STATUTORY INSTRUMENTS
SUPPLEMENT No. 8 **28th March, 2014**

STATUTORY INSTRUMENTS SUPPLEMENT

to The Uganda Gazette No. 18 Volume CVII dated 28th March, 2014

Printed by UPPC, Entebbe, by Order of the Government.

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

2014 No. 30.

THE NATIONAL DRUG POLICY AND AUTHORITY (CONDUCT OF ECTOPARASITICIDES FIELD TRIALS) REGULATIONS, 2014

ARRANGEMENT OF REGULATIONS

Regulation

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

2014 No. 30.

The National Drug Policy and Authority (Conduct of Ectoparasiticides Field Trials) Regulations, 2014.

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

IN EXERCISE of the powers conferred on the Minister responsible for health by section 40 of the National Drug Policy and Authority Act, Cap 206 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 (Conduct of Ectoparasiticides Field Trials) Regulations, 2014.

2. Interpretation.

In these Regulations, unless the context otherwise requires—

"Act" means the National Drug Authority Act;

"adverse event" means any undesirable change in the health of an animal used in a field trial or a side-effect that occurs in an animal used in a field trial, during the field trial or within a determined period of time after the field treatment has been completed;

"Authority" means the National Drug Authority;

"comparator product" means an investigational product or placebo, used as a reference in a field trial;

"consent" means a written, signed and dated voluntary confirmation by an owner of an animal about his or her willingness for the animal to be used in a field trial, after being informed of all the aspects of the field trial that are relevant to the decision to be made by the owner of the animal regarding the field trial;

"ectoparasiticide" means an agent that is applied directly to an animal to kill ticks, mites, lice, fleas, tsetse flies, biting and nuisance flies and other ectoparasites;

"field trial" means an ectoparasiticide field trial;

"investigational product" means an pharmaceutical form of an ectoparasiticide or a placebo being tested or used as a reference in a field trial, and includes an investigational product which is registered by the Authority but is, for the purposes of the field trial—

(a) used or assembled, whether formulated or packaged, in a way different from the form of the registered product;

(b) used for an indication which not included in the characteristics of the product in the registration; or

(c) used to gain further information about the form of that product as registered;

"investigator's brochure" means a document containing a summary of the field and non-field data relating to an investigational product which are relevant to the study of the investigational product in animals, human beings and the environment exposed to the product;

"principal investigator" includes a research institution or organization that conducts a field trial;

"side effect" means an unintended effect occurring at normal dose related to the pharmacological properties of an ectoparasiticide;

"sponsor" means a person who is responsible for the management and financing of a field trial.

3. Requirement for field trials for ectoparasiticides.

(1) Subject to this regulation, field trials shall be conducted for ectoparasiticides that are registered under the Act and for ectoparasiticides that are not registered under the Act, prior to the ectoparasiticides being supplied, administered or used in Uganda.

(2) Where an ectoparasiticide is registered, a field trial shall be conducted where the Authority or the Ministry responsible for animal health so requires, to determine the effectiveness and safety of the ectoparasiticide in Uganda, before it is supplied, administered or used.

(3) Where a field trial is for an ectoparasiticide that is not registered by the Authority under the Act, the field trial shall be conducted to ascertain—

(a) the effectiveness and safety of the ectoparasiticide in animals;

(b) the safety of the ectoparasiticide to humans;

(c) the safety of the ectoparasiticide to the environment; and

(d) any other factor, as may be deemed necessary by the Authority.

(4) A field trial shall be conducted for a period of at least six months.

4. Requirement for authorisation to conduct field trials.

A person shall not start or cause to be started a field trial or conduct a field trial, without the authorisation of the Authority.

5. Application for authorisation to conduct a field trial.

(1) A person who requires to conduct a field trial shall make an application to the Authority using Form 39 in Schedule 1 to these Regulations.

(2) An application for authorisation to conduct a field trial shall be made by a sponsor who shall be a permanent resident of Uganda.

(3) A sponsor may be—

(a) the holder of the patent of the ectoparasiticide;

(b) the manufacturer of the ectoparasiticide; or

(c) an agent of the holder of the patent or of the manufacturer, of the ectoparasiticide.

(4) Where an application for authorisation to conduct a field trial is made by an agent, the agent shall submit a power of attorney attesting to the appointment as agent or a letter of authorisation written in the format in Form 40 in Schedule 1 to these Regulations.

