Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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1. GUIDANCE ON RISK-BASED CLASSIFICATION OF DEFICIENCIES

Introduction

1.1 This document serves as a guide to help regulated facilities understand the criteria used by BoMRA to categorise deficiencies in GxP based on risk. It promotes consistency in deficiency classification and provides clarity on the conditions and practices considered unacceptable by the Authority, enabling facilities to understand how identified deficiencies may impact their overall compliance status.

1.2 These guidelines establish the compliance criteria applicable to all regulated establishments involved in the distribution and sale of regulated products, encompassing both public and private sector entities at national and local levels. They apply to all regulated premises including wholesalers, distributors, retailers, and dispensaries handling medical devices and both human and veterinary medicinal products.

1.3 For the purposes of this guideline, GxP shall mean adherence to applicable good practice standards, including but not limited to

a. GLP — Good Laboratory Practice
b. GPP — Good Pharmacy Practice
c. GSDP — Good Storage and Distribution Practice
d. GVMP — Good Veterinary Medicinal Practice
e. GAP — Good Agricultural Practice
f. GCP – Good Clinical Practices

1.4 Determination of classification of GMP (Good Manufacturing Practices) deficiencies is addressed under a separate document ***BOMRA/IL/IL/P08/G01/A01*** and is therefore not included herein.

2. Definitions

2.1 Critical deficiency

a. A *critical* deficiency may be defined as an observation that has produced, or may result in a significant risk of producing, a product that is harmful to the user.
b. A significant deviation from GxP guidelines or legislation which leads to a significant risk to the patient or public health.

2.2 Major deficiency

A *major* deficiency may be defined as a non-critical observation that:

a. indicates a major deviation from the GxP guide;
b. indicates a failure to carry out pharmaceutical operations as per duties outlines in the guidelines, legislation or internal procedures

c. indicates a failure of the person responsible for quality assurance/quality control to fulfil his or her duties;

d. consists of several other minor deficiencies, none of which on its own may be major, but which together may represent a major deficiency and should be explained and reported as such.

2.3 Minor deficiency

a. A deficiency may be classified as minor if it cannot be classified as either critical or major but indicates a departure from GxP.

b. A deficiency may be minor either because it is judged to be minor or because there is insufficient information to classify it as major or critical.

c. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of the products manufactured, e.g. in some circumstances an example of a *minor* deficiency may be categorized as major.

3. Abbreviations

3.1 **BoMRA** – Botswana Medicines Regulatory Authority

3.2 **CAPA** – Corrective and Preventative Action

3.3 **SOP** – Standard Operating Procedures

3.4 **GxP-** a collective term for a set of quality guidelines and regulations that govern the pharmaceutical, medical device, food, and cosmetic industries. The "G" stands for "Good," the "x" represents the specific practice area, and "P" stands for "Practice.

3.5 **VICH** - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products)

4. COMPLIANCE RISK SCORE

4.1 Inspectors will generally consider the following when assigning risk ratings:

a. Risk will be assigned in relation to the nature of the deficiency, nature of the deviation, types of products handled and frequency of occurrences.

b. Risks maybe upgraded/ downgraded from one class to the next depending on the evidence supporting the non-conformance and the nature of the deficiency and how critical the observation is.

c. All observations shall be discussed with the applicant and agreed upon during the inspection. In the event of disagreement, the applicant should be able to defend their position with clear reputable references on the finding in a CAPA response.

d. Recurring observations from previous inspections may be upgraded. For example, a deficiency that was reported during a previous inspection and not corrected shall be reported in a higher classification of observation depending on its risk to patients.

5. Examples of Critical, Major and Minor Observations

a. The following are typical GxP non-conformances inspectors may observe during an inspection. It is not intended to be an all-inclusive/exhaustive list, and Inspectors may identify other observations.

5.1 Critical Observations

a. No Continuous supervision by authorised person/suitably qualified person (Sale of medicines in the absence of an authorised person.)
b. No temperature control and/or continuous temperature monitoring
c. Operating without a valid BoMRA License
d. Dispensing of expired, rejected, returned, or recalled products
e. Inadequate control of controlled substances e.g including imbalances in the controlled substances register.
f. Evidence of dispensing without prescription/No retained records of prescriptions
g. Presence and sale of unregistered products or falsified/substandard products
h. Evidence of gross pest infestation or widespread accumulation of residues and extraneous matter indicative of inadequate cleaning.
i. Inadequacy in storage conditions such as medicines not stored according to labelling conditions

5.2 Major Observations

a. Missing more than 60% of the required SOPs
b. Inadequate continuous temperature monitoring records
c. Absence of calibration records for equipment and devices.
d. Absence of automatic backup power supply (wholesalers).
e. Expired, rejected, recalled products not segregated from the saleable stock
f. No entry restrictions into the dispensary
g. Sale of medicines to unauthorised persons or establishments.
h. Buying from unauthorised persons/establishments
i. Inadequate storage facility such as lack of segregation, overstocking and keeping of medicines on the floor etc

j. Discrepancies in stock records,

5.3 Minor Observations

a. Non display of labels, certificates, and licenses
b. Missing reference materials
c. No evidence of fire protection
d. Missing Job descriptions and training records
e. Missing less than 40% of the required SOPs
f. No counselling room (for pharmacy), etc

6. DECISION ON COMPLIANCE

The status of GxP compliance shall be determined based on the nature and number of deficiencies identified during inspection.

	Deficiency scenario	Compliance Risk Score	Inspection conclusion
1.	No critical or major deficiencies and/or less than 2 minors	Low	Operating at an acceptable level of compliance with GxP guidelines Approval of licensing may be granted
2.	More than 2 minor deficiencies	Low	Operating at an acceptable level of compliance with GxP guidelines, CAPA submitted within ten (10) working days. Failure to submit satisfactory CAPA (within 2 cycles of review), facility is issued a Closure of Inspection Regulatory Letter All facilities with closed inspections shall be required to reapply for licensing with applicable fees.
3	Less than 5 Major Deficiencies	Medium	Operating at an acceptable level of compliance with GxP guidelines, CAPA submitted within ten (10) working days Failure to submit satisfactory CAPA (within 2 cycles of review), facility is issued a Closure of Inspection Regulatory Letter

			All facilities with closed inspections shall be required to reapply for licensing
4.	More than 1 Critical deficiencies or more than 5 major deficiencies	High	Operating at an unacceptable level of compliance with GxP guidelines, Immediate suspension of license, CAPA submitted within seven (7) working days. Facility to remain closed until the Authority lifts the suspension Facility may submit a written appeal against suspension within 30 calendar days of receiving the suspension notice Failure to submit CAPA within seven (7) working days, facility is issued a Withdrawal of License Regulatory Letter All facilities with withdrawn licenses shall be required to reapply for licensing with applicable fees Administrative and/or legal enforcement actions are applied as necessary

7. REFERENCES

a) Medicines and Related Substance Act, 2025
b) Medicines and Related Substances Regulations, 2019
c) Guidelines on Operating a Standalone Pharmacy ***BOMRA/IL/IL/P01/G01***
d) Guidelines for Operating a Within group Pharmacy ***BOMRA/IL/IL/P01/G02***
e) Guidelines for Operating a Veterinary Medicinal Products Retailer ***BOMRA/IL/IL/P03/G01***
f) Guidelines on Good Distribution Practises of Pharmaceutical Products ***BOMRA/IL/IL/P01/G03***
g) Guidelines for Operating a Schedule 4 and Complementary Distributor ***BOMRA/IL/ILP01/G04***
h) Guidelines on Good Distribution Practises for Medical devices ***BOMRA/IL/IL/P01/G05***