ETHIOPIAN FOOD AND DRUG AUTHORITY

ORGANIZATIONAL STRUCTURE DESCRIPTION MANUAL: DUTIES AND RESPONSIBILITIES

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Document History

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001	New Organizational Structure Description	June, 2020
002	• Topographic modification • Formatting and numbering as per the SOP for document control and management • Adding description of all DDGs, LEOs, EOs, Branch Office, Desks and Teams	10.03.2025

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Foreword

A well-defined organizational structure is fundamental to meet legal, technical and administrative obligations. It ensures the effective delegation of authority, promotes specialization, facilitates communication, and enables the alignment of functions. Proper structure fosters a system of checks and balances that is essential for transparent, accountable and evidence-based regulatory decision-making.

As Ethiopia moves to establish a stable, well-functioning, and integrated regulatory system, transforming its organizational structure has become a top priority. An effective structure—one that ensures a clear line of command, promotes transparency and accountability, facilitates communication, and enables functional integration and alignment—is essential for ensuring patient safety, enhancing regulatory efficiency and effectiveness, and supporting both internal and external coordination.

This document aligns Ethiopia's civil service laws and guidelines, and global best practices. It provides:

- Describes the line of command and reporting across the organization
- Defined duties and responsibility of Lead Executive Offices, Executive offices, Desks, Teams, and Branch Offices.
- Defines the line of communication, relationships, and alignment among functions.

The successful adoption of this manual will improve communication, improve transparency and accountability, enhance line of command, streamline regulatory processes, reduce regulatory inefficiencies, enhance alignment, and. Ultimately, it will contribute to improved patient safety, and better-informed regulatory policy decisions. The EFDA remains committed to for the implementation of the organizational structure, providing training to staff, and ongoing structural updates to ensure sustained regulatory compliance and continuous system improvement.

Heran Gerba
Director General, EFDA

Acronyms and Abbreviations

ADE	Adverse Drug Event
ADRs	Adverse Drug Reactions
AEFI	Adverse Event Following Immunization
AMA	African Medicine Agency
AMC	Antimicrobial consumption
AMR	Antimicrobial Resistance
BCLEO	Branch Coordination Lead Executive Office
CAPA	Corrective and Preventive Actions
DBMS	Database Management System
DACA	Drug Administration and Control Authority
DDG	Deputy Director General
EFDA	Ethiopian Food and Drug Authority
EO	Executive Office
FSQCL	Food Safety and Quality Control Laboratory
e-GP	Electronic Government Procurement
eRIS	Electronic Regulatory Information System
FCTC	Framework Convention on Tobacco Control
FHRSDIP	Food and Health Products Regulatory Sector Medium-Term Development and Investment Plan
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GRevPs	Good Review Practices
GSP	Good Storage Practice
GMP	Good Manufacturing Practice
HSDIP	Health Sector Development and Investment Plan
IFMIS	Integrated Financial Management Information System
IVD	In Vitro Diagnostics
IGAD	Intergovernmental Authority on Development

ISCMIS	Integrate Civil Service Management Information System
ICT	Information Communication Technology
ISO/IEC	Organization for Standardization/International Electrotechnical Commission
INCB	International Narcotics Control Board
KPI	Key Performance Indicators
LEO	Lead Executive Office
MEMA	Medicine Evaluation and Market Authorization
MMIE	Medicine Manufacturers Inspection and Enforcement
M&E	Monitoring and Evaluation
MUE	Medicine Use Evaluation
MOH	Ministry of Health
MOU	Memorandum of Understanding
MQC	Medicine Quality Control
NDAC	National Drug Advisory Committee
PILs	Package Information Leaflets
PMS	Post Market Surveillance
PVCT	Pharmacovigilance and Clinical Trial
PIC/s	Pharmaceutical Inspection Co-operation Scheme
POE	Ports of Entry
PPE	Personal Protective Equipment
PSURs	Periodic Safety Update Reports
QMS	Quality Management System
REC	Regional Economic Community
RMPs	Risk Management Plans
RRB	Regional Regulatory Bodies
SDS	Safety Data Sheets
SPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
WHO	World Health organization

Acknowledgments

The Ethiopian Food and Drug Authority (EFDA) extends its sincere appreciation to all institutions, professionals, and technical experts who contributed to the development of **Organization Structure Description Manual: Duties and Responsibilities**. This manual is the result of a collaborative effort that brought together EFDA top management, Lead Executive Offices, Executive Office, Branch offices, Technical Advisers, stakeholders and partners to establish a standardized organizational structure for EFDA.

Finally, EFDA also thanks the members of the national technical working group, subject matter experts, and reviewers who participated in drafting, validating, and refining the manual through workshops and technical review sessions. Your collective effort will have a lasting impact on strengthening regulatory system, and improving patient safety.

Executive Summary

The Ethiopian Food and Drug Authority (EFDA) is mandated to safeguard public health through the regulation and control of food, medicine, medical devices, cosmetics, and other related products. Its organizational structure is designed to ensure operational efficiency, transparency, accountability, communication, alignment and responsiveness in the delivery of its core regulatory functions.

This manual outlines the hierarchical framework, delineates duties and responsibilities across Lead Executive Offices (LEOs), Executive Offices (EOs), Branch office, Desks and Teams, and promotes alignment with national legal and policy frameworks. The organizational structure of EFDA comprises the Director General's Office, Deputy Director Generals, and multiple core and support offices. Each LEOs, EOs, desks and teams have defined duties and responsibilities to ensure coordination, alignment and performance.

The EFDA consists of a Director General, Office of Director General, three Deputy Director Generals, Management Chief Executive Officer, 13 LEOs, 7 branch offices, and 11 EOs overseeing various regulatory and quality functions. It operates through specialized 79 desks, 25 teams and 15 Ports of Entry.

The manual emphasizes the importance of interdepartmental communication, strategic leadership, and performance-based operations. As EFDA continues to respond to emerging health threats, evolving technologies, and public health priorities, a well-articulated organizational structure remains vital.

The manual will be periodically reviewed and updated to remain relevant to the current legal mandates, institutional arrangements, and stakeholder needs. This structured approach supports transparency, institutional memory, and efficiency in regulatory service delivery.

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Terms and Definitions

Authority means the Ethiopian Food and Drug Authority;

Food means any substance, whether processed or semi-processed, which is intended for human consumption, and includes plants, and plant and animal products placed on the market or offered for use by the public; salt, water, alcohol or other drink, and any substance which has been used in the manufacture or treatment of food but does not include medicine, cosmetic, and tobacco products;

Medicine means any substance or mixture of substance used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of human and it includes articles intended for use as a component of any of the above specified articles;

Medical Device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related articles and their accessories, which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, and intended by the manufacturer to be used, alone or in combination, for medical purpose and includes device intended for related medical use and control of contraception;

Organogram means a visual diagram that shows the internal structure of an organization. It outlines the relationships and relative ranks of positions, departments, or employees, showing who reports to whom;

Organization means a group of people who work together in a structured way to achieve specific goals or purposes;

Proclamation means the Food and Medicine Administration Proclamation No.1112/2019;

Regulated Product means any product administered in accordance with the Proclamation and includes food, medicine, medical device, traditional, complementary or alternative medicine, blood and blood products, cosmetic, and tobacco products;

Responsibility means the duty or obligation to perform or complete a task or role assigned to someone;

Structure means the way in which an institution is arranged, including the hierarchy, roles, departments, and communication systems. It defines how tasks are divided, coordinated, and supervised.

1. Introduction

1.1. Background

The Ethiopian Food and Drug Authority (EFDA) is a national regulatory authority mandated to protect public health by ensuring the safety, quality, and/or effectiveness of food, medicines, medical devices, cosmetics, and other regulated health products. It also regulates alcohol and tobacco products to reduce their consumption and mitigate their harmful health and socio-economic impacts.

The Ethiopian Food and Drug Authority (EFDA) is established under Proclamation No. 1263/2021 and its mandate defined under the Food and Medicine Administration Proclamation No. 1112/2019, and Council of Ministers Regulation No. 531/2023. EFDA was established to safeguard the public health by ensuring the safety, quality and/or effectiveness of food, and medical products as well as other regulated health products.

The EFDA origins trace back to its initial establishment as a department under the Ministry of Interior, later moved under the Ministry of Health. In 1999, a significant milestone was reached with the formation of the Drug Administration and Control Authority (DACA), laying the foundation for a more structured regulatory system.

Subsequently, further restructuring led to the creation of the Ethiopian Food, Medicine and Healthcare Administration and Control Authority, broadening its scope to regulate not only regulated products but also health services, health professionals, environmental and hygiene, and health facilities. However, this broad mandate resulted in strategic dispersion and inefficiency, hampering the Authority’s effectiveness in protecting public health.

To resolve these challenges, the government reformed the Authority’s focus through Proclamation No. 1112/2019 and Regulation No. 531/2023, limiting EFDA’s mandate to the regulation of food, medicine, medical devices, cosmetics and related products. and establishments associated with these products (e.g. production, importation, exportation, and distribution of regulated products).

