PHARMACY COUNCIL OF THE GAMBIA
Pipeline, off-Kairaba Ave – opposite Mosque
Serrekunda
Tel: +220 438 3841, +220 738 2655/769 0904
P.O.Box 4527 Bakau
Website: www.gpc.gm

Standards for Pharmacy Practice in The Gambia

PCG-GL-301, Version 2.0 – 05 May 2020

Table of Contents

1 LIST OF ABBREVIATIONS AND ACRONYMS

CMS Central Medical Stores
GPP Good Pharmacy Practice;
PCG Pharmacy Council, The Gambia
RMS Regional Medical Store

2 INTRODUCTION

2.1 Background and Legal Basis

2.1.1. Medicines are an essential and critical part of health-care services and often an essential component of many disease prevention programmes and virtually all disease treatment plans.

2.1.2. Pharmacists and pharmacy support personnel are specifically educated and trained health professionals who are charged with the management of the distribution of medicines to consumers and engaged in appropriate efforts to assure their safe and efficacious use.

2.1.3. The regulation of the practice of pharmacy in The Gambia is governed by the provisions and requirements of the Pharmacy Council Act, 2014, by which the Pharmacy Council, The Gambia (PCG) was established as the regulatory body for the practice of pharmacy, and by the Pharmacy Regulations 2018.

2.1.4. Part II Section 6 (d), (e) and (j) of the Act require that the PCG shall prescribe and enforce practice standards, conduct and discipline among registered persons and promote the highest standards of pharmacy practice.

2.2 Purpose

2.2.1. Good Pharmacy Practice is the practice of pharmacy that responds to the needs of the people who use the pharmacy services to provide optimal, evidence-based care.

2.2.2. These Standards set out the requirements of pharmacy practice in The Gambia to promote and protect the health and safety of the general public through safeguarding, maintaining and enforcing the highest standards in the practice of pharmacy and for connected matters.

2.3 Scope

2.3.1. It applies to pharmacists and pharmacy support personnel involved in any area of pharmacy practice.

2.3.2. These standards apply to premises and facilities licenced under the Act and operated by registered pharmacists, pharmacy support personnel and for instructors of academic training courses and CPD programmes accredited by the Council.

3 REQUIREMENTS OF GOOD PHARMACY PRACTICE

3.1. Good Pharmacy Practice requires that:

- a pharmacist's and pharmacy support personnel's first concern in all settings is the welfare of patients;
- the core of the pharmacy activity is to help patients make the best use of medicines and related products.
- Fundamental functions include
  - the dispensing and supply of medicines and related products of assured quality, safety and efficacy,
  - the provision of appropriate information and advice to the patient,
  - administration of medicines, if required, and
  - the monitoring of the safety and effectiveness of medicine use;
- an integral part of the pharmacist's and pharmacy support personnel's contribution is the promotion of rational and economic prescribing, as well as dispensing; and
- the objective of each element of pharmacy service is:

I. relevant to the patient

II. clearly defined, and

III. effectively communicated to all those involved.

- Multidisciplinary collaboration among healthcare professionals is the key factor for successfully improving patient health and safety.

3.2. In satisfying these requirements, the following conditions are necessary:

- the wellbeing of patients should be the main philosophy underlying practice, even though it is accepted that ethical and economic factors are also important;
- pharmacists and pharmacy support personnel should have input into decisions about the use of medicines in accordance with the relevant guidelines;
- A system should exist that enables pharmacists and pharmacy support personnel to report and to obtain feedback about adverse drug reactions, adverse events, medicine-related problems, medication errors, misuse or medicine abuse, defects in product quality or suspected counterfeit products. This reporting may include information about medicine use supplied to patients or health professionals, either directly or through pharmacists or pharmacy support personnel (***Medicines and Related Products Act Section 4c***);
- the relationship with other health professionals, particularly medical doctors, should be established as a therapeutic collaborative partnership that involves mutual trust and confidence in all matters relating to pharmacotherapy;
- the relationship between pharmacists and pharmacy support personnel should be one of colleagues seeking to improve pharmacy service, rather than acting as competitors;

