MEDICINES CONTROL AGENCY

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Guideline for Inspections

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1 INTRODUCTION

1.1 Legal Basis

1.1.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

1.1.2. An essential part of any medicines and related products control system is the provision of an inspection body with the responsibility and authority to inspect some or all of the activities involved in import, storage, distribution, supply or sale of medicines and related products.

1.1.3. The powers of inspectors by the MCA are stipulated in the Medicines and Related Products Act, 2014 ("Act"), Part II, Section 4 (h) and Part VIII, Section 57 and 58.

1.1.4. The Medicines and Related Products Regulations, 2019 ("Regulations") details the legal requirements.

1.1.5. Persons involved in the import, storage, distribution, supply or sale of medicines and related products are required to familiarise themselves with this document and the above stated law.

1.2 Interpretation and Abbreviations

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm**

1.3 Purpose and Scope

1.3.1. This guideline describes the types of inspections, what it entails, what needs to be inspected and the preparation of premises in anticipation of inspection.

1.3.2. Inspectors examine the systems used to receive, store and distribute medicines and related products.

1.3.3. It applies to medicines and related products as defined in the Act and the Regulations imported, stored, distributed, supplied or sold in The Gambia.

1.3.4. There is a separate guideline for inspections of manufacturing of medicines and related products and for the conduct of clinical trials.

1.4 Main objectives of inspection

1.4.1. Inspections are conducted to ensure that medicines and related products, either nationally manufactured or imported, meet the required standards of quality in order to protect patients and the public.

1.4.2. Inspections by the Agency before a storage facility can get licensed or before the licence get renewed are to ensure that the premise is suitable for the storage of medicines and related products.

1.4.3. Inspections at the port of entry are to ensure that only medicines and related products of the required quality and approved quantity are imported into The Gambia.

1.4.4. Inspections of premises where medicines and related products are stored and distributed are conducted to ensure that the premises are licensed for the business and that international standards for storage (e.g. good storage practice) and distribution (good distribution practice) are applied to safeguard the quality of the products.

2 INSPECTORS

2.1 Inspector qualification

2.1.1. Inspectors are officers who have working experience in pharmacy practice or related area.

2.1.2. Inspectors are suitably trained in inspectorate functions. They may also be part-time inspectors as part of inspection teams.

2.1.3. All inspectors are authorised by the MCA and in case of joint inspections by the respective authority.

2.2 Attributes of an inspector

2.2.1. An inspector should possess the following attributes:

- Good knowledge of pharmacy laws and regulations to be enforced;
- Good command of technical terms and excellent communication skills;
- Awareness of the probable methods of using forged or false documents and skills in determining the genuineness of documents presented for examination;
- Maturity, honesty and integrity;
- Responsible conduct which commands respect;
- Willingness to accept challenges;
- Ability to organise their own work with minimum supervision;
- Ability to assess facts quickly and take rational and sound decisions without delay;
- Ability to assess character and honesty of persons being interviewed;
- Good public relations image with key personnel/pharmacists in charge of premises while remaining firm, fair and resolute;
- Ability to hold discussion with personnel at the completion of inspection;
- Ability to motivate other inspectors;
- Commitment to hard work and long hours;
- Ethical approach to any potential conflict of interest;
- Have good eye sight;
- Always be presentable and have a pleasant character;
- Ability to adopt new work and assignment; and

- Be punctual.

3 TYPES OF INSPECTIONS

There are five types of inspections:

- Routine (Comprehensive)
- Concise
- Follow-up
- Special
- Investigative

3.1 Routine (Comprehensive) Inspection

3.1.1. Routine or Comprehensive inspections are generally full inspections of all components of applicable regulatory requirements, standards and good practices.

3.1.2. They are conducted for

- existing operating premises on certain intervals;
- licensing of storage facilities;
- premises that have important changes in its key personnel, equipment or change to a new location; or
- premises that have a history of non-compliance.

3.1.3. The inspection may be announced for a new premise but can be unannounced for established ones.

3.2 Concise Inspection

3.2.1. Concise inspections are generally conducted with a view to assessing a limited number of standards of applicable regulatory requirements and good practices selected as indicators of overall performance and identification of significant changes which has been introduced since last inspection.

3.2.2. The outcome of concise inspections helps in the proper assessment of the premise.

3.2.3. These inspections can be announced or unannounced.

3.3 Follow-Up Inspection (reassessment or re-inspection)

3.3.1. Follow-up inspections are made to monitor corrective measures that have been undertaken following recommendation and notice given during a previous inspection.

3.3.2. Where a time limit was given for undertaking corrective measures depending on the deficiencies and work to be undertaken, normally restricted to specific requirements, inspections are conducted to verify the adherence to timelines.

3.3.3. The inspections can be announced or unannounced.

3.4 Special Inspection

3.4.1. Special inspections are conducted to assess the performance of new premises or new practices whose scope of operations was previously unknown or where product complaints were received by the MCA.

3.4.2. These inspections can also be conducted to gather specific information on a product or group of products or to investigate specific operations such as repackaging or labelling.