(5) The application shall be accompanied by—

(a) the field trial protocol in the format in Schedule 2 to these Regulations;

(b) evidence of approval to conduct the field trial, granted by the Uganda National Council of Science and Technology;

(c) the principal investigator's brochure or prescribing information data sheet in the format in Schedule 2 to these Regulations;

(d) a declaration by the principal investigator in Form 41 in Schedule 1 to these Regulations;

(e) a declaration by the principal investigator, in the format in Schedule 2 to these Regulations, where the principal investigator is a research institution or organization;

(f) the information to be provided to the owners of the animals to be used in the field trial and the written consent forms of the owners;

(g) evidence of insurance of the animals to be used in the field trial and indemnity for the principal investigator;

(h) the prescribed fees; and

(i) any other requirement as may be determined by the Authority.

6. Approval of field trial by the Uganda National Council of Science and Technology.

An applicant shall prior to making an application to the Authority for authorisation to conduct a field trial, get approval to carry out the field trial, from the Uganda National Council of Science and Technology or an institution authorised to do so by the Uganda National Council of Science and Technology.

7. Consideration of application by the Authority.

(1) Upon receipt of an application for authorisation of a field trial, the Authority shall verify whether the application conforms to the requirement of these Regulations.

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

(3) Where the Authority does not accept an application, the Authority shall, in writing, inform the applicant of this and the reasons for the decision.

(4) Where the Authority is satisfied with an application, the Authority shall approve the application and grant a field trial certificate to the sponsor.

(5) The Authority may grant a field trial certificate with conditions.

(6) A field trial certificate shall be in Form 42 in Schedule 1 to these Regulations.

8. Authorisation of field trials.

In considering an application for a field trial, the Authority shall take into account—

(a) the relevance of the field trial;

(b) the suitability of the principal investigator;

(c) the quality of the facilities to be used for the field trial;

(d) the adequacy and completeness of the information to be given and the procedure to be followed, to obtain the consent of the owners of the animal to be used in the field trial;

(e) the provision for indemnity for the principal investigator and insurance for the animals to be used in the field trial; and

(f) the terms of the agreement between the sponsor and the principal investigator.

9. Field trial certificate.

A field trial certificate shall—

(a) authorise the sponsor to conduct the field trial;

(b) authorise the sponsor to import the investigational product to be used in the field trial;

(c) provide that the field trial is to be conducted in accordance with the protocol approved by the Authority and any other conditions of the authorisation to conduct a field trial as the Authority may determine;

(d) indicate the duration of the field trial; and

(e) contain any other information as may be necessary.

10. Importation and manufacture of drugs for field trials.

(1) A sponsor who is granted a field trial certificate under these Regulations shall apply to the Authority for a permit to import the investigational product approved for the field trial.

(2) The Authority shall grant a permit for the importation of the investigational product which shall be limited to only the investigational products approved for the field trial.

(3) Where the investigational product is to be manufactured in Uganda, the sponsor who is granted a field trial certificate under these Regulations shall apply to the Authority for a licence to manufacture the investigational product approved for the field trial.

(4) The licence granted under subsection (3) shall be for the manufacture of only the investigational products approved for the field trial.

(5) For the avoidance of doubt, where an ectoparasiticide to be imported or manufactured under this regulation is not registered by the Authority under the Act, the ectoparasiticide shall not be registered before the field trial report is approved by the Authority.

11. Authorisation to deviate from conditions of field trial.

(1) A sponsor who intends to deviate from the protocol approved by the Authority or from any other condition of the field trial specified in the field trial certificate shall notify the Authority prior to the deviation.

(2) An application for deviation from a condition of a field trial shall be made using Form 43 in Schedule 1 to these Regulations and shall be accompanied by—

(a) evidence of approval of the amendment to the protocol by the Uganda National Council of Science and Technology or an institution authorised to do so by the Uganda National Council of Science and Technology; and

(b) the prescribed fees.

(3) An application for deviation from a condition of a field trial shall be considered using the procedure and requirements for an application for authorisation to conduct a field trial.

12. Amendments to conditions of field trial by the Authority.

(1) The Authority may, on its own initiative, make amendments to the conditions for conducting a field trial where it is necessary for the safety or scientific validity of the field trial.

(2) Where the Authority proposes to make an amendment to the conditions for conducting a field trial, the Authority shall before making the amendments, give notice to the sponsor and the principal investigator, with reasons for the amendment.

(3) The Authority shall request the sponsor to give a written response to the proposed amendments prior to effecting the amendments.

(4) The Authority shall, in making amendments to the conditions of conducting a field trial, take into consideration the response of the sponsor.

13. Conclusion of a field trial

(1) A sponsor shall within ninety days after the conclusion of a field trial, in writing, inform the Authority of the conclusion of the field trial, using the format for the field trial report in Schedule 2 to these Regulations.

(2) The Authority may during the course of a field trial, request the sponsor to submit an interim report of the field trial.

