QUALITY ASSURANCE PLAN THE GAMBIA

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APPROVED BY:

Markieu Janneh Kaira, Executive Director

NAME AND TITLE

SIGNATURE

DATE

FORWARD

The Medicines Control Agency (MCA) was established by an Act of Parliament and assented on 24th December 2014. The Agency is mandated to regulate the manufacture, import, wholesale, storage, distribution and supply of medicines and related products, and to ensure that all medicines and related products sold and used in the country conform to the required standards of quality, safety and efficacy throughout the product lifecycle in The Gambia.

In pursuance of the Medicines and Related Products Act 2014, Part VIII, MISCELLANEOUS, Section 64 Guidelines herein quoted "the Agency may publish guidelines in connection with matters provided for under this Act for the purpose of giving guidance", the MCA deems it very essential to develop written Guidelines and Standard Operating Procedures (SOPs) to guide the implementation of the various regulatory functions of MCA in ensuring the safety, efficacy and quality of medicines and related products available to the population.

ACKNOWLEDGEMENTS

The Medicines Control Agency (MCA) wishes to thank the Ministry of Health, members of the MCA Governing Board, the Technical Working Group, staff of the Medicines Control Agency and the various institutions for their support in the development of the original document (first version).

Special thanks is extended to the Global Fund through Action Aid International The Gambia (AAITG) for their financial support in the development of the Quality Assurance Policy and Plan, some regulatory guidelines and SOPs for use by MCA and its stakeholders.

Thanks is also extended to key stakeholders for their valuable contributions and participation in the validation of the first version of the Quality Assurance Plan including the Directorate of National Pharmaceutical Services, Pharmacy Council, Medical and Dental Association, Pharmaceutical Society of The Gambia, Nurses and Midwives Council, Regional Health Directorates, National Aids and TB Control Programs, National Public Health Laboratory Services and Gambia Standards Bureau.

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1 LIST OF ABBREVIATIONS AND ACRONYMS

CTD	Common Technical Document
DNPS	Directorate of National Pharmaceutical Services
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
MCA	Medicines Control Agency
MoH	Ministry of Health
NGO	Non-Governmental Organisation
NMP	National Medicines Policy
NMQCL	National Medicines Quality Control Laboratory
PMS	Post Marketing Surveillance
PV	Pharmacovigilance
QA	Quality Assurance
QAP	Quality Assurance Plan
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedures
WHO	World Health Organization

2 OPERATIONAL DEFINITIONS

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

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this plan.

External laboratory: an accredited quality control laboratory for medicines or related products selected by MCA according to their standards to conduct QC testing for medicines or related products

Quality Assurance (QA): a wide-ranging concept covering all matters that individually or collectively influences the quality of a product; it is the totality of the arrangement made with the object of ensuring that medicines and related products are of the quality required for their intended use

Quality Control (QC): refers to the sum of all procedures undertaken to ensure the identity and purity of a particular medicine or related product

Quality Management System (QMS): an appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality

Quality Monitoring: all activities undertaken to ensure that the products continue to conform with the manufacturer's established quality specifications during the manufacturing, storage, distribution and use of such products,

including but not limited to, reporting of deficient products and surveillance, as part of a Quality system

3 INTRODUCTION

Issues related to the quality of medicines and related products remain an increasing global concern, especially in developing countries. The safety, efficacy, and quality of medicines and related products are sustained by the efforts of multiple institutions and their concerted activities. Achieving a high level of quality of medicines and related products requires their effective legislation and regulation, a competent medicines regulatory authority, good practices and standards with adequate quality assurance measures and quality control systems and appropriate product information.

Good practices in a medicines and related products supply system form an important part of ensuring that the quality of medicines and related products is maintained throughout the supply management chain. Manufacturers achieve their product quality during the production of their products and testing to assure quality prior to their release for distribution. This attention to quality must continue throughout the supply and distribution network.

The shelf-life of a medicine and related product is determined by the chemical and physical properties and influenced by the temperature, humidity and packaging material, and how it is packaged, stored, and transported. Appropriate containers and packaging materials are essential to preventing or minimising problems of the quality caused during product handling and distribution. Since resources are often limited at all supply levels, priorities for QA activities should be targeted. This document serves to ensure that a supply and distribution system has a satisfactory QA plan in place by the regulatory authority to ensure product quality is maintained throughout the distribution system.

