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Guideline for Licensing of Premises

PCG-GL-201, Version 2.0 – 15 October 2022

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1 LIST OF ABBREVIATIONS AND ACRONYMS

MCA	Medicines Control Agency
NMC	Nurses & Midwives Council of The Gambia
PCG	Pharmacy Council of The Gambia
SOP	Standard Operating Procedure

2 INTRODUCTION

2.1 Legal Basis

2.1.1. The regulation of licensing of premises in The Gambia from which medicines are supplied, sold or dispensed is governed by the provisions and requirements of the Pharmacy Council Act, 2014, referred to in this guideline as Act, 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 Sections 21 – 23 and Part V Section 24 of the Act stipulate the requirements and conditions for licensing of premises.

Note: The licensing of warehouses and other storage facilities of medicines is regulated by the Medicines Control Agency (MCA) The Gambia in accordance with the Medicines and Related Products Act, 2014.

2.1.3. The Pharmacy Regulations 2018, referred to in this guideline as Regulations, detail the legal requirements with respect to licences, 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 application and procedures for new licensing of premises, for the renewal of such premise licences and for changes to a licence.

2.2.2. It applies to premises, where medicines are sold, supplied, dispensed or compounded.

2.2.3. This document applies to medicines and related products as defined in the Medicines and Related Products Act, 2014.

2.2.4. The licensing of premises by the Council shall ensure that the premise is suitable for the supply of medicines and related products, where applicable.

3 GENERAL REQUIREMENTS

3.1. The PCG provides licences for the following pharmaceutical outlets:

- Wholesale pharmacy businesses
- Retail Pharmacies (Community Pharmacies)
- Drugstore outlets
- Veterinary drugstores.

3.2. The PCG provides a permit to supermarkets to sell medicines.

- 3.3. Each licence or permit covers only a single premise.
- 3.4. All premise licence holders must be resident in The Gambia.
- 3.5. A licence by the PCG will only be granted, if a supervisor is responsible for the premise who is registered with the PCG, or in case of veterinary drugstores with the Veterinary Council or in case of nurse dispensers with the Nurses and Midwives Council (NMC).
Note: In case of veterinary drugstores the Veterinary Council will endorse the registration on the application form.
- 3.6. A premise licence by the PCG will only be issued when the proposed location of the premise, premise conditions and personnel comply with the Act and Regulations. The PCG may deviate from the Regulations concerning the distribution of pharmacies in The Gambia, where necessary.
- 3.7. A permit will only be granted to supermarkets for ‘Over-The-Counter’ (OTC) medicines as stipulated in the Medicines and Related Products Regulations, 2020.
- 3.8. The PCG charges non-refundable application fee (currently GMD 250) and fees for licences and permits as specified in the Schedule of the Regulations. The fees shall be paid to a bank and account number provided by the PCG. The fees are due at the time of submission of an application for licensing (permit).
- 3.9. The licence holder has to apply for its renewal annually and for changes in the Supervisor, location or name of the premise.
- 3.10. A change in the kind of pharmaceutical outlet requires an application for a new licence.

4 APPLICATION FOR NEW LICENSING

- 4.1. For the licence of a premise (or in case of supermarkets a permit) the Premise Licensing Application Form must be completed by the applicant. The application form (PCG-F-201-01) is available from the PCG website: www.gpc.gm.
- 4.2. The completed, signed and dated application form shall be provided together with the required documentation as hard copies by post or in person to the PCG office: PHARMACY COUNCIL OF THE GAMBIA, Off Kairaba Avenue, Pipeline (opposite Mosque), Serrekunda, P.O.Box 4527 Bakau, or shall be sent by email to info@gpc.gm.
- 4.3. The following documents must be submitted with the application:
 - a) Copy of Identification Card or Passport for identification;
 - b) Copy of Business registration;
 - c) Copy of Tax Identification (TIN);
 - d) Copy of the Supervisor’s current Registration certificate with the respective Council (except supermarkets and veterinary drugstores); and
 - e) Copies of registration certificates of other personnel, as applicable.
- 4.4. Any other additional documents might be requested by PCG.
- 4.5. The documents must be written in English. If the original is written in another language, a certified translation must be provided.

- 4.6. The PCG inspectorate will contact the applicant for a suitable date to meet for an assessment visit to inquire about the location and suitability of the anticipated premise and the anticipated personnel and will make recommendations as appropriate. If possible, this visit should take place at the premise.
- 4.7. The applicant is required to respond **latest 45 days** following the assessment visit and inform the PCG about the implementation plan of the recommendations by the inspectors, if any. After this deadline the application will be rejected.
- 4.8. After a timely response following the assessment visit, the inspectors conduct an inspection visit of the premise to confirm whether the recommendations were implemented, to verify the suitability of the premise and personnel, and the adherence to regulatory requirements before a licence can be granted (for details refer to the PCG *Guideline for Inspections of Premises*).

