

PILOT: BAU NEW MEDICINE APPLICATIONS FOR REGISTRATION

This document is intended to provide communication to applicants with regards to the pilot that will be conducted on new medicine applications planned to be submitted from 01 August to 30 September 2021. This will be a “living document” and will be updated.

Document History

First Publication – Version 1	June 2021
Second Publication – Version 2	July 2021

BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

1. INTRODUCTION

SAHPRA plans to implement new ways of working and would like to begin by conducting a pilot. The pilot will be conducted on new medicine applications planned to be submitted from **01 August to 30 September 2021**. Pre-submission meetings will be scheduled between the SAHPRA team and the Applicant to discuss the applications to be included in the pilot.

Version 2 provides further guidance regarding the pilot for new medicine applications planned to be submitted from **01 August to 30 September 2021**.

2. PRE-SUBMISSION MEETINGS

The pre-submission meetings will provide a common understanding of what supporting documentation is required to evaluate an application as well as resolve any issues before the application is submitted. This will enable proper planning for submissions and enhance management of both timeframes and resources.

SAHPRA envisages that the benefits of the Pre-Submission meeting should result in:

- Improved quality of subsequent application
- Enhanced transparency of the review process
- Smoother review process
- Potentially shorter total review timelines should the application meet all requirements post pre-submission meetings and evaluation
- Provide the relevant SAHPRA units the opportunity to re-align resources to accommodate the arrival of the submission/application

Meetings will be conducted on Microsoft Teams via a link provided by SAHPRA after agreement on a set date and time. Considering the tight schedules within SAHPRA, kindly note that the Agency will not reschedule or cancel a meeting. If you need to cancel, advise us as soon as possible so we can allocate your slot to other interested participants.

2.1 Requesting a meeting

- Step 1 - Complete the meeting request form which includes the following information:
 - Completed Module 1.2.1 if available, other the details can be included in the appended meeting request form
 - Other relevant information to be discussed during the meeting
- Step 2 - Send an email with completed meeting request form and set of slides for presentation (see 2.3 below) to NewAppsPilot@sahpra.org.za.
 - NB:** If the application has been submitted already, submit your slides **48hrs** before the meeting.
 - *(Further contact SAHPRA on the following numbers 012 501 0369/ 0713022135/ 082 688 9955 for further enquiries that may be more urgent to be communicated via email)*

2.2 Duration of Meeting

45 mins will be allocated for a pre-submission meeting.

2.3 Requirements for the pre-submission meeting

To ensure that the pre-submission meeting is beneficial, please prepare a briefing package with full set of slides to be presented at the meeting. This must include:

- The agenda
- The presentation that details your product:
 - Including the information as would be required during admin screening
 - The information as would be required by technical screening (Inspectorate, Quality, BE, Clinical)
- The regulatory pathway to be followed (i.e. Abridged Review, Verification Review, Full Review)

2.3 At the pre-submission meeting

- Presentations should be kept succinct considering that relevant SAHPRA staff would have perused the slide deck and related information prior to the meeting.
- No additional material outside the scope of the meeting will be entertained at the pre-submission meeting
- The Pre-Submission meeting is only limited to the discussions on the applications to be included in the pilot.
- No Audio or video recording will be allowed. A verbal summary of the pre-submission engagement will be done by the designated SAHPRA staff member capturing the following:
 - important points as highlighted by either party during the discussion
 - agreements reached on any discussion point
 - agreement on the way forward with the application
 - clarification on any topic that was sought during the session
 - action items

2.4 After the Pre-submission meeting

- The above summary document will be shared with all participants within 10 business days from the date of the engagement.

Note: Applicants are encouraged to participate and benefit from this initiative for planned submissions for the period of **01 August to 30 September 2021**.

DocuSigned by:

Boitumelo Semete Makokotlela

E2EBB277730A46A...

CHIEF EXECUTIVE OFFICER