



**PHARMACY, MEDICINES & POISONS BOARD**

**GUIDELINES FOR REVIEW/EVALUATION**

**OF**

**CLINICAL TRIAL APPLICATIONS**

**FOR VACCINES AND BIOLOGICALS**

**IN**

**MALAWI**

## **1. INTRODUCTION**

The clinical trial application must undergo a review or evaluation before being granted authorisation to conduct the trial in Malawi by PHARMACY, MEDICINES AND POISONS BOARD (PMPB). The guideline is a detailed procedure for assuring the scientific review of studies and research involving human subjects in Malawi

Applicant should note that the review process takes approximately six ( 6) weeks.

## **2. DEFINITION OF TERMS**

- **Clinical trial application**

The clinical trial application (CTA) or submission is the dossier that includes all documentation pertaining to the conduct of clinical trial in Malawi according to the regulation. The dossier will include a cover letter, a protocol, an investigator's brochure or product information, CV's of investigators according to Pharmacy Regulation Cap 35:03

- **Administrative staff**

A person appointed in the PMPB as administrative personnel such as an administrative clerk. Such person should be aware of the regulation pertaining to the conduct of clinical trial in Malawi and have a basic knowledge of medicine. That person should be computer literate.

- **Technical staff**

A person appointed in the PMPB as a Registration Officer. Such person should have a qualification in medicine or pharmacy. It is advisable that the person undergo a GCP and GMP training. That person will be the contact person at the PMPB for applicants, evaluators and the Ethics committee.

The technical staff will attend all meetings with expert advisors to record all their recommendations. During the PMPB internal meetings prior to issuing an approval /rejection or otherwise decision he/she will report on the expert, advise, to Head of Technical Services.

- **Evaluator**

The evaluator is a scientist or medical practitioner that may be appointed by the PMPB to evaluate CTA according to their expertise. The evaluator should be aware of, and should comply with, GCP and the applicable regulatory requirements in Malawi. The evaluator may be commissioned to attend the meetings with expert advisors and report to the PMPB.

The evaluator should have sufficient time to evaluate properly the trial within the agreed period of review. The duration of the appointment of an evaluator to the expert committee should be specified to the evaluator.

- **Clinical Trial Review Committee**

The PMPB will put in place a committee to review clinical trial applications in Malawi. The expert committee shall at least include the following:

- Medical practitioners:
  - Paediatrician from NHSRC
  - specialist in public health from COMREC
  - a specialist in internal medicine
- An expert in clinical pharmacology
- An expert in Epidemiology
- An expert in toxicology and drug safety
- An expert in biotechnology
- An expert in virology and microbiology
- An expert in immunology
- A Biostatistician
- A specialist in Bioethics
- An expert in Veterinary Science

This list is not exhaustive, other committee members can be coopted to give an opinion on specific trials, but do not attend all expert committee meetings.

A chairperson should be nominated by the PMPB, the vice chairperson will be nominated by the Review committee. The chairperson of the expert committee should be a member of the Board to be able to present the document prepared by his committee.

The PMPB may use the support from an ad-hoc expert group either national or international in addition to or instead of the evaluator. To this purpose the PMPB may seek support from international organisations (i.e. WHO, EDCTP)

## **2.1 TERMS OF REFERENCE OF CLINICAL TRIAL REVIEW COMMITTEE**

- To review and evaluate Clinical Trial Applications and investigational products
- Review and develop guidelines for CT
- Review of inspection and Adverse Event reports from Clinical Trial
- Implement continuing oversight of ongoing CT by conducting site inspections
- Review periodic CT progress reports
- Review and approve any amendments to approved protocols
- Recommend importation and release of Investigational product
- Make decisions and recommendations to the Board of Directors of PMPB
- Any other issues related to CT involving medicines, medical devices and biologicals

## **3. PROCEDURES FOR REVIEW/ EVALUATION**

### **3.1 CTA number**

The applicant will deliver the CTA at the PMPB office on a specific date of submission set up by the PMPB. Three (3) copies of the applications should be provided. The administrative staff of the PMPB will receive the dossier for the conduct of clinical trial in Malawi using a vaccine or biological product.

- a. The investigational product will be allocated a number which will be used for all clinical trial using the same investigational drug.

b. A tracking number will be allocated to the clinical trial according to the following type of submission:

- Type 1: first submission of clinical trial using the product in Malawi
- Type 2: for a resubmission of a clinical trial in Malawi
- Type 3: for subsequent submission following a first approval in Malawi
- Type 4: for clinical trial using an already registered and marketed product in Malawi

c. The PMPB will be encouraged to use a year cycle to register clinical trial submission. Therefore a CTA might receive a number such as: (file number). (type of study). (Year. ascending number): 089.2.2005.45

This number will also be used to file the application. All correspondence from or to the PMPB should be using it as a reference number for that application.

