number:

2.3. S.1.2 Structure (name, manufacturer)

(a) structural formula, including relative and absolute stereochemistry:
(b) molecular formula:
(c) relative molecular mass:

2.3. S.1.3 General Properties (name, manufacturer)

(a) physical description (e.g. appearance, colour, physical state):
(b) solubilities:

In common solvents:

Dose/solubility volume calculation:

Medium (e.g. pH 4.5 buffer)	**Solubility (mg/ml)**

(c) Physical form (e.g. polymorphic form(s), solvate, and hydrate):

Polymorphic form:
Solvate:
Hydrate:

(d) Other:

Property	
pH	
pK	
Partition coefficients	
Melting/boiling points	
Specific optical rotation (specify solvent)	
Refractive index (liquids)	
Hygroscopicity	
UV absorption maxima/molar absorptivity	
Other	

2.3. S.2 Manufacture (name, manufacturer)

2.3. S.2.1 Manufacturer(s) (name, manufacturer)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing, and storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address (including block(s)/unit(s))	*Responsibility*	*APIMF/CEP number (if applicable)*

(b) Manufacturing authorization for the production of API(s) and, where available, certificate of GMP compliance (GMP information should be provided in *Module 1*):

2.3. S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer)

(a) flow diagram of the synthesis process (es):
(b) brief narrative description of the manufacturing process (es):
(c) alternate processes and explanation of their use:
(d) reprocessing steps and justification:

2.3. S.2.3 Control of Materials (name, manufacturer)

(a) Summary of the quality and controls of the starting materials used in the manufacture of the API:

Step/starting material	*Test(s)/method(s)*	*Acceptance criteria*

(b) Name and manufacturing site address of starting material manufacturer(s):

(c) Where the API(s) and the starting materials and reagents used to manufacture the API(s) are *without* risk of transmitting agents of animal spongiform encephalopathies, a letter of attestation confirming this can be found in:

2.3. S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)

(a) Summary of the controls performed at critical steps of the manufacturing process and on intermediates:

Step/starting material	*Test(s)/method(s)*	*Acceptance criteria*

2.3. S.2.5 Process Validation and/or Evaluation (name, manufacturer)

Description of process validation and/or evaluation studies (e.g. for aseptic processing and sterilization):

2.3. S.2.6 Manufacturing Process Development (name, manufacturer)

Description and discussion of the significant changes made to the manufacturing process and/or manufacturing site of the API used in producing comparative bioavailability or biowaiver, stability, scale-up, pilot and, if available, production scale batches:

2.3. S.3 Characterisation (name, manufacturer)

2.3. S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)

(a) List of studies performed (e.g. IR, UV, NMR, MS, elemental analysis) and conclusion from the studies (e.g. whether results support the proposed structure):

(b) Discussion on the potential for isomerism and identification of stereochemistry (e.g. geometric isomerism, number of chiral centres and configurations) of the API batch (es) used in comparative bioavailability or biowaiver studies:

(c) Summary of studies performed to identify potential polymorphic forms (including solvates):

(d) Summary of studies performed to identify the particle size distribution of the API:

(e) Other characteristics:

2.3. S.3.2 Impurities (name, manufacturer)

(a) Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation:

(i) List of API-related impurities (e.g. starting materials, by-products, intermediates, chiral impurities, degradation products), including chemical name, structure and origin:

API-related impurity (chemical name or descriptor)	*Structure*	*Origin*

(ii) List of process-related impurities (e.g. residual solvents, reagents), including compound names and step used in synthesis:

Process-related impurity (compound name)	*Step used in synthesis*

(b) Basis for setting the acceptance criteria for impurities:

(i) Maximum daily dose (i.e. the amount of API administered per day) for the API, corresponding to ICH Reporting/ Identification/ Qualification Thresholds for the API-related impurities and the concentration limits (ppm) for the process-related impurities (e.g. residual solvents):

Maximum daily dose for the API:	*<x mg/day>*	
Test	*Parameter*	*ICH threshold or concentration limit*
API-related impurities	Reporting Threshold	
	Identification Threshold	
	Qualification Threshold	
Process-related impurities	<solvent 1>	
	<solvent 2>, etc.	

(ii) Data on observed impurities for relevant batches (e.g. comparative bioavailability or biowaiver, stability batches):

Impurity (API-related and process-related)	*Acceptance Criteria*	*Results (include batch number* and use**)*		

*** include strength, if reporting impurity levels found in the FPP (e.g. for comparative studies);**

**** e.g. comparative bioavailability or bio waiver studies, stability**

(iii) Justification of proposed acceptance criteria for impurities:

2.3. S.4 Control of the API (name, manufacturer)

2.3. S.4.1 Specification (name, manufacturer)

(a) API specifications *of the FPP manufacturer*:

Standard (e.g. Ph.Int., Ph.Eur., BP, USP, House)		
Specification reference number and version		
Test	*Acceptance criteria*	*Analytical procedure (Type/Source/Version)*
Description		
Identification		
Impurities		
Assay		
etc.		

2.3. S.4.2 Analytical Procedures (name, manufacturer)

Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing): ……
……..

See *2.3.R Regional Information* for summaries of the analytical procedures and validation information (i.e. *2.3.R.2 Analytical Procedures and Validation Information*).

2.3. S.4.3 Validation of Analytical Procedures (name, manufacturer)

(a) Summary of the validation information (e.g. validation parameters and results):……..
……..

See *2.3.R Regional Information* for summaries of the analytical procedures and validation information (i.e. *2.3.R.2 Analytical Procedures and Validation Information*).

2.3. S.4.4 Batch Analyses (name, manufacturer)

(a) Description of the batches:

Batch number	*Batch size*	*Date and site of production*	*Use (e.g. comparative bioavailability or biowaiver, stability)*

(b) Summary of batch analyses release results *of the FPP manufacturer* for relevant batches (e.g. comparative bioavailability or bio waiver, stability):

Test	*Acceptance Criteria*	*Results*		
		<batch x>	*<batch y>*	*etc.*
Description				
Identification				
Impurities				
Assay				
etc.				

(c) Summary of analytical procedures and validation information for those procedures not previously summarised in 2.3.S.4.2 and 2.3.S.4.3 (e.g. historical analytical procedures):

……

2.3. S.4.5 Justification of Specification (name, manufacturer)

Justification of the API specification (e.g. evolution of tests, analytical procedures and acceptance criteria, differences from officially recognised compendial standard(s)):

……

2.3. S.5 Reference Standards or Materials (name, manufacturer)

(a) Source (including lot number) of primary reference standards or reference materials (e.g. Ph.Int, Ph.Eur. BP, USP, in-house):

(b) Characterization and evaluation of non-official (e.g. not from an officially recognised pharmacopoeia) primary reference standards or reference materials (e.g. elucidation of structure, certificate of analysis):

Description of the process controls of the secondary reference standard (comparative certificate of analysis and IR spectra against primary standard)

2.3. S.6 Container Closure System (name, manufacturer)

Description of the container closure system(s) for the shipment and storage of the API (including the identity of materials of construction of each primary packaging component and a brief summary of the specifications):

Packaging component	*Materials of construction*	*Specifications (list parameters e.g. identification (IR))*

(b) Other information on the container closure system(s) (e.g. suitability studies):

2.3. S.7 Stability (name, manufacturer)

2.3. S.7.1 Stability Summary and Conclusions (name, manufacturer)

(a) Summary of stress testing (e.g. heat, humidity, oxidation, photolysis, acid/base): and results:

Stress condition	*Treatment*	*Results (e.g. including discussion whether mass balance is observed)*
Heat		
Humidity		
Oxidation		
Photolysis		
Acid		
Base		
Other		

(b) Summary of accelerated and long-term testing parameters (e.g. studies conducted):

Storage condition (?C, % RH)	*Batch number*	*Batch size*	*Container closure system*	*Completed (and proposed) testing intervals*

Summary of the stability results observed for the above accelerated and long-term studies:

Test	*Results*
Description	
Moisture	
Impurities	
Assay	
etc.	