(3) Where a sponsor is requested to submit an interim report, the sponsor shall make the report using the format for an interim field trial report in Schedule 2 to these Regulations.

(4) A sponsor may, before the date indicated in the field trial certificate or before the occurrence of the event specified in the field trial protocol as the event which indicates the end of the field trial, terminate a field trial and where the sponsor terminates a field trial the sponsor shall, within fifteen days of the termination, notify the Authority.

(5) A notification made under subregulation (4) shall give reasons for the termination, indicate how the investigational product that is not used is to be disposed of and the effective date of the termination and shall be in the format in Schedule 2 to these Regulations.

14. Suspension or termination of field trial

(1) The Authority may by notice, suspend or terminate a field trial, where—

(a) the conditions of a field trial certificate are not complied with; or

(b) the Authority has information regarding the safety or scientific validity of the field trial or the conduct of the field trial.

(2) The notice by the Authority shall be served on the sponsor or the principal investigator.

(3) A notice shall apply to the field trial generally, or to one or more of the field trial sites.

(4) Where a notice is for suspension of the field trial, the suspension shall be for the period specified in the notice.

(5) A notice shall indicate, where applicable, the conditions to be fulfilled before the field trial or, as the case may be, the conduct of the field trial at a particular site, may resume.

(6) The Authority shall before issuing a notice, inform the sponsor or the principal investigator of the notice and the reasons for the notice and advise the sponsor or the principal investigator to make a written representation on the intended suspension or termination within five days.

(7) The Authority shall consider the written representation of the sponsor or principal investigator made under subregulation (6) and inform the sponsor or principal investigator of its decision within seven working days.

(8) Subregulation (6) shall not apply where it appears to the Authority that there is an imminent risk to the health or safety of any of the animals used in a field trial or any person involved in a field trial.

PART III—CONDUCT OF FIELD TRIALS

15. Principles to govern field trials

A sponsor or a principal investigator shall conduct a field trial in accordance with the following principles—

(a) the anticipated benefits of the field trial shall justify the risks;

(b) the safety, and well being of the animals and persons used or involved in a field trial shall prevail over the interests of science and society;

(c) prior to the field trial, there shall be adequate information on the investigational product to be used, which shall support the field trial;

(d) a field trial shall be scientifically sound;

(e) a person registered as a veterinary surgeon or who is licensed to practice veterinary surgery under the Veterinary Surgeons Act shall be available to provide treatment to the animals and to make animal health related decisions related to the field trial;

(f) a person appointed as the monitor of the field trial shall be qualified and with experience to conduct the field trial;

(g) the owner of the animals shall prior to the field trial, give written consent for the animals to be used in the field trial; and

(h) the investigational product shall be used in accordance with the field trial protocol.

16. Responsibilities of a sponsor.
The sponsor shall—

(a) be responsible for the investigational product and the information supplied in support of the application for authorisation of the field trial;

(b) be responsible for updating the information relevant to the investigational product or application;

(c) appoint the principal investigator;

(d) provide the investigational product, including the active comparator and placebo, where required, which is characterised as appropriate, to the stage of development of the investigational product and which is manufactured in accordance with Good Manufacturing Practices and is labeled in a manner that protects blinding, where this is required;

(e) provide appropriate storage conditions such as temperature, protection from light, shelf life, indications and contra indications, reconstitution fluids and procedures, and devices for product application;

(f) maintain records of the shipment, receipt, disposition, return and where necessary, the destruction of the investigational product;

(g) maintain a system for retrieving the investigational product and document the retrieval deficient product recall, reclaim after trial completion and expired product reclaim;

(h) maintain a system for the disposal of the used investigational product that is not used and document the process; and

(i) maintain sufficient quantities of the investigational product used in the field trial to reconfirm specifications, where required, and records of the analyses and characteristics of the batch samples; and

(j) retain samples of the investigational product after the field trial in accordance with the requirements of these Regulations and the conditions of the field trial certificate.

17. Responsibilities of the principal investigator.

A principal investigator shall—

(a) provide written information to the owner of the animals to be used in the field trial and obtain their consent to the field trial;

(b) provide all relevant information to the persons to conduct the field trial;

(c) apply the investigational product to only the animals involved in the field trial;

(d) store or cause to be stored safely, the investigational product and, in accordance with the field trial protocol, manage the handling and dispensing of the investigational product to the animals in the field trial;

(e) maintain a full inventory of the receipt and usage of the investigational product;

(f) within 48 hours of becoming aware, report any suspected adverse event to the Authority; and

(g) provide for the care of the animals used in the field trial.

18. Labeling.

An investigational product shall be labelled as specified in Form 44 in Schedule 1 to these Regulations.