- organisations, group practices and pharmacy managers should accept a share of responsibility for the definition, evaluation and improvement of quality of pharmacy practice;
- the pharmacist and pharmacy support personnel should be aware of essential medical and pharmaceutical information (i.e. diagnosis, laboratory test results and medical history) about each patient.
- the pharmacist and pharmacy support personnel need evidence-based, unbiased, comprehensive, objective and current information about therapeutics, medicines and related products in use, including potential environmental hazard caused by disposal of pharmaceutical waste (for disposal refer to the Medicines Control Agency (MCA) *Guideline for Safe Disposal of Medicines and Related Products as updated from time to time,* which applies and is available from the ***MCA website: www.mca.gm***.
- pharmacists and pharmacy support personnel in each practice setting should accept personal responsibility for maintaining and assessing their own competence throughout their professional working lives. While self-assessment is important, an element of assessment and monitoring by the Pharmacy Council, The Gambia is also relevant in ensuring that pharmacists and pharmacy support personnel maintain standards and comply with requirements for continuous professional development (***Pharmacy Council Act 2014:Section 6j and PCG current Guidelines on Continuing professional Development available at www.gpc.gm***);
- educational programmes for entry into the pharmacy profession shall appropriately address both current and foreseeable changes in pharmacy practice (***PCG current Guidelines on Accreditation of training courses available at www.gpc.gm)***; and
- national standards of pharmacy practice shall be adhered to by pharmacists and pharmacy support personnel.

4 MINIMUM STANDARDS FOR PREMISES

4.1. Patients and the public should receive pharmacy services from premises that are licensed as suitable for the services being provided (***Refer to PCG Pharmacy Council Regulations 2018)***.

4.2. The design and layout of the premises should permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and shall minimise the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of products (***Refer to PCG Pharmacy Council Regulations 2018)***.

4.3. The current licence for the premise shall be displayed within the premises in clear view of the public.

4.4. The premises shall be constructed to ensure that the entry of pests (e.g. insects, rodents) is prevented, and that the premises can be easily cleaned, disinfected and controlled of pests (***Refer to PCG Pharmacy Council Regulations 2018)***.

4.5. All parts of the premises namely walls, floors, windows, ceiling, woodwork, shelves, counters, etc) shall be maintained in an orderly, clean and tidy condition.

4.6. Premises shall be maintained to a level of hygiene appropriate for provision pharmacy services (e.g. clean wash-hand basin, source of tap water and a closed drainage system, functioning toilet facilities).

4.7. The supervising pharmaceutical personnel shall take all reasonable steps to ensure that working conditions are so arranged as to protect the health and safety of the public and people working in the premises and comply with relevant legislation relating to safety in the workplace (e.g. fire procedures, electrical equipment, etc).

4.8. Pharmaceutical premises shall be opened to the public for business only when the required pharmaceutical personnel are present.

4.9. Control of access to premises shall be of such a nature that only registered pharmacy personnel have direct access to pharmacy medicines and prescription-only medicines.

4.10. Pharmacy services provided shall be in an environment that is appropriate for the provision of healthcare. Premises should protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services. The area(s) shall have sufficient space to promote appropriate counselling and demonstration of the correct and safe use of specific medicines or related products as required (***Refer to PCG Pharmacy Council Regulations 2018)***.

4.11. Storage areas shall have sufficient shelving adequately constructed and shall be secure and large enough to allow for orderly arrangement of stock and proper stock rotation. For details on storage refer to the MCA *Guideline for Storage and Distribution of Medicines and Related Products as updated from time to time*, available from the MCA website: www.mca.gm.

4.12. The minimum area for the dispensary necessary to allow a safe and efficient flow of work, effective communication and supervision shall be adequate to the number of prescriptions dispensed, the daily pattern of prescription peaks, the configuration of available space and the space available elsewhere in the premises for storage of stock.

4.13. The supervising pharmacy personnel shall ensure that written instructions are in place and accessible to staff that describe all key procedures in detail.

5 MINIMUM STANDARDS FOR PHARMACY SERVICES

5.1 Procurement

5.1.1. The pharmaceutical aspects of the purchase of all medicines and related products for wholesaling shall be supervised by a registered pharmacist to control all medicines and related products.

5.1.2. The pharmaceutical aspects of the purchase of all medicines and related products for retail purposes shall be supervised by a registered pharmaceutical personnel to control all medicines and related products, which are purchased or supplied.

5.1.3. Supervising pharmacy personnel shall not purchase, sell or supply any medicines or related product where he/she has any reason to doubt its safety, quality or efficacy.

5.1.4. Supervising pharmacy personnel shall know and select manufacturers or suppliers by applying various quality parameters.

5.1.5. Supervising pharmacy personnel shall be satisfied that both the supplier and the source of any medicine or related product purchased locally are reputable and licensed by PCG or MCA respectively.

5.1.6. Regard shall be paid to the storage conditions before purchase and to the labels, leaflets, physical appearance, origin and subsequent chain of supply of the medicines or related products concerned (***Refer to current MCA guidelines on Storage and distribution of Medicines***).

5.1.7. A Formulary and/or the Standard Treatment Guideline should be used as the basis for medicine therapy and the promotion of the rational use of medicine (Refer ***to MCA Act 2014: Section 4i&j***).

5.1.8. Delivery of medicines and related products should be made directly to the relevant licensed premise. Where delivery is not direct to the premise, procedures shall be established and followed to ensure secure receipt of medicines and related products and their onward passage to the premise (***Refer to current MCA guidelines on Storage and distribution of Medicines***).