(c) Proposed storage statement and re-test period (or shelf-life, as appropriate):

Container closure system	*Storage statement*	*Re-test period**

* indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile APIs)

2.3. S.7.2 Post-approval Stability Protocol and Stability Commitment (name, manufacturer)

(a) Stability protocol for *Primary stability batches* (e.g. storage conditions (including tolerances), batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	*Details*	
Storage condition(s) (?C, % RH)		
Batch number(s) / batch size(s)		
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

(b) Stability protocol for *Commitment batches* (e.g. storage conditions (including tolerances), batch numbers (if known) and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	*Details*	
Storage condition(s) (?C, % RH)		
Batch number(s) / batch size(s)	*<not less than three production batches>*	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

(c) Stability protocol for *Ongoing batches* (e.g. storage conditions (including tolerances), batch sizes and annual allocation, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	*Details*	
Storage condition(s) (?C, % RH)		
Annual allocation	*<at least one production batch per year (unless none is produced that year) in each container closure system >*	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

2.3. S.7.3 Stability Data (name, manufacturer)

(a) The actual stability results should be provided in *Module 3*.

(b) Summary of analytical procedures and validation information for those procedures not previously summarised in 2.3.S.4 (e.g. analytical procedures used only for stability studies):

2.3. P DRUG PRODUCT (or FINISHED PHARMACEUTICAL PRODUCT (FPP))

2.3. P.1 Description and Composition of the FPP

(a) Description of the FPP:

(b) Composition of the FPP:

(i) Composition, i.e. list of all components of the FPP and their amounts on a per unit basis and percentage basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Component and quality standard (and grade, if applicable)	*Function*	*Strength (label claim)*					
		Quant. per unit	*%*	*Quant. per unit*	*%*	*Quantity per unit*	*%*
<complete with appropriate title e.g. Core tablet, Contents of capsule, Powder for injection>							
Subtotal 1							
<complete with appropriate title e.g. Film-coating >							
Subtotal 2							
Total							

(ii) Composition of all *components purchased as mixtures* (e.g. colourants, coatings, capsule shells, imprinting inks):

(c) Description of accompanying reconstitution diluent(s), if applicable:

(d) Type of container closure system used for the FPP and accompanying reconstitution diluent, if applicable:

2.3. P.2 Pharmaceutical Development

2.3. P.2.1 Components of the FPP

2.3. P.2.1.1 Active Pharmaceutical Ingredient:

(a) Discussion of the:

(i) compatibility of the API(s) with excipients listed in 2.3.P.1:

(ii) key physicochemical characteristics (e.g. water content, solubility, and particle size distribution, polymorphic or solid state form) of the API(s) that can influence the performance of the FPP:

(iii) for fixed-dose combinations, compatibility of APIs with each other:

2.3. P.2.1.2 Excipients

Discussion of the choice of excipients listed in 2.3.P.1 (e.g. their concentrations, their characteristics that can influence the FPP performance):

2.3. P.2.2 Finished Pharmaceutical Product

2.3. P.2.2.1 Formulation Development

(a) Summary describing the development of the FPP (e.g. route of administration, usage, optimization of the formulation, etc.):

(b) Information on primary (submission, registration, and exhibit) batches including comparative bioavailability or biowaiver, stability, commercial:

(i) Summary of batch numbers:

Batch number(s) of the FPPs used in			
Bioequivalence or biowaiver			
Dissolution profile studies			
Stability studies (primary batches)			
‹packaging configuration I›			
‹ packaging configuration II›			
‹*Add/delete as many rows as necessary*›			
Stability studies (production batches)			
‹ packaging configuration I›			
‹ packaging configuration II›			
(Add/delete as many rows as necessary)			
Validation studies (primary batches) if available			
‹ packaging configuration I›			
‹ packaging configuration II›			
(Add/delete as many rows as necessary)			
Validation studies (at least the first three consecutive production batches)or code(s)/version(s) for process validation protocol(s)			

(ii) **Summary of formulations and discussion of any differences:**

Component and quality standard (e.g. NF, BP, Ph.Eur, in-house)	*Relevant batches*							
	Comparative bioavailability or biowaiver		*Stability*		*Process validation*		*Commercial (2.3.P.1)*	
	<Batch nos. and sizes>		*<Batch nos. and sizes>*		*<Batch nos. and sizes>*		*<Batch nos. and sizes>*	
	Theor. quantity per batch	**%**	**Theor. quantity per batch**	**%**	**Theor. quantity per batch**	**%**	**Theor. quantity per batch**	**%**
<complete with appropriate title e.g. Core tablet, Contents of capsule, Powder for injection>								
Subtotal 1								
<complete with appropriate title e.g. Film-coating >								
Subtotal 2								
Total								

(c) Description of batches used in the comparative *in vitro* studies (e.g. dissolution) and in the *in vivo* studies (e.g. comparative bioavailability or biowaiver), including strength, batch number, type of study and reference to the data (volume, page):

(d) Summary of results for comparative *in vitro* studies (e.g. dissolution):

(e) Summary of any information on *in vitro-in vivo* correlation (IVIVC) studies (with cross-reference to the studies in *Module 5*):

(f) For scored tablets, provide the rationale/justification for scoring:

2.3.P.2.2.2 Overages

Justification of overages in the formulation(s) described in 2.3.P.1:

2.3. P.2.2.3 Physicochemical and Biological Properties

Discussion of the parameters relevant to the performance of the FPP (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties):

2.3. P.2.3 Manufacturing Process Development

(a) Discussion of the development of the manufacturing process of the FPP (e.g. optimization of the process, selection of the method of sterilization):

(b) Discussion of the differences in the manufacturing process (es) for the batches used in the comparative bioavailability or bio waiver studies and the process described in 2.3.P.3.3:

2.3. P.2.4 Container Closure System

(a) Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP):

(b) For a device accompanying a multi-dose container, a summary of the study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume):

2.3. P.2.5 Microbiological Attributes

Discussion of microbiological attributes of the FPP (e.g. preservative effectiveness studies):

2.3. P.2.6 Compatibility

Discussion of the compatibility of the FPP (e.g. with reconstitution diluent(s) or dosage devices, co-administered FPPs):

2.3. P.3 Manufacture:

2.3. P.3.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, and testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

Name and address (include block(s)/unit(s))	*Responsibility*

(b) Manufacturing authorization, marketing authorization and, where available, WHO-type certificate of GMP (GMP information should be provided in *Module 1*):

2.3. P.3.2 Batch Formula

(a) List of all components of the FPP to be used in the manufacturing process and their amounts on a per batch basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Strength (label claim)			
Master production document reference number and/or version			
Proposed commercial batch size(s) (e.g. number of dosage units)			
Component and quality standard			
(and grade, if applicable)	**Quantity per batch (e.g. kg/batch)**	**Quantity per batch (e.g. kg/batch)**	**Quantity per batch (e.g. kg/batch)**
<complete with appropriate title e.g. Core tablet, Contents of capsule, Powder for injection>			
Subtotal 1			
<complete with appropriate title e.g. Film-coating >			
Subtotal 2			
Total			

2.3. P.3.3 Description of Manufacturing Process and Process Controls

(a) Flow diagram of the manufacturing process:

(b) Narrative description of the manufacturing process, including equipment type and working capacity, process parameters:

(c) Justification of reprocessing of materials:

2.3. P.3.4 Controls of Critical Steps and Intermediates

(a) Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:

Step (e.g. granulation, compression, coating)	*Controls*

2.3. P.3.5 Process Validation and/or Evaluation

Summary of the process validation and/or evaluation studies conducted (including product quality review(s) where relevant) and/or a summary of the proposed process validation protocol for the critical steps or critical assays used in the manufacturing process (e.g. protocol number, parameters, and results):

2.3. P.4 Control of Excipients

2.3. P.4.1 Specifications

Summary of the specifications for officially recognised compendial excipients which include supplementary tests not included in the officially recognised compendial monograph(s):

2.3. P.4.2 Analytical Procedures

Summary of the analytical procedures for supplementary tests:

2.3. P.4.3 Validation of Analytical Procedures

Summary of the validation information for the analytical procedures for supplementary tests (where applicable):

2.3. P.4.4 Justification of Specifications

Justification of the specifications (e.g. evolution of tests, analytical procedures and acceptance criteria, exclusion of certain tests, differences from officially recognised compendial standard(s)):

2.3. P.4.5 Excipients of Human or Animal Origin

(a) For FPPs using excipients *without* risk of transmitting agents of animal spongiform encephalopathies, a letter of attestation confirming this can be found in:

(b) CEP(s) demonstrating TSE-compliance can be found in:

2.3. P.4.6 Novel Excipients

Novel excipients are not accepted in the Prequalification Programme.

2.3. P.5 Control of FPP

2.3. P.5.1 Specification(s)

(a) Specification(s) for the FPP:

Standard (e.g. Ph.Int., BP, USP, House)			
Specification reference number and version			
Test	**Acceptance criteria (release)**	**Acceptance criteria (shelf-life)**	**Analytical procedure (type/source/ version)**
Description			
Identification			
Impurities			
Assay			
etc.			

2.3. P.5.2 Analytical Procedures

(a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing):

See *2.3.R Regional Information* for summaries of the analytical procedures and validation information (i.e. *2.3.R.2 Analytical Procedures and Validation Information*).

2.3. P.5.3 Validation of Analytical Procedures

(a) Summary of the validation information (e.g. validation parameters and results):

See *2.3.R Regional Information* for summaries of the analytical procedures and validation information (i.e. *2.3.R.2 Analytical Procedures and Validation Information*).

2.3. P.5.4 Batch Analyses

(a) Description of the batches:

Strength and batch number	Batch size	Date and site of production	Use (e.g. comparative bioavailability or biowaiver, stability)

(b) Summary of batch analyses release results for relevant batches (e.g. comparative bioavailability or biowaiver, stability):

Test	Acceptance criteria	Results		
		<batch x>	<batch y>	etc.
Description				
Identification				
Impurities				
Assay				
etc.				

(c) Summary of analytical procedures and validation information for those procedures not previously summarised in 2.3.P.5.2 and 2.3.P.5.3 (e.g. historical analytical procedures):

2.3. P.5.5 Characterisation of Impurities

(a) Identification of potential and actual impurities:

Degradation product (chemical name or descriptor)	*Structure*	*Origin*

Process-related impurity (compound name)	*Step used in the FPP manufacturing process*

(b) Basis for setting the acceptance criteria for impurities:

(i) Maximum daily dose (i.e. the amount of API administered per day) for the API, corresponding ICH Reporting/ Identification/ Qualification Thresholds for the degradation products in the FPP and the concentration limits (ppm) for the process-related impurities (e.g. residual solvents):

Maximum daily dose for the API:	**<x mg/day>**	
Test	**Parameter**	**ICH threshold or concentration limit**
Degradation product	Reporting Threshold	
	Identification Threshold	
	Qualification Threshold	
Process-related impurities	<solvent 1>	
	<solvent 2>, etc.	

(ii) Data on observed impurities for relevant batches (e.g. comparative bioavailability or biowaiver):

Impurity (degradation product and process-related)	*Acceptance criteria*	*Results*		
		<batch no., strength, use>		

(iii) Justification of proposed acceptance criteria for impurities:

2.3. P.5.6 Justification of Specification(s)

Justification of the FPP specification(s) (e.g. evolution of tests, analytical procedures and acceptance criteria, differences from officially recognised compendial standard(s)):

2.3. P.6 Reference Standards or Materials

(a) Source (including lot number) of primary reference standards or reference materials (e.g. Ph.Int., Ph.Eur., BP, USP, in-house) *not* discussed in 3.2.S.5:

(b) Characterization and evaluation of non-official (e.g. not from an officially recognised pharmacopoeia) primary reference standards or reference materials (e.g. elucidation of structure, certificate of analysis) *not* discussed in 3.2.S.5:

(c) Description of the process controls of the secondary reference standard (comparative certificate of analysis and IR spectra against primary standard) *not* discussed in 3.2.S.5:

2.3. P.7 Container Closure System

(a) Description of the container closure systems, including unit count or fill size, container size or volume:

Description (including materials of construction)	*Strength*	*Unit count or fill size*	*Container size*

(b) Summary of specifications of each primary and functional secondary (e.g. foil pouches) packaging components:

Packaging component	*Specifications (list parameters e.g. identification (IR))*
HDPE bottle	
PP cap	
Induction sealed liners	
Blister films (PVC, etc.)	
Aluminum foil backing	
etc.	

(c) Other information on the container closure system(s):

2.3. P.8 Stability

2.3. P.8.1 Stability Summary and Conclusions

(a) Summary of stress testing and results (e.g. photostability studies, cyclic studies, freeze-thaw studies):

(b) Summary of accelerated and long-term testing parameters (e.g. studies conducted):

Storage conditions (?C, % RH)	*Strength and batch number*	*Batch size*	*Container closure system*	*Completed (and proposed) test intervals*

Summary of the stability results observed for the above accelerated and long-term studies:

Test	**Results**
Description	
Moisture	
Impurities	
Assay	
etc.	

(c) Proposed storage statement and shelf-life (and in-use storage conditions and in-use period, if applicable):

Container closure system	**Storage statement**	**Shelf-life**

2.3. P.8.2 Post-approval Stability Protocol and Stability Commitment

(a) Stability protocol for *Primary stability batches* (e.g. storage conditions (including tolerances), batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	**Details**
Storage condition(s) (?C, % RH)	
Batch number(s) / batch size(s)	
Tests and acceptance criteria	Description
	Moisture
	Impurities
	Assay
	etc.
Testing frequency	

Parameter	**Details**
Container closure system(s)	

(b) Stability protocol for *Commitment batches* (e.g. storage conditions (including tolerances), batch numbers (if known) and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	**Details**	
Storage condition(s) (?C, % RH)		
Batch number(s) / batch size(s)	*<not less than three production batches in each container closure system>*	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing Frequency		
Container Closure System(s)		

(c) Stability protocol for *ongoing batches* (e.g. storage conditions (including tolerances), number of batches per strength and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	**Details**	
Storage condition(s) (?C, % RH)		
Batch size(s), annual allocation	*<at least one production batch per year (unless none is produced that year) in each container closure system >*	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

2.3. P.8.3 Stability Data

(a) The actual stability results should be provided in *Module 3*.

(b) Summary of analytical procedures and validation information for those procedures *not* previously summarised in 2.3.P.5 (e.g. analytical procedures used only for stability studies):

(c) Bracketing and matrixing design and justification for *Commitment* and/or *Ongoing stability batches*, if applicable:

2.3. A APPENDICES

2.3. A.1 Facilities and Equipment (name, manufacturer)

Summary of information on facilities and equipment, in addition to the information provided in other sections of the submission: Not applicable.

