MEDICINES CONTROL AGENCY

THE GAMBIA

5-YEAR STRATEGIC PLAN 2019-2023

MAY 2019

ABBREVIATIONS

AOHJ	– Association of Health Journalists
AU	– African Union
DLEAG	– Drug Law Enforcement Agency of The Gambia
DNP	– Directorate of National Pharmaceutical Services
ECOWAS	– Economic Community of West African States
ED	– Executive Director
EU	– European Union
FDB	– Food & Drugs Board
GMP	– Good Manufacturing Practice
HR	– Human Resource
IE &C	– Information, Education & Communication
ICT	– Information & Communication Technology
IPC	– Inter-Process Communication
IEC	– Information, Education and Communication
MCA	– Medicines Control Agency
MDTF	– Multi-Disciplinary Task Force
MOH	– Ministry of Health
MOU	– Memorandum of Understanding
NAFDAC	– National Agency for Food & Drug Administration & Control
NDP	– National Drug Policy
NEPAD	– New Partnership for Africa's Development
NGOs	– Non- Governmental Organizations
NTK	– Need To Know
OIE	– Office International des Epizooties (World Organisation for Animal Health United Nations)
PEDs	– Priority Endemic Diseases
PESTEL	– Political, Economic, Social, Technical, Environmental, Legal
PMI	– President's Malaria Initiative
QA	– Quality Assurance
QC	– Quality Control
QMS	– Quality Management System
SBCC	– Social Behavioural Change Communication
SGS	– Societé Generale de Surveillance
SOP	– Standard Operating Procedure
SWOT	– Strengths, Weaknesses, Opportunities, Threats
TA	– Technical Advisor
WAHO	– West African Health Organization
UNICEF	– United Nations International Children's Emergency Fund
WHO	– World Health Organization

ACKNOWLEDGEMENTS

The Medicines Control Agency would like to acknowledge the World Health Organization for the technical assistance in the facilitation of the initial assessment and preparatory work towards the development of this Strategic Plan. Special gratitude goes to the consultant Benjamin Kwame Botwe for his expertise in this area and for drafting and facilitating the development of the Strategic Plan and Operational Plan.

We would like to acknowledge and thank the West African Health Organization for their support and all the World Bank team members on the ECOWAS Medicines Regulatory Harmonization led by Aissatou Diack for accepting to include this activity in the action plan for The Gambia and her personal presence to ensure the activity is completed successfully.

Finally, on behalf of the Governing Board of the Agency, the Executive Director wishes to express its sincere thanks to all staff of the Agency and acknowledge the various stakeholders in the Public Sector, Private Sector, International Organizations and NGOs who have contributed in diverse ways to make this Strategic Plan a reality. Without their input and co-operation it would not have been possible to carry out this work.

LAMIN SAMATEH
BOARD CHAIRMAN

MARKIEU JANNEH KAIRA
EXECUTIVE DIRECTOR

TABLE OF CONTENT

EXECUTIVE SUMMARY

The Medicines Control Agency (MCA) was established under the Medicines and Related Products Act, 2014 with the mandate to regulate and control the manufacture, importation, exportation, distribution, use and advertisements of medicines and related products with respect to ensuring their quality, safety, and efficacy in The Gambia. The law defines medicines to include a substances or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal; restoring, correcting or modifying organic functions in man or animal; nutritional supplements, or herbal medicines.
Related product has been defined by the Act to mean an article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal.

Upon the setting up of the Agency by the appointment and inauguration of the Board and the appointment of the Executive Director and some other critical staff, it has become imperative to have a guide that will provide a strategic direction for the Agency over the next five years.

The Five-Year Strategic Plan 2019-2023 is therefore developed based on the mandate given by the Act, experiences and lessons learnt over the last three years of the existence of the Agency, international best practices and results of some internal and environmental assessments undertaken so far.

The purpose of this first Strategic Plan is to:

1. Design strategies for achieving the vision, mission and objectives of the Agency.
2. Provide a long-term perspective of what the Agency would look like in the future.
3. Develop performance indicators for monitoring and evaluation. .
4. Develop an Operational Plan and budget as a basis to seek for both technical and financial assistance to facilitate the achievement of the set objectives.

The process of developing this Strategic Plan involved assessment of the state of medicines and related products regulation by the World Health Organization in 2016 during which Board members, professional bodies, partners and private sector players were engaged. Additionally, there was a self-assessment of the MCA on its regulatory functions using the World Health Organization (WHO) Global Benchmarking Tools, and a further assessment on Quality Management Systems situation by WAHO. All levels of management, staff and various stakeholders and professional groups were engaged for their inputs and buy-in. Upon performing a SWOT and PESTEL analysis, vision and mission statements were developed and strategic goals identified to be able to achieve the mission of the MCA.