EFDA now plays a focused role in regulating critical products that impact public health. Despite this refined mandate, the Authority continues to face challenges such as:

- Weak communication channels
- Lack of transparency and accountability

- Overlapping roles and unclear responsibilities
- Limited coordination between Lead Executives Offices and branch offices
- Delays in decision-making processes

To address these challenges, the EFDA has undergone legal, technical and administrative reforms including structural reform, with defined duties and responsibilities assigned across LEOs, EOs and Branch Offices. A well-defined organizational structure is fundamental to EFDA's success in fulfilling its legal and policy obligations. It enables:

- Effective delegation of authority
- Promotion of specialization
- Improved communication
- Coordination and alignment of LEOs, EOs and Branch offices
- A system of checks and balances for transparent, accountable and evidence-based decision-making.

The current structure reflects a coordinated system of LEOs, EOs, branch offices, teams and desks, each with clearly defined roles, responsibilities, and reporting lines. This ensures clarity, accountability, alignment and operational efficiency across all regulatory functions. Ultimately, EFDA's organizational structure is a key enabler of its performance, allowing it to effectively achieve its core mission of protecting and promoting public health.

1.2. Policy, Legal, and Institutional Framework

The Ethiopian Food and Drug Authority (EFDA) operates within a defined policy and legal framework that establishes its authority, structure, and operational mandates. To define and strengthen the regulatory scope and institutional relevance of EFDA, Proclamation No. 1263/2021 was enacted. This proclamation reaffirms EFDA's status as an autonomous federal regulatory body accountable to the Ministry of Health and enhances its powers to regulate all food, medicine, medical device, cosmetics and other related health products and practices in Ethiopia.

The cornerstone of EFDA's legal basis is Proclamation No. 1112/2019, which provides power for the regulation of food, medicines, medical devices, cosmetics and other related health products, and associated establishments. This proclamation outlines the Authority's duties and responsibility to ensure the safety, quality and/or effectiveness of regulated products. It also defines the regulatory

systems and functions including registration and market authorization, regulatory inspection, laboratory testing service, licensing establishments, market control and surveillance, vigilance, clinical trial oversight.

In addition, Council of Ministers Regulation No. 531/2023 was introduced to detail the mandate, structure, governance, and operational arrangements of EFDA. This regulation provides the organizational blueprint for EFDA, defining the internal structure, staffing, reporting lines, and governance procedures. It also sets standards for performance management, financial oversight, and administrative efficiency.

EFDA's legal framework is complemented by national strategic policies including the National Health Policy, Nation Medicine and Medical Devices Policy, the National Food and Nutrition Policy, the Health Sector Development and Investment Plan (HSDIP), and Food and Health Products Regulatory Sector Medium-Term Development and Investment Plan (FHRSDIP). These documents provide policy alignment and strategic guidance for EFDA's operational priorities and service delivery approaches.

Institutionally, EFDA functions as an autonomous agency under the Ministry of Health, with clear accountability mechanisms and collaborative linkages with various stakeholders, including regional health bureaus, regional regulatory bodies, customs authorities, Police Commission, academic institutions, associations, partners and international regulatory bodies such as the WHO, African Medicines Agency (AMA), Intergovernmental Authority on development (IGAD), and other Regional Economic Communities (REC). Through memorandums of understanding (MOUs) and regulatory cooperation platforms, EFDA maintains cross-sectoral engagement and international alignment.

Internally, EFDA operates using structured tools such as Directives, guidelines, manuals, Standard Operating Procedures (SOPs), Job Descriptions, and Performance Appraisal Systems to guide the work of its LEOs, EOs, branch offices, desks, teams and staff. These instruments ensure consistency, compliance, and transparency across all regulatory activities.

The integrated legal, technical and administrative framework enables EFDA to fulfill its mandate effectively and adapt to the dynamic public health and regulatory landscape in Ethiopia.

1.3. Objectives of the Manual

This manual is designed to achieve the following key objectives:

- To clearly define the duties, responsibilities, and reporting lines within EFDA's organizational structure.
- To promote transparency, accountability, and consistency in the execution of EFDA's mandates.
- To facilitate efficient coordination and communication between LEOs, EOs, branch offices, desks, and teams.
- To guide capacity building, staffing, and performance evaluation processes based on clearly defined roles.

1.4. Scope of the Manual

This manual covers all top leadership, LEOs, EOs, branch offices, desks, and teams operating under EFDA, including their core functions, interrelations, and reporting mechanisms. It provides a clear delineation of duties and responsibilities to avoid duplication of roles, minimizes role confusion and promote organizational synergy.

The manual is applicable to internal staff, government stakeholders, and external partners who interact with EFDA. It serves as a foundational document for institutional reform, capacity building, and performance monitoring across all levels of the organization.

2. Duties and Responsibilities

2.1. EFDA Advisory Board

a. Introduction

The EFDA is an independent Authority which operates within the framework of the Executive Agencies Proclamation No. 1263/2021. The Advisory Board was established under the Regulation No. 531/2023 article 6 (1). The members of the board including the chairperson are appointed by the Minister of the Ministry of Health. The main role of the advisory board is to advise the Minister and EFDA Director General on strategic and operational matters of EFDA.

b. Organization and Accountability

The Board is accountable to the Ministry of Health. however, it shall be independent in undertaking its responsibilities.

c. Duties and Responsibilities

Considering the regulation No. 531/2023, article 9, the Board will have the following duties and responsibilities;

- Advise the Authority on policy, short and long-term strategic plans and annual work plan;
- Advise and provide recommendation to the Authority, either by itself or through establishment of technical committee as appropriate, on matters that require scientific analysis and recommendation, findings, research and regulatory systems;
- When deems it necessary, establish technical committee to undertake a particular work related to the Board mandate;
- Advise the Authority on identified gaps based on performance evaluation and issues that needs priorities;
- Conduct physical supervision on matters related the Authority
- Submits reports on its activity to the Minister of the Ministry of Health.
- Invite technical experts to its meeting, when it deems necessary
- Issue internal regulation for working and session procedure
- Provide advice on other regulatory related matters as needed.

2.2. Director General

a) Introduction

The Director General is the chief executive officer of the EFDA and responsible for providing strategic leadership and oversight in ensuring the safety, quality and effectiveness of food, medicine, medical devices, cosmetics and related health products in Ethiopia. This includes formulating and enforcing regulatory policies, guiding institutional operations, ensuring compliance with national and international standards, coordinating and engaging stakeholders, and advising the government on public health matters related to regulated products.

b) Organization and Accountability

The Director general is accountable to the Ministry of health and manages the following three Deputy Director Generals, Lead Executive Offices and Executive Offices.

1. Medicine Sector Deputy Director General
2. Medical Device Sector Deputy Director General
3. Food Sector Deputy Director General
4. Quality Management System Lead Executive Office
5. Intelligence and illegal Trade Prevention Lead Executive Office
6. Director General Office
7. Management Chief Executive Office
8. Branch Coordination Lead Executive Office

c) Duties and Responsibility

As per Regulation No. 531/2023, article 11, the Director General shall be the chief executive officer of the Authority and has the following duties and responsibility

- Direct and administer the activity of the Authority
- Exercise the powers and functions of the Authority specified under Article 5 of this Regulation No 531/2023
- Employ and administer employees of the Authority in accordance with the Federal Civil Service Law
- Prepare annual plans and budget of the Authority; implement same upon approval by the Government
- Effect payments in accordance with the approved plan and budget of the Authority
- Represent the Authority in all its dealings with third parties
- Prepare and submit performance and financial report of the Authority to the Government

- Establish technical working group, follow the performance; cause the benefits of the team members be decided by a Directive to be issued by the Ministry of Finance
- Delegate part of its Power and Functions to the officials or employee of the Authority.