POLICY STATEMENT

'The National Medicines Policy (NMP) aims to contribute to the attainment of quality health services for the population of The Gambia through ensuring the continuous availability, accessibility and affordability of essential medicines of appropriate quality, safety and efficacy and by promoting their rational use.'

3.1 Purpose of this document

This Quality Assurance Plan (QAP) ensures that all medicines and related products are of the required quality for their intended use. The QAP forms part of the Quality Management System with the objectives to:

- establish and maintain a comprehensive quality assurance system to ensure that the required safety, efficacy and quality of medicines and related products are maintained throughout the medicines supply chain;
- promote and reinforce a good understanding of the need for effective quality assurance of medicines and related products by all those involved in the supply chain, including the consumer; and
- improve technical capacity on quality assurance.

This document guides MCA and stakeholders on the requirements needed for achieving and maintaining quality standards for medicines and related products.

3.2 Scope

This QAP applies to medicines and related products as defined in the Medicines and Related Products Act, 2014 and the Medicines and Related Products Regulations, 2020. However, household chemical substances are not included in this QAP.

This document applies to personnel working at the Medicines Control Agency (MCA), the Directorate of National Pharmaceutical Services of the Ministry of Health (MoH) and other personnel working at every stage of the supply chain to ensure quality, safety and efficacy up the point of use.

The QAP is to be used for supply and distribution systems in both the **public** and the **private** sectors including health facilities, pharmaceutical outlets, **NGOs** and research institutions.

4 ROLES AND RESPONSIBILITIES IN THE QUALITY ASSURANCE SYSTEM

Public health is known to be promoted by the availability of safe, efficacious and quality medicines and related products. Medicine Regulatory Authorities throughout the world develop various systems to contribute to this objective.

Even though the problem of sub-standard and falsified medicines is global, the West African sub-region is however plagued with a high incidence, hence the urgent need to develop and maintain the Quality Assurance Plan and advocate for its implementation.

PRINCIPLE:

NO MEDICINE SHALL BE IMPORTED, DISTRIBUTED OR OFFERED FOR SALE IN THE GAMBIA UNLESS IT IS REGISTERED BY THE MEDICINES CONTROL AGENCY.

The following public institutions play a critical role in QA of medicines and related products:

<u>THE MINISTRY OF HEALTH</u>

- Promotion and Protection of public health;
- Responsible for policy formulation including the National Health Policy and National Medicines Policy;
- Responsible for planning, budgeting, organisation and coordination of the health sector at all levels;
- Quality Assurance of public health services.

<u>MEDICINES CONTROL AGENCY (MCA)</u>

- The MCA, as mandated by the Medicines and Related Products Act, 2014, regulates the manufacturing, importation, exportation, distribution, sale,

advertisement, promotion and use of medicines and related products in the country.

Functions also include

- Product registration, licensing, quality control, pharmacovigilance, post-marketing surveillance and inspections;
- To prescribe quality standards for medicines and related products;
- To ensure the publication of all the relevant guidelines.

DIRECTORATE OF NATIONAL PHARMACEUTICAL SERVICES (DNPS)

The Directorate of National Pharmaceutical Services has the following major functions:

- Responsible for the coordination of implementation of the National Medicines Policy (NMP);
- Planning and Management of the public pharmaceutical sector including human resource development;
- Coordination of the Monitoring and Evaluation of the pharmaceutical sector;
- Public health procurement and supply chain management of medicines and related products;
- Rational Use of Medicines.

NATIONAL MEDICINES QUALITY CONTROL LABORATORY

- Performs quality control testing of medicines and related products;
- Supports the work of the Medicines Control Agency.

Note: This laboratory is not yet established

DIRECTORATE OF NATIONAL PUBLIC HEALTH LABORATORY SERVICES

- Establishes and enforces quality assurance mechanism for both public and private laboratories;
- Supports the work of the Medicines Control Agency.

GAMBIA STANDARDS BUREAU

- Develops and promotes national standards in public and industrial welfare, health and safety;
- Promotes information dissemination on standards;
- Supports the work of the Medicines Control Agency.

PHARMACY COUNCIL

- Enforcing the code of ethics and good pharmacy practice and standards;
- Registration of pharmaceutical personnel and licensing of premises;
- Collaborates with the Medicines Control Agency.

