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COMMUNICATION TO STAKEHOLDERS

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Certification Variation Screening – Type II Proprietary name change applications and TOA's

Document History

First Publication – Version 1	October 2022
Second Publication – Version 2 (Feedback from the Screening Pilot)	December 2022

INTRODUCTION

The certification unit is processing a large number of applications with administrative queries, which then results in the delay of generating the revised registration certificate. The unit will be introducing a pilot to include administrative screening on receipt of all certification variation applications. The revised process will be implemented once the pilot is completed.

PILOT

The pilot will commence from the 14 October 2022 to 30 November 2022. All Type II variation applications for a TOA and/or proprietary name change (certification variation applications) will be administratively screened before they will be shared with the specific units (Inspectorate and/or Naming and Scheduling). The purpose of the pilot is to ensure that we have improved quality submissions and a more efficient certification variations process by checking:

- The correctness of documentation
- Correct fees paid

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- No technical variations (Additional/New Manufacturer and/or primary packer) are included with TOA/Proprietary name change applications (except if prior PEM approval received and included in the submission)

  Note

  For TOA variation applications, where the proposed new applicant does not have a contract with the relevant local primary packer and/or FPRC, then deletion and replacement of local sites will be accepted.

- Incorporate certification administrative screening checklist into the variations validation template

THE PILOTING PROCESS WILL INCLUDE THE FOLLOWING STEPS:

- Applications received through the FTP will be uploaded by the Variations team

- Certification variations teams will be notified of the new applications

- Administrative screening is conducted using a draft screening checklist – done within 5 working days of receipt

- Queries will be communicated to the applicant

- Applicant will be requested to submit the correct information in a replacement sequence. For example, if the certification variation application was submitted with sequence 0004 the replacement sequence will be 0004-1. The applicant should also provide proof of upload of the response to the certification email variations@sahpra.org.za and certificationvariations@sahpra.org.za.

- Compliant submissions will be allocated to the respective units

Note that the evaluation process will only start once the applications have passed the screening process.

IMPLEMENTATION

Implementation of the streamlined certification process will commence on the 15 January 2023.

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Once the pilot is completed, the administrative screening checklist and an updated communication will be shared with the relevant stakeholders in December 2022.

FEEDBACK ON THE CERTIFICATION SCREENING PILOT

The certification screening pilot commenced between 14th October 2022 to 30th November 2022. All Type II variation applications for a TOA and/or proprietary name change (certification variation applications) were administratively screened before they were shared with the specific units (Inspectorate and/or Naming and Scheduling).

For the duration of the pilot we have received a total of 72 applications (line items) for screening.

A breakdown of the applications processed in the pilot is presented in the table below:

Applications	No. of Applications – *line items*
Transfer of Applicancy/ TOA Applications received	32
Proprietary name change applications received	29
Combined TOA and proprietary name change applications	11
Total	72

Out of the 72 applications processed in the pilot 42 % (30 applications) had queries.

Below is a list of common queries that were processed during the pilot phase.

1.   Errors on the medicine register details – Module 1.5.2.2.1

  ➢ Current column and the current registration certificate do not correspond

  ➢ Sites added to the proposed column without Inspectorate approval

  ➢ Incorrect/outdated site names on the proposed column i.e. SABS/RIIP name change

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> ➤ Applicant's adding the DVP approved sites under approved column and not proposed column – Note DVP summary is an addendum to the RC it needs to be included under proposed column

2. Incorrect proprietary name/registration number

3. Incomplete submissions

   > ➤ Not all documents required are provided
   > ➤ POP, current registration certificate/OML, application forms for all strengths

4. Pending Certificate Variation In-process

   > ➤ A TOA or proprietary name change applications is pending when the applicant submits a different certificate variation

5. Technical variation included

   > ➤ New Manfuacturer and or pirmary packer included with the certificate variation, without a motivation

6. Multiple queries

   > ➤ Combination of the above queries

VALIDATION TEMPLATE FOR VARIATIONS

The certification screening checklist was drafted based on the findings from the pilot, this checklist will be included in the Validation Template for Variation applications.

The certification variation checklist will be listed under section A.4 ADMINISTRATIVE SCREENING (CERTIFICATION).

Applicant's will be required to complete section A.4 ADMINISTRATIVE SCREENING (CERTIFICATION), when submitting a Type II proprietary name change application and/or TOA, once the validation template for variation applications are finalised and published for implementation.