5 APPLICATION FOR RENEWAL OF LICENCES

- 5.1. The premise licence (or in case of supermarkets permit) must be renewed every year.
- 5.2. For the renewal of a licence (permit) the Premise Licensing Application Form must be completed by the applicant. The application form is available from the PCG website: www.gpc.gm.
- 5.3. The application for renewal must be submitted to the PCG between 1st January and 1st March every year. Late application for renewal will attract a penalty as determined by the PCG.
- 5.4. The completed, signed and dated application form shall be provided together with the required documentation as hard copies by post or in person to the PCG office: PHARMACY COUNCIL OF THE GAMBIA, Off Kairaba Avenue, Pipeline (opposite Mosque), Serrekunda. P.O.Box 4527 Bakau or sent by email to info@gpc.gm.
- 5.5. The following documents must be submitted with the application:
 - a) Copy of the previous year's licence;
 - b) Copy of the supervisor's current Registration certificate with the respective Council (except supermarkets and veterinary drugstores); and
 - c) Copies of certificates of other personnel, as applicable.
- 5.6. Any other additional documents might be requested by PCG.
- 5.7. In case of any changes since the last year, which do not need an application, they must be declared in the application form for renewal of the licence.
- 5.8. The PCG inspectorate may visit the premise for inspection before renewal of the licence (for details, refer to the PCG *Guideline for Inspections of Premises*).

6 APPLICATION FOR CHANGES

- 6.1. Planned changes in Supervisor, location of the premise (relocation) or name of the premise must be applied for to the PCG.
- 6.2. The completed, signed and dated Premise Licensing Application Form, available from the PCG website, shall be provided together with the required documentation as hard copies by post or in person to the PCG office:

PHARMACY COUNCIL OF THE GAMBIA, Off Kairaba Avenue, Pipeline (opposite Mosque), Serrekunda. P.O.Box 4527 Bakau or sent by email to info@gpc.gm.

- 6.3. The PCG will acknowledge the receipt of the application within two weeks. The requested change can only become effective after issuance of the changed licence by PCG.

7 ISSUEING OF A LICENCE

- 7.1. In case of new licences, if all requirements are met, the licence will be issued within one (1) month after the approval following the inspection visit.
- 7.2. A new permit to supermarkets will be issued one (1) month after reception of the valid application. An inspection visit by PCG may be carried out before issuing a permit.
- 7.3. In case of renewals the licence or permit will be issued before 31st March of the year after receipt of the valid application in due time.
- 7.4. In case of the change of name of the premise the applicant will receive the changed licence within one (1) month of the application.
- 7.5. For the relocation of a premise or change of Supervisor the changed licence will be issued by PCG within six (6) months from date of receipt of the application with the exception of relocation or change of Supervisor from an urban to a rural settlement, which may be granted within one (1) month.
- 7.6. The licence will stipulate the business to be carried out on the premise, the name and registration number of the supervisor and the expiry date.
- 7.7. A wholesale licence pharmacy business cannot be issued a licence for retail.
- 7.8. The original, current licence must be displayed in the premise in accordance with the Regulations, Section 28, and the registration certificate of the supervisor must be available at the premise.

8 FINAL PROVISIONS

- 8.1. This guideline is the second version. It will become effective on 15 October 2022 and be published on the PCG website.
- 8.2. The document will be reviewed within 2 years of becoming effective.

9 DOCUMENTS NEEDED FOR THIS GUIDELINE

Document ID	Title (as referenced on the document)
PCG-F-201-01	Premise Licensing Application Form
PCG-F-201-02	Change of Premise Licensing Application Form