2.3. A.2 Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)

Summary of the information assessing the risk with respect to potential contamination with adventitious agents: Not applicable.

2.3. A.3 Excipients

Summary of the details of manufacture, characterization and controls, with cross references to supporting safety data (nonclinical and/or clinical) for the novel excipients: Not applicable. Novel excipients are not accepted in the Prequalification Programme.

2.3. R REGIONAL INFORMATION

2.3. R.1 Production Documentation

2.3. R.1.1 Executed Production Documents

List of batches (including strengths) for which executed production documents have been provided (e.g. comparative bioavailability or biowaiver batches):

2.3. R.1.2 Master Production Documents

The blank master production documents for each strength, proposed commercial batch size and manufacturing facility should be provided in *Module 3*.

2.3. R.2 Analytical Procedures and Validation Information

ANALYTICAL PROCEDURES AND VALIDATION INFORMATION SUMMARIES

ATTACHMENT NUMBER:			
HPLC Method Summary		**Volume/Page :**	
Method name:			
Method code:		**Version and/or Date:**	
Column(s) / temperature (if other than ambient):			
Mobile phase (specify gradient program, if applicable):			
Detector (and wavelength, if applicable):			
Flow rate:			
Injection volume:			
Sample solution concentration			
(expressed as mg/ml, let this be termed “A”):			
Reference solution concentration (expressed as mg/ml and as % of “A”):			
System suitability solution concentration			
(expressed as mg/ml and as % of “A”):			
System suitability tests (tests and acceptance criteria):			
Method of quantification (e.g. against API or impurity reference standard(s)):			
Other information (specify):			

ATTACHMENT NUMBER:					
Validation Summary		**Volume/ Page:**			
Analytes:					
Typical retention times (RT)					
Relative retention times ($RT_{Imp.}/RT_{API\ or\ Int.\ Std.}$):					
Relative response factor ($RF_{Imp.}/RF_{API}$):					
Specificity:					
Linearity / Range:	Number of concentrations: Range (expressed as % "A"): Slope: Y-intercept: Correlation coefficient (r^2) :				
Accuracy:	Conc.(s) (expressed as % "A"): Number of replicates: Percent recovery (avg/RSD):				
Precision/ Repeatability: (intra-assay precision)	Conc.(s) (expressed as % "A"): Number of replicates: Result (avg/RSD):				
Precision/ Intermediate Precision: (days/analysts/ equipment)	Parameter(s) altered: Result (avg/RSD):				
Limit of Detection (LOD): (expressed as % "A")					
Limit of Quantitation (LOQ): (expressed as % "A")					
Robustness:	Stability of solutions: Other variables/effects:				
Typical chromatograms or spectra may be found in:					
Company(s) responsible for method validation:					
Other information (specify):					

PART II- BIOEQUIVALENCE TRIAL INFORMATION

Non-proprietary name of the finished pharmaceutical product (FPP)			
Proprietary name of the finished pharmaceutical product (FPP)			
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph)			
Applicant name and address			
Dosage form			
Reference Number(s)			
Strength(s)			
Route of administration			
Proposed indication(s)			
Name and address of the Contract Research Organisation(s) where the clinical studies proving efficacy and safety of the product were conducted. *(Add as much rows as necessary)*			
Contact information	Name: Phone: Fax: Email:		

1.0 SUMMARY OF BIOAVAILABILITY/BIOEQUIVALENCE STUDIES PERFORMED

*(Provide a brief description of each comparative bioavailability study included in the submission) *…*

2.0 TABULATION OF THE COMPOSITION OF THE FORMULATION(S) PROPOSED FOR MARKETING AND THOSE USED FOR BIOEQUIVALENCE STUDIES

(State the location of the master formulae in the quality part of the submission) (Tabulate the composition of each product strength using the table below. For solid oral dosage forms the table should contain only the ingredients in tablet core /contents of a capsule. A copy of the table should be filled in for the film coating/hard capsule, if any.

Important: *If the formulation proposed for marketing and those used for bioequivalence studies are not identical, copies of this table should be filled in for each formulation with clear identification in which bioequivalence study the respective formulation was used) *…*

Component and Quality Standard	*Function*	*Strength (label claim)*			
		XX mg		*XX mg*	
		Quantity per unit	*%**	*Quantity per unit*	*%**
TOTAL					

**each ingredient expressed as a percentage of the total core or coating weight*

Composition of the batches used for clinical, bioequivalence or dissolution studies				
Batch number				
Batch size (number of unit doses)[1]				
Comments, if any				
Comparison of unit dose compositions and of clinical FPP batches (duplicate this table for each strength, if compositions are different)				
Ingredients	*Unit dose (mg)*	*Unit dose (%)*	*Biobatch (kg)*	*Biobatch (%)*
Equivalence of the compositions or justified differences				

[1]Bioequivalence batches should be at least of pilot scale (10% of production scale or 100,000 capsules/tablets whichever is the greater) and manufacturing method should be the same as for production scale.

2.1 HAS COMPARATIVE BIOAVAILABILITY DATA BEEN SUBMITTED FOR ALL STRENGTHS?

(If comparative bioavailability data has not been submitted for all strengths, provide a scientific justification for not submitting such data; append copies of all references cited in the justification. Justification should include – but is not limited to – argumentation related to dose-proportional composition, dose-linearity of pharmacokinetics (Cmax and AUC,), discriminatory (with regard to bioavailability differences) power of dissolution tests employed)

*…

Sections 3.0 – 11.0 below should be copied and completed separately for each bioequivalence study performed.

3.0 CLINICAL STUDY REPORT

Study #:
Study Title:
Location of Study Protocol:
Start and stop dates for each phase of the clinical study:
*…

3.1 ETHICS

(a) Name of review committee, date of approval of protocol and consent form, location of approval letter in the submission
*…

(b) State location of a reference copy of the informed consent form
*…

3.2 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

(a) Name of principal investigator(s) (State location of C.V. in the submission)
*…

(b) Clinical Facility (Name and full mailing address)
*…

(c) Clinical Laboratories (Name and full mailing address)
*…

(d) Analytical Laboratories (Name and full mailing address)
*…

(e) Company performing pharmacokinetic/statistical analysis (Name and full mailing address)
*…

3.3 STUDY OBJECTIVES

Briefly state the study objectives.

*…

3.4 INVESTIGATIONAL PLAN

3.4.1 Overall Study Design and Plan – Description

(Describe the type of study design employed in 1-2 sentences)

*…

3.4.2 Selection of Study Population

*…

3.4.2.1 Inclusion Criteria

*…

3.4.2.2 Exclusion Criteria

(List the exclusion criteria applied to subjects)

*…

3.4.2.3 Removal of Trial subjects from Trial or Assessment

*…

(a) Number of subjects enrolled in the study

(All subjects including alternates, withdrawals, and dropouts)

*…

(b) Withdrawals

(Identify each withdrawal by subject and provide the reason for withdrawal and at what point in the study the withdrawal occurred)

*…

3.4.2.4 Health Verification

(Individual data should be included in the submission)

*…

(a) List criteria used and all tests performed in order to judge health status

*…

(b) Indicate when tests were performed

*…

(c) Study site normal values
(State location in submission of study site normal values for blood clinical chemistry, haematology, and urinalysis clinical screen)
*…

(d) Report any results that were outside of study site normal values
(State location in submission of the summary of anomalous values)
*…

