Quality Medicines for Malawi

PHARMACY AND MEDICINES REGULATORY AUTHORITY

Form CT 8.

Confidential PMRA ACT [CHAPTER 35:01]

APPLICATION FOR AUTHORIZATION TO CONDUCT A CLINICAL TRIAL

(To be submitted in triplicate)

1. Particulars of applicant

If an individual: Full names ……

Date and place of birth ……

Qualifications ……

Address (Home) …… ……

(Business) ……

If a company: Name of company ……

Physical address ……

. …… ……

Registered office ……

Postal address ……

Telephone number ……

Position of person in the company who is making the application on behalf of the company

……

State the main field of manufacture of the company, if applicable ……

……

2. State the name of the medicine, its chemical composition, graphic and empirical formulae, animal pharmacology, toxicity and teratology as well as any clinical or field trials in humans or animals, or any other relevant information and supply reports, if any

……

3. State any adverse or possible reactions to the medicine ……

4. State therapeutic effects of the medicine ……

5. (a) Has the medicine been registered in the country of origin? YES /NO *

6. If **YES** a valid certificate of registration in respect of such medicine issued by the appropriate authority established for the registration of medicines in the country of origin shall accompany this application.

If NO state details ……

(b) Have clinical trials been conducted in the country of origin? YES / NO*

If YES state details ……

If NO give reasons why ……

……

(c) Has an application for the registration of the medicine been made in any other country? YES/NO*

If YES state details including the date on which the application was lodged

……

(d) Has the medicine been registered in any other country? YES/NO*

If YES state details ……

(e) Has the registration of the medicine been rejected, or refused, deferred or cancelled in any country? YES/NO*

If YES. state details …… ……..

(f) What is the status of the medicine in Malawi?

Tick (✓) whichever is appropriate

Registered	
Unregistered	
Application for registration has been submitted	

7. State the name(s), address(es) and telephone numbers) and qualifications of the person(s) who will conduct the trial

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Name	Qualifications	Address and Telephone number (Business)	Address and telephone number (Home)
……	……	……	……
……	……	……	……
……	……	……	……

8. State the name, physical address and telephone number of the institution or the places where the trial will be conducted

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9. State the purpose of the trial and the reasons thereof

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10. State the time period for the trial ……

11. Description of the type of trial (e.g. controlled, open) trial design (e.g. parallel groups, crossover technique) blind technique (e.g. double blind, simple blind) randomization (e.g. method and procedure) or any other type of trial

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12. Description of participants (e.g. age group of persons or animals, type or class of persons or animals, sex, etc.)

…… ……..

13. Criteria for inclusion or exclusion of participants ……

……

14. Number of participants expected to take part in the trial and a justification thereof (e.g. based on statistical considerations)

……

15. Administration route, dosage, dosage interval and period for the medicine being tested and the medicine being used as a control

…… ……

16. Control groups (placebo, other therapy, etc.) ……

……

17.(a) State whether any other medicine will be given concomitantly. YES/NO*

If YES, state the name of the medicine ……

(b) State whether a person already on another medicine will be given the experimental medicine at the same time or whether the participant will be taken off the other medicine.

18. Recording of effects: give a description of the methods of recordings and times of recordings

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19. State clinical and laboratory tests, pharmacokinetic analysis, etc., that are to be carried out

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20. State the method of recording adverse reactions and provisions for dealing with same and other complications

…… .

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21. State antidote ……

22. State the procedure for the keeping of participant lists and participant records for each participant taking part in the trial +

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23. State where the trial code will be kept and how it can be broken in the event of an emergency ……
……

……

24. State the measures to be implemented to ensure the safe handling of medicines and to promote and control compliances with the prescribed instructions

…… ……

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25. Evaluation of results, state the description of methodology (e.g. statistical methods)

…… ……

26. State how the persons or owners of animals are to be informed about the trial ……

……

27. State how the staff involved are to be informed about the way the trial is to be conducted and about the procedures for medicine usage and administration and what to do in an emergency ……

……

28. State whether there are any ethical or moral considerations relating to the trial, giving details

……

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29. State the name and address of the company who will insure all the participants in the proposed trial ++

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30. State the amount of insurance in respect of each participant ……

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31. State the quantity of the medicine for which exemption is required if the medicine is not registered

…… ……

32. Particulars of persons who will take part in the clinical trial+++

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Name	**Occupation**	**Address**	**Date and place of birth**
1. ……	……	……	……
2. ……	……	……	……
3. ……	……	……	……

33. Particulars of animals that will take part in the clinical trial.

Kind and breed of animal ……
……

……

Age of animal, if known ……
Name and addresses of owners of animals.

Name **Address**

1. …… ……

2. …… ……

34. Attached is a sample of the medicine, together with methods of analysis and storage conditions.

Date ……
……

Signature of applicant

Countersignature of medical superintendent or senior medical officer if the clinical trial is to be conducted in a hospital or a medical institution. ++++

Date …… ……

Notes

**Delete the inapplicable*

+, item 21: Records should permit easy identification of individual participants.

++, item 28: A letter from the insurance company shall be attached to the application indicating the insurance company's consent to the propose insurance and a copy of the proposed insurance policy.

+++, item 31: The consent of each person or the guardian of such person who will participate in the trial is required to be attached to the application Form M.C. 17.

The consent of each owner of an animal which will participate in the trial is required to be attached to the application, this item should be countersigned by a veterinary surgeon if the trial is to be conducted in a veterinary hospital.

FOR OFFICIAL USE ONLY

1 Clinical Trial Review Committee's comments on the application ……

…… ……

2. Application approved/disapproved by the Acting Director General.

Comments ……,,

……

Date …… ……

Director General PMRA