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Guideline for Inspection of Premises

PCG-GL-302, Version 1.0 – 15 January 2020

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1 LIST OF ABBREVIATIONS AND ACRONYMS

MCA Medicines Control Agency (The Gambia)
PCG Pharmacy Council of The Gambia
SOP Standard Operating Procedure

2 INTRODUCTION

2.1 Legal Basis

2.1.1. The regulation of the practice of pharmacy in The Gambia and its inspection is governed by the provisions and requirements of the Pharmacy Council Act, 2014, by which the Pharmacy Council of The Gambia (PCG) was established as the regulatory body for the practice of pharmacy.

2.1.2. Part VI Section 37 and 38 of the Act entitles inspectors authorised by the Council to enter premises for inspections and section 39 empowers them to close a premise.

2.1.3. The Pharmacy Regulations 2018 detail the legal requirements with respect to premises, personnel, activities and fees.

2.1.4. The Standards of Pharmacy Practice in The Gambia published by the Pharmacy Council sets the standards in the various practice areas.

2.2 Purpose and Scope

2.2.1. This guideline describes the procedures of inspections of premises where medicines are sold, supplied, dispensed or compounded, of the activities carried out on the premises and of the people who carry out the activities.

2.2.2. It focuses on legal requirements for premises and personnel and on the standards for pharmacy practice in The Gambia.

2.2.3. It describes the duties of inspectors, types of inspections, what it entails, what needs to be inspected and the preparation of premises in anticipation of inspection.

2.2.4. The guideline applies to practicing wholesale pharmacy businesses, retail pharmacies (community pharmacies), public and private health institutions including hospitals and clinics that provide pharmacy services, drug store outlets, veterinary clinics and supermarkets.

2.3 Main objectives of premise inspection

2.3.1. Inspections by the Council before a premise can get licensed are to ensure that that the premise is suitable for the anticipated practice of pharmacy and that the business will be carried out by personnel as required.

2.3.2. Inspections of practicing premises are conducted by the Council to ensure that

- the premise license is valid;
- the personnel is registered with the respective Council and carry out the business as required;

- the business is carried out in accordance with the license;
- the premise remains suitable; and
- the standards for pharmacy practice are applied.

3 INSPECTORS

3.1 Inspector qualification

3.1.1. Inspectors are officers who have working experience in pharmacy practice.

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

3.1.3. All inspectors are authorised by the PCG and in case of joint inspections by the respective authority.

3.2 Attributes of inspectors

3.2.1. An inspector should possess the following attributes:

- Good knowledge of pharmacy practice, 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.

4 TYPES OF INSPECTIONS

There are five types of inspections;

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

4.1 Routine (Comprehensive) Inspections

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

4.1.2. They are conducted for

- licensing of new premises;
- existing operating premises on certain intervals;
- premises that has important changes in its key personnel or changed to a new location; and
- premises that have a history of non-compliance.

4.1.3. The inspections may be announced for a new premise to be licensed but are usually unannounced for operating premises.

4.2 Concise Inspections

4.2.1. 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.

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

4.2.3. These inspections can be announced or unannounced.

4.3 Follow-Up Inspections (reassessment or re-inspection)

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

4.3.2. 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.

4.3.3. The inspections can be announced or unannounced.

4.4 Special Inspections

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

4.4.2. These inspections can also be conducted to gather specific information on specific operations or to advice personnel on regulatory requirements.

4.4.3. These inspections should be unannounced.

4.5 Investigative Inspections

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

4.5.2. The inspection should be unannounced.

5 INSPECTIONS FOR LICENSING OF PREMISES

5.1. When an application for a premise license is approved (refer to the respective guideline for licensing), an assessment visit will take place to inquire about the location and suitability of the anticipated premise and the anticipated personnel.

5.2. The inspectors will make recommendations and inform the applicant that an inspection visit will follow.

5.3. The inspectors will visit the premise for inspection, given that the applicant has responded within the required timeframe of 45 days from the assessment visit.

5.4. They will verify that the recommendations are implemented and that the premise fulfils the regulatory requirements.

5.5. They will verify that the anticipated name of the premise (Sign Board) is in line with the recommendations.

5.6. They will inspect the conditions and working areas of the premise to verify their suitability for the anticipated business to be carried out.

5.7. They may verify the information of anticipated personnel provided with the application.

5.8. The inspectors will review the anticipated procedures and verify their suitability.

5.9. They will remind the premise supervisor to be aware of the applicable regulatory requirements and the standards of pharmacy practice in The Gambia.

6 INSPECTIONS OF PRACTICING PREMISES

Site visits may include any premise or facility or process involved in selling, supplying, dispensing and/or compounding medicines.