3.4.3 Products Administered

3.4.3.1 Test Product
*…

(a) Batch number, size and date of manufacture for the test product
*…

(b) Potency (measured content) of test product as a percentage of label claim as per validated assay method
(This information should be cross-referenced to the location of the certificate of analysis in the submission)
*…

3.4.3.2 Reference Product
(Append to this template a copy of product labelling (summary of product characteristics), as authorised in country of purchase, and English translation if appropriate)
*…

(a) Name and manufacturer of the reference product
*…

(b) Batch number and expiry date for the reference product
*…

(c) Purchase, shipment, storage of the reference product
(This information should be cross-referenced to location in submission of documents (e.g. receipts) proving conditions)
*…

(d) Potency (measured content) of the reference product as a percentage of label claim, as measured by the same laboratory and under the same conditions as the test product
(This information should be cross-referenced to the location of the certificate of analysis in the submission)
*…

(e) Justification of choice of reference product
(Provide short summary here and cross-reference to location of comprehensive justification in study protocol)
*…

3.4.4 Selection of Doses in the Study
*…

(a) State dose administered
(Indicate the number of dosage units comprising a single dose, e.g., 400 mg as 1 x 400 mg or 2 x 200 mg tablets)
*…

3.4.5 Selection and Timing of Dose for Each Subject

(a) State volume and type of fluid consumed with dose
*…

(b) Interval between doses *(i.e., length of washout)*
*…

(c) Protocol for the administration of food and fluid
*…

(d) Restrictions on posture and physical activity during the study
*…

3.4.6 Blinding

3.4.6.1 Identify which of the following were blinded. If any of the groups were not blinded, provide a justification for not doing so

a) study monitors: Yes ☐ / No ☐ If No, justify:_____
b) subjects: Yes ☐ / No ☐ If No, justify:_____
c) analysts: Yes ☐ / No ☐ If No, justify:_____
*…

3.4.6.2 Identify who held the study code and when the code was broken
*…

3.4.7 Drug Concentration Measurements
*…

3.4.7.1 Biological fluid(s) sampled
*…

3.4.7.2 Sampling Protocol

*…

(a) Number of samples collected per subject

*…

(b) Volume of fluid collected per sample

*…

(c) Total volume of fluid collected per subject per phase of the study

*…

(d) List the study sampling times

*…

(e) Identify any deviations from the sampling protocol

(State location of summary in the submission)

(Describe and explain reasons for deviations from sampling protocol. Comment on impact on study. Indicate whether the deviations were accounted for in the pharmacokinetic analysis)

*…

3.4.7.3 Sample Handling

*…

(a) Describe the method of sample collection

*…

(b) Describe sample handling and storage procedures

*…

3.5 COMMENTS FROM REVIEW OF SECTION 3.0 – *NDA USE ONLY*

4.0 TRIAL SUBJECTS

4.1 Demographic and Other Baseline Characteristics

*…

(a) Identify study population (i.e., normal, healthy adult volunteers or patients)

*…

(b) Summary of ethnic origin and gender of subjects

*…

(d) Range and mean age ± SD of subjects

*…

(e) Range and mean height and weight ± SD of subjects
*…

(f) Identify subjects whose ratio is not within 15% of the values given on a standard height/weight table
*…

4.2 Number of smokers included in the study
*…

(a) Indicate how many cigarettes smoked per day per subject
*…

(b) Comment on the impact on study
*…

4.3 COMMENTS FROM REVIEW OF SECTION 4.0 – *NDA USE ONLY*

5.0 PROTOCOL DEVIATIONS

5.1 Protocol deviations during the clinical study
(Describe any such deviations and discuss their implications with respect to bioequivalence)
*…

5.2 COMMENTS FROM REVIEW OF SECTION 5.0 – *NDA USE ONLY*

6.0 SAFETY EVALUATION

6.1 Identify adverse events observed
(List any adverse events by subject number. State whether a reaction occurred following administration of the test or reference product, identify any causal relationships, and note any treatments required. State location of this summary in the submission)
(Discuss the implications of the observed adverse events with respect to bioequivalence)
*…

6.2 COMMENTS FROM REVIEW OF SECTION 6.0 – *NDA USE ONLY*

7.0 EFFICACY EVALUATION –
Efficacy Results and Tabulations of Individual Trial Subjects Data

7.1 Presentation of Data
*…

(a) State location in submission of tables of mean and individual subject concentrations
*…

(b) State location in submission of (mean and individual) linear and semi-logarithmic subject drug concentration vs. time plots
*…

7.2 Pharmacokinetic (PK) Parameters

		Test			Reference	
Parameter	Arithmetic Mean	Standard deviation	Inter individual coefficient of variation (%)	Arithmetic Mean	Standard deviation	Inter individual coefficient of variation (%)
AUC_T (units)						
AUC_I (units)						
C_{max} (units)						
T_{max} (units)						
$T_?$ (units)						

(State method of AUC calculation and method of extrapolation. Indicate location of description in protocol)
*…

(b) Ratio of AUC_T to AUC_I
(State mean ratio for both test and reference, state location in submission where individual ratios can be found,)
*…

7.3 Statistical Analysis
(Provide the following results from the ANOVA (non-parametric) on the logarithmically transformed AUC_T and C_{MAX} and other relevant parameters, e.g. in the case of steady-state designs, $AUC_?$, C_{MAX} , and C_{MIN} ; state software which has been used for computing ANOVA)
*…

(a) Geometric means, Results from ANOVA, Degrees of Freedom (DF) and derived CV (intraindividual)

Parameter	*Test*	*Reference*	*% Ratio of Geometric Means*	*90% Confidence Interval*	*DF*	*CV (%)*
AUC_T (units)						
AUC_I (units)						
C_{max} (units)						

*…

(b) Period and/or sequence effects

(State whether any period- and/or sequence-effects have been found. If yes, provide short discussion of effects here, and state location in submission where comprehensive explanation is provided)

*…

7.4 DISCUSSION OF RESULTS

(State location of the discussion of the results in the submission. If the discussion currently included in the study report does not include comparisons of results, including inter- and intraindividual variability, of this study with published results (literature, product information of reference product (innovator), such a discussion should be provided here and copies of the references used should be appended to this document)

*

7.5 COMMENTS FROM REVIEW OF SECTION 7.0 – *NDA USE ONLY*

8.0 ANALYTICAL STUDY REPORT

8.1 Analytical Technique

*…

8.1.1 Analytical protocol

(State the location of the analytical protocol)

*…

8.1.2 Identify analyte(s) monitored

*…

8.1.3 Comment about source and validity of reference standard
*…

8.1.4 Identify analytical technique employed
*…

8.1.5 Identify method of detection
*…

8.1.6 Identify internal standard
*…

8.1.7 If based on a published procedure, state reference citation
*…

8.1.8 Identify any deviations from protocol
*…

8.1.9 Dates of subject sample analysis
*…

8.1.10 Longest period of subject sample storage
(Identify the time elapsed between the first day of sample collection and the last day of subject sample analysis)
*…

8.1.11 State whether all samples for a given subject were analysed together in a single analysis run
*…

8.2 Standard Curves
(State location in submission of tabulated raw data and back calculated data with descriptive statistics)
*…

(a) List number and concentration of calibration standards used
*…

(b) State number of curves run during the study
*…

(c) Summarize descriptive data including slope, intercept, correlation coefficients
*…

(d) Describe the regression model used including any weighting
*…

(e) State the limit of quantitation (LOQ)
(Summarize inter-day and intra-day precision and accuracy at the LOQ)
*…

8.3 Quality Control Samples

*…

(a) Identify the concentrations of the QC samples, their date of preparation and the storage conditions employed prior to their analysis