Strategic Goals

- Establish an effective and efficient medicines and related products regulatory system
- Mobilize technical and financial resources for the implementation of Regulatory Functions
- Set up a functioning Quality Control Laboratory to support regulatory activities
- Set up a Quality Management System (QMS) and undertake Operational Research activities to support regulatory functions
- Develop and Implement an effective Information Management System
- Promote Partnership and Cooperation

1. BACKGROUND

1.1. NATIONAL DEVELOPMENT PLAN FOR THE GAMBIA

The National Development Plan for The Gambia (2018 – 2021) among its strategic priorities seeks to strengthen the provision of logistics, infrastructure, equipment, transport and supplies at all levels. The NDP refers to the National Medicines Policy (NMP) which aims to contribute to the attainment of quality health services for the population by ensuring the continuous availability and accessibility of essential medicines and other health commodities of appropriate quality, safety, and efficacy and by promoting their rational use. It further states that Government will collaborate with other stakeholders to strengthen an effective and sustainable Supply Chain Management System for drugs, surgical and other commodities including basic equipment. Furthermore, Government will invest in laboratory and diagnostic equipment, supplies and reagents for improvement in clinical diagnosis and management.

The plan identifies leadership and governance, which deals with ensuring strategic policy frameworks combined with effective oversight, coalition building, accountability, regulations, incentives, and attention to health systems design, as the weakest component of the health system in the Gambia. The Strategic Plan of the Medicines Control Agency will be in line to address this gap as far as the regulation of medicines and related products are concerned.

1.2. NATIONAL HEALTH SECTOR POLICY AND STRATEGIC PLAN

The National Health Policy 2012- 2020 sets some key objectives that include:

- To ensure available and affordable essential medicines that are safe, efficacious and of the required quality;
- To ensure availability of consumption data on medicines and other medical supplies.

Policy measures set out to achieve the above objectives include transforming the supply management system for essential medicines for the public sector into a semi-autonomous institution, advocating for increased government funding for pharmaceuticals, improving the drug supply system and promoting the rational use of medicines and supplies, strengthening the National Medicines Regulatory Authority and enacting the necessary laws toward attaining quality products, encouraging greater private sector involvement in the provision of essential medicines especially for the rural community, establishing quality control testing of pharmaceuticals and strengthening and maintaining the Logistics Management Information System (LMIS). A number of the policy measures including the review of the law and setting

up of the Medicines Control Agency have already been achieved. The Strategic Plan therefore will give direction to the operationalization of the MCA to improve its performance.

1.3. NATIONAL DRUGS POLICY

The Gambia has a National Drugs Policy that was last reviewed in 2007 which makes provisions for local drug production, storage, distribution, disposal of unwanted drugs, quality assurance, drug legislation and control of advertising and promotion among others. The policy makes a commitment that any deficiencies in the then existing legislation, the Medicines Act (1984) and the Medicines Regulations (1986), and the Drug Control Act (2003), will be rectified by amendments to the legislation, and/or drafting of additional legislation or regulations, which will be carried out in consultation with all affected parties. This resulted in the need for the establishment of an autonomous Medicines Regulatory Authority to address the gaps in legislation and regulatory functions. Assessment of the then Medicines Board was done followed by the review and updating of the legislation and finally leading to the passing of the Medicines and Related Products Act, 2014 and the Pharmacy Council Act, 2014 that set up the Medicines Control Agency and the Pharmacy Council, respectively.

1.4. THE NATIONAL PHARMACEUTICAL SERVICES

Up to December 2014, the National Pharmaceutical Services (NPS) under the Ministry of Health was in charge of matters of drug policy, government procurement, storage, distribution and use of medicines. It also had an arm, the Medicines Board, which was responsible for medicines regulation and pharmacy practice. Among the achievements made by the Medicines Board in preparation for the current dispensation were:

- Development of various guidelines and forms to guide the implementation of regulatory activities;
- Trained staff on inspectorate activities
- Set up a functioning Mini lab and trained quality control laboratory staff;
- Planned the preparation of a register of listed products in The Gambian market;
- Conducted inspection activities;
- Facilitated the drafting of the Medicines and Related Products Act, 2014 and the Pharmacy Council Act, 2014 which were enacted into law by the Gambian Legislature, signed by the President of The Gambia and printed into handbills leading to the establishment of the Medicines Control Agency and the Pharmacy Council.

1.5. THE MEDICINES AND RELATED PRODUCTS ACT, 2014

The Medicines and Related Products Act, 2014 ("Act") was passed and signed by the President on 26th December 2014 to regulate the quality, safety and efficacy of products regulated under this Act.

The Act makes provisions for:

- Governance and functions of the Agency
- Finances of Agency
- Types of licenses to be issued

- Control of sale, information and advertising
- Manufacturing, import and export controls
- Registration of Products and granting of marketing authorization
- Scope of Products to be regulated
- Clinical Trials and Medicines Safety Monitoring (Pharmacovigilance)
- Market Controls and Anti-counterfeiting
- Control of Narcotics and Psychotropic substances for medical use
- Quality Control of medicines and related products
- Power to make regulations

Regulatory functions covered under this law are Product Registration and Marketing Authorization, Licensing, Inspection, Quality Control, Clinical Trials, Post-Marketing Surveillance, Pharmacovigilance and Advertisement and Promotion.