6.1 Areas to be inspected

- Wholesale
- Community Pharmacy
- Drugstore
- Health institution Pharmacy
- Veterinary Drugstore
- Supermarket

6.1.1. The inspectors will visit the premise to verify that the premise license is available, valid and genuine. If the premise license is not available will be noted as a critical finding. If the premise is not licensed or the license

has expired or give reasonable grounds to believe that it is not genuine, the inspectors are authorised to close the premise immediately.

6.1.2. The inspectors will verify that the premise continues to be suitable and that the regulatory requirements are fulfilled.

6.1.3. They will review the arrangements of medicines with respect to separate and clearly identified areas for the schedules and categories of medicines.

6.2 Personnel to be inspected

6.2.1. The inspectors will verify that the valid PCG registration certificate of the responsible practitioner is available and conspicuously displayed in the premise. If the registration certificate of the responsible practitioner is not available, it is considered a critical finding and the inspectors may close the premise immediately.

6.2.2. In case of veterinary medicines to be sold, supplied, dispensed or compounded from the premises, the inspectors will verify the registration of the responsible practitioner with the Veterinary Council.

6.2.3. They will inquire about the employed or hired personnel and consult the personnel files and Attendance Register (Supervision Register) to verify their number and status and that the staffing fulfils the minimum requirements including supervisor's attendance in accordance with the Act and Regulations. Annex 1 provides an overview.

6.2.4. If other health professionals are employed or hired, the inspectors will note their cadre, name and registration or certificate numbers and verify their qualifications.

6.2.5. The inspectors will meet with the personnel present at the time of visit to verify their availability.

6.3 Activities to be inspected

6.3.1. The inspectors will verify that no other business is carried out than that for which the premise is licensed.

6.3.2. They will assess the maintenance of the premise to ensure appropriate conditions.

6.3.3. The inspectors will review the pharmacy practice procedures including procedures for handling of medicines.

6.3.4. They will review the record keeping verifying that regulatory requirements and standards of pharmacy practice are met.

6.4 Closure of premises

6.4.1. If the inspectors have reasonable grounds to believe that there exists a health hazard on the premise, the inspectors shall close the premise immediately.

7 INSPECTION PROCESS

7.1 During an inspection

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

7.1.2. The inspectors should identify themselves as authorised inspectors and inform the inspectees about the type, purpose and scope of inspection.

7.1.3. The inspectors will

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

7.1.4. The inspectors may ask for additional documentation during the inspection. They may also change the focus of the inspection if they suspect serious non-compliance.

7.1.5. If any medicine is taken during the inspection, complete a confiscation/seizure form. If the medicine is confiscated for suspected quality issues the inspectors will not pay for the sample.

7.1.6. Upon completion of inspection, the inspectors should conduct an exit meeting to provide feedback and to discuss the findings with the inspectee. The inspector may agree timelines for corrections and corrective actions.

7.2 Grading of inspection findings

7.2.1. Deficiencies found during inspections are graded at 3 levels; critical, major and minor deficiency (finding).

7.2.1. A **critical** finding is any departure from regulatory requirements or good practices that result in a significant risk to customers, patients or public health. This includes the selling or supplying or dispensing or compounding of medicines from unlicensed premises, premises not staffed in accordance with regulatory requirements and premises on which non-licensed activities are carried out.

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

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

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

7.3 After the inspection

7.3.1. The inspectorate will provide a post inspection letter or email within 15 working days confirming the inspection outcome.

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

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

8 PREPARATION AT THE PREMISES FOR INSPECTIONS

8.1. There should be a procedure in place for self-inspections.

8.2. This procedure should include instructions for the staff on how to receive the inspectors, which senior staff members 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 the premise.

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

8.4. **Self-inspection**

8.4.1. The quality system at the premises should include self-inspections. These should be conducted to monitor implementation and compliance with the applicable regulatory requirements and standards of pharmacy practice and, if necessary, to trigger corrective measures.

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

8.4.3. 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.

9 FINAL PROVISIONS

5.1. This guideline is the first version. It will become effective on 15 January 2020 and be published on the PCG website.