*…

(b) State the number of QC samples in each analytical run per concentration

*…

8.4 Precision and Accuracy

*…

(a) Summarize inter-day and intra-day precision and accuracy of QC samples analysed during subject sample analysis and inter-day precision of back-calculated standards

*…

8.5 Repeat Analysis

(a) List repeats by sample identification and include the following information for each repeat: initial value; reason for repeat; repeat value(s); accepted value; and reason for acceptance

*…

(b) Report the number of repeats as a percentage of the total number samples assayed

*…

8.6 Chromatograms

(State the location in the submission where the sample chromatograms can be found. The chromatograms should be obtained from a minimum of two analytical batches and include at least 20% of the subjects, up to a maximum of five. A complete set includes standards, QC samples, pre-dose and post-dose subject samples for both phases. Each chromatogram should be clearly labelled with respect to the following: date of analysis; subject ID number; study period; sampling time; analyte; standard or QC, with concentration; analyte and internal standard peaks; peak heights and/or areas)

*…

8.7 COMMENTS FROM REVIEW OF SECTION 8.0 – NDA USE ONLY

9.0 ANALYTICAL VALIDATION REPORT

9.1 Precision and Accuracy

*…

(a) Summarize inter-day and intra-day accuracy and precision during assay validation

*…

(b) Summarize inter-day and intra-day accuracy and precision during assay re-validation

(If applicable)

*…

9.2 Stability

(For each section provide the location of the raw data, a description of the methodology employed and a summary of the data)

(a) Summarize data on long-term storage stability

*…

(b) Summarize data on freeze-thaw stability

*…

(c) Summarize data on bench top stability

*…

(d) Summarize data on autosampler storage stability

*…

(e) Summarize data from any other stability studies conducted (e.g., stock solution stability)

*…

9.3 Specificity

(Methods to verify specificity against endogenous/exogenous compounds & results)

*…

9.4 Recovery

(Method and results of assessment for analyte and internal standard including mean and CV%)

*…

9.5 COMMENTS FROM REVIEW OF SECTION 9.0 – NDA USE ONLY

10.0 QUALITY ASSURANCE

10.1 Internal quality assurance methods

(State locations in the submission where internal quality assurance methods and results are described for each of study sites (see 3.2 b-d)

*…

10.2 Monitoring, Auditing, Inspections

(Provide a list of all monitoring and auditing reports of the study, and of recent inspections of study sites by regulatory agencies. State locations in the submission of the respective reports for each of study sites (see 3.2 b-d)

*

10.3 COMMENTS FROM REVIEW OF SECTION 10 – NDA USE ONLY

CONCLUSIONS AND RECOMMENDATIONS – NDA use only

PART II- QUALITY INFORMATION SUMMARY

1. The QIS template should be completed to provide a condensed summary of the key quality information for product dossiers (PDs) containing APIs of synthetic or semi-synthetic origin and their corresponding products that are filed with the National Drug Authority, Uganda.

2. The QIS constitutes part of the Product Dossier (PD). The QIS provides an accurate record of technical data in the PD at the time of Registration

and thereafter serves as an official reference document during the course of GMP inspections, variation assessments and reregistration assessments as performed by NDA. The QIS is a condensed version of the Quality Overall Summary – Product Dossier (QOS-PD) and represents the final, agreed upon key information from the PD review (inter alia identification of the manufacturer(s), API/FPP specifications, stability conclusions and relevant commitments).

3. The QIS template is structured to permit the rapid assembly of the QIS by copying requisite information from the corresponding portions of the QOS-PD filed with the original PD. It is acknowledged that the numbering of the sections may not be entirely sequential. Those sections not considered necessary to be included in the QIS have been removed (e.g. 2.3.S.5 Reference Standards or Materials) and the remaining sections have retained their numbering to be consistent with the original PD.

4. For original PDs, the QIS should be provided in Word format at the time of PD submission. The QIS should be revised and submitted with the change history (see table at the end of the template) each time additional data is provided during the assessment process. If no revision is necessary due to no change in the information, a statement should be made to this effect in the covering letter. For variations and reregistration dossiers, the QIS should be completed in its entirety (regardless of the proposed change), it should include information on all strengths, with any changes highlighted and it should be provided at the time of filing.

When completing the QIS template, this covering Foreword should be deleted.

QUALITY INFORMATION SUMMARY (QIS)

INTRODUCTION

(a) Summary of product information:

Non-proprietary name of the finished pharmaceutical product (FPP)			
Proprietary name of the finished pharmaceutical product (FPP)			
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph)			
Applicant name and address			
Contact information	Name: Phone: Fax: Email: Website:		
Dosage form			
Reference Number(s)			
Strength(s)			
Route of administration			
Proposed indication(s)			
Authorised Agent			
Contact information	Name: Phone: Fax: Email: Website:		

(b) Administrative Summary:

Reference number e.g. A001	
Applicant's date of preparation or revision of the QIS	
Internal version and/or date of acceptance	(NDA use only)

Related dossiers (e.g. FPP(s) with the same API(s) submitted to the Prequalification Programme by the applicant):

Reference/ File *number (e.g. A001)*	**Prequalified (Y/N)**	**API, strength, dosage form** *(e.g.. Abacavir (as sulphate) 300 mg tablets)*	**API manufacturer** *(including address)*

2.3. S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API)) (NAME, MANUFACTURER)

Indicate which option applies for the submission of API information:

Name of API:	
Name of API manufacturer	
•	Certificate of suitability to the European Pharmacopoeia (CEP) ? Active pharmaceutical ingredient master file (APIMF) procedure:
•	APIMF number assigned by WHO (if known): _____ ; version number (and/or date) of the open part: _____ ; version number (and/or date) of the closed part: _____ ;
•	Full details in the PD

2.3. S.2 Manufacture (name, manufacturer)

2.3. S.2.1 Manufacturer(s) (name, manufacturer)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing, and storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address (including block(s)/unit(s))	*Responsibility*	*APIMF/CEP number (if applicable)*	*Letter of access provided?*

2.3. S.4 Control of the API (name, manufacturer)

2.3. S.4.1 *Specification (name, manufacturer)*

API specifications of the FPP manufacturer:

Standard (e.g. Ph.Int., Ph.Eur., BP, USP, House)		
Specification reference number and version		
Test	Acceptance criteria	Analytical procedure
(Type/Source/Version)		
Description		
Identification		
Impurities		
Assay		
etc.		

2.3. S.6 Container Closure System (name, manufacturer)

(a) Description of the container closure system(s) for the storage and shipment of the API:

2.3. S.7 Stability (name, manufacturer)

2.3. S.7.1 Stability Summary and Conclusions (name, manufacturer)

(c) Proposed storage conditions and re-tests period:

Container closure system	Storage statement	Re-test period*

* indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile APIs)

WRITTEN COMMITMENTS OF THE MANUFACTURER

API

If applicable (primary stability study commitment):

The Applicant (or API manufacturer) undertook in writing (date of letter of commitment) to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year) and to report any significant changes or out-of-specification results immediately to WHO for the following batches :

<Batch numbers, manufacturing dates, batch size, and primary packing materials>

If applicable (commitment stability studies):

Since stability data on three production scale batches were not provided with the application, the remaining number of production scale batches should be put on long-term stability testing and the data should be provided as soon as available. Any significant changes or out-of-specification results should be reported immediately to WHO. The approved stability protocol should be used for commitment batches.

API option 2 - CEP

The Applicant provided a commitment in writing (date of letter of commitment) to inform WHO in the event that the CEP is withdrawn. Note that withdrawal will require additional consideration of the API data requirements to support the dossier.