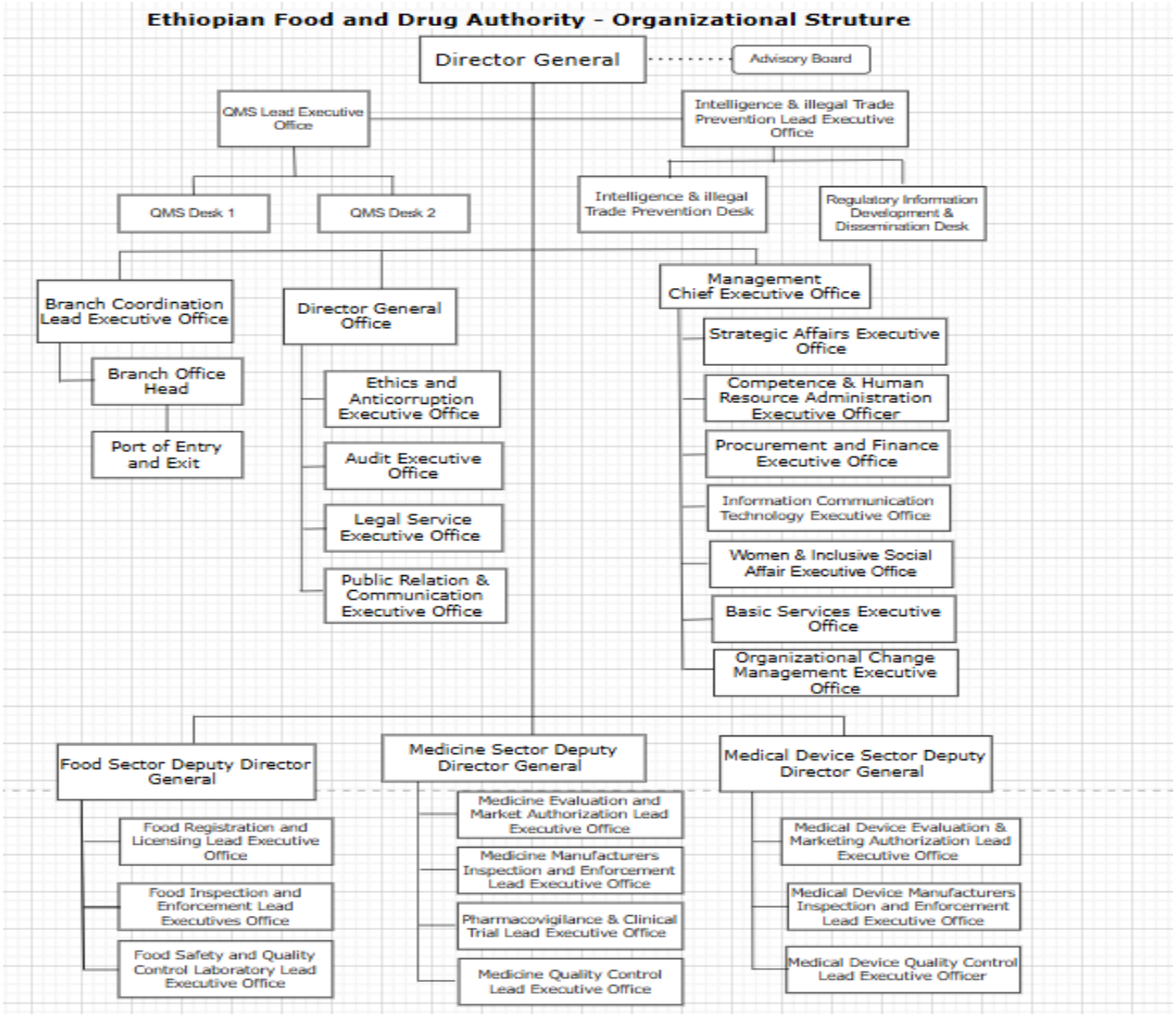


***Fig 2.2**: Director General Organizational Chart*

2.2.1. Office of the Director General

a. Introduction

The Office of the Director General is established to support the Director General and oversees the strategic leadership and overall management of the Authority, and closely monitors the implementation of high-level activities and management committee decisions. It ensures the implementation of national policies, strategies and laws related to food, medicines, medical device, cosmetics, and related health products regulation. It closely monitoring daily operations, ensuring timely implementation of urgent activities and Management Committee decisions, coordinating technical and policy advisors, coordinates with national and international stakeholders and enhancing the overall effectiveness of the Authority's core functions.

b. Organization and accountability

The Office of the Director General is accountable to the Director General and leads the following Four Executive Offices:

1. Legal Services Executive Office
2. Ethics Monitoring Executive Office
3. Public Relation and Communication Executive Office
4. Audit Executive Office

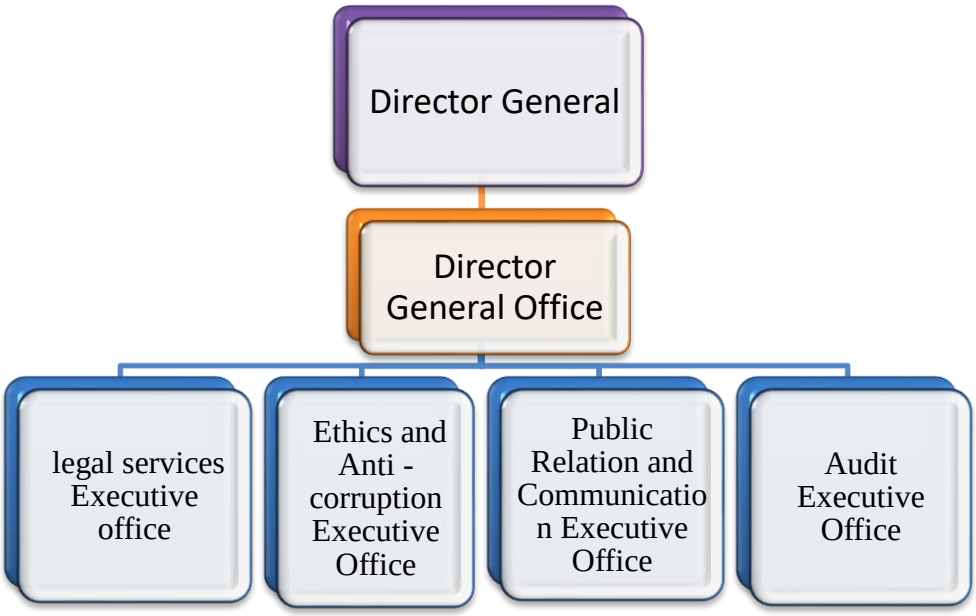


Fig 2.2.1. *Director General Office Organizational Chart*

c. Duties and responsibility of the Office of Director General

- Coordinate the work organized under the office

- Coordinate the technical and policy advisors of the director general
- Accept issues identified by the Director General and providing the necessary answers
- Prepare the necessary explanations and analyzes on the matters presented to the Director-General so that the Director-General can respond to them.
- In consultation with the Director-General, set up a system in which both organizations and individuals who have been subject to administrative action by the authority can submit complaints, and will monitor its performance.
- Devise the procedures and strategies for which the office is managed by the authority
- Acs as a secretariat of the leadership and management committee.
- Monitor and support the main strategic activities of the authority office
- Liaising and coordinating with stakeholders
- Facilitates a joint forum with the Director General or the relevant Sectoral Deputy Director Generals by inviting and hosting stakeholders from partner organizations, international institutions and foreign countries.
- Identify issues that need a decision by the top management in terms of the tasks and responsibilities given by the law office and presents them supported by evidence, monitor their implementation, and presents the results to the management.
- Prepare and execute protocol agreement documents by the court and other stakeholders together with the relevant parties.
- Prepare and present the schedule for management meetings, ensures that the forums are held according to the schedule, and monitors the implementation of decisions and directions.
- Prepare agendas for meetings chaired by senior management and distributes them to attendees; keeps minutes of meetings or causes them to be kept, and sends the minutes to work departments and relevant parties.
- Receive suggestions related to ethics and corruption and ensures their correctness; When the recommendations are confirmed to be correct, it will conduct an investigation and follow up on actions taken in relation to ethics and corruption.

2.2.1.1. Audit Executive Office

a. Introduction

The Audit Executive Office is established to ensure the effective implementation of the Authority's strategic plans, policies, and programs by safeguarding financial, human, and material resources against waste, fraud, and mismanagement. The Office ensures that allocated resources are utilized effectively, efficiently, and economically, while strengthening governance, accountability, and internal control systems in line with the Financial Management Proclamation, federal rules, regulations, and other applicable laws. Audits are conducted using modern technology systems, including: Integrated Financial Management Information System (IFMIS), Electronic Government Procurement (e-GP), Electronic Payment (e-Payment) platforms, eRIS and e-SW

b. Organization and accountability

The Audit Executive Office is accountable to Director General's Office and will have the following Two Teams;

1. Performance Audit Team
2. Financial Audit Team

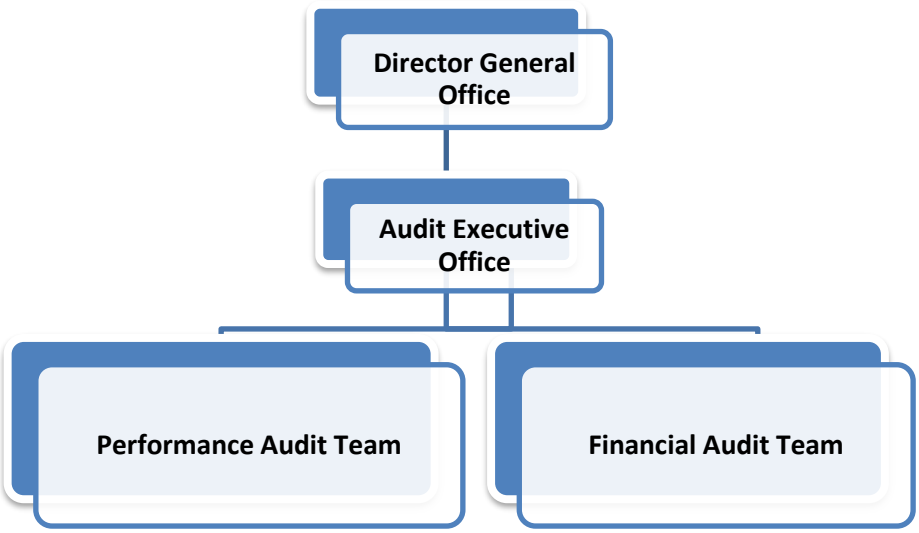


Fig 2.2.1.1: *Audit Executive Office Organizational Chart*

c. **Duties and Responsibilities of the Audit Executive Office**

- Overseeing the proper management and utilization of Authority resources.
- Ensuring corrective measures are taken and monitored following audit findings.
- Establishing and maintaining robust internal control and financial management systems.
- Protecting the Authority resources from misuse, inefficiency, and waste.
- Supporting governance reform, accountability, and continuous institutional improvement.