1.6. THE MEDICINES CONTROL AGENCY (MCA), THE GAMBIA

The Medicines and Related Products Act, 2014 led to the establishment of the Medicines Control Agency ("Agency") in March 2015 as the regulatory body responsible for the regulation and control of the quality, safety and efficacy of products regulated under this Act. The Governing Board made up of a Chairperson; the Permanent Secretary of the Ministry of Health; a representative of the Medical and Dental Association; the Director General of the National Drug Enforcement Agency; the President of the Pharmaceutical Society of Gambia; the Registrar of the Pharmacy Council; the Director of National Pharmaceutical Services; a representative of the Veterinary Practitioners Association; a representative of the Consumer association; a representative of the Herbal Practitioners Association; a legal practitioner from the Attorney General Chambers not below the rank of a Senior State Counsel; and the Executive Director of the Agency, who is the secretary to the Board has been constituted and inaugurated. The Board is mandated to ensure the proper and effective performance of the functions of the Agency enshrined in Section 4 of the Medicines and Related Products Act, 2014.

An Office and Operational Premises has been acquired as temporary offices rented for the MCA.

2. SITUATIONAL ANALYSIS

A desk review of existing documentation was done, including a review of the National Development Plan for The Gambia, National Health Sector Policy and Strategic Plan, National Drug Policy, Medicines and Related Products Act, 2014 and The Pharmacy Council Act, 2014. This was followed by internal and external stakeholder consultations. The following stakeholders were involved in the process:

- Medicines Control Agency Staff;
- Medicines Control Agency Board Members;
- Private sector stakeholders such as Importers and Wholesalers of medicines;
- Public sector, NGOs and International Organizations;
- Pharmacy Council Members.

As part of the process courtesy calls were paid to the following:

- Minister of Health of The Gambia;
- World Health Organization Representative for The Gambia;
- Executive Director, Drug Law Enforcement Agency of The Gambia (DLEAG).

The following key issues were identified based on the outcomes of the reviews, stakeholder consultations and field observations:

a. Current systems in place for control of imports are not resilient enough and most players in the industry expect this to be strengthened in order to improve the quality of medicines and related products in the country;
b. Currently there are overlaps in some functions stipulated in the Medicines and Related Products Act and the Pharmacy Council Act with respect to the Inspection and Licensing of Pharmaceutical Premises. However, this issue was recognized and resolved through a Memorandum of Understanding (MOU) between the Medicines Control Agency and Pharmacy Council;
c. Inadequate inspection and non-regulation of storage facilities in both the public and private sectors;
d. Illegal sale of medicines in the open market;
e. Inadequate Human Resources for the MCA;
f. Inadequate office space, laboratory and other physical infrastructure;
g. Inadequate public education on the safe use of medicines and related products;
h. Insufficient decentralization of the activities of the MCA.

3. ENVIRONMENTAL ANAYLSIS

3.1. SWOT ANALYSIS

This analysis is aimed at categorizing the issues identified into internal and external factors affecting MCA which will be useful in planning a strategy to address them.

a. The analysis of internal factors focused on the:
    - Internal abilities which the MCA could use or build upon to achieve its goals (strengths).
    - Internal abilities that are available on a reduced scale, unable to serve as the basis of support for the MCA and which may become internal obstacles to the achievement of its mandate (weaknesses).

b. The analysis of the external factors focused on issues external to the MCA, they included:
    - Issues that could be beneficial to the MCA in achieving its mandate (opportunities).
    - Issues that could hinder the MCA from achieving its mandate (threats).

STRENGTHS	**WEAKNESSES**
The identified strengths of the MCA are as follows: • Enactment of the Medicines and Related Products Act 2014 and establishment of MCA as an autonomous body • Listing and registration of medicines and related products currently on The Gambian market • Availability of Draft Regulations 2018 • Availability of regulatory guidelines, SOPs and relevant tools • Availability and implementation of a Quality Management System (QMS) plan; • Inspections, Post-Marketing Surveillance and Pharmacovigilance Activities • System in place for authorization of Clinical Trials • Presence of an organizational structure • Availability of a Quality Assurance Plan 2017 for products regulated by the Agency • Self-benchmarking of MCA using the WHO Global Benchmarking Tool • Adapted the WAHO Common Technical Document for registration of medicines. • Availability of annual work plans • Availability of MCA Procurement Manual 2018.	The following weaknesses were noted: • Inadequate office infrastructure • No Quality Control Laboratory • Inadequate institutional capacity for medicines and related products regulation and quality control • Inadequate technical expertise both in terms of sufficient numbers and mixed appropriate skills • Inadequate logistical support for running MCA operations • Inadequate financial resources • Inadequate public awareness on the workings of the MCA • Inadequate education of the general public on safe use of medicines and related products. • Lack of Monitoring and Evaluation framework for the MCA services • Limited ICT infrastructure for the institutional, effective administration, archiving and managerial efficiency
OPPORTUNITIES	**THREATS**
• Political commitment to support medicines and related products regulation – demonstrated by the enactment of the Medicines and Related Products Act 2014 • Existence of development partners and diseases control programs to support the development of the human and technical resources to the MCA	• The potential for other state agencies and professional bodies to consider some aspects of the MCA functions as an overlap on their functions or roles leading to conflict • Inability of government to adequately fund the activities of the MCA • The tendency for some stakeholders or business interests to view the MCA as an