OTHER HEALTH PROFESSIONAL COUNCILS

- Enforcing the code of ethics and good professional practice;
- Registration of relevant professionals;
- Collaborate with the Medicines Control Agency.

STAKEHOLDERS (Importers, Retailers, Health institutions, etc)

- Compliance with regulatory requirements of MCA

4.1 Coordination of the QAP Maintenance

The maintenance of this plan is coordinated by the MCA to ensure that all requirements of the QAP are adhered to.

There are collaboration between all parties including governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of medicines and related products to patients and customers to ensure the quality, safety and efficacy of these products and to prevent the exposure of patients and customers to substandard and falsified medicines and related products.

5 ELEMENTS OF QUALITY ASSURANCE (QA)

The quality of medicines and related products in the country is assured through adequate procedures for products marketing authorisation/registration, prequalification / approval of suppliers, monitoring of supply and distribution system, post marketing surveillance including inspections and pharmacovigilance and quality control. The quality system includes managerial, technical and legal aspects. The elements of QA consist of the following:

a) Selection of products

The MoH and Directorate of National Pharmaceutical Services are responsible for the selection of medicines and related products for the public sector in accordance to public health needs and WHO recommendations. In the private sector it is the responsibility of each importer to select appropriate products, which will be based on customers' requirements.

Selection criteria are:

General

- Public health relevance
- Evidence of efficacy and safety
- Appropriate dosage form and strength of medicines
- Comparative cost-effectiveness

Quality

- Appropriate shelf-life
- Acceptable stability
- Acceptable bioavailability of medicines
- Acceptable conformity

The MCA is responsible for the control of the products before registration or import to ensure that the selection criteria are met.

b) Procurement

The Directorate of National Pharmaceutical Services is responsible for the procurement of medicines and related products for the public sector. In the private sector it is the responsibility of each importer to procure appropriate products, which will be based on customers' requirements.

- Selection of prequalified/approved suppliers and formation of strategic alliances, where applicable
- Compilation of appropriate product specifications
- Request of samples from new suppliers
- Collection and maintaining information on supplier performance

The MCA is responsible for licensing importers and for the control that products are procured from reliable sources.

c) Product Registration/Marketing authorisation

The registration of medicines and related products is the responsibility of MCA. The Agency refers to the Common Technical Document (CTD).

- Documentation of proof of quality, safety and efficacy
- Product packaging and labelling
- Request of specific reports and data for certain medicines or related products (e.g. bioavailability and stability studies, where necessary)
- Quality control testing
- Good Manufacturing Practice inspections, as applicable

The MCA provides guidelines for registration of products including a guide for application in the Common Technical Document (CTD) Format and for labelling of medicines. The MCA works in accordance with SOPs for registration of products.

d) Import and export authorisation and Port clearance

The MCA is responsible for the permit to import and export products.

- Import and export application
- All FPPs and related products need to be authorised for use in The Gambia by the MCA before importation into the country
- Import clearance permit and Export permit processing

The MCA provides guidelines for import and export and port clearance and works in accordance with SOPs.

e) Receipt

The control of the quality of products at reception is the responsibility of MCA.

- Inspection/Verification of consignment at the warehouse during offloading
- Random sampling for quality control

The MCA provides guidelines for inspections and works in accordance with SOPs.

f) Storage

For the public sector the Directorate of National Pharmaceutical Services is responsible for appropriate storage of products. The control of storage is the responsibility of the MCA.

Appropriate storage includes:

- Inventory control procedures
- Provision for appropriate storage including adequate temperature and humidity control, lighting and adequate ventilation, security, cleanliness and pest control
- Explicit enforcement of cold chain procedures
- Maintaining adequate records

The MCA provides a guideline for storage and distribution. All stakeholders shall adhere at all levels countrywide.

g) Transportation and Distribution

For the public sector the Directorate of National Pharmaceutical Services is responsible for appropriate transportation and distribution of products. The control of appropriate transportation and distribution is the responsibility of the MCA.

Appropriate transportation ensures that products reach their destination in good quality. Depending on the type and nature of product and the transportation routing, the following standards are to be maintained:

- Provision for appropriate transport including adequate temperature control, security, and cleanliness
- Temperature sensitive products to be transported in cold boxes/containers
- Explicit enforcement of cold chain procedures
- Supply in open vehicles to be appropriately covered to prevent water, light and dust
- Transportation to be accompanied with the relevant documents (e.g. consignment documents, time logs, etc)

Guidance on transportation is included in the MCA guideline for storage and distribution.

h) Inspections

Inspection of the products and premises is the responsibility of the MCA, where inspection of pharmacy practice and standards including the premises in which they operate is the responsibility of the Pharmacy Council.
The MCA establishes and maintains an effective Inspectorate to ensure that quality requirements are implemented in all aspects and at all levels of the medicines and related products supply chain.