d. Duties and Responsibilities of Performance Audit Team

- Prepare the team's annual audit plan, direct and coordinate its implementation.
- Organize and coordinate planned audit activities for the fiscal year.
- Conduct performance audits through document review and on-site field verification.
- Prepare and submit audit reports with findings, recommendations, and follow-up actions.
- Liaise with audited departments to ensure corrective actions are implemented.
- Establish and lead field audit teams to execute planned activities.
- Ensure auditors have access to necessary working tools, materials, and training.
- Support capacity building and professional development of audit team members.
- Monitor and evaluate the effectiveness of corrective actions taken by audited units.
- Provide advisory input to management on improving performance efficiency and value for money.

e. Duties and Responsibilities of Financial Audit Team

- Prepare and implement the annual financial audit plan in alignment with the Authority priorities.
- Verify the accuracy of revenues collected by tax offices and service outlets.
- Audit expenditures on chemicals, laboratory equipment, and other procurements, ensuring compliance with government and institutional procedures.
- Audit financial operations of programs, projects, and grant accounts to confirm legality and alignment with budgetary provisions.
- Ensure that financial management systems comply with proclamations, regulations, and internal policies.
- Review budget allocations to confirm appropriateness and lawful utilization.
- Conduct legality and compliance audits, including detailed verification of financial statements.

- Prepare audit papers, working papers, and evidence-based reports.
- Conduct internal control testing and apply analytical audit procedures.
- Determine appropriate audit samples based on risk assessments and testing outcomes.
- Lead entry and exit meetings with audited departments; prepare agendas and document proceedings.
- Draft, review, and finalize audit reports, ensuring accuracy, balance, and practical recommendations.
- Monitor and follow up on corrective actions taken in response to audit findings.
- Ensure audit staff are adequately resourced, trained, and supported with tools and materials.
- Provide advisory input to management on financial risk, fraud detection, and internal control improvements.
- Perform additional financial and compliance audit tasks as assigned by senior management or the Ministry of Finance.

2.2.1.2. Ethics and Anti-Corruption Executive Office

a. Introduction

The Ethics and Anti-Corruption Executive is a key component in establishing good governance and a strong ethical framework within the Ethiopian Food and Drug Authority (EFDA). This role is dedicated to creating a responsible and efficient work environment by helping the Authority's employees and leadership avoid corruption, misconduct, and other ethical lapses. The primary objective of the Ethics Executive is to protect the institution's reputation by proactively preventing corruption, identifying and addressing knowledge gaps, and monitoring the implementation of legal and operational systems. This executive supports the EFDA's effectiveness and integrity through training, investigating corruption-vulnerable procedures, and ensuring necessary actions are taken.

The Executive is an integral part of the organizational structure, reporting directly to the Office of the Director General. This reporting structure guarantees the Executive’s neutrality and independence, helping to minimize potential external influence. The Executive is accountable not only for the execution of its work plan but also for the overall effectiveness of anti-corruption efforts. The role requires the Executive to report any challenges or issues to the relevant authorities, ensuring that appropriate support and action are provided. The performance of the Executive is measured through regular evaluations and reports.

The primary reason for establishing this executive office is to prioritize good ethics and corruption prevention within the Authority. Unethical practices and corruption can severely damage the Authority's effectiveness, public trust, and institutional reputation. The Ethics Executive is responsible for ensuring that anti-corruption laws and ethical codes are put into practice. The responsibility is not merely to take action after an act of corruption has occurred but to focus on prevention, which helps to avoid the waste of money, time, and human resources.

b. Organization and Accountability

The Ethics and Anti-Corruption Executive Office reports directly to the Office of the Director General.

c. Duties and Responsibilities of Ethics and Anti-Corruption Executive Office

- Study and identify gaps in ethics and corruption prevention among the Authority's leadership and employees.
- Develop training documents and guidelines.
- Organize and deliver practical, task-oriented training.
- Ensure adequate understanding of anti-corruption policies, laws, regulations, and directives.
- Prepare awareness papers, brochures, and memos.
- Identify and evaluate procedures vulnerable to corruption and misconduct.
- Propose solutions and monitor their implementation.
- Study and identify procedures that are susceptible to theft and misconduct.
- Establish ethical inquiry systems.
- Regularly evaluate and improve procedures.
- Identify potential conflicts of interest among public officials, government appointees, and other leaders.
- Develop preventative measures.
- Establish a conflict-of-interest monitoring system.
- Collect and evaluate evidence of conflicts of interest.
- Prepare an asset declaration and registration guideline.
- Ensure all employees and leadership declare their assets.
- Improve and prepare asset declaration forms.
- Provide clearance for departing employees and notify the relevant body.

- Monitor the implementation of asset declaration.
- Take immediate action upon suspicion or receiving a tip regarding preparations to commit corruption.
- Identify and evaluate corruption tips.
- Coordinate corruption investigation processes.
- Coordinate with relevant bodies to ensure appropriate action is taken.
- Prepare corruption prevention reports.
- Prepare messages to raise awareness about ethics and corruption prevention.
- Coordinate media and public relations activities.
- Provide awareness briefings.
- Develop internal and external communication strategies.
- Submit periodic reports to the Director General and the Federal Ethics and Anti-Corruption Commission.
- Prepare performance reports.
- Prepare and maintain ethics monitoring documents.
- Prepare corruption investigation reports.

2.2.1.3. Legal Service Executive Office

a. Introduction

The main purpose of the Legal Service Executive Office is to facilitate the organization's regulatory mission through the preparation, introduction, and oversight of various legal frameworks; the provision of legal counsel and services to different operational units; and representation of the authority in legal proceedings. In addition, the office seeks to promote a culture of legality and to develop model legal frameworks for use by regional regulatory institutions.

b. Organization and accountability

Legal Service Executive Office is accountable to the Office of the Director-General. To effectively carry out its mandate, the Executive Office is organized into two Teams:

1. Legal services
2. Law formulation and awareness creation

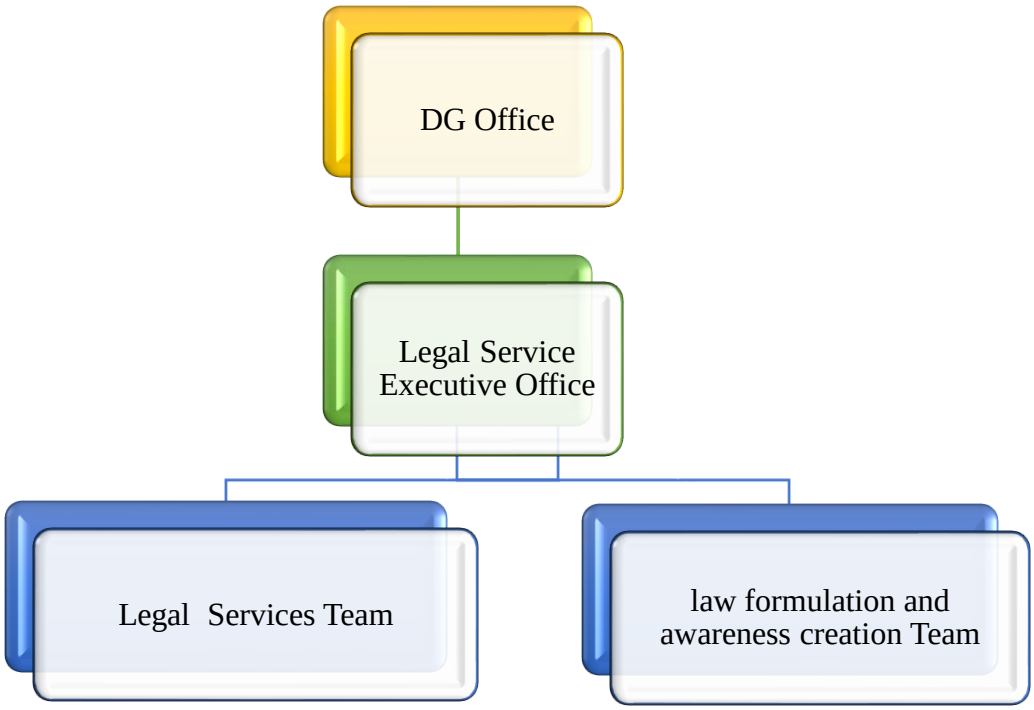


Fig 2.2.1.3: *Legal Service Executive Office Organizational Chart*

c. Duties and Responsibilities of the Executive Office

- Drafts, approves, disseminates, repeals, and oversees the implementation of laws, including proclamations, regulations, and directives.
- Provides technical support to regional regulatory bodies in drafting, approving, and publicizing laws.
- Organizes awareness and capacity-building training for the Authority's leadership and regional regulatory bodies on newly issued or repealed directives.
- Facilitates the implementation of international conventions ratified by Ethiopia and monitors compliance.
- Submits proposals for the development or repeal of directives related to regulated products.
- Provides professional legal support during operations based on surveillance findings, including on-site participation.
- Provides legal assistance during inspections upon request from inspection departments, including on-site presence. Offers legal advice and opinions prior to the enforcement of administrative measures.
- Ensures that proper actions are taken when legal violations are identified.