19. Records to be maintained.

(1) The sponsor shall keep the records, documents and information of a field trial for a period of two years, after completion of the field trial.

(2) Notwithstanding subregulation (1), where the ectoparasiticide is to be registered, the records, documents and information of a field trial shall be kept for two years after the registration of the ectoparasiticide.

(3) For the purposes of this regulation, a sponsor shall maintain, for the investigational product used in a field trial—

(a) the investigator's brochure for the investigational product and a record of the changes made to the investigator's brochure, if any, including the rationale for each change;

(b) a record of the adverse events of the investigational product, that occurred inside or outside Uganda, indicating the indication for use and the dosage form of the investigational product at the time of the adverse event;

(c) a record of the animals used in the field trial with their identifications and contacts of the owners of the animals;

(d) a record of the shipment and receipt of the investigational product and where applicable, a record of the return and destruction of the investigational product; and

(e) a copy of the protocol and consent forms, at the field trial site.

20. Urgent safety measures.

(1) A sponsor and a principal investigator shall take the appropriate safety measures to protect the animals in a field trial against any immediate hazard to their health or safety.

(2) Where safety measures are taken, the sponsor or the principal investigator shall within three working days from the date measures are taken, inform the Authority of the measures and the circumstances that gave rise to the measures.

21. Insurance and indemnity.

(1) The sponsor shall provide insurance, against any field trial related injuries that may arise during the field trial, for the animals used in the field trial.

(2) The sponsor shall indemnify the principal investigator against claims that may arise during or from the field trial, except claims that are as a result of malpractice or negligence of the sponsor.

PART IV—PHARMACOVIGILANCE

22. Notification of adverse events.

(1) A principal investigator shall report, to the sponsor, any serious adverse event which occurs in an animal used in a field trial, during a field trial.

(2) The report shall identify each animal referred to in the report by a number assigned to that animal.

(3) Where the serious adverse event reported results in the death of an animal used in the field trial, the principal investigator shall supply the sponsor with any additional information requested by the sponsor.

(4) The sponsor shall keep detailed records of the adverse events relating to a field trial which are reported by the principal investigator.

(5) The Authority may, by written notice, request for the reports of the adverse effects from the sponsor.

23. Notification of suspected unexpected serious adverse reactions.

(1) A principal investigator shall record and report to the sponsor any suspected unexpected serious adverse reaction which occurs during the course of a field trial.

(2) The sponsor shall, within seven days of receipt of becoming aware, report to the Authority, any suspected unexpected serious adverse reactions.

(3) A sponsor shall inform the principal investigator of any suspected unexpected serious adverse reaction which occurs during the course of another field trial for which the sponsor is responsible, where the reaction is in relation to an investigational product used in the field trial.

(4) The Authority shall keep a record of all suspected unexpected serious adverse reactions relating to an investigational product which are reported to the Authority.

PART V—INSPECTION OF FIELD TRIALS AND ENFORCEMENT

24. Requirements for inspection of field trials.
The Authority may any reasonable time, inspect the staff and the facilities used for the field trial, for compliance with the conditions of the field trial certificate.

25. Offences.
(1) A person commits an offence, who—

(a) in an application for authorisation to conduct a field trial or in the course of conducting a field trial, provides to the Authority, information which is false or misleading in a material particular;

(b) has in his or her possession an investigational product, in contravention of these Regulations;

(c) fails to comply with a notice of suspension or termination;

(d) sells or supplies, or procures the sale or supply, of an investigational product, for a field trial, where the labeling of the investigational product is contrary to the requirements of these Regulations; or

(e) contravenes any of other provision of these Regulations.

(2) A person who commits an offence under subregulation (1) is on conviction liable to a penalty specified in the Act.

SCHEDULES

Schedule 1

Forms

Regulation 5 (1)

FORM 39

FIELD TRIAL APPLICATION FORM

Part 1: Identification of the field trial

1. Title of the field trial
2. Contact person and contact details
3. [*Insert Authority reference number*]
4. Declaration of intent signed by the applicant

We, the undersigned have submitted all the documentation required and have disclosed all the information required, for the approval of this application.
We have read the field trial protocol and the investigator's brochure which are attached to this application.
We agree to ensure that the field trial shall be conducted in accordance with the field trial protocol and the relevant laws.