• Collaboration with other Medicines Regulatory Authorities within the sub-region and globally in the areas of informtion sharing, harmonization of medicines regulation, capacity building, etc • Recognition on the part of key stakeholders with regards to the importance of medicines regulation in achieving national healthcare objectives • Potential for collaboration with state and security agencies such as Customs, Gambia Ports Authority, Police, DLEAG and National Environmental Agency and professional bodies e.g. Pharmacy, Medical and Dental, Nurses and Veterinary Councils to enhance the Agency's regulatory activities.	additional bureaucratic bottleneck that may affect their usual way of doing business • Presence of fake and substandard medicines in the market • Lack of functional QC Laboratory • Inadequate financial support for sustainability of regulatory activities • The absence of the requisite technical base in country to support the operations of the MCA such as control of clinical trials, regulation of biologicals and new health technologies. • Risk of public out cry if it is general knowledge that medicines used in the country are not subject to any quality testing at country level.

3.2. PESTEL ANALYSIS

POLITICAL

The political dispensation in The Gambia hopes to provide a new focus and a new direction as far as health is concerned. National policies on health as well as Ministerial Health Policies and strategies are likely to gather a new momentum of implementation. Currently, the operational cost of the MCA (e.g. salaries, renting of office space, vehicle) is being met by the Government of the Gambia (GoG) through the disbursement of its subvention by Ministry of Finance. However, the increase in its allocation is necessary for MCA to build its capacity and improve services and these will affect the strategic direction of the MCA.

ECONOMIC

The MCA is a government subvented Agency and will definitely be affected by national budget and economic health. For that matter budgetary allocations to the Agency which is, the main income source of the Agency, the internally generated funds obtained from fees charged, is likely to be affected by overall economy and purchasing power of the country.

SOCIAL

Like any developing country south of the Sahara and within the ECOWAS region, there is a high disease burden that calls for multisectoral approach to health provision. Availability of a wide variety of medicines and related products are available through government or the private sector. Inadequate regulation of such products is likely to affect health outcomes. With the general literacy rate in the country, general attitude towards quality and safety of products calls for effective medicines and related products regulation.

TECHNOLOGICAL

The depth of penetration of mobile technology within the country provides a very useful opportunity for information dissemination on product quality, safety and efficacy. It also provides an avenue for participation of the citizenry in regulation through a properly organized feedback system. Technology will be harnessed internally to improve on inter-departmental communication and thereby improve efficiency and effectiveness. Technology externally will improve information dissemination to professionals, applicants and the general public. Mobile phone technology could be used for authentication of registered products by the general public as a means of fighting the presence of substandard and falsified medicines and related products on the Gambian market.

ENVIRONMENTAL

Work culture and ethics of the general population including staff and clients of the MCA are likely to influence the workings of the Agency. The plurality of the press, both print and electronic, presents as a strength and opportunity for the operations of the MCA. The presence of other agencies in the regulatory space and the perceived overlap of function also pose a threat to the MCA.

LEGAL

The existence of an enabling law that provides the legal basis for the regulation of medicines and related products clearly sets the scope and extent of the working of the MCA. The Gambia is also a member of international health agencies like the WHO and UNICEF. Additionally, it is a signatory to various international conventions including the International Conventions on Narcotics and Psychotropic substances that provide addition legal basis and benchmarking.

4. MANDATE, VISION, MISSION

4.1. MANDATE

The Medicines and Related Products Act, 2014 established the Medicines Control Agency (MCA) with the mandate to regulate and control the manufacture, importation, exportation, distribution, use and advertisements of medicines and related products with respect to ensuring their quality, safety, and efficacy. Related products include homeopathic medicines, cosmetics, medical devices and household chemicals substances.

4.2. VISION

A Medicines and Related Products Regulatory Agency of Excellence.

4.3. MISSION

The Medicines Control Agency, The Gambia exists to achieve the highest possible standards of quality, safety and efficacy for medicines and related products by employing effective, efficient and transparent regulatory systems using competent and highly motivated human resource to safeguard public health.

5. STRATEGIC GOALS, OBJECTIVES AND ACTIVITIES

5.1. STRATEGIC GOALS

From the SWOT and PESTEL analyses, as well as gaps identified in the WHO benchmarking and the QMS assessment reports, the following strategic goals or broad objectives are identified to be worked on the next five years to achieve mandate, vision and mission of the MCA.