### **3.2 Screening**

The screening of a CTA will be quantitative, done by the administrative staff and qualitative done by the technical staff.

- **Quantitative**

Using a checklist, the administrative staff will verify that all requested documents in the application form are in the dossier (annex 1). The dossier will be referred to a technical staff member of the PMPB for a qualitative screening.

- **Qualitative**

The qualitative screening will be to ensure that all documentations submitted are of good quality and in accordance with the regulation of Malawi.

This screening will particularly focus in the examination of the validity of such document as:

- GMP certificate
- Authorisation of the CT in the country of origin
- Batch release certificate from manufacturer
- Ethics committee approval letter

- Investigator's CV
- Financial declaration
- Insurance certificate

The result of the screening will be communicated to the applicant within two (10) working days after the reception of the application.

The screening form will be forwarded by fax to the applicant.

The applicant will have (10) working days to forward any outstanding documents in triplicate.

### **3.3 Dispatching**

Following the receipt of the response from the applicant, the technical staff will review the application or may allocate the application to an evaluator for scientific review or may use the support of an ad-hoc expert or expert group. The determination of the evaluator will be based on the field of the study and the available expertise in the committee.

### **3.4 Evaluation by expert**

Scientific aspects of study will be examined by the evaluator. The evaluator will inform the PMPB technical staff of the receipt of the CTA. The time frame allocated for the review will be three (3) weeks.

The report from the evaluator will be in a format agreed upon by the PMPB advisory body. A final report will be forwarded to the technical staff.

If the technical staff performs a scientific evaluation and uses the support of an ad-hoc expert or expert group, the time frame allocated for the review will depend on the time required to convene a consultation meeting with the expert (group), but all effort shall be made to minimise the time elapsed.

### **3.5 Preparation of document**

The technical staff will collate a document to be evaluated by the Clinical Trial Review Committee. That document will consist of the reports from the evaluators or by the technical staff after consultation with the ad-hoc expert group and a copy of the application form submitted by the applicant. Enough copies will be made to be distributed to all expert committee members 1 week before the meeting.

### **3.6 Peer review**

The expert committee of the PMPB should meet to discuss the report of the clinical trial. During the meeting the technical staff or evaluator will present the report to colleagues and will answer to all questions. The result of this collaborative session will be collated into recommendations to the applicant.

The expert committee meeting should be schedule at 2 weeks before the Board meeting.

### **3.7 Report to PMPB**

Following the expert meeting, a recommendation will be forwarded to the Board regarding the approval of the study. The Board will make the final decision regarding this trial after a discussion.

If there is any concern in that study regarding the ethics, the Board will communicate with the Ethics committee who reviewed that trial.

### **3.8 Recommendation to applicant**

Following the Board meeting, the recommendation should be communicated to the applicant.

The PMPB will determine the category to give to the CTA:

- 1: Study is approved and the authorisation is issued.
- 2. Study is not approved because: (issues to be communicated to the applicants)
- 3. Study is not considered for approval and therefore the application is rejected.

For category 2, the PMPB technical staff will communicate the recommendation to the applicant within five (5) days. The response from the applicant will be considered at the subsequent Board scheduled meeting. The subsequent decision will be communicated to the applicant.

If changes have to be made to the protocol, investigator's brochure or any other document, the amended document should be submitted with the response.

For category 3, the applicant is not expected to answer to the PMPB concerns, but can resubmit another application and make an appeal to the PMPB decision in writing.

<b>Date of submission</b>	<b>Screening</b>	<b>Response from applicant</b>	<b>Evaluation period</b>	<b>Distribution of committee document</b>	<b>Date of expert committee meeting</b>	<b>Date of PMPB meeting</b>



## PHARMACY, MEDICINES & POISONS BOARD

### SCREENING FORM

PROTOCOL NUMBER:  
PMPB NUMBER:  
DATE OF EC MEETING:

CONTACT PERSON:  
FAX NUMBER:  
TEL NUMBER:  
E-mail address:

<b>DOCUMENT</b>	<b>SUBMITTED</b>	<b>OUTSTANDING ITEMS</b>
<b>Cover letter</b>		
<b>Protocol (Date)</b>		
<b>Investigator's brochure (Date)</b>		
<b>Patient informed consent</b>		
<b>Ethics approval letter</b>		
<b>Investigator's CV</b>		
<b>Batch release certificate</b>		
<b>GMP certificate</b>		
<b>Authorisation of the CT from the country of origin</b>		
<b>Insurance certificate</b>		
<b>Financial declaration</b>		
<b>Questionnaire</b>		