



PROCEDURE FOR CONSULTATION MEETINGS WITH CLINICAL TRIAL APPLICANTS

This document has been prepared to serve as a guideline for applicants who wish to request a meeting with South African Health Products Regulatory Authority (SAHPRA). SAHPRA reserves the right to request any additional information to be furnished to establish whether such meeting may be relevant as it is reliant upon a small group of highly specialised experts.

Guidelines and application forms are available from the office of the Chief Executive Officer and the SAHPRA website.

First publication released for comment - Title "Proposed template for consultative meetings with potential applicant"	November 2017
Published for implementation	November 2019

MRS P NKAMBULE
ACTING CHIEF EXECUTIVE OFFICER

TABLE OF CONTENTS

	Page
1 PREAMBLE.....	3
2 INTRODUCTION	3
3 PROCEDURE WHEN APPLICANTS REQUEST A MEETING	3
4 PROCEDURE WHEN SAHPRA REQUEST A MEETING.....	4
5 CONDUCT OF THE MEETING	4

1 PREAMBLE

It is recognised that meetings between applicant for a clinical trial and the South African Health Products Regulatory Authority (SAHPRA) are useful but expensive and time consuming for both parties. Procedures need to be established to optimize the benefits to both parties in such meetings.

Meetings may be requested by an applicant/sponsor or SAHPRA/CTC may suggest to an applicant that a meeting would be of value.

2 INTRODUCTION

The SAHPRA/CTC recognises the benefits of engagement with potential applicants in the following cases:

- 2.1 Pre-investigational meetings, for guidance and clarification purposes before a potential applicant designs non-clinical or clinical studies for a new health product, indication or combination.
- 2.2 For clarification of exceptional queries following Clinical Trial Applications review feedback to the applicant/ sponsor or any other issues that cannot be resolved through normal channels.
- 2.3 As a report-back of exceptional or unexpected interim results from ongoing study(ies).

All correspondence requesting a consultative meeting with SAHPRA/CTC should be directed to the Office of the CEO to be considered on merit. This should be accompanied by a full justification for such a meeting which will assist the CEO to take a decision.

3 PROCEDURE WHEN APPLICANTS REQUEST A MEETING

When the applicant/sponsor request a meeting with SAHPRA/CTC, the following procedure should be followed:

- 3.1 Communication with the CEO requesting a meeting with SAHPRA/CTC:
 - 3.1.1 Setting out the reasons why such a meeting should be considered;
 - 3.1.2 Describing the current stage of the specific clinical trial (or clinical development program);
 - 3.1.3 Including list of the representatives of the applicant/sponsor that will attend the meeting and explaining the role and qualifications of each representative;
 - 3.1.4 Including a list of queries for which responses are expected;
 - 3.1.5 Describing the format by which the applicant proposes to address SAHPRA/CTC.
- 3.2 The communication should be accompanied by supporting documentation that includes:
 - 3.2.1 A summary of the nature of the investigational product including registration status elsewhere;
 - 3.2.2 A synopsis of the specific clinical trial (or trials);
 - 3.2.3 The SAHPRA tracking number (if applicable) and protocol number;
 - 3.2.4 Date of SAHPRA approval of the trial if relevant;
 - 3.2.5 Brief summary of pre-clinical and clinical safety results to date;
 - 3.2.6 Brief summary of pre-clinical and clinical efficacy results to date;

Clinical Trials

Procedure for Consultation Meetings

- 3.2.7 Any reports of the independent Data Safety Monitoring Board (DSMB) or equivalent and/or Human Research Ethics Committee relating to the trial;
- 3.2.8 Reports on audit (internal and external) and/or inspectorate findings, if available.
- 3.3 SAHPRA will decide on suitable date, venue, relevant format and allowable number of representatives (with relevant expertise) of the applicant/sponsor that may attend and the decision will be communicated to the applicant.
- 3.4 Full documentation supporting the applicant's request must be made available to SAHPRA at least five working days before the scheduled meeting date.
- 3.5 The meeting can be face-to-face or teleconference/videoconference

4 PROCEDURE WHEN SAHPRA REQUEST A MEETING

When the SAHPRA requests a meeting, the following procedure should be followed:

- 4.1 The applicant/sponsor may be invited by SAHPRA to attend the meeting.
- 4.2 The meeting can be face-to-face or teleconference/videoconference.
- 4.3 SAHPRA will provide the purpose for the meeting to the applicant/sponsor.
- 4.4 SAHPRA will decide on suitable date, venue, relevant format and number of representatives (with relevant expertise) of the applicant/sponsor that may attend.
- 4.5 The applicant/sponsor should provide the applicable documents (refer to section 3.2).

5 CONDUCT OF THE MEETING

- 5.1 The maximum duration of the meeting will be 30 minutes, ten minutes of which must be the applicant's presentation and the remainder for discussion. The time allocation must be adhered to strictly. The applicant's presentation should focus on the issues under discussion or in dispute, and avoid lengthy introduction and discussions. Any deviations from the agreed agenda will not be accepted.
- 5.2 SAHPRA reserves the right to immediately cancel the meeting if the designated applicant/sponsor representatives are not present and/or if undesignated person(s) are included e.g. lawyers and activist.
- 5.3 SAHPRA may be represented by internal and/or external experts.
- 5.4 It should be assumed that the SAHPRA representatives should be well aware of the background to the study provided in the supporting documentation.
- 5.5 SAHPRA will designate the chair of the meeting.
- 5.6 Any verbal responses during the meeting are non-committal and non-binding to SAHPRA.
- 5.7 The applicant/sponsor will receive a formal written response within 15 working days of the meeting.

Note: Meetings will not be granted without full compliance with these requirements