5.2. The document will be reviewed within 3 years of becoming effective.

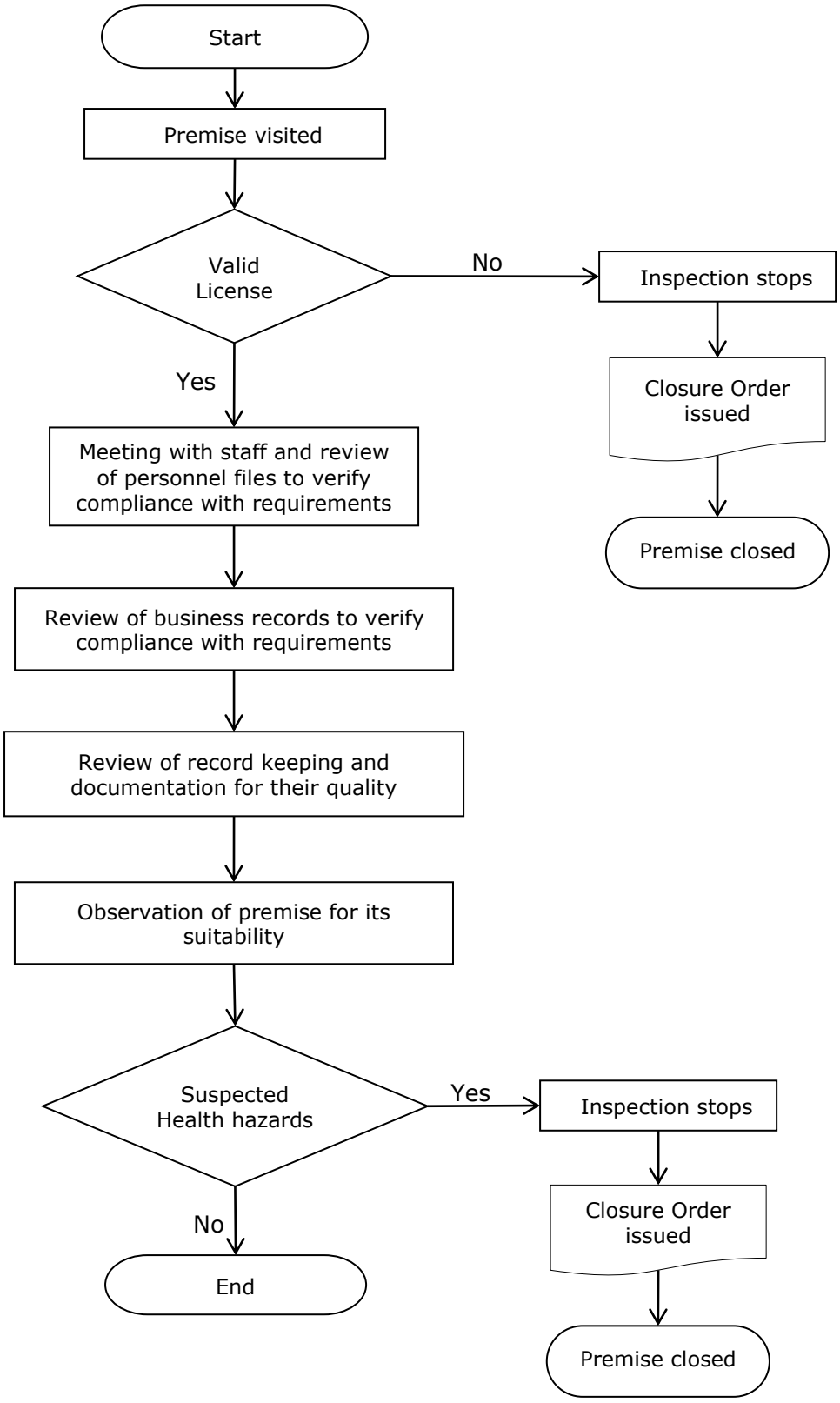
10 REFERENCES

- Pharmacy Council Act, 2014
- Pharmacy Regulations 2018
- Standards of Pharmacy Practice in The Gambia (PCG-GL-301)

11 DOCUMENT HISTORY

Version:	Issue Date:	Reasons for Change:
1.0	15 January 2020	New document

12 FLOW CHART: INSPECTION VISIT



ANNEX 1: MINIMUM STAFFING AND SUPERVISION REQUIREMENTS

Table 1: Staffing

	Wholesale Outlet	Retail Pharmacy	Retail Drugstore
Pharmacist	**1**	**1**	**/**
Pharmacy Technician/ Nurse Dispenser	**1**	**2**	**1**
Dispensing Assistant	**1**	**2**	**/**

Table 2: Supervision

	Pharmacist	Pharmacy Technician/ Nurse Dispenser
Wholesale Outlet operating ≥ 10 hours	**2** hours/day	**/**
Retail Pharmacy operating ≥ 14 hours	**4** hours/day	**/**
Retail Drugstore operating ≥ 14 hours	**/**	**10** hours/day

Note: A pharmacist may supervise not more than one (1) wholesale and two (2) retail pharmacies at a time.

Table 3: Staffing of Health institutions

	Minor Health Centre	Major Health Centre	General Hospital	Specialist/ Teaching Hospital
Pharmacist	**/**	**1**	**2**	**14**
Pharmacy Technician/ Nurse Dispenser	**1**	**3**	**8**	**15**
Dispensing Assistant	**3**	**5**	**10**	**/**