Name of applicant:
Signature:
Designation:
Date:

Name of principal investigator:
Signature:
Designation:
Date:

Part 2: Investigational product to be used in the field trial

1. Name of investigational product
2. Registration number
3. Manufacturer (include all sites)
4. Active ingredient, complete composition, potency and presentation
5. Evidence of manufacture under conditions compliant with current codes of Good Manufacturing Practice

6. Release specifications and tests. *(Include certificate of analysis).*
7. Approved package insert, if available.
8. Comparator, concomitant and rescue medications (antidotes) and placebo.
9. Proprietary name and INN
10. Active ingredient, composition, and presentation
11. Registration number and country of registration
12. Approved package insert (*to be appended to application*).
13. Evidence that placebo is manufactured under Good Manufacturing Practice.
14. Details of handling the investigational product.
15. Shipping, delivery and distribution of investigational product.
16. Details of storage requirements and arrangements where necessary and monitoring during distribution.
17. Details of dispensing the investigational products and waste disposal procedures.
18. Packaging and labeling of the investigational products.
19. Estimates of quantities of each product to be used for the field trial, and for which an import permit is needed.

Part 3: History of previous and in-progress field trials

1. List the titles of previous trials with this or similar field trial product in Uganda or in other countries.

2. Include a letter or certificate from the regulatory authority of the country where previous trials have been undertaken, including those in-progress, indicating whether those trials were in compliance to Good Field Practices.

3. Append summaries of the interim or final report, of those trials to this application, as may be applicable. *(This may be in the investigators brochure).*

Form 40

Regulation 5 (4)

LETTER OF AUTHORIZATION FROM HOLDER OF PATENT OF ECTOPARASITICIDE, LICENCED PERSON OR MANUFACTURER OF ECTOPARASITICIDE

Dae: ……..…….
(Name of holder of patent, licensed person or manufacturer)…….
……...……..
a company operating under the laws of ……., located in ……,
Local company name and address

Tel no: …….
Fax no:…….…….
E-mail address: ……...

Field trial protocol number ……...
Release date: …….

……..……..(name and address of person resident in Uganda) is authorized to represent us in Uganda for the application of a field trial certificate and to conduct the field trial and will be responsible for all matters pertaining to the field trial.

Yours faithfully,

……
(Authorized Name and Signature)
For: The holder of patent, licensed person or the manufacturer

FORM 41

Regulation 5(5)(d)

DECLARATION BY INVESTIGATOR

Field trial protocol number ……
Name: ……
(Attach curriculum vitae).

I am aware of the responsibilities of my role as investigator in field trial number …… as required by the laws of Uganda.

I have read and understand the attached field trial protocol, investigators brochure and supporting documentation and I will comply with the procedures and requirements included in them.

I have read the attached information as submitted to the Authority and confirm that the information is complete, true and accurate, and conforms to the field trial protocol and supporting documentation.

I will not commence with the field trial before written authorization has been received from the Authority. I will provide the Authority and other relevant bodies with the information as required.

I will obtain the consent of all the owners of the animals to be used in the field trial. I will ensure that every animal in the field trial is treated ethically.

I will ensure that a veterinary doctor is involved in the field trial.

I DECLARE: I have no conflict of interest in terms of financial interests or personal relationships that may inappropriately influence my responsibilities and conduct of this field trial.

I DECLARE: I have not previously been associated with any field trial that has been terminated, or a field trial site that was closed, due to failure to comply with relevant laws for the conduct of field trials.

SIGNED …… *Date* …….

WITNESS:……*Signature*……..*Date*……

FORM 42

Regulation 7(6)

ECTOPARASITICIDE FIELD TRIAL CERTIFICATE

Ectoparasiticide field trial certificate number ……………………………….. issued under section 40 of the Act by the Authority.

Name of sponsor..……………………………………………………………
Physical address…………Telephone number ……………Fax number………
E-mail address
… … … … … … . … .
Title of field trial protocol: ….…….…….…….…….…….…….…….…….……..…
Number of field trial protocol:………………………………………………
Date of approval:……………………………Date of expiry:…………………
Name and address of principal investigator……………………………………
Investigational product…………………………………………………….
Field trial site ……………………………………………………………….

The conditions of this field trial certificate -

____
____
____
____
____
____

……………………………… ……..……………………
Executive Secretary *Date*

Form 43

Regulation 11 (2)

APPLICATION FOR DEVIATION FROM FIELD TRIAL CERTIFICATE

Title of the field trial:

Number of the field trial protocol:

Date:

1. APPLICANT

1. Name
2. Address
3. Telephone
4. Fax number

2. PARTICULARS OF FIELD TRIAL (original application)

1. Field trial number:
2. Date of approval of original protocol:
3. Principal investigator approved for the field trial:
4. Number of sites approved for the field trial:
5. Number of animals approved for the field trial:

3. AMENDMENT PARTICULARS

1. Does the applicant wish to increase the number of animals participating in the field trial?

   Yes ❒

   No ❒

2. Does the applicant wish to change the dose or regimen of the investigational product?

   Yes ❒

   No ❒

3. Does this amendment request require a new consent form to be signed by the owners of the animals involved in the field trial?

