Inspection & Licensing of Pharmaceutical Operations

bsi. ISO 9001:2015 Quality Management

BMRA MEDICINES REGULATORY AUTHORITY

Promoting access to safe medicines

In accordance with MRSA, 2013

1. All premises shall be inspected to assess compliance to the act, regulations, international standards and set guidelines before granting or re-granting a license
2. Inspection of new premises shall be announced while for renewal of license it may or may not be announced.
3. Compliant new premises will be inspected and licensed within four (4) weeks while License renewals will be inspected and licensed within six (6) weeks.
4. Expedited license applications which costs an extra cost fee will be inspected and licensed within two (2) weeks.
5. All applications for license shall be accompanied by a prescribed fee as set out in schedule 5 of the MRSR, 2019.
6. All Licensed premises are subjected to at least one (1) inspection per year.
7. An application for license renewal shall be made at least three (3) months before the expiry of a license. The applicant shall refer to the relevant guidelines for application forms.

Post Inspection Compliance

The following process apply to premises which do not comply with the set standards and guidelines:

1. A final report with non-conformances or deficiencies shall be issued to the applicant, giving them ten (10) working days to address non-conformances.
2. Whereby no action to address non-conformances has not been submitted to the authority within the stipulated time, the applicant shall be issued with a notice to annul the application for new applicants.
3. Lack of compliance to the above for new premises, shall result in the application being declared null and void.
4. Lack of compliance to (b) for License renewal, shall result in the applicant being given a notice for suspension of the licence.
5. If non-conformance addressed require inspection the applicant shall submit a new application and pay the prescribed re-inspection fee as per schedule 5 of the regulations..

Variation of License

1. A license holder shall apply to the Authority for variation of his or her license (MRSR 2019, sec 22(1))
2. The application shall be in the prescribed application form, accompanied by a fee as set out in schedule 5 of the MRSR, 2019
3. The Authority may approve the amendments and where the Authority does not approve, it shall inform the unsuccessful in writing, stating the reasons for the decision. (MRSR 2019, sec 22(3))
4. The authority may also decide the variation is significant and requires inspection to assess compliance to the act, regulations, international standards and set guidelines before granting or re-granting a license.

Suspension or Withdrawal of a License

1. Where the license holder does not meet the required standards and guidelines, the authority may suspend or withdraw a license. (MRSR 2019, sec 23(1)).
2. In general, the procedure for suspension and/or withdrawal of licence shall be guided by the applicable risk score profile of the facility as defined in the guideline for classification of deficiencies.
3. The Authority shall notify the license holder of the decision and may indicate the actions to be taken by the license holder and give the license holder seven days to respond (MRSR 2019, sec 23(2)).
4. The facility shall remain closed for the suspension duration of 30 days while action is being taken to address non-conformances.
5. Where a license is withdrawn the facility shall cease to operate. (MRSR 2019, sec 23(4)).
6. The license holder shall re-apply for a license and pay the prescribed fees as set out in schedule 5 of the MRSR, 2019.

Post licensure Notification

An application shall be made by the responsible pharmacist to inform the authority of any post licensure changes that are instituted in the premises.

Release of Customer Information

1. BOMRA Inspections and licensing department holds the information relating to customers in strict confidence as the terms and conditions of services provided. Except for information that the customer places in the public domain or when agreed between the Inspectorate and the customer, all other information is considered proprietary information and shall be regarded as confidential.
2. The inspection body shall seek authorization and clearance from the Chief Executive Officer, before any customer information is placed in the public domain or shared with a third party.
3. The inspection body shall notify the customer in advance, unless prohibited by law, when the inspection body is required, by law or authorized by contractual arrangements, to release confidential customer information.
4. Information about the customer obtained from other sources other than the customer (e.g. complainant), shall remain confidential between the inspection body and the customer. Identity of the source can only be shared with the customer if the source has agreed to it in writing.
5. The following information about the customer shall be shared through BoMRA public domains
    - Company Name (licensee and business name)
    - License number
    - Business address (physical address)
    - Type of business (authorized activity)
    - Premises contact details (email, telephone line)
    - RP Name
    - License validity


80 ml

BOMRA

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