10 REFERENCES

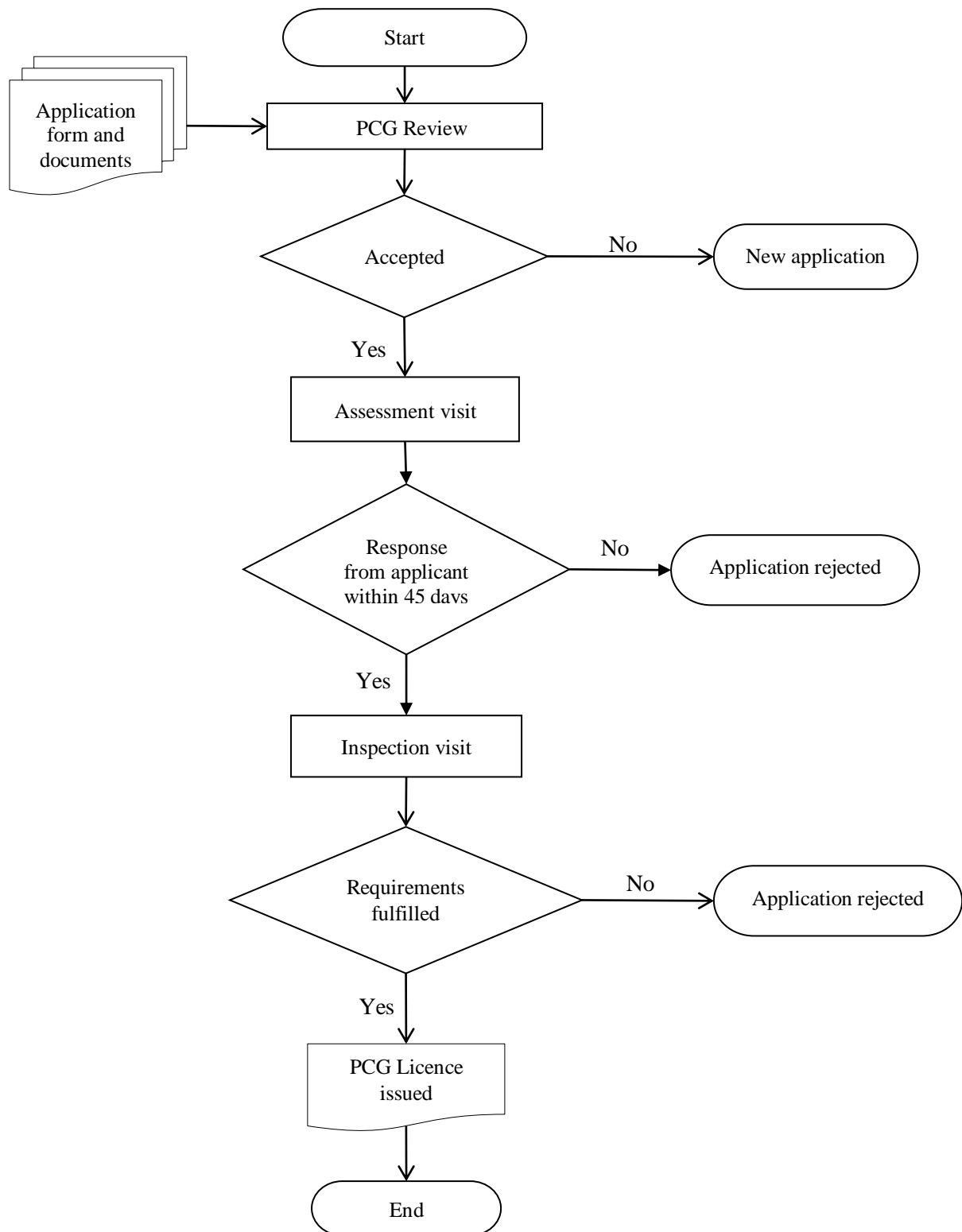
- Pharmacy Council Act, 2014
- Pharmacy Regulations 2018
- Medicines and Related Products Act, 2014

- Medicines and Related Products Regulations, 2020
- Standards of Pharmacy Practice in The Gambia (PCG-GL-301)
- Guideline for Inspection of Premises (PCG-GL-302)

11 DOCUMENT HISTORY

Version:	Issue Date:	Reasons for Change:
1.0	15 January 2020	New document
2.0	15 October 2022	Editorial changes; application form for licensing added; cross-reference to MCA included; permits and renewal for supermarkets more detailed

12 FLOW CHART: NEW LICENSING



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 \geq 10 hours	2 hours/day	-
Retail Pharmacy operating \geq 14 hours	4 hours/day	-
Retail Drugstore operating \geq 14 hours	-	10 hours/day

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

ANNEX 2: LOCATION OF PREMISES

The minimum distance from mass transit points to a retail pharmacy or drugstore and from a pharmacy or drugstore to another pharmacy or drugstore distance shall be 200 metres.

Mass Transit Points are:

- Banjul Albert Market Area
- Westfield Junction Area
- Serrekunda Market Area
- Brusubi Roundabout ('Turntable') Area
- Brikama Market Area
- Soma Market Area
- Basse Market Area
- Farafeni Market Area

For the rest of the communities the minimum distance from a pharmacy or drugstore to another pharmacy or drugstore shall be 500 metres and from a pharmacy or drugstore to a public health facility including hospitals and clinics 200 metres.