5.1.9. Wholesaling of pharmaceuticals by licensed wholesalers shall be restricted to only licensed premises by relevant authorities.

5.2 Storage and Distribution

5.2.1. Appropriate storage for medicines and related products shall be provided in all licensed premises. Approved store-keeping procedures and adequate stock control systems shall be in place.

5.2.2. Stock rotation shall always be done on the "FIRST EXPIRY, FIRST OUT" (FEFO) or "FIRST IN - FIRST OUT" (FIFO) basis. Stock that expires first or is received first shall therefore be used first.

5.2.3. Details on storage and distribution are described in the MCA *Guideline for Storage and Distribution of Medicines and Related Products as updated from time to time*, which applies and is available from the MCA website: www.mca.gm.

5.2.4. A safe system of work shall be established and maintained by supervising pharmaceutical personnel to eliminate, as far as possible, errors in any component of the pharmaceutical service.

5.2.5. Written procedures shall ensure:

- that the procurement and distribution process is fully documented;
- effective batch recall of medicines when necessary; for recall requirements refer to the MCA *Guideline for Recall of Medicines and*

Related Products as updated from time to time, which applies and is available from the MCA website: www.mca.gm.

- that optimal storage conditions are monitored (including during transportation) ***refer to PCG Regulations 2018;***
- the safety of medicines; and
- that patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date. Medicines and related products shall not be wholesale when less than three (3) months to expiry and not less than one (1) month for retailing.

5.3 Pharmacies in Health Facilities

5.3.1. The guidelines and standard operating procedures for storage and distribution practices shall be available and implemented

5.3.2. Pharmaceutical services offered to the public by these facilities shall be restricted to their clientele

5.4 Dispensing

5.4.1. The dispensing process is divided into several steps, namely:

- Screening and interpreting the prescription,
- selection or preparation of the medicine and labelling, if applicable,
- issuing the medicine to the patient and
- provision of information and instructions to the patient to ensure the safe and effective use of medicine.

5.4.2. The person who is responsible for the dispensing of a prescription shall ensure that all steps of the dispensing process have been performed by an appropriately authorised person. (see Guidelines on Dispensing)

5.4.3. Details on dispensing are described in the Guidelines for Dispensing of Medicines as updated from time to time.

5.4.4. Systems shall be in place to ensure that the distribution of medicines and related products is reliable and secure to the point of delivery.

5.4.5. No information may be divulged about the affairs of any person obtained in the course of dispensing a prescription except to a person authorised to have access to such information and acting within his/her lawful jurisdiction.

5.5 Patient Information

5.5.1. Patient information is of vital importance in the correct use of medicines and related products. Lack of information and misunderstanding may contribute to the failure of the therapy or to increased risk of adverse effects.

5.5.2. Pharmacy personnel shall, within their scope of practice, give advice and information to patients on how to use medicines and related products safely and effectively to maximise therapeutic outcomes.

5.5.3. Pharmacy personnel shall therefore have access to as much information as they require within their ethical and professional judgement to meet the individual needs of patients which includes the patient's medical/clinical records.

5.5.4. Upon receipt of a prescription, or a request for dispensing of medicine on own initiative, pharmaceutical personnel shall counsel each patient or patient's caregiver on matters which, in the professional judgement, will enhance or optimise the medicine therapy prescribed.

5.5.5. The pharmacy personnel shall assess each patient's ability to understand the information imparted by question and answer and shall be able to modify his/her approach accordingly. Care should be taken with counselling where understanding is likely to be a problem.

5.5.6. Confidentiality of the patient shall be respected. The provision of advice shall take place in a suitable environment and the patient should be put at ease, especially with regard to sensitive information.

5.5.7. Patient medication records shall be kept and readily available in the pharmacy, except in health facility pharmacies where the pharmaceutical personnel have access to the necessary information in the patient's medical/clinical records.

5.5.8. The pharmacy personnel shall ensure a system is in place to guarantee the confidentiality of data relating to individual patients.

5.5.9. When called upon by a member of the public to advice on symptoms, the request shall be dealt with by authorised pharmaceutical personnel. Where necessary, arrangements shall be in place to ensure that an intervention by pharmaceutical personnel can be made at an appropriate stage. The following steps shall be taken:

- sufficient information shall be obtained to enable a proper assessment of the situation to be made including information about
  - who has the problem,
  - what the symptoms are,
  - how long the condition has persisted,
  - any action that has already been taken, and
  - which medicines the person concerned is already using including traditional therapies;
- it shall be decided whether the symptoms might be associated with a serious condition, and in such circumstances the patient shall be referred for immediate medical advice;
- in the case of a minor self-limiting health problem, appropriate advice shall be given and a medicine recommended only when necessary; and
- the patient record shall be updated, whether medicine has been supplied or not and the patient advised to consult a health facility should the symptoms persist beyond a stated time.