   Yes ❒

   No ❒

   If "Yes" please submit new PIL together with this application.

Field trial protocol amendment number:
Number and date of amendment (for each document submitted):
General motivation for the proposed amendment: [List all of the issues included in the amendment and provide the rationale for each amendment]

Details of the proposed amendment: [For each amendment, provide reasons for amendment and clearly highlight changes to the original protocol; this can be done either as "old text" replaced with "new text" or with the old text deleted with a line through it and the new text in bold and underlined]

4. Will this amendment apply to all approved site(s)?

   Yes ❒

   No ❒

   If No: Specify the sites for which the amendment will apply:

4. APPROVAL BY THE UGANDA NATIONAL COUNCIL OF SCIENCE AND TECHNOLOGY

1. Date of application to the Uganda National Council of Science and Technology:

2. Date of approval by the Uganda National Council of Science and Technology:

I or we, the undersigned, agree to conduct the field trial under any conditions that may be granted by the Authority.

_____ _____

Applicant (Sponsor or principal investigator) *Date*

Form 44

Regulation 18

LABELLING INVESTIGATIONAL PRODUCTS FOR FIELD TRIAL

The following information shall be labelled on the outer carton and the unit packs of the investigational product for a field trial:

Parameters	*Labels for outer cartons*	*Labels for unit packs*
Number of protocol	√	√
Group code	√	√
Product name or code	√	√
Dosage form	√**	√**
Name of active substance	√**	√**
Strength of active substance	√**	√**
Dilution for different species	√	√
Batch number	√**	√**
Manufacturing date or retest date	√	√
Expiry date	√	√
For field trial use only	√	√
Name and address of manufacturer or final release or product owner (corporate address)or sponsor	√***	√***
Route of administration	√	√
Storage conditions	√	√
Pack sizes (unit/volume)	√	√

*(** Where applicable*
**** With letter of authorization*
If the investigational product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner carton)

SCHEDULE 2

Regulation 5(5)(a)

FORMAT FOR FIELD TRIAL PROTOCOL

(When designing a field trial protocol, the mode of action exhibited by the active substance for example, killing, repellent, anti-feeding, as well as the life cycle of the parasite for example length, seasonality and the parasitic stages shall be taken into account. A field trial protocol shall, where applicable, contain the following particulars).

1. Name and particulars of the investigational product

(1) State the name or code number under which the investigational product is to be imported and known during the field trial. (*A separate application is required for each field trial)*

(2) State clearly the proprietary name, approved or INN or generic name, strength or dosage form, pharmaceutical form, description, labeling, include also information leaflet of the product.

2. Details of the manufacturer

(1) Name of the manufacturer
(2) Physical address
(3) Postal address, telephone and fax numbers, email address and website
(4) Country of origin

3. Identification of the field trial

(1) Title of the field trial
(2) Version

4. Aim of the field trial

(1) Objectives of the field trial
(2) Rationale of field trial.

5. Trial sites

At least two sites in two different geographical zones shall be considered.

6. Dates of field trial

(1) Start date of the field trial
(2) Completion date of the field trial
(The field trial shall be conducted for a continuous period of six months to cater for the wet and dry seasons in Uganda).

7. Sponsor

(1) Name
(2) Address
(3) Telephone and fax numbers, email address

8. Principal investigator

(1) Name
(2) *(Attach curriculum vitae of principal investigator)*
(3) Address
(4) Telephone and fax numbers, email address

9. Animals to be used in the field trial

(1) Species
(2) Identification number of animal
(3) Number of animals involved in the field trial
(4) Sex
(5) Age
(6) Weight

10. Husbandry

Complete description of the management systems

11. Description of the field trial

The animals must be infested with a suitable numbers of parasites. The adequacy of infestation shall be addressed in the statistical, parasitological and field relevance of the level of infestation. For a field trial to be considered valid, parasites shall be recovered from at least eighty percent of the negative control animals at each post-treatment observation.

Untreated control groups shall be used provided there are no serious welfare implications of the disease.

(1) Trial design (for example randomised controlled trial, open-label parallel group, cross-over technique)
(2) Criteria for inclusion of animals and exclusion of some.
(3) Group allocation.
(4) Treatment procedure including other treatments these animals are to receive during the field trial irrespective whether there is interaction with the investigational product.

(5) Sample size: statistically adequate numbers of treated and control animals to be included in each field trial in order to achieve the objectives of the field trial based on statistical consideration which shall be sufficient to allow dropout and variability of effect.

