South African Health Products
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3 August 2022

GUIDELINE FOR THE PROCEDURE OF 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 the availability of a small group of highly specialized experts.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue	November 2019
2	– These sections: 1,2,3,4 & 5 revised on the new SAHPRA Guideline Template – Old Guideline number (6.29) changed to SAHPGL-CEM-CT-06	03 August 2022

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Contents

1. INTRODUCTION

South African Health Products Regulatory Authority (SAHPRA) and the CTC recognizes the benefit of engagements with applicants during the conduct of clinical trials. Although these meetings do highlight important considerations for the regulatory process, it is equally important that there are efficient and consistent procedures to optimize the benefit to both parties and the timely conduct of such meetings.

1.1 Purpose

This document has been prepared to serve as a guideline in the procedure to follow for applicants who wish to request a meeting with the South African Health Products Regulatory Authority (SAHPRA). This document also gives guidance to applicants with whom SAHPRA intends to meet in special circumstances where it is necessary.

1.2 Scope

Meetings may be requested by an applicant/sponsor or in specific cases the SAHPRA/Clinical Trials Committee (CTC) may suggest to an applicant that a meeting would be of value. The SAHPRA/CTC will consider engagement with potential and existing applicants in the following cases:

1.2.1 Pre-submission/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.

1.2.2 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.

1.2.3 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 description and justification for such a meeting which will assist the CEO to take a decision.

2. LEGAL PROVISION

This guideline is established in terms of Regulation 30 of the medicines and related substances act, 101 of 1965, conduct of clinical trials.

3. PROCEDURE WHEN APPLICANTS REQUEST A MEETING

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

3.1 Communication with the CEO requesting a meeting with SAHPRA/CTC must contain:

3.1.1 A clear outline and description of the reasons why such a meeting should be considered;

3.1.2 Description of the current stage of the specific clinical trial (or clinical development program);

3.1.3 A 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 A list of queries for which responses are expected;

3.1.5 A Description of 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);

3.3.3 The SAHPRA tracking number (if applicable) and clinical trial protocol number;

3.3.4 Date of SAHPRA approval of the trial if relevant;

3.3.5 Brief summary of pre-clinical and clinical safety results to date;

3.3.6 Brief summary of pre-clinical and clinical efficacy results to date;

3.3.7 Any reports of the independent Data Safety Monitoring Board (DSMB) or equivalent and/or Human Research Ethics Committee relating to the trial;

3.3.8 Reports on audit (internal and external) and/or inspectorate findings, if available.

3.3 SAHPRA will decide on the acceptance of the meeting and communicate to the applicant a suitable date and time, venue /virtual meeting, relevant format and allowable number of representatives (with relevant expertise) of the applicant/sponsor team that may attend the meeting.

3.4 Full documentation (including the presentation) 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 REQUESTS A MEETING

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

4.1 In specific cases 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 a suitable date and time, venue, relevant format and number of representatives (with relevant expertise) of the applicant/sponsor team that may attend.

4.5 The applicant/sponsor should provide the applicable documents (refer to section 3.2) and any other requested documents that are pertinent to the meeting.

5. CONDUCT OF THE MEETING

5.1 The maximum duration of the meeting will be 30 minutes, ten minutes of which are allocated for the applicant's presentation and the remainder is allocated 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 a lengthy introduction and discussions. Any deviations from the agreed agenda will not be accepted as this will derail and waste the limited time dedicated to this meeting.

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 activists.

5.3 SAHPRA may be represented by internal and/or external experts.

5.4 It should be assumed that the SAHPRA representatives will be 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 Based on the type of consultation meeting, the applicant/sponsor will receive a formal written response within 15 working days of the meeting if so communicated during the meeting.

- In case of a pre-submission consultation, the applicants should take their own minutes in preparation of submission of a formal application
- In case of a matter under consideration by CTC/SAHPRA (already submitted Clinical Trial Application), the written response will be provided to the Applicant following the meeting.

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

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old Guideline for Procedure of Consultation Meetings with Clinical Trials Applicants, document number 6.29. It will be reviewed in this timeframe or as and when required.