5.5.10. The pharmacy personnel shall utilise experience to select medicines taking into account their quality, effectiveness and safety.

5.5.11. The pharmacy personnel should do his/her best to ensure that the patient or caregiver is provided with appropriate information about the correct use the medicine.

5.5.12. The pharmacy personnel should do appropriate follow-up of the therapy with the patient's co-operation.

6 MINIMUM STANDARDS FOR PHARMACY PERSONNEL

6.1. Persons who practise in a pharmacy shall be registered with the Pharmacy Council, The Gambia in accordance with the requirements (***Refer to PCG Act 2018 and the current Guidelines on Registration of Pharmacy Personnel***).

6.2. Pharmacists and pharmacy support personnel shall receive sufficient education and training to enable them to provide competently the professional services being offered. Continuing professional development is a professional obligation (***Refer to PCG Act 2018 and the current Guidelines on Accreditation of Training courses and Guidelines on CPD***).

6.3. Pharmacy personnel shall ensure that any services provided, comply with law, standards and guidelines issued by PCG, MCA or other appropriate bodies.

6.4. Pharmacy personnel shall cooperate with inspectors of the PCG, MCA or other appropriate bodies and take corrective measures in respect of deficiencies with regard to inspection reports (***refer to PCG Act 2014 Section 34 & 36***).

6.5. The responsibilities of the pharmacist and the Pharmacy personnel working in a pharmacy or drugstore shall be clearly defined and include:

- Continually review his/her level of professional knowledge and expertise by self-assessment (self-audit);
- Being aware of and implement as soon as possible legislative changes, which affect pharmacy practice;

6.6. Pharmacy personnel shall provide patient-centred care by understanding what is important to the individual, working in partnership with others, communicating effectively and adapting the care to meet the individual’s needs.

6.7. Detailed procedures relating to hygiene shall be established and adapted to the different needs within the pharmacy or drugstore. They shall include procedures relating to the health, hygiene practices and clothing of personnel, as applicable.

7 MINIMUM STANDARDS FOR PHARMACY MANAGMENT

7.1. The pharmacy should be organised in such a way that its services and processes contribute to the highest quality of pharmaceutical care.

7.2. A collection of all legislation, standards, guidelines, policies and procedures relevant to the pharmacy and drugstore shall be maintained in a current state and be accessible by all pharmacy staff.

7.3. Documented procedures shall be in place to ensure that pharmacy staff are aware of relevant requirements, and apply these to the handling, sale and required record keeping of medicines available in the pharmacy or drugstore.

7.4. The pharmacy should define quality objectives that should reflect the need

7.5. The process of quality improvement should include monitoring

7.6. The responsible pharmaceutical personnel and staff should document all complaints, processes and interventions to improve performance.

7.7. Lines of communication should be clearly specified between the pharmacy and other healthcare providers.

7.8. Adverse drug reaction reporting shall be done in accordance with the MCA guidelines for reporting adverse drug reactions in The Gambia (***Refer to current MCA Guidelines on Pharmacovigilance***).

8 MINIMUM STANDARDS FOR ACADEMIC TRAINING COURSES AND CPD PROGRAMS ACCREDITED BY THE COUNCIL

8.1 accreditation process for an academic training course or a CPD programme shall be per the current PCG Accreditation guidelines as published by the Council.

8.2 any major deviance that may negatively impact on the outcome of a program shall be duly communicated to the Council and a salvage plan shall be agreed with the Council in writing to mitigate undue disruption to the deliverance and impact of the course or programme.

8.4 academic training institutions and CPD offering programmes shall uphold to minimum standards of instructions and requirements for delivering their courses of learning and/ or programmes of training and such course or training programmes shall be updated periodically to be relevant to changes in practices over time.

9 FINAL PROVISIONS

9.1 This guideline is the first version published by the PCG and shall be enforceable effective on the date approved.

9.2 The document will be reviewed as and when required.

10 ATTACHMENTS

None

11 REFERENCES

- Pharmacy Council Act, 2014
- Pharmacy Council, The Gambia, Pharmacy Regulations 2018
- MCA Guideline for Safe Disposal of Medicines and Related Products
- MCA Guideline for Storage and Distribution of Medicines and Related Products
- MCA Guideline for Recall of Medicines and Related Products
- Guidelines for Dispensing of Medicines and other guidelines cited in the document
- The South African Pharmacy Council, Good Pharmacy Practice Manual, Fourth edition, 2010

12 DOCUMENT HISTORY

Version:	**Issue Date:**	**Reasons for Change:**
1.0	18 Nov 2018	New document
2.0	05 May 2020	Address and telephones updated