API option 3 - full details in the PD (ongoing stability study commitment)

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends should be investigated. Any confirmed significant change, out-of-specification result, or significant atypical trend should be reported immediately to WHO. The possible impact on batches on the market should be considered in consultation with WHO inspectors.

FPP

If applicable (primary stability study commitment):

The Applicant undertook in writing (date of letter of commitment) to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year) and to report any out-of-specification results or significant changes immediately to WHO for the following batches :

<Batch numbers, manufacturing dates, batch size, primary packing materials >

If applicable (commitment stability studies):

Since stability data on three production scale batches was not provided with the application, the Applicant undertook in writing, (date of letter of commitment) to put the remaining number <e.g. additional two (2)> production scale batches of < FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> on long-term stability testing. Any out-of-specification results or significant changes during the study should immediately be reported to WHO. The approved stability protocol should be used for commitment batches.

If applicable (the proposed commercial batch size is 200 000 units (x units) or less)

The Applicant undertook in writing (date of letter of commitment) to place the first three batches of any production size larger than x units on stability. The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change, out-of-specification result, or significant atypical trend will be reported immediately to WHO.

Ongoing stability study commitment

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product manufactured in every primary packaging type will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends should be investigated. Any confirmed significant change, out-of-specification result, or

significant atypical trend should be reported immediately to WHO. The possible impact on batches on the market should be considered in consultation with WHO inspectors.

If applicable (validation of production batches)

Since validation data on production scale batches of not less than three (3) consecutive batches of <FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> were not provided with the application, the Applicant submitted a written commitment (date of letter of commitment) that a validation report —in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the WHO inspection team. The approved validation protocol should be used for commitment batches.

FORM 2

Regulation 6 (1)

APPLICATION FORM FOR REGISTRATION OF VACCINES AND OTHER IMMUNOLOGICAL PRODUCTS FOR HUMAN OR VETERINARY USE

THE NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Section A: General Information

1. Proprietary (commercial or trade) name: ……
2. Non-proprietary (common) name: ……
3. Concentration:.....
4. Pharmaceutical form: .....
5. Contact pharmacist: .....
   Postal address:.....
   Phone:…… Fax:……e-mail:……
6. Agent: .....
   Postal address:.....
   Phone:…… Fax:……e-mail:……
7. Applicant: .....
   Postal address:.....
   Phone:…… Fax:……e-mail:……
8. Manufacturer of active ingredients: .....
   Postal address:.....
   Phone:…… Fax:……e-mail:……
9. Manufacturers of vaccines or other immunological products:
   .....
   Physical address of manufacturing site:
   Postal address:.....
   Phone:…… Fax:……e-mail:……

10. Other manufacturers involved in the manufacturing process:

	Name	*Physical address of manufacturing site*	*Activity*
1			
2			
3			
4			

11. Official responsible for releasing batches of vaccines or other immunological product: .....

    Postal address:.....

    Phone:…… Fax:……e-mail:……

12. Commercial presentation of product:.....

13. Route of administration:.....

14. Conditions of storage or conservation:.....

15. Dispensing requirements:.....

16. Strength per dosage unit:.....

17. Declaration:

Name of signatory:.....

I the undersigned hereby apply for registration of the product detailed above and declare that all the information herein and in the appendices is correct and true.

Fee enclosed:.....Signed:.....Date:.....

Full name of Signatory:.....

Designation and qualifications: .....

Section B: Administrative information

1. Table of contents

2. Summary of product characteristics and product labeling

3. List of countries where the product has already been licensed and summary of the approval conditions (attach validated copies of marketing authorization/product licences issued by the appropriate regulatory authority):

4. A declaration signed by each of the experts who performed the product evaluation from the standpoint of quality, nonclinical studies and clinical studies. Attach a summary of their academic records and employment experience.

5. Evaluation of the possible environmental risks posed by the use and/or disposal of the vaccine and give proposals in that regard and the indications or warnings to be included on the product label.

Section C: Summary of quality information.

Summary of the quality (chemical, pharmaceutical, and biological), nonclinical and clinical information presented in appendix III, IV, and V.

Section D: Quality Information

The chemical, pharmaceutical, and biological data on development, the manufacturing process, certificates of analysis, characterization and properties, quality control, specifications and stability of each of the active ingredients and vaccines or other immunological product.

Section E: Non-clinical studies

1. Particulars of toxicological tests done:
2. Particulars of pharmacological (pharmacodynamic and pharmacokinetic) tests done:

Appendix 4: Clinical studies

Particulars of tests which have been performed on humans regarding safety and efficacy of the product and the indications for which it will be us

SCHEDULE 3

FORM 3

Regulation 14 (1)

CERTIFICATE FOR REGISTRATION OF HUMAN OR VETERINARY DRUGS, PREPARATION AND VACCINES OR OTHER IMMUNOLOGICAL PRODUCTS

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Registration number:……

Date of registration:…….

Expiry date of registration:……

Category of drug or preparation:
Human Veterinary

1. Product information

Proprietary (trade) name:……. Generic name (the International Non-proprietary name; for herbal product, state botanical name):……
Dosage form:…….. Strength(s) per dosage unit:……
Description of drug or preparation:……
Therapeutic category:……..
Indication:……

2. Approved manufacturer(s) information for the product

Production stage	*Name of manufacturer*	*Street address of site*	*Manufacturing step*

3. Product shelf-life

The approved shelf-life of this product when packaged and labeled as detailed in the application and modified in subsequent correspondence is as follows.

Pack description	*Shelf-life*	*Storage conditions*

4. Restrictions on sale or distribution of drug or preparation

- ☐ Scheduled narcotic;
- ☐ Restricted prescription-only distribution (specify - for example, hospitals only);
- ☐ Prescription only;
- ☐ Pharmacy only;
- ☐ Over-the-counter (OTC)

SCHEDULE 4

FORM 4

Regulation 19 (1)

APPLICATION FOR REGISTRATION OF IMPORTED HERBAL MEDICINE PRODUCTS FOR HUMAN USE

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

SECTION A: GENERAL INFORMATION

Particulars of the applicant

Name……

Physical address (Plot No./street No./country) ……

Postal address (if different) ……

Phone:……Fax: ……e-mail:……

Particulars of the Product

Proprietary name (Trade name): ……

Pharmaceutical form: ……Pack size(s) applied for:……

Description of the drug (colour, shape, size etc.):……

Main indication(s):……

Particulars of the manufacturer and activities of the manufacturer

	Name	*Physical address of the manufacturing plant*	*Activities undertaken at the manufacturing plant*
1			
2			
3			

Authorised agent in Uganda

Name of agent: ……

I the undersigned hereby apply for registration of the above-mentioned product and declare that all the information herein and in the appendices is correct and true.

I enclose a fee of ……

Date: …… Signed: ……

Full name of signatory: ……

Designation and qualifications:

SECTION B: PACKAGING SPECIFICATIONS AND PRODUCT COMPOSITION

1. Specifications of the packaging material

a) Primary (inner) container(s):

b) Outer packing:

2. Product composition *Give the formula of the product in terms of a dosage unit*

a) Active ingredients

Processed plant/other natural material	*Source (part of plant or non-plant material used)*	*Quantity per unit dose*	*Plant species*

b) Inactive ingredients

Approved name	*Quantity per unit dose*	*Reason for inclusion*

3. **Additional raw materials** *Give details of any additional raw materials used in the manufacturing process but not found in the final product:*

SECTION C: CHEMISTRY AND PHARMACEUTICAL ASPECTS

1. Raw material specifications and analytical control methods used:
   (a) Crude plant/non-plant material (source of active ingredients)
   (b) Processed plant/non-plant material (active ingredients)……
   (c) Inactive ingredient ……

2. Details of manufacturing procedures (incl. packaging) and summary of equipment used:
   (a) Summary of manufacturing process:
      (i) Preparation of processed raw material from crude plant/non-plant material
      (ii) Preparation of manufactured product from processed raw material

(b) Summary of equipment used

3. Details of in-process control procedures……

4. Specifications and analytical tests of manufactured product ……

5. Test methods……

6. Stability studies on manufactured product (based on two batches ……

7. Complete, filled batch manufacturing records for one commercial batch

SECTION D: SAFETY AND EFFICACY

1. Safety

(i) Evidence of safety in use

(ii) Side effects, contra-indications, precautions etc.