- Drafts service and procurement agreements, Memoranda of Understanding (MoUs), and other legal instruments with national and international partners, and reviews drafts submitted by other institutions.
- Collects and organizes evidence for litigation and represents the Authority in court proceedings.
- Conducts legal research on issues affecting the Authority, submits findings to the relevant body, and monitors implementation.
- Serves on committees established to review complaints submitted by organizations or individuals affected by administrative measures.

d. Duties and Responsibilities of Legal Services Team

- File lawsuits on behalf of the Authority in regular courts and defend the institution when legal action is brought against it.
- Represent the Authority in administrative appeals before the Civil Service and argue cases to their conclusion.
- Prepare and present appeals against decisions issued by administrative bodies or regular courts.
- In cases of criminal acts involving regulated products within the Authority's branch offices in Addis Ababa or elsewhere, gather substantiated evidence, submit cases to the appropriate justice organs, and conduct regular follow-ups.
- Present evidence and witnesses in criminal court proceedings.
- For criminal acts occurring in regional branch offices, travel to the respective locations to collaborate with regional justice institutions or empowered judicial bodies, gather evidence, and file charges.
- Provide legal consultation services to all relevant work units of the Authority, including its regional branch offices, on regulatory and other fundamental laws.
- Draft terms and conditions for procurement, payments, and service agreements undertaken in collaboration with other institutions.
- Prepare MoUs and review drafts prepared by external institutions, providing appropriate feedback.
- Develop legal documents for regional branch offices and advise on administrative measures from a legal perspective.

- Deliver regular training to regulatory experts on relevant laws.
- Design training manuals and provide capacity-building sessions for justice organs (Police, Prosecutors, and Judges) on regulatory laws and emerging challenges.
- Identify gaps in the Authority's regulatory laws and propose solutions to address them.

e. Duties and Responsibilities of the law formulation and awareness creation Team

- Conduct studies to support the preparation of implementation proclamations.
- Ensure that draft legal frameworks are developed in line with the legal system and based on study findings.
- Identify, on a regular basis, challenges related to the implementation of proclamations within the Authority's regulatory units.
- Revise existing directives or prepare new ones in a timely manner.
- Organize consultations with relevant stakeholders on draft guidelines.
- Engage with the Ministry of Justice to address gaps in draft directives, provide comments on behalf of the Authority, and follow up until the proclamations are enacted and put into operation.
- Conduct studies and provide legal advice to the Authority on preparation of new laws.
- Perform other related duties as required.

2.2.1.4. Public Relation and Communication Executive Office

a. Introduction

The Public Relation and Communication Executive Office serves as the institution's official spokesperson. Its primary objective is to ensure the timely dissemination of information on regulatory activities to the public and key stakeholders through various communication channels. In addition, it is responsible for gathering public opinions and concerns related to the regulatory process, enabling the institution to make necessary adjustments.

b. Organization and accountability

The Public Relation and Communication Executive Office is accountable to the Office of the Director-General. To effectively carry out its mandate, the Executive Office is organized into three Team:

1. Internal and External Communication Team
2. Event and Digital Media Team
3. Food and Health Products Information Preparation and Dissemination Team

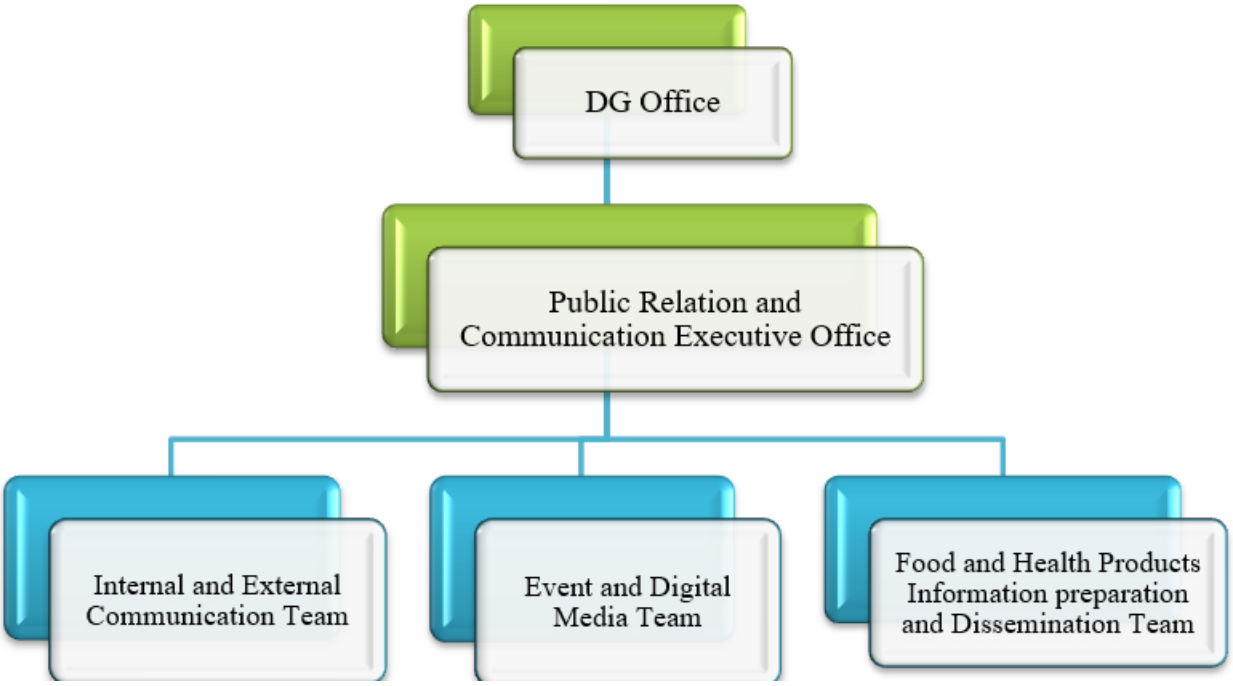


Fig 2.2.1.4: *Public Relation and Communication Executive Office Organizational Chart*

c. Duties and Responsibilities of the Public Relation and Communication Executive Office

- Organize and lead forums, discussions, and dialogues that promote transparency and help people understand the institution's policies, guidelines, rules, and national issues.
- Act as a link between the government, public, and institution; lead, coordinate, and monitor the implementation of these communication activities.
- Build working relationships with the institution's service users, as well as with domestic and international media, and improve communication efforts.
- Keep track of the institution's bilateral and multilateral signing protocols and provide explanations to media outlets.
- Serve as the institution's spokesperson.
- Carry out media monitoring activities related to the institution.
- Create various programs for radio, television, and other media outlets.
- Organize press conferences to share the institution's work, performance, and future plans.
- Collaborate with other processes to enhance the institution's image and support its vision and mission.

- Write articles and reports about the institution and ensure they are shared through private and government media outlets, as well as social media platforms.
- Conduct field visits to gather feedback from stakeholders and the public about the institution's activities.

d. Duties and Responsibilities of Internal and External Communication Team

- Craft and deploy essential information regarding food and health related products and other regulated products via targeted communication channels.
- Serve as the central hub for media engagement, managing outreach, official messaging, and real-time monitoring of coverage and public perception.
- Direct crisis communication and coordination, developing plans and acting as the lead point of contact during public health emergencies.
- Proactively shape the narrative by generating and distributing timely content for both the public and media throughout critical events.
- Function as a strategic public relation advisor, overseeing and implementing a full spectrum of national public relations initiatives.
- Provide strategic guidance for internal and external communication activities.

e. Duties and Responsibilities of Event and Digital Media Team

- Manage the official’s digital presence, including social media platforms and website.
- Monitor and analyze engagement metrics to shape strategies for digital communication.
- Oversee content development and updates for social media and the website.
- Design and implement digital campaigns to promote regulatory information and educational materials.
- Assess digital performance to refine and improve future outreach strategies.
- Build and maintain relationships with key stakeholders, industry partners, health organizations, and advocacy groups.
- Organize public meetings, forums, and discussions to gather input and translate feedback into actionable initiatives.
- Develop collaborative strategies to improve accessibility and reach.
- Plan, coordinate, and deliver events.
- Select and conduct institutional visits that may positively or negatively impact the office and the nation’s image.