(6) The applicant is required to justify the group size and it is recommended to seek the advice of a statistician.

(7) Ectoparasite count according to stages of engorgement and species shall be indicated.

(NB. An appropriate method shall be described to fit this purpose).

12. Demonstration of efficacy

(1) The methods to be used for the assessment of efficacy shall be relevant for the parasite species involved and for the level of efficacy to be demonstrated.

(2) The methods used for the assessment of efficacy shall be justified.

13. Efficacy calculations

A description of the method used to calculate efficacy of the product shall be provided.

14. Test facilities, equipment, and materials

(1) There shall be—

(a) in case of large animals, adequate pasture for continued exposure to re-infestation;

(b) suitable handling facilities for handling the animals during ectoparasiticide counts;

(c) suitable equipment and measuring containers for accurate measurements and application of the field trial formulation as well as that of the positive control formulation; and

(d) protective clothing, appropriate to the type of formulation under test.

(2) The amount of investigational product to complete the field trial should be stated and justification given.

15 **Suspected adverse event**

There shall be in place—

(a) methods of recording and reporting suspected adverse events or reactions; and

(b) provisions for dealing with complications for example anti dots.

16. Evaluation of results

(1) A description of data management procedures shall be provided.

(2) Statistical methods and considerations: Any statistical significant difference between the treated and the control group shall always be interpreted in terms of biological and field significance.

(3) The animals that are withdrawn from a field trial shall be indicated and the reasons for withdrawal indicated.

17. Compensation of owner

A statement about the compensation of an owner of the animals used in a field trial shall be included in case of death and injury of the animals, as a result of the field trial .

18. Environment Impact Assessment

Proof of an Environment Impact Assessment study shall be submitted at the end of the field trial.

FORMAT FOR PRINCIPAL INVESTIGATOR'S BROCHURE

TITLE PAGE
NAME OF SPONSOR
Product
Name
Chemical and generic (if approved)
Trade name (if legally permissible and desired by the sponsor)

INVESTIGATOR'S BROCHURE
Edition number
Release date
Previous edition and its numbers
Dates of previous editions

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE
Confidentiality Statement (optional)
Signature page (optional)

(1) Table of contents

(2) Summary

(3) Introduction

(4) Physical, chemical and pharmaceutical properties formulation

(5) Non field studies
  (a) Non field pharmacology
  (b) Pharmacokinetics and product metabolism in animals
  (c) Toxicology

(6) Effects in humans
  (a) Pharmacokinetics and product metabolism in humans
  (b) Safety and efficacy
  (c) Marketing experience

(7) Summary of data and guidance for the investigator.

(8) Reference on publications and reports (to be provided at the end of each chapter)

(9) Appendices (if any)

Regulation 5(5) (e)

FORMAT OF DECLARATION BY PRINCIPAL INVESTIGATOR WHICH IS A RESEARCH INSTITUTION OR ORGANISATION

Name:	
Contact details	
Contact person (director)	
Physical address	
Declaration of capacity and interests	

1 Field trial site
For each field trial site list the following -

(1) Site identifier (name)

(2) Physical address: (include GPS coordinates)

(3) Telephone and fax numbers

(4) E-mail address

2 Description of the site facility and staff -

(1) Infrastructure on the site

(2) Facility for special examination, if required

(3) Capacity to collect, prepare, store and transport field samples

(4) Storage and handling facility for the field trial product

(5) Name and qualification of person with responsibility for dispensing field trial product.

3. Particulars of individual to head the field trial

Name:	
Qualifications	
Contact details	
Physical address	
Declaration of capacity and interests	

4. Particulars of other staff to be involved in the file trial

Name:	
Qualifications	
Contact details	
Physical address	
Declaration of capacity and interests	

5. Where a farm is to be used as the site for the field trial indicate the administrator or farmer responsible for the farm and the contact details of theta person.
(*Append the agreement authorizing the field trial at the farm).*

6. Where applicable, append agreement between the sponsor and the research institution or organization.

7. Animals to be used in the field trial

Number of field trial sites	
Total number of animals to be enrolled in all sites	
Intended number of animals at each site – evidence of availability	

8. Duration
Estimated duration of field trial : *(Start and completion dates)*

9. Field trial monitoring and reports
   (1) Describe the safety and monitoring plan for each site.
   (2) Describe the system to be used to detect, record, assign causality and the actions for adverse events.
   (3) Describe the actions to be taken following reports of suspected adverse events.
   (4) Dates of submission of interim reports
   (5) Dates of submission of final report

10. Description of the field trial
   (1) Is the title of the field trial fully descriptive?
   (2) Summarized rationale for this field trial, including relevance to Uganda

(3) Brief background information which shall include -

(a) the problem statement and the justification of the field trial;

(b) the properties of the field trial product;

(c) a description of risks of the field trial protocol and the potential harms of the field trial product;

(d) a summary report that establishes the probable safety and efficacy of the investigational product in animals;

(e) evidence that the formulations used in the pre-field trial and in previous field trials are identical to that in this application and where there are any variations, the variations should be highlighted and justified; and

(f) published reviews or reports relevant to the indicated ectoparasites and this type of product.