- Establish an effective and efficient medicines and related products regulatory system
- Mobilize technical and financial resources for the implementation of regulatory functions
- Set up a functioning Quality Control Laboratory to support regulatory activities
- Set up a Quality Management System (QMS) and undertake Operational Research activities to support regulatory functions
- Develop and Implement an effective Information Management System
- Promote Partnership and Cooperation.

5.2. SPECIFIC OBJECTIVES AND ACTIVITIES

For each goal, specific objectives are set, which are measurable, and activities to achieve the objectives indicated as below. Timelines are set for each of the activities and this is used to design an implementation framework.

5.2.1 GOAL 1

Establish an effective and efficient medicines and related products regulatory system.

Specific objective 1

- Recruit, develop and maintain adequate Human Resource (HR) Capacity

Activities

- Identify the HR needs of the Agency and develop an HR plan
- Recruit and retain key and relevant staff
- Identify training needs and develop training plan

Specific Objective 2

- Develop and provide appropriate regulatory tools for the efficient operations of MCA

Activities

- Identify and prepare initial drafts of required guidelines, forms, policies, manuals & SOPs based on best practices
- Organize stakeholder retreats to validate the tools
- Print and disseminate the tools
- Monitor and evaluate use of the regulatory tools

Specific Objective 3

- Acquire adequate office infrastructure and facilities

Activities

- Follow up application for official allocation of land for the MCA complex
- Design a concept for a new MCA building complex
- Construction of office complex and laboratory facility

Specific Objective 4

- Provide and maintain adequate logistics and IT infrastructure

Activities

- Procure the necessary office infrastructure
- Acquire necessary operational vehicles
- Procure server, computers and other hardware, appropriate software and accessories

Specific Objective 5

- Ensure transparency in the performance of all regulatory functions.

Activities

- Develop a communication plan
- Periodically publish bulletins and newsletters electronically and print
- Maintain an up to date website
- Develop and maintain internal and external communication systems

Specific Objective 6

- Ensure that there is a results-based monitoring and evaluation system

Activities

- Develop M&E plan
- Conduct regular monitoring and evaluation
- Write and disseminate reports

5.2.2 GOAL 2

Mobilize technical and financial resources for the implementation of Regulatory Functions

Specific Objective 1

- Set up and implement a product registration & evaluation system

Activities

- Source, procure and install a medicines and related products registration software
- Set up an archival and retrieval system for product dossiers.
- Organize dossier evaluation retreats
- Develop, publish and disseminate product registers
- Organize training for manufacturers and importers on registration guidelines and dossier submission rules.
- Train assessors on the new ECOWAS CTD format

Specific objective 2

- Set up and implement an Inspectorate System

Activities

- Conduct Post Marketing Surveillance (PMS) activities to clean market of illegal sale of medicines
- Strengthen system for import and export control
- Develop and sign MOU with Customs on import and export control
- Inspect premises including warehouses of Central Medical Stores, NGOs, and Importers

Specific objective 3

- Strengthen the Pharmacovigilance (PV) systems

Activities

- Review and implement the existing PV plan
- Review and update existing PV guidelines and tools
- Set up and operationalize the Medicines Safety Expert Committee
- Sensitize and train public and private health professionals on PV
- Train and motivate PV contact persons to encourage reporting
- Become full member of the WHO Collaborative Centre (Uppsala Monitoring Centre)

Specific objective 4

- Strengthen control and oversight of Clinical Trials (CT)

Activities

- Create a CT repository
- Adapt AVAREF guidelines for control of clinical trials
- Conduct Good Clinical Practice (GCP) Inspection
- Train staff on Clinical Trial Application evaluation and GCP

Specific objective 5

- License the appropriate facilities

Activities

-
- License manufacturers, Importers and warehouses/ storage facilities
- Organize training for organizations involved in manufacture, importation, warehousing/ storage

5.2.3 GOAL 3

Set up a functioning Quality Control Laboratory to support regulatory activities

Strategic Objective 1

- Acquire premises and logistics for the establishment of Medicines Quality Control Laboratory

Activities

- Design a layout for QC Laboratory
- Construct QC Laboratory complex
- Identify and list equipment consumables needs
- Procure, install and qualify the equipment

Strategic objective 2

- Build Laboratory HR capacity

Activity

- Identify lab HR needs, recruit, train and retain

Strategic objective 3

- Develop a Laboratory Information Management System

Activities

- Develop and implement Lab Quality Manual, SOPs, validation processes and Recording systems
- Procure an appropriate Laboratory Information Management System

5.2.4 GOAL 4

Set up a Quality Management System (QMS) and undertake Operational Research activities to support regulatory functions

Specific Objectives 1

- Develop a QMS plan towards ISO 9001:2015

Activities

- Develop relevant SOPs for implementation of QMS
- Train staff on QMS implementation
- Implement the QMS in all departments
- Develop a roadmap towards implementation and maintaining of QMS

Specific Objective 2

- Establish a QMS for ISO 9001:2015

Activities

- Implement roadmap and seek certification for ISO 9001:2015
- Conduct internal audits of the state of implementation of the QMS
- External audit of the system for purposes of accreditation/ certifications
- Recruit a consultant to support the MCA to establish a Quality Management System