- Prepare concise reports summarizing events, visits, and activities. Organize and manage communication across multiple platforms.

f. Duties and Responsibilities of the Food and Health Products Information Preparation and Dissemination Team

- Ensure continuous preparation and dissemination of food and health information through the website, social media, newspapers, broadcast media, and relevant journals on a daily, weekly, monthly, and quarterly basis; monitor outcomes and report regularly to the relevant body.
- Manage the toll-free line (8482), respond to public inquiries, and forward information promptly to the concerned body.
- Identify, collect, and organize information on food, health related products, and regulated products.
- Edit, prepare, and disseminate information on food and health related products and other regulated products.
- Plan and implement promotions, awareness campaigns, advisory services, and information platforms.
- Share information with international journals and trade press.
- Develop public mobilization materials promoting quality and safety food and health related products.
- Prepare and distribute public campaign materials, educational manuals, and guidance documents.
- Produce regulatory documents and scientific resources.
- Offer editorial support for scientific publications, reports, and manuscripts.
- Manage internal communication through newsletters, multimedia, and staff updates.

2.2.2. Quality Management System Lead Executive Office

a. Introduction

The Quality Management System Lead Executive Office (QMS LEO) operates cross-functionally and reports to the Director General and oversees the development, implementation, and maintenance of quality systems. It ensures consistent delivery of regulatory services that meet customer needs and expectations, coordinates audits, manages process & document control, and drives continuous improvement. The office also implements risk management system in line with

national and international standards, and supports training, communication, and reporting quality performance metrices. Structurally, it operates cross-functionally, reporting directly to top management to ensure strategic alignment

b. Organization and accountability

The Lead Executive Office of Quality Management System is accountable to the Director General and it has two operational Desks:

1. Quality Management Desk One
2. Quality Management Desk Two

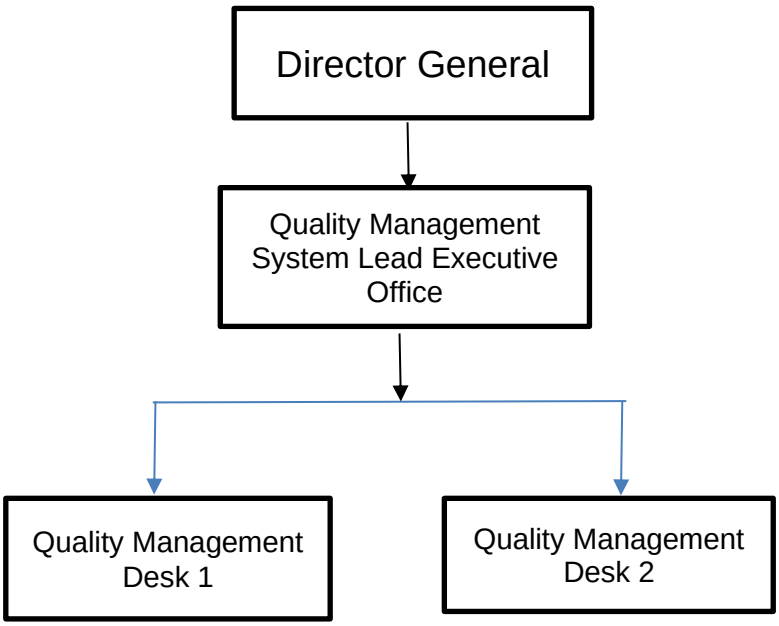


Fig 2.2.2: *QMS LEO Organizational Chart*

c. Duties and Responsibilities of QMS LEO

Quality Management Lead Executive Office has the following roles and responsibilities.

- Develop, implement, and maintain comprehensive Quality and Risk Management Systems in accordance with national and international standards, including ISO 9001:2015, ISO/IEC 17025:2017, ISO/IEC 17020:2012, ISO 13485:2016, ISO/IEC 27001:2022, ISO 31000, and WHO guidelines.
- Coordinate risk identification, assessment and mitigation of quality-related risks and ensures appropriate risk controls.
- Manage processes and documentation in alignment with applicable standards, ensuring timely review, revision, and control to maintain regulatory compliance and support accreditation

- Coordinate designing of functional laboratory systems and ensures environmental conditions meeting specified regulatory limits and quality standards.
- Oversee equipment qualification (IQ, OQ, PQ), calibration, preventive maintenance, and maintains comprehensive device history records.
- Coordinate conducting internal audits; identifies non-conformities; manages root cause investigations; implements and verifies effectiveness of corrective and preventive actions (CAPA).
- Establish and manage customer complaint management system
- Coordinate validation and verification of laboratory test methods; participation in proficiency testing schemes; evaluates performance and oversees corrective action implementation for non-conformities.
- Prepare the authority for accreditation and maintains international recognition through continuous quality improvement and system effectiveness evaluation.
- Coordinate training, mentoring, and guidance to staff on quality procedures, regulatory requirements, and best practices.
- Coordinate the development, implementation, and effectiveness evaluation of training programs
- Lead, supervise, and monitor QMS staff to ensure performance, compliance, and effective implementation of the Quality Management System, while identifying competency gaps, providing training, and mentoring to maintain qualified personnel.
- Plans and mobilizes necessary resources to support implementation and maintenance of QMS and risk management activities.
- Plans, organizes, and coordinates QMS-related activities, liaising with internal LEOS/EOs/Branch Offices and external stakeholders to ensure alignment and compliance.
- Continuously monitors and evaluates the implementation and performance of the Quality Management System.

d. Duties and Responsibilities of QMS LEO Desk 1 and Desk 2

Quality Management Lead Executive Office Desk 1 and Desk 2 has the following roles and responsibilities.

- Develops, implements, and maintains Quality and Risk Management Systems aligned with national and international standards (e.g., ISO 9001:2015, ISO/IEC 17025:2017, ISO/IEC

17020:2012, WHO guideline on the Implementation of Quality Management Systems for National Regulatory Authorities, TRS 1025, 2020, Annex 13; WHO Good Practices for Pharmaceutical Quality Control Laboratories, TRS 1052 2024, Annex 4 for the testing of drugs; ISO/IEC 17025:2017 for testing of products; ISO 13485:2016 for medical devices, ISO 27001:2022 for Information Security; ISO 31000 for risk management).

- Identifies and assesses quality-related risks and ensure appropriate controls are in place to mitigate them.
- Prepares quality policy, quality manuals, procedures, safety manuals, guidelines and records in line with nation and international standards (e.g., ISO 9001).
- Ensures timely review and revision of documentation to maintain regulatory compliance and international recognition.
- Monitors and ensures organizational compliance with internal and external quality standards and regulatory requirements.
- Designs functional laboratory systems and ensures environmental conditions are within specified limits.
- Oversees equipment qualification (DQ, IQ, OQ, PQ), calibration, preventive maintenance, and maintains device history records.
- Plans, schedules and conducts internal audits, identifies areas for improvement, follows up on preventive and corrective actions, and verifies their implementation.
- Identifies, documents, and investigates non-conformances and implement corrective and preventive actions (CAPA).
- Establishes and manages a customer complaint handling system, investigates complaints, proposes procedural improvements, communicates findings, and implements preventive and corrective actions as needed.
- Leads the validation and verification of laboratory test methods, coordinates laboratory participation in proficiency testing schemes and evaluates performance, prepares reports and oversees the implementation of corrective actions for non-conformities.
- Establishes and maintains an institutional documentation system, including master, controlled document distribution and obsolete document removal.
- Prepares the authority for accreditation and international recognition.
- Continuously monitors and evaluates the effectiveness of the quality management system.

- Provides training and guidance to employees on quality procedures, policies, and best practices.
- Properly utilizes necessary resources for quality management system activities;
- Plans, organizes, and coordinates quality and risk management system activities.
- Monitors, evaluates and reports on implementation and performance of QMS activities.