The following types of inspections are to be conducted by MCA:

- Pre-approval inspection (GMP, GCP)
- Routine inspection
- Special/investigative inspection
- Concise inspection
- Follow – up inspection

The following premises and facilities associated with product supply and the distribution chain are to be inspected regularly:

- Ports of entry or at the warehouse during offloading
- Central and Regional Medical Stores
- Health facilities (public, private, NGOs, research institutions)
- Wholesalers and Warehouses (both established and new ones before they are licensed)
- Pharmacies, Drug stores and other outlets (both established and new ones in collaboration with other stakeholders)
- Manufacturing facilities (both established and new ones, before they are licensed)
- Clinical trial sites

The MCA provides guidelines for inspections and performs inspections in accordance with SOPs.

The MCA collaborates with the Pharmacy Council and other law enforcement agencies.

i) Quality Control Testing

The MCA and National Medicines Quality Control Laboratory are responsible for quality control testing. In order to execute the plan effectively the NMQCL needs to be upgraded in terms of equipment, reagents and consumables as well as personnel capacity building.

- The National Medicines Quality Control Laboratory (NMQCL) should work towards functionality and achieving accreditation
- MCA ensures that samples of products are systematically selected for QC testing at MCA recognised laboratories. Samples collected during PMS will be screened and processed as highlighted under PMS section (k) below.
- MCA selects an accredited external laboratory to carry out specific activities related to quality testing of samples, when required

The MCA and NMQCL will provide guidelines and works according to SOPs.

j) Rational Use of Medicines

MCA is responsible to promote the rational use of medicines which is essential to maximise the therapeutic benefit to the patient and reduce wastage and hazards arising from irrational practices.

- Medicines are provided to patients appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community
- Adherence to the National Formulary and Standard Treatment Guidelines
- Appropriate physical surrounding, adequate shelves and storage, proper work surface and suitable handling equipment
- Avoidance of repackaging unless quality control is in place
- Appropriate product information and sensitisation of the general public

The MCA provides guidelines for **advertisement** which will also help to ensure that scientific studies and surveillance on medicines and related products are not misused and/or disguised for promotion. MCA works in accordance with SOPs.

k) Post Marketing Surveillance

This is the responsibility of MCA. The Agency maintains a Risk-Based Post Marketing Surveillance (RB-PMS) to effectively monitor the safety, quality and efficacy of medicines and related products released in the market. Registration alone does not guarantee that a product will maintain its safety, quality and efficacy after it has been released in the market, as the product is affected by many other factors such as storage and transportation. The MCA collaborates with other relevant stakeholders in RB-PMS activities.

The risk-based testing involves three levels: The level one is visual and physical inspections, which involves inspection of the packaging and labelling (including the expiry date, manufacturers details, patient information leaflet), product physical qualities (e.g. colour, taste, smell, presence of growth/ particles) and determination of the registration status. The level two involves basic screening tests using mini lab (Thin Layer Chromatography -TLC) or use of technological devices, for the detection of active pharmaceutical ingredient (API). The products that pass the levels one and two testing may proceed to level three, which is the compendial or confirmatory testing. The level three involves the use of functional QC laboratory which MCA does not have yet and is also not available nationally. Particular attention is accorded to high risk products and products that are of prime importance to public health programmes or those that are potentially dangerous, unstable or difficult to formulate.

l) Pharmacovigilance (PV)

This is the responsibility of MCA in collaboration with other Health Professional Councils.

The MCA is the core of the National PV System and is mainly involved in the monitoring and reporting of adverse drug reactions. However, the functionality of the system is directly dependent on the active participation of all healthcare professionals, other stakeholders and the general public.

The MCA provides guidelines for pharmacovigilance and works in accordance with SOPs. It strengthens collaboration with other stakeholders and the WHO Uppsala Monitoring Center.

m)Product Complaint Handling, Quarantine and Recalls

This is the responsibility of MCA with the support of; the Directorate of National Pharmaceutical Services (for the public sector) and Pharmacy Council and other Health Professional Councils for the private sector. The Agency registers and investigates complaints on product quality and takes appropriate regulatory actions.

Products cleared from the Ports are to be kept under quarantine until a release note is issued by the MCA. Batches suspected or identified to have quality or safety problems are to be quarantined unless released by MCA.

The manufacturers, importers, distributors or wholesalers are responsible for the recall of their products from the market, if they are or if they become defective in their quality, safety or efficacy, or are potentially harmful. The recall could be voluntary or requested by MCA depending on the level of hazard involved. The MCA must be informed of any recall and supervises the procedure.

The MCA provides guidelines for handling and management of complaints, quarantine and product recalls and works in accordance with SOPs.

n) Safe disposal of products

The control of safe disposal of products is the responsibility of the MCA in collaboration with the National Environmental Agency, and for the public sector in collaboration with the Directorate of National Pharmaceutical Services. However, the necessary equipment for safe disposal needs to be made available.

- The MCA, in collaboration with other stakeholders, approves and witnesses the disposal of unusable medicines and related products.
- No product within the supply chain should be disposed of without approval of the MCA.

The MCA provides guideline for safe disposal and works in accordance with SOPs.

o) Licensing

The MCA licenses importers, exporters, storage facilities and manufacturer of medicines and related products.

The licences ensure that only qualified and approved and/or suitable persons or entities carry out the respective business.

The MCA provides guidelines for licensing and works according to SOPs.

6 DOCUMENTATION

All stakeholders are requested to ensure that every activity that has a possible impact on the product quality is recorded and that documents are maintained for at least one year after expiry of products. The MCA records any quality assurance or control measure.

The MCA maintains the documentation on products for at least ten years after a product is withdrawn from the market unless a longer period is required by agreement with customers or by law or regulation, and documentation on quality measures for at least five years.

7 TRAINING

All personnel must be quality conscious and should be adequately trained and motivated.

The MCA ensures that staff and other personnel involved in quality assurance and control activities are trained to fulfil their functions and duties. The training is carried out in accordance with MCA guidelines and SOPs.

8 QUALITY MANAGEMENT SYSTEM

The MCA has implemented a Quality Management System (QMS) in accordance with ISO 9001:2015 requirements and has been accredited since June 2019. In this context MCA conducts regularly internal audits and monitors and evaluates quarterly key functions as laid down in its Monitoring & Evaluation Plan and SOP to ensure appropriate performance.

9 EVALUATION OF THE QAP

The QAP will be reviewed within 5 years.

Objectives

- To ensure quality and safety of a product from **selection** to **use**
- To assess the quality of products
- To assure quality

Key Performance Indicators are

- 100% availability of valid SOPs and guidelines
- 20% of marketed products registered
- Number of products imported
- Number of complaints reviewed and response time captured
- Number of premises inspected

Goals of Performance

The goals are to ensure that the required quality, safety and efficacy of medicines and related products are maintained throughout the supply chain.

10 REFERENCE DOCUMENTS FOR THE QAP

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2020
- Quality Assurance Policy The Gambia, 2013 (not published)
- The Gambia National Medicines Policy, 2007
- National Health Policy, Republic of The Gambia, 2012-2020
- MSH & WHO, Drug and Therapeutics Committee Training Course. Session 5, Pharmaceutical Quality Assurance, Participants' Guide, 2007

- WHO Model Quality Assurance System for Procurement Agencies (MQAS), Annex 6, WHO Technical Report Series No 937, 2006
- WHO Good Manufacturing Practices (GMP) for Pharmaceutical Products: Main Principles, Annex 2, WHO Technical Report Series 986, 2014
- Global Fund, Quality monitoring activities for pharmaceuticals, October 2014
- Global Fund, Quality Assurance Policy for Pharmaceutical Products, amended and restated 14 December 2010
- Global Fund, Quality Assurance Policy for Diagnostic Products, 2010 – amended 04 May 2017

11 DOCUMENT HISTORY

Version	Issue date	Reason for Changes
1	24 Nov 2017	New document
2	07 Dec 2020	Inclusion of Regulations and Quality Management System, deletion of part of the quality control aspects due to unavailability of a national laboratory

12 GRAPHIC: FUNCTIONS OF THE MCA

PMS Post-Marketing Surveillance
PV Pharmacovigilance