Specific Objective 3

- Develop and Implement appropriate systems for information and documentation management

Activities

- Identify and procure appropriate software
- Train staff and end users on the software
- Develop a data protection policy, SOP and systems for QMS

Specific objective 4

- Conduct research into medicines importation, distribution and usage patterns

Activities

- Conduct research on antibiotic and controlled medicines use patterns
- Study the types and forms of medicines imported
- Conduct a survey on substandard and falsified medicines on the Gambian market

5.2.5 GOAL 5

Develop and Implement an effective Information Management System

Specific Objective 1

- Develop and maintain a management information systems

Activities

- Recruit consultant to develop computerized Information Management System and train staff on its use
- Set up an intranet for internal communications
- Review and constantly update information on the website
- Set up software application for interaction with stakeholders

Specific Objective 2

- Keep healthcare professionals and other stakeholders informed about product quality, safety and efficacy issues

Activities

- Issue "Dear Healthcare Professional Letters" to disseminate information
- Issue advertisers' announcements, disclaimers and drug alerts to educate the public
- Conduct orientation session for stakeholders (NAMs, policy makers)

Specific Objective 3

- Educate the general public on the safe use of medicines and related products

Activities

- Organize orientation session for Senior journalist and Association of Health Journalists (AOHJ) members
- Participate in TV and Radio talk shows and programmes and publish articles

Specific Objective 4

- Create Public Awareness on the existence & functions of the MCA

Activities

- Launch the MCA with adequate publicity

- Develop and implement an advocacy plan
- Orientation/ Sensitization visits to Governors/ Chiefs in the Regions

Specific Objective 5

- Develop SBCC strategy

Activities

- Conduct rapid assessment of SBCC approaches for medicines regulation
- Develop messages based on the outcome of the assessment
- Pre-test the messages
- Validate the messages
- Produce posters, fliers, hand-outs, billboards, leaflets and stickers, TV and radio spots, SBCC manuals and flip charts
- Dissemination through TV, radio, print, website, community engagement (district authorities, MDTFs and IPC networks) and a hotline

5.2.6 GOAL 6

International collaboration and harmonization

Specific Objective 1

- Participate in the ECOWAS and African Medicines Harmonization initiatives

Activities

- Undertake a study tour at Ghana FDA and lead auditors training at SGS Ghana
- Attend ECOWAS heads of NMRAs meetings

Specific Objective 2

- Participate in international conferences and exchanges on medicines and related products regulation

Activities

- Attend International Conference of Drug Regulatory Authorities and International Federation of Pharmacists
- Attend AU NEPAD regional regulatory meetings
- Attend World Health Assembly and other WHO facilitated meetings

6. GUIDING PRINCIPLES AND STRATEGY

6.1. GOOD REGULATORY PRACTICES

In performing its functions, the Agency shall apply principles of Good Regulatory Practices, which include but are not limited to:

- Ensuring transparency and accountability;
- Promoting stakeholders' participation and building consensus; and
- Observing a code of conduct and managing any potential conflict of interests.

6.2. TECHNICAL ADVISORY COMMITTEES

The MCA shall perform its scientific functions through the use of Scientific and Technical Advisory Committees. This is premised on the fact that products regulated under the Medicines and Related Products Act 2014 are used for practice in various scientific and health professional areas. Disciplines like Clinical Trials, Pharmacovigilance, Veterinary medicines and related products call for such an approach.

6.3. INTERNATIONAL HARMONIZATION

The Agency shall fully participate in international medicines and related products regulatory harmonization efforts at the WHO, AU NEPAD and WAHO levels. It will enter into MOUs with other regulatory agencies where necessary and participate in various cooperating arrangements within the world health environment. The MCA will consider the scientific opinions expressed by other stringent NMRAs and international bodies such as ICH, WHO and OIE in its decisions on medicines and related products quality, safety and efficacy.

6.4. DECENTRALIZATION

Taking note of the fact that the functions of the Agency cannot all be performed in Banjul, MCA will deploy staff at strategic locations and other Health regions over the next five years. In the meantime, MOU will be established with regional health administrations and also with Customs for the control of the ports of entry. Training will be provided for staff of other agencies approved to perform some of the functions of the MCA on its behalf.

6.5. HUMAN RESOURCE MANAGEMENT

Staff recruitment will be through advertisements and interviews. The existing staff shall be given first preference and offered permanent placement in accordance with their levels of competence.

In terms of staff capacity buildings, short, medium- and long-term strategies will be employed. In the short term, the MCA will:

- Engage consultants to conduct training workshops for staff on Dossier Evaluation, Inspection and the relevant WHO Good Practices such as Good Storage and Distribution Practices, etc.
- Contact WHO, Global Fund and other bilateral or multilateral partners to assist in the establishment of a Level 1 Quality Control Laboratory to start with.
- Contact international agencies such as WHO and WAHO for their schedule for training workshops and apply for staff to participate in programmes relevant to the MCA.