2.2.3. Intelligence and Illegal Trade Prevention Lead Executive Officer

a. Introduction

The Lead Executive Office reports to the Director General and is primarily responsible for combating illicit trade. This involves investigating its root causes, analyzing the distribution networks for non-compliant products, gathering intelligence, and coordinating with relevant stakeholders to ensure enforcement.

b. Duty and responsibility

- Conduct a survey that identifies the root causes and potential sources of illicit food and medical products.
- Map national high-risk areas for the circulation of illicit medical products.
- Conduct pre-operational surveillance to identify smuggling routes and methods used in border areas
- Recruit, train, and operational deployment of non-office-based intelligence personnel
- Implement preventive measures to stop controlled products from endangering public health, in coordination with neighboring countries and international organizations like Interpol
- Analyze market survey data to strategically direct surveillance efforts towards high-priority areas
- Develop and implement strategic protocols and operational systems to prevent illegal activities.
- Conduct intelligence gathering in areas vulnerable to illegal trade; analyzes data and presents findings to key stakeholders.
- Conducting joint operational activities based on intelligence sharing with key stakeholders
- Receives complaints from informants regarding illegal trade, conducts investigations to verify intelligence and executes operations based on findings

- Develop a system for coordinated action with relevant government agencies including the Customs Commission and security forces and non-governmental organizations to prevent illegal trade.
- Identify and examine potential agents and informants, providing specialized training to ensure high-quality intelligence gathering.
- Develop and implement an intelligence protocol to incentivize reporting of illegal activities by informants and agents.
- Design strategy to protect the public/society from illegal trade, by identifying the areas of cooperation with other units in an organized and informed manner.

c. Organization and accountability

The Lead Executive Office of Intelligence and Illegal Trade Prevention is accountable to the Director General and supervises two desks.

1. Intelligence and Illegal Trade Prevention Desk
2. Regulatory Information Preparation and Distribution Desk

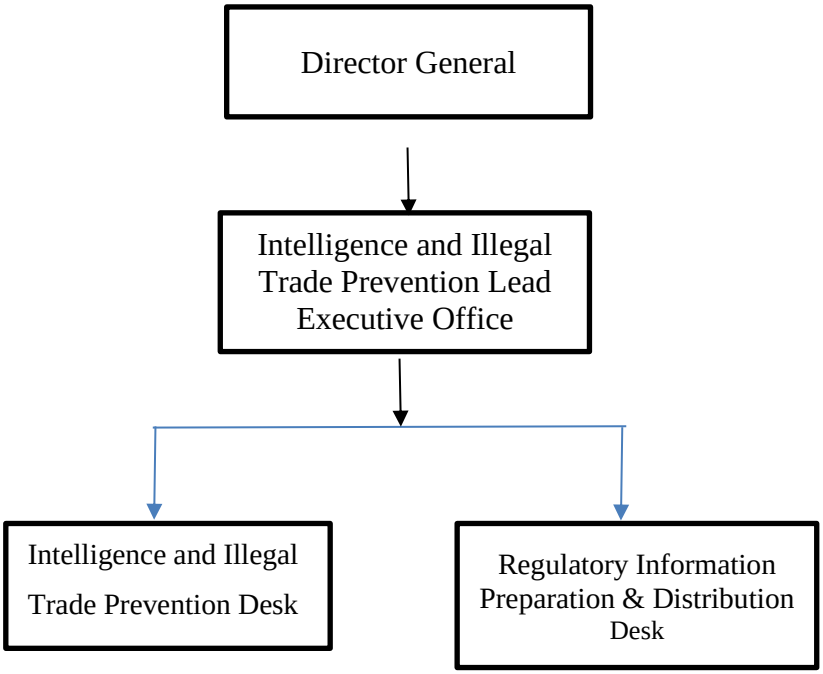


Fig 2.2.3: *Intelligence and Illegal Trade Prevention LEO Organizational chart*

d. Duties and responsibilities of Intelligence and Illegal Trade Prevention Desk

- Identify and map national high-risk areas for the circulation of illicit medical products
- Conduct pre-operational surveillance to identify smuggling routes and methods used in border areas

- Recruit, train, and operational deployment of non-office-based intelligence personnel, including assigning and monitoring field missions.
- Analyze market survey data to strategically direct surveillance efforts towards high-priority areas
- Conducts intelligence gathering in areas vulnerable to illegal trade; analyzes data and presents findings to key stakeholders and based on intelligence sharing with key stakeholders, conducting joint operational activities
- Develop and implement strategic protocols and operational systems to prevent illegal activities.
- Implements preventive measures to stop controlled products from endangering public health in coordination with neighboring countries and international organizations like Interpol.
- Work with relevant government agencies including Customs Commission, security forces and non-governmental organizations to prevent illegal trade.
- Create various capacity building platforms that strengthen the capacity of the desk and works in coordination with the steam.

e. Duties and Responsibilities Regulatory Information Preparation and Distribution Desk

- Receive quality defect compliant and other relevant information from public and stakeholder through 8482 free toll
- Analyze received compliant information of product quality defect for input intelligent information sharing
- Conduct surveys to assist in the preparation of regulatory information on regulated products
- Facilitate the necessary trainings for the employees under the desk to build their capacity
- Prepare information that can be used for regulatory information by working in cooperation with other units in the sector.
- Prepare detailed operating instructions to make the work process efficient and effective for the preparation of regulatory data, and monitor its implementation.
- Organize and provide information to stockholders on the main regulatory issues: such as storage or production area (Premises), Professionals, product, Practice.

- Prepare list of questions and provide feedback on the quality, safety, efficacy and rational use of medicines from the public and health professionals about the health professionals and health institutions that the EFDA regulate.
- Promote the activities of the center, establish relationships with centers in other countries, conduct studies on the information provided to the public and health professionals, and follow up on their implementation based on the research in order to increase the overall capacity of the health regulatory information center,
- Monitor international and national current information about alert that may cause harm to the society
- Facilitate the storage of regulatory information in a database in an organized manner for analysis and retrieval of the information when required.
- In collaboration with PVTC LEO, disseminate current and reliable information on quality and safety of food and medicines, health professionals, traditional and complementary medicines. Ensure and monitor that the information reached the target audience properly, collect and use the feedback as input for improvement
- Collect and organize information on health and health-related institutions that have been subject to regulatory measures, the information will be provided to the public and other relevant parties.
- Evaluate performance and design strategies for strengthening the regulatory information system.
- Together with the lead executive office, supervise the proper conduct of the preparation of regulatory information

2.2.4. Management Chief Executive Office

a. Introduction

The Management Chief Executive Office plans, organizes, directs, monitors and supports, coordinates, provides operational and policy directions for the subordinates to be effective, and formulates strategies to build the capacity of the subordinates; Makes decisions on matters beyond the executive's control; Communicates decisions and directions as an institution; It designs the next management procedures and strategies of the institution, creates ownership and partnership by introducing and creating awareness about management to the society and stakeholders, works on behalf of the authority to establish effective and sustainable cooperation, and is organized to help the director general by ensuring that works are being done properly.

b. Organization and accountability

The Management Chief Executive Office has been accountable to the Director General and it has the following seven Executive Offices;

1. Strategic Affairs Executive Office
2. Procurement and Finance Executive Office
3. Competency and Human Resource Administration Executive Office
4. Information and Communication Technology Executive Office
5. Women's and Social Affairs Inclusive Implementation Executive Office
6. Organizational Change Management Executive Office
7. Basic service Executive Office

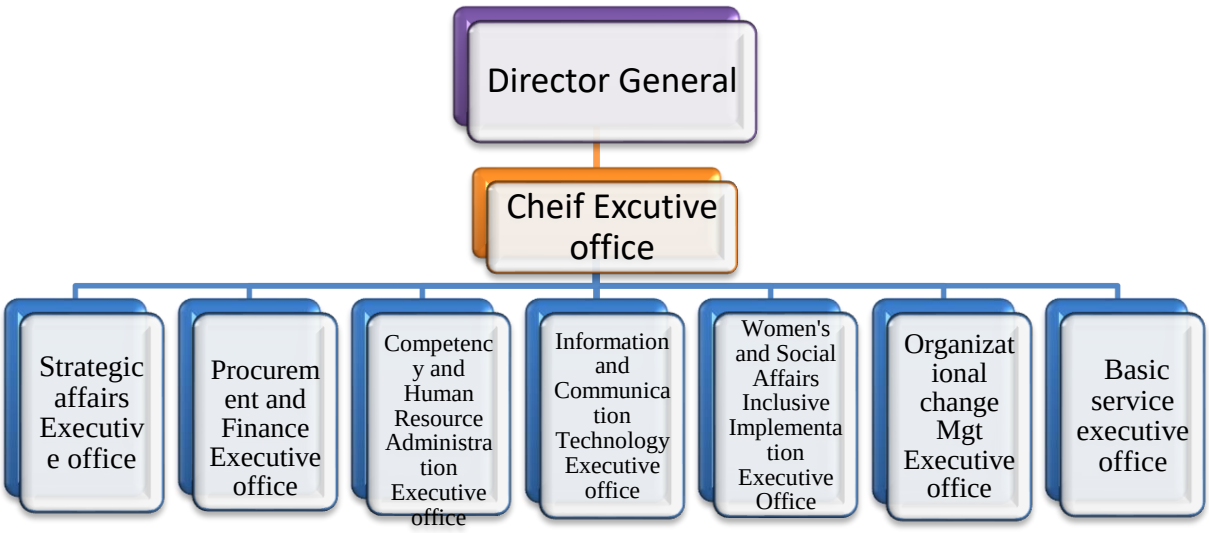


Fig 2.2.4: *Management Chief Executive Office Organizational Chart*

c. Duties and Responsibilities of the Management Chief Executive Office

- Coordinates the development of strategies, programs and strategies directed by the operational management.
- By identifying the legal gap of the work management, rules and regulations will be prepared by the relevant work executive's office.
- Ensures that policies, laws, operating instructions and standards are properly implemented by Executive offices.
- Ensures that sufficient budget is allocated for executive activities, and monitors the appropriate use of the allocated budget.
- support, monitors and coordinates the Executive offices to do effective work
- To create a strong working relationship and coordination between the Executive offices and take corrective action by quickly evaluating gaps when they arise.
- The performance parameters set to measure the effectiveness and efficiency of the executive offices will be evaluated periodically to ensure their effectiveness.
- Professionals in the field of work implement strategies and programs in order to improve their performance, and monitor their implementation.
- Designs incentive strategies to encourage professionals who achieve effective performance, and monitors its implementation.
- It creates ownership and partnership by promoting and creating awareness of the executive's strategies and practices to the community and stakeholders.
- Regarding the executive, works to establish effective and sustainable cooperation with international and national institutions on behalf of the authority.
- Evaluating, controlling, verifying, directing and coordinating the activities performed by the executive offices under the sector.
- Monitoring and supporting the activities carried out by the executives under the sector;
- Directing and coordinating the access to capacity building training by executives and professionals under the sector;