3.4.3. They can be done in order to advise importers, wholesalers, retailers or storekeepers on regulatory requirements.

3.4.4. The inspection should be unannounced.

3.5 Investigative Inspection

3.5.1. Investigative inspections are conducted to verify complaints received about non-compliance with regulatory requirements or standards of good and/or professional practice.

3.5.2. The inspection should be unannounced.

4 PREMISES AND WHAT TO BE INSPECTED

Site visits may include any premise or facility or process involved in purchasing, storing, distributing, supplying and/or selling medicines or related products.

4.1 Premises to be inspected

- Ports of entry (POEs) - Sea, Air and Land or at offloading at the warehouses/storage facilities before release or rejection of the products;
- Wholesalers, warehouses/storage facilities, Central Medical Stores, Regional Medical Stores;
- Pharmaceutical stores at Hospitals and Health Centres, public and private;
- Pharmacies, Drugstore outlets, Private or NGO Clinic Pharmacies; and
- Any other premise where medicines or related products are stored, distributed or supplied.

4.2 What to be inspected

- Status of licence(s);
- Existence of medicines or related products in unauthorised markets;
- General condition of premise including all facilities and equipment;
- Storage conditions including temperature and humidity monitoring, as applicable;
- Transportation arrangements, where applicable;
- Stock and stock management;

- Record keeping and documentation such as e.g. Import Clearance Permits (where applicable), invoices, receipts, suppliers' documentation, relevant regulatory documentation; and
- Products including their physical quality and labelling.

5 INSPECTION PROCESS

5.1 During an inspection

5.1.1. Inspections are usually conducted by at least two inspectors. It can happen that inspectors of the Medicines Control Agency (MCA) and of the Pharmacy Council of The Gambia (PCG) or of other stakeholders conduct joint inspections.

5.1.2. The inspectors will identify themselves as authorised inspectors.

5.1.3. The inspection team will

- interview personnel;
- review documents; and
- assess the premise and products.

5.1.4. The inspection team may ask for additional documentation and take samples during the inspection. They may also change the scope of the inspection if they suspect any non-compliance.

5.1.5. If any sample is taken during inspection, a copy of the completed sample collection form will be provided to the person in-charge of the facility.

5.1.6. Upon completion of inspection, the inspectors will hold an exit meeting with the personnel to provide feedback, to discuss the outcome of the inspection findings and further steps. The inspector may agree on timelines with the inspectee for corrective actions.

5.2 Grading of inspection findings

5.2.1. Deficiencies found during inspections are graded at 3 levels.

5.2.2. A **critical** finding is any departure from regulatory requirements, standards or good practices that result in a significant risk to customers, patients or public health. This includes the supplying of medicines or related products from unlicensed premises and activities which increase the risk of supplying substandard or falsified medicines or related products.

5.2.3. A **major** finding is a non-critical deficiency which indicates a serious deviation from regulatory requirements, standards or good practices that might result in a risk to customers, patients or public health.

5.2.4. A combination of several 'minor' deficiencies which on their own are minor may together represent a major deficiency and will be explained and reported as such.

5.2.5. A **minor** deficiency indicates a departure from applicable regulatory requirements, standards or good practices but might not result in a risk to customers, patients or public health.

5.3 After the inspection

5.3.1. After the inspection, the inspectorate will communicate findings, observations and necessary actions to be taken in a letter or by email to the licence holder or authorised person–within 15 working days following the inspection.

5.3.2. The inspectorate will review the response of the inspectee, if one is received, and may conduct a follow-up inspection and/or provide a written feedback.

5.3.3. If the compliance to the inspection findings is poor, regulatory actions may be taken.

6 PREPARATION AT THE PREMISES FOR INSPECTIONS

6.1. There should be a procedure in place for inspections.

6.2. This procedure should include instructions for the personnel how to receive the inspectors, which senior personnel should be notified, and what arrangements should be made, such as workspace for the inspectors, ready availability of documents and records, and providing access to sites.

6.3. This allows the inspection to commence promptly and in an orderly fashion.

Self-inspection

6.4. The quality system at the premises should include self-inspections. These should be conducted to monitor implementation and compliance with the applicable regulatory requirements, standards and good practices and, if necessary, to trigger corrective actions.

6.5. Self-inspections should be conducted in a detailed way by a designated, competent person.

6.6. The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report and the records of any corrective actions taken.

7 FINAL PROVISIONS

7.1. This guideline is the second version published by the MCA and will become effective on 01 July 2020.

7.2. The guideline will be reviewed within 5 years of becoming effective.

8 REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019
- Pharmacy Council Act, 2014

- MCA Guideline for Storage and Distribution of Medicines and Related Products (MCA-GL-301)
- MCA Guideline for Repackaging and Labelling of Medicines (MCA-GL-101)
- MCA Guideline for National Pharmacovigilance System
- MCA Guidelines for Importation of Medicines and related Products (MCA-GL-103)
- MCA Guideline for Recall of Medicines and Related Products (MCA-GL-303)
- MCA Guideline for Safe Disposal of Medicines and Related Products (MCA-GL-304)

9 DOCUMENT HISTORY

Version #	**Implementation Date**	**Reasons for Change:**
1	13 December 2017	New document
2	01 July 2020	Editorial changes, harmonisation of format for MCA guidelines, inclusion of joint inspections with other stakeholders.