In the medium term, the MCA will:

- Collaborate with Medicines Regulatory Authorities (e.g. Ghana's FDB and Nigeria's NAFDAC) with regards to attachment of Staff to their agencies for training.
- Identify opportunities for training attachments at the SWISSMEDIC, Health Canada, Indonesian and Malaysian Medicines Regulatory Agency amongst others.

In the long term, the MCA will identify potential staff to be developed through appropriate post-graduate academic and professional training for senior positions within the MCA. These potential staff may pursue a Master's Degree or Membership and Fellowship in the following areas:

- Pharmaceutical Analysis & Quality Control
- Pharmaceutical Quality Assurance & GMP
- Pharmaceutical Science & Management Studies
- Pharmaceutical Services & Medicines Control
- Pharmaceutical Microbiology
- Financial Management
- Medical Products Regulatory Affairs

These courses are offered but not limited to Universities in Ghana, Nigeria, UK, Ireland and other professional academic institutions such as the West Africa Post Graduate College of Pharmacists

6.6. MONITORING AND EVALUATION

The Strategic Plan shall be monitored through a results-oriented monitoring and evaluation scheme annually. This will form the basis for operational planning and for annual or midterm review of objectives and strategies, activities and key performance indicators to achieve the overall goals of the MCA.

7. ORGANIZATIONAL CULTURE AND ETHICS

In order to discharge its duties effectively, the MCA shall function within a corporate cultural environment that safeguards its independence of action, integrity, effectiveness and impartiality.

Procedures would be laid down giving the mechanism by which employees of the Agency are appointed and the security of their tenure of service guaranteed. The conditions of service, remuneration and working arrangements will be such that vested interests cannot exert any undue influence over staff or others working for the Agency.

By the nature and operations of the MCA staff are supposed to abide by the following:

- Dressing appropriately when on duty
- Not divulging information (Need-To-Know Principle)
- Ensure the confidentiality of sensitive data
- To observe the oath of secrecy
- Key technical staff must be well informed on issues relating to medicines and related products
- Staff must be courteous
- Staff must be faithful, sincere and of high integrity
- Staff should not be involved in any activity that is liable to create a conflict of interest.
- Ready to work outside the normal working hours
- Staff should not overly expose themselves to the public

- All categories of staff should not grant interviews without authorisation

8. GOVERNANCE STRUCTURE

The MCA shall be made up of the following Departments:

- Office of the Executive Director;
- Finance and Administration;
- Quality Control Laboratory;
- Inspection, Post-marketing Surveillance and Enforcement;
- Medicines Safety Monitoring (Pharmacovigilance) and Clinical Trials;
- Medicines and Related Products Evaluation and Registration;

The functions performed by the Departments may be organized under various Units for the efficient administration of the organisation.

The Organogram of the MCA is attached as Annex 1.

8.1. GOVERNING BOARD

The Governing Board shall have twelve (12) members to be appointed by the President of the Republic of The Gambia.

The Agency shall be governed by a Board consisting of:-

(a) A Chairperson;
(b) The Permanent Secretary of the Ministry;
(c) A representative of the Medical and Dental Association;
(d) The Director General of the National Drug Enforcement Agency;
(e) The President of the Pharmaceutical Society of Gambia;
(f) The Registrar of the Pharmacist Council;
(g) The Director of National Pharmaceutical Services;
(h) A representative of the Veterinary Practitioners Association;
(i) A representative of the Consumer association;
(j) A representative of the Herbal Practitioners Association;
(k) A legal practitioner from the Attorney General Chambers not below the rank of a Senior State Counsel; and
(l) The Executive Director of the Agency, who shall be the Secretary to the Board.

The members of the Board other than the ex officio members shall be appointed by the President after consultation with the Public Service Commission. The members of the Board other than an ex-officio member shall hold office for a period of three years renewable once. A member of the Board may at any time resign from office in writing addressed to the Minister of Health. The Board shall ensure the proper and effective performance of the functions of the Agency.

The Governing Board shall have the powers and duties to:

- Approve regulations for implementation of the Act;
- Approve the Strategic Plan of the Agency;
- Approve the annual work plan and budget of the Agency;
- Review the quarterly reports presented by the Executive Director;
- Monitor and evaluate implementation of the Act;
- Approve the individuals recommended to be Directors by the Executive Director;
- Establish committees whenever it deems necessary.

8.2. MANAGEMENT

The Executive Director, Deputy Executive Director and the Directors of Departments shall constitute the strategic or top management team of the MCA.
The general management staff of the MCA shall be made up of the Executive Director, Deputy Executive Director and the Directors of the various Departments and Heads of Units.
The functions for the various officers and departments are as described below

8.2.1 EXECUTIVE DIRECTOR

The **Office of the Executive Director** shall house the Legal Officer, Internal Auditor, Procurement Officer, Quality Systems Manager, and Communication and IT Officer. There will be an administrative Assistance to assist in the day to day management of the office.