2.2.4.1. Strategic Affairs Executive Office

a. Introduction

The Strategic Affairs Executive Office plays a key role in guiding EFDA towards a strategic and long-term operational framework. It focuses on developing sustainable solutions, strengthening financial resources, and building institutional capacity beyond short-term problem-solving. The office is responsible for designing, resourcing, and implementing strategic plans and projects aligned with the Authority's vision and mission. It also leads essential project planning, resource mobilization, and management. Overall, it drives EFDA's shift from reactive operations to a more strategic and transformative approach.

b. Organization and accountability

The Strategic Affairs Executive Office has been accountable to the chief executive office and will have the following Two Team under its structure

1. Planning, Budgeting, Monitoring and Evaluation Team
2. Projects, Resource Mobilization, and Grant Management Team

Fig 2.2.4.1: *Strategic Affairs Executive Office Organizational Chart*

c. Duties and Responsibilities of the Strategic Affairs Executive Office

- Provide overall management and strategic direction of the office.
- Ensure coordination and consistency between all planning, budgeting, projects, and grants activities.
- Guarantee that all plans, budgets, projects, and grants align with the Authority's vision, mission, and strategic priorities.
- Develop, update, and improve the Authority's long-term, medium-term, and short-term strategic plans.
- Formulate operational implementation strategies to achieve the Authority's overall objectives.
- Draft and/or amend proclamations, regulations, directives, and policies for the regulatory sector.
- Ensure the implementation and monitoring of the Authority's strategic plans across all regions, zones, and districts.
- Develop national studies, training programs, documents, and operational systems and monitor their implementation.
- Prepare annual program budget that is aligned with the Authority's strategic priorities.
- Manage and control the budget allocated at the Authority level.
- Prepare and submit annual, quarterly, and monthly budget requests to relevant bodies.
- Evaluate budget utilization by comparing it with planned outcomes and implement necessary corrective actions.
- Execute, monitor, and improve all budget operations on the IFMIS.
- Collaborate with relevant departments on budget reconciliation, adjustments, and continuous improvement of financial operations.
- Conduct joint budget utilization reviews with relevant internal and external bodies.
- Prepare a budget utilization analysis and present it to the management committee.

- Identify, formulate, and develop projects that align with the Authority's responsibilities and strategic operations.
- Prepare project concepts, proposals, and detailed project implementation plans.
- Manage projects from inception to closure, monitoring implementation and preparing completion reports.
- Develop a project risk management framework and monitor its implementation throughout the project lifecycle.
- Identify the financial resources needed to support the Authority's projects and programs.
- Develop and implement a comprehensive resource mobilization strategy.
- Build and maintain strong partnerships with development partners, international organizations, and private sector entities.
- Provide project proposal documents to secure funding from donors and partners.
- Facilitate the signing of contracts and agreements with donors and project partners.
- Manage full grant cycle, including inception, agreement, implementation, monitoring, and closure.
- Ensure all financial transfers, project activities, and grant requirements comply with donor agreements and the Authority's internal policies and financial directives.
- Ensure grant funds are utilized efficiently, transparently, and with accountability.
- Develop the overall M&E framework of the Authority.
- Establish Key Performance Indicators (KPIs) for plans and projects to measure results.
- Collect and analyze performance data to inform management decisions and strategic planning.
- Prepare evaluation reports, highlighting successes, challenges, and recommendations for improvement.
- Ensure data integrity and monitor the quality of all performance data.
- Prepare and submit monthly, quarterly, semi-annual, and annual performance reports for the Authority and the regulatory sector.

- Plan performance review forums and ensure corrective actions are taken based on findings.
- Support senior management by reviewing all performance reports and providing strategic recommendations for improvement.
- Coordinate joint planning and performance review activities with RRBs.
- Evaluate internal team performance and implement necessary corrective actions.
- Manage all high-level communication related to strategic matters for the Authority's senior leadership.
- Develop and provide M&E capacity-building training to staff across the Authority.
- Submit regular financial and performance reports to donors and partners as required.
- Manage financial controls to ensure all project and operational expenditures are consistent with approved budgets.

d. Duties and Responsibilities of Planning, Budgeting, Monitoring and Evaluation Team

- Develop, update, and improve the Authority's long-term, medium-term, and short-term strategic plans.
- Formulate operational implementation strategies to achieve the Authority's vision, mission, and overall objectives.
- Draft and/or amend proclamations, regulations, directives, and policies for the regulatory sector.
- Ensure the implementation and monitoring of the Authority's plans across regions, zones, and districts.
- Develop national studies, training programs, documents, and operational systems and monitor their implementation.
- Continuously improve and provide support for the M&E of plan implementation.
- Prepare and submit monthly, quarterly, semi-annual, and annual performance reports for the Authority and the regulatory sector.
- Plan performance review forums and ensure corrective actions are taken.
- Prepare annual program budget that aligns with the Authority's strategic priorities.

- Manage and control the budget allocated at the Authority level.
- Prepare and submit annual, quarterly, and monthly budget requests.
- Evaluate budget utilization comparing with planned outcomes and taking corrective actions.
- Execute, monitor, and improve budget operations on IFMIS.
- Continuously monitor and improve budget operations, and collaborate with relevant departments on reconciliation and adjustments.
- Conduct joint budget utilization reviews with relevant bodies.
- Prepare a budget utilization analysis and present it to the management committee.

e. Duties and Responsibilities of Projects, Resource Mobilization, & Grant Management Team

- Identify, formulate, and develop projects that align with the Authority's responsibilities and operations.
- Prepare project concepts, project implementation documents (proposals), and detailed project plans.
- Manage projects from start to finish, monitoring their implementation and preparing project completion reports.
- Develop a project risk management framework and monitor its implementation.
- Coordinate and monitor communication among project stakeholders.
- Submit project performance reports to donors and partners.
- Identify the financial resources needed to support the Authority's projects and programs.
- Develop and implement a resource mobilization strategy.
- Build and plan strong partnerships with development partners, international organizations, operational partners, and private sector entities.
- Provide high-quality project proposal documents to secure funding.
- Ensure that financial transfers and project activities comply with the requirements of donor partners and the Authority's internal policies.
- Facilitate the signing of contracts with donors and project partners.

- Ensure that relevant parties fulfill their expected roles.
- Manage the full grant cycle (inception, agreement, implementation, monitoring, and closure).
- Ensure that all past grant agreement requirements have been met.
- Ensure that grant funds are utilized efficiently, transparently, and with accountability.
- Prepare and submit regular financial and performance reports to donors and partners.
- Manage financial controls and ensure that project expenditures are consistent with the approved budget.
- Strictly adhere to the Authority's financial directives and grant agreements.

2.2.4.2. Competency and Human Resource Administration Executive Office

a. Introduction

The workforce is an organization’s most valuable resource. The Executive Office should focus on attracting qualified candidates and retaining top talent. This includes offering career development and training to prepare employees for current and future roles. Fair compensation should be ensured through competitive pay structures and benefits that reward performance. Productivity and efficiency can be improved through effective performance management systems.

Strong employee relations must be fostered through open communication, teamwork, and addressing employee concerns. The human resource function should ensure compliance with legal, ethical, and policy standards, aligning workforce planning with organizational goals. Supporting employee motivation and well-being involves promoting work-life balance, job satisfaction, and engagement. Human resource should also guide employees through organizational changes and foster a culture rooted in values, discipline, and a positive work environment.

b. Organization and accountability

The Competency and Human Resource Administration Executive Office has been accountable to the chief executive office and will have the following Three Team under its structure;

1. Human Resource Administration Team
2. Human Resource Competency and Development Team

3. Record and Archive Management Service Team

