# NAMIBIA MEDICINES REGULATORY COUNCIL



**MINISTRY OF HEALTH AND SOCIAL SERVICES**

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| **Standard Operating Procedure (SOP)** | **Doc. No**: NMRC/Reg/001/2016 |
| ***Title: SOP for Receiving and Screening of dossiers for Registration*** | ***Supersedes: N/A*** |
| Effective date: ***1st April 2016*** | Review date: ***March 2017*** |
| *Prepared by/sign/date* | *Reviewed by/sign/date* | *Approved by/sign/date* |

**SOP for Receiving and Screening dossiers for Registration**

**Document Revision History Record**

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| **Revision No.**  | **Date** | **Details of revision** | **Reason for revision** | **Issue date** | **Revision No./date** | **Approved by/ on** |
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1. **OBJECTIVE**
2. To describe the process that should be followed when receiving and screening registration dossiers for medicines registration.
3. To ensure dossier application submitted meet the minimum requirements for processing.

**2.0 DEFINITIONS**

1. **Screened application**: Is an application that has been screened as per the set requirements and meets all critical requirements as per the screening checklist.
2. **Rejected application**: Is an application that does not meet one or more critical requirement(s) as per the screening checklist.

**3.0 RESPONSIBILITIES**

**3.1**. **Registrar of Medicines**.

1. Approval of this SOP before use.

**3.2. Head, Registration.**

1. Verify all the processes involved are comprehensive and workable.
2. Review of the SOP.
3. Ensure that the SOP is followed accordingly and that every deviation is addressed.
4. Assign a Pharmacist to be responsible for screening of new dossiers each month.
5. To ensure that all persons responsible for screening have been properly trained.

**3.3. NMRC staff; Screening Pharmacist, Administrative officers, Receptionist, Data Typist and Work-hand**.

1. Implement the procedures for consistently in line with the procedures set forth in this SOP.
2. Forward any queries to the supervisor.

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**4.0. DISTRIBUTION.**

1. Registrar of Medicines
2. Head, Registration
3. NMRC staff; Screening Pharmacist, administrative officers, Receptionist, Data Typist and Work-hand.

**5.0. RESOURCES**

1. Computers
2. Printers
3. Paper

**6.0. PROCEDURE.**

**6.1. RECEIVING OF THE DOSSIER**

1. When the Applicant brings the dossier(s), the Receptionist should call the Administrative Officer to receive the dossier(s).
2. The Administrative Officer should get proof of payment for screening from the Applicant before receiving the application.
3. Once proof of payment has been provided, then the Administrative Officer should print an acknowledgement letter (as per annexure B). The acknowledgement letter should include screening serial number(s)\* for the application(s) submitted.
4. An acknowledgement letter should be stamped and signed. A copy of the letter should be made; the original should be given to the Applicant/ Local Representative and a copy attached to the dossier(s)
5. Once receiving has been done, the Work-hand should transfer the received dossier to Pharmacist responsible for screening.
6. The Screener should verify documents provided.
7. The Screener should acknowledge receipt of dossier in the database or shared excel sheet. By entering in the appropriate column the date received, the name of the applicant, number of volumes, name of product, screening serial number and his/her name.

\**The screening serial number should start with S for Screening, followed by screening year (e.g. 16) then forward slash (/) then serial numbers starting from 001*

**6.2. TECHNICAL SCREENING**

1. Open the dossier to begin the technical screening process.
2. Screen the dossier as per the attached approved screening checklist (as per annexure A).
3. The screener allocates the name to the screening serial number and writes the number on the top right hand corner of each volume of the dossier.
4. The screener should file the copy of the acknowledgement letter.
5. Once the screening has been finalized, an email (as per annexure C) should be sent to the Applicant using the official email address. This should be done within five (5) working days from the date of receipt of the dossier.
6. The outcome of the screening should be communicated to the Applicant using the screening checklist which should be signed by the Registrar, dated and stamped.

**6.3. SCREENING OUTCOME**

1. Approved means the applicant has to pay the application fee for the next evaluation process
2. Rejected means the applicant has to come and collect his/her application dossier

* 1. **Reference Documents.**
1. Dossier Screening checklist
2. Acknowledgement letter for receipt of Dossier Application(s)
3. Amendment of Schedules: Medicines and related substances control Act, 2003 (Regulation 47)

**8.0. Attachments to the SOP: Annexures**

**8.1. Annexure A- Screening Checklist**





**8.2. Annexure B- Acknowledgement letter for receipt of Dossier Application(s)**



**8.3 Annexure C- Email template to the Applicant regarding the screening outcome**