2. Efficacy

(i) Main pharmacological and clinical effects

(ii) Evidence of efficacy in use for proposed indications

(iii) Justification for combination products

FORM 5

Regulation 19 (1)

APPLICATION FORM FOR REGISTRATION OF IMPORTED HERBAL MEDICINE PRODUCTS FOR VETERINARY USE

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

SECTION A: GENERAL INFORMATION

Particulars of the applicant

Name……

Physical address (Plot No./street/country)……

Postal address (if different)……

Phone: …… Fax: ……e-mail:……

Particulars of the product

Proprietary name (Trade name): ……

Pharmaceutical form: …… Pack size(s) applied for:……

Description of the drug (colour, shape, size etc.):……

Main indication(s):.....……

Species of animals for which it is intended:

……

Particulars of the manufacturer and activities of manufacturer

	Name	*Physical address of manufacturing plant*	*Activity undertaken at manufacturing plant*
1			
2			
3			

Authorised agent in Uganda

Name of agent ……

I the undersigned hereby apply for registration of the above-mentioned product and declare that all the information herein and in the appendices is correct and true.

I enclose a fee of ……

Date:……Signed: ……

Full name of signatory: ……

Designation and qualifications: .....

SECTION B: PACKAGING SPECIFICATIONS AND PRODUCT COMPOSITION

1. Specifications of the packaging material
   (a) Primary (inner) container(s):
   (b) Outer packing:

2. Product composition *Give the formula of the product in terms of a dosage unit*

a) Active ingredients

Processed plant/other natural material	*Source (part of plant or non-plant material used)*	*Quantity per unit dose*	*Plant species*

b) Inactive ingredients

Approved name	*Quantity per unit dose*	*Reason for inclusion*

3. Additional raw materials Give details of any additional raw materials used in the manufacturing process but not found in the final product:

SECTION C: CHEMISTRY AND PHARMACEUTICAL ASPECTS

1. Raw material specifications and analytical control methods used:
   (a) Crude plant/non-plant material (source of active ingredients)……
   (b) Processed plant/non-plant material (active ingredients)……
   (c) Inactive ingredients ……

2. Details of manufacturing procedures (including packaging) and summary of equipment used:

   (a) Summary of manufacturing process:

      (i) Preparation of processed raw material from crude plant/non-plant material

      (ii) Preparation of manufactured product from processed raw material

   (b) Summary of equipment used

3. Details of in-process control procedures…….

4. Specifications and analytical tests of manufactured product……

5. Test methods ……

6. Stability studies on manufactured product (based on two batches)

7 Complete, filled batch manufacturing records for one commercial batch

SECTION D: SAFETY AND EFFICACY

1. Safety

(1) Evidence of safety in use
(2) Side effects, contra-indications, precautions etc.
(3) Withdrawal periods for meat, milk, eggs, etc.

2. Efficacy

(1) Main pharmacological and clinical effects

(2) Evidence of efficacy in use for proposed indications

(3) Justification for combination products

FORM 6

Regulation 19 (2)

APPLICATION FORM FOR REGISTRATION OF LOCAL HERBAL MEDICINE PRODUCT

1(a)	Particulars of applicant i.e. name and contact address: (Email address inclusive),telephone number	
(b)	Age (where applicable)	d) Gender (where applicable)
(c)	Marital status(where applicable)	e) Educational background (if applicable)
2.	Reference of Local Council (with signature and stamp) or certificate of incorporation	
3.	Name of product (As it appears on the pack):	
4.	Dosage form and pack size:	
5.	Mode of administration (Topical, Oral)	
6.	Common name(s)/ source plant(s) that's active (botanical name(s))	
7.	Herbarium specimen number). (Got from the National Herbarium). (Evidence of authenticity of the plants used.)	
8.	Community and name by which its known by the community /if applicable	
9.	Part of the plant or method of preparation used (e.g. leaf, root, oil, extract etc.)	
10.	Strength/quantities per dosage form (where applicable to a prepared dose such as tablet, mixture etc.)	
11.	Indication for use as given on the pack/literature/manufacturer's instructions)	
12.	Major side/adverse effects, if any :	
13.	Storage conditions	
14.	Shelf life	

15.	Address of the manufacturer	
16.	Period during which the herbal medicine product has been in use	
17	Any written literature to support use of the product	
18.	Method/outlet used for sale and address of location	
19.		
	Signature	
	Date	

SCHEDULE 5

FORMAT OF REGISTER FOR SURGICAL INSTRUMENTS

Regulation 26

Name and particulars of applicant (patent holder, licensed person, manufacturer or agent)	*Manufacturer*	*Name of surgical instrument*	*Pack sizes*	*Country of manufacture*	*Registration No. of Authority*

SCHEDULE 6

FORM 7

Regulation 27 (2)

APPLICATION FORM FOR THE REGISTRATION OF SURGICAL INSTRUMENTS

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Particulars of the applicant
Name:.....

Physical address:.....

Postal address (if different):
Phone: ……Fax:……e-mail:.....

1. Particulars of the surgical instrument
Proprietary/brand name: .....

Brief description of the device:
.....

Class of the device:
.....

Intended use and method of use:
.....

Medical specialty in which device is used:
.....

Contraindications, warnings, precautions, potential adverse effects:
.....

List of accessories and other devices or equipment to be used in combination with the device:

Variations in shape, style or size of the device, if applicable:

.....

Labelling description:

.....

Packaging description including pack sizes:

.....

Recommended storage condition:

.....

Two samples submitted when practicable (Yes/No):

.....

Certificate of analysis submitted (Yes/No):

.....

Evidence of repeat sales in country of manufacture submitted (Yes/No):

.....

Copy of a licence from the country of manufacture or evidence of conformity to standards from a certification body submitted (Yes/No):

.....

Summary information on pre-clinical design verification and validation submitted (Yes/No):

.....

2. Particulars of the manufacturer and activities of the manufacturer

	Name	*Address of manufacturing plant*	*Activity undertaken at the manufacturing plant*
1			
2			
3			

Copy of manufacturing license(s) submitted (Yes/No):

.....

Evidence of repeat sales in country of manufacture provided (Yes/No):
.....

Manufacturer's declaration of conformity to essential principles of safety and performance submitted (Yes/No):
.....

3. Authorised agent in Uganda:

Name of the authorised agent:
.....

I, the undersigned hereby apply for registration of the device detailed above and declare that all the information herein and in the appendices is correct and true.

Fee enclosed: .....Signed: .....

Date:.....

Full name of signatory:

.....

Designation and qualifications:.....….....

SCHEDULE 7

FORM 8

Regulation 30(2)

CERTIFICATE FOR REGISTRATION OF SURGICAL INSTRUMENTS

NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Licence number:.....

Issue date: .....

Class of surgical instrument:.....

Product name:.....

Manufacturer name and address: .....

Application number:.....

Components/parts/accessories/devices for this licence

ID Number	*Model*	*Name*

RUHAKANA RUGUNDA (DR.)
Minister of Health.