11. Objectives of the field trial *(List the primary and secondary objectives and provide justification)*

12. Trial design: describe and justify each component

13. The eligibility of the animals involved in the field trial in relation to -

(a) the inclusion criteria *(list and justify each)*

(b) the exclusion criteria *(list and justify each)*

14. The treatment regimens for each group.

15. Follow-up, sampling collection and monitoring plans; immediate monitoring - intermediate monitoring - long term monitoring.

16. The outcomes measurements and analysis which shall -

(a) describe each outcome or variable (including safety and efficacy);

(b) describe the samples that will be collected and the analyses to be conducted on each sample;

(c) where applicable, provide evidence that the laboratories that will conduct the safety screening, and that the end-point assays are accredited and competent to do the assays;

(d) describe the intended statistical analysis to be conducted. Provide evidence that the field trial is powered to provide the intended outcome.

17. Indicate whether sub-studies are intended and if so provide full details.

18. Will field samples be stored for any period beyond the duration of this trial?
    (1) What is the purpose of such archiving?
    (2) What controls are to be placed on their confidentiality and possible future use?

19. Informed consent from the owners of the animals.
    (1) Append a copy of informed consent from the owners of the animals.
    (2) Are there separate informed consent from the owners of the animals for the sub-studies.

20. Publication policy
    Provide details of the intentions of the sponsor and the principal investigator to publish the outcomes of this field trial, if applicable.

FORMAT FOR END OF FIELD TRIAL REPORT

1. Title page
2. Synopsis
3. Table of contents for the field trial report
4. Ethics
5. Principal investigator and administrative structure of the field trial
6. Introduction
7. Objectives of the field trial
8. Investigation plans
9. Animals used in the field trial
10. Efficacy evaluation
11. Safety evaluation
12. Discussion and overall conclusion
13. Tables, figures and graphs referred to but not included in the text
14. Reference list
15. Appendices

Regulation 13 (3)

FORMAT FOR INTERIM FIELD TRIAL REPORTS

Date

The Executive Secretary
National Drug Authority

INTERIM FIELD TRIAL REPORT
This is the interim report of (insert the title and the number of the field trial protocol and the reference of the Authority) conducted by (insert the name of the sponsor).

Number of animals screened: (insert number**)**

Number of animals randomised: **(**insert number**)**

Number of animals discontinued: **(**insert number**)**

Reasons for discontinuation: **(**insert reasons for discontinuation of each animal)

Number of animals that completed field trial: **(**insert number**)**

Number of suspected adverse events: **(**insert number**)**

Number of endpoints: (if applicable, insert number)

Last batch of investigational product collected back from field trial site: (insert batch number and date collected)

Last batch of investigational product sent back to (originating site) for destruction: (insert batch number and date sent); if local destruction, attach copy of destruction certificate issued by the Authority.

List of personnel involved in the field trial after approval by the Authority, if any (attach their curriculum vitae and declarations)

List of monitor and audit reports to date.

Regulation 13 (5)

FORMAT OF REPORT FOR TERMINATED FIELD TRIAL

Date……..
The Executive Secretary
National Drug Authority

REPORT OF TERMINATED FIELD TRIAL

Title and number of field trial protocol …….

Reference or registration number of Authority ……

The following is a summary of the (title of the field trial)……..trial conducted in …….. (insert name of institution):

First animal in: ……. (insert date)

Last animal in: ……. (insert date)

Last animal out: ……. (insert date)

Number of animal screened: …….

Number of animals randomized: ……

Number of animals discontinued: ……..

Reasons for discontinuation: …….

List of discontinuation: …… (List of individual discontinued animal(s))

Number of animals that completed field trial: ……

Number of serious adverse events: …….

Number of endpoints: …… (insert number if applicable, if not, to be removed)

Last batch of drug supplies collected back from site: ……. (insert date)

Last batch of drug supplies sent back to …….. (originating site) for destruction: ……. (insert date); if local

Destruction, attach copy of Authority destruction certificate.

List of any changes in trial personnel – including full CV and Declaration

List of monitor and audit reports to date.

RUHAKANA RUGUNDA (DR.)
Minister of Health.