Functions of the Executive Director shall be as follows among others:

- The Executive Director shall be the administrative and technical head of the Agency and shall direct and administer the day to day activities of the Agency.
- Recommend senior staff for appointment by the Governing Board
- Oversee the preparation and implementation of the Strategic and Operational Plan of the Agency.
- Develop and establish a Quality Management System for the efficient and effective management of the organization.
- Exercise the functions and duties of the Agency.
- Administer personnel of the Agency following the basic principles of The Gambia Labour legislation.
- Prepare and submit to the Governing Board an annual Operational Plan and budget of the Agency and implement same upon approval.
- Submit quarterly reports to the Governing Board.
- Establish technical committees with the approval of the Governing Board.
- Approve registrations for medicines and related products upon recommendation from the medicines evaluation committee.
- Approve and issue appropriate licenses.
- The Executive Director may delegate part of his/her functions to other employees of the Agency to the extent necessary for the efficient performance of its activities.

8.2.2 DEPUTY EXECUTIVE DIRECTOR

The Deputy Executive Director shall among others;

- Act in the absence of the Executive Director
- Report to the Executive Director and provide technical direction to the MCA to ensure its efficient operation.
- Be required to provide basic training where necessary and on the job mentoring to staff in all the technical departments.
- Facilitate and coordinate capacity building of personnel of organizations dealing with products regulated by the Agency
- Support the Executive Director in identifying technical areas that need external consultancy services, develop TORs and assist in the processes leading to the procurement of such services.

8.2.3 DIRECTOR FINANCE AND ADMINISTRATION

The Director of the Department of Finance and Administration shall report to the Executive Director and shall carry out the following functions to support the core regulatory activities of the Agency:

- Coordinate the preparation of the annual operational budget of the Agency;
- Ensure accountability of the resources of the Agency
- Prepare quarterly statement of Accounts for the attention of the Executive Director
- Lead in the resource mobilization efforts of the Agency
- Be in charge of the Human Resource management activities with the Agency
- Be in charge of general administration duties including transport, maintenance, security and estates

8.2.4 DIRECTOR QUALITY CONTROL AND ANALYSIS

The Director of the Quality Control Laboratory shall report to the Executive Director and be responsible for the following functions:

- Laboratory management;
- Pre- and post-registration analysis of products regulated by the Agency;
- Issue certificate of analysis for all products tested;
- Development, review and validation of analytical methods;
- Research into product quality trends.

8.2.5 DIRECTOR LICENSING, POST-MARKETING SURVEILLANCE, INSPECTION AND ENFORCEMENT

The Director of the Department of Licensing, Inspection, Post-marketing Surveillance and Enforcement shall report to the Executive Director through the Deputy Executive Director and shall be responsible for the following functions:

- Pre-licensing and post-licensing inspections of premises and organisations involved in manufacturing, import, export, distribution, sale or supply of products regulated by the Agency;
- Routine inspection of medical stores, warehouses and other storage facilities;
- Post-marketing surveillance activities;

- Port of Entry inspections and sampling of products for import and export regulated by the Agency;
- Enforcement of quality assurance systems in organisations dealing with products regulated by the Agency;
- Collection of data on imports and exports of products regulated by the Agency;
- Coordinate research activities of the Agency
- Liaise with the Drug Law Enforcement Agency on issues relating to Narcotics and Psychotropic medicines;
- Supervise safe disposal of products regulated by the Agency;
- Liaise with the National Environmental Agency on issues relating to manufacturing and disposal of products regulated by the MCA.

8.2.6 DIRECTOR CLINICAL TRIALS AND PHARMACOVIGILANCE

The Director of the Department of Medicines Safety Monitoring (Pharmacovigilance) and Clinical Trials shall report to the Executive Director through the Deputy Executive Director and shall be responsible for the following functions:

- Conduct Pharmacovigilance (safety monitoring) of medicines regulated by the Agency;
- Coordinate with other Agencies on the monitoring of Adverse Events after Immunization;
- Be responsible for Vaccines control and regulation of Blood and blood products;
- Be responsible for Lot Release of Biological products
- Receive and evaluate applications for Clinical Trials;
- Follow up on Clinical Trials to ensure compliance with Good Clinical Practice including Good Clinical Laboratory Practice.

8.2.7 DIRECTOR EVALUATION AND REGISTRATION

The Director of the Department of Medicines and Related Products Evaluation and Registration shall report to the Executive Director through the Deputy Executive Director and shall be responsible for the following functions:

- Receiving of applications for registration of products regulated by the Agency including dossiers and samples;
- Evaluation of dossiers and submission of samples for QC analysis;
- Liaise with stakeholders in the Classification of medicines and related products;
- Creation and maintenance of product registers;
- Review of labelling and promotional information;
- Receipt and processing of applications for advertisements of products regulated by the Agency;
- Dissemination of current product information and alerts;
- Review of standards and specifications;
- Receive and evaluate applications for import and export permits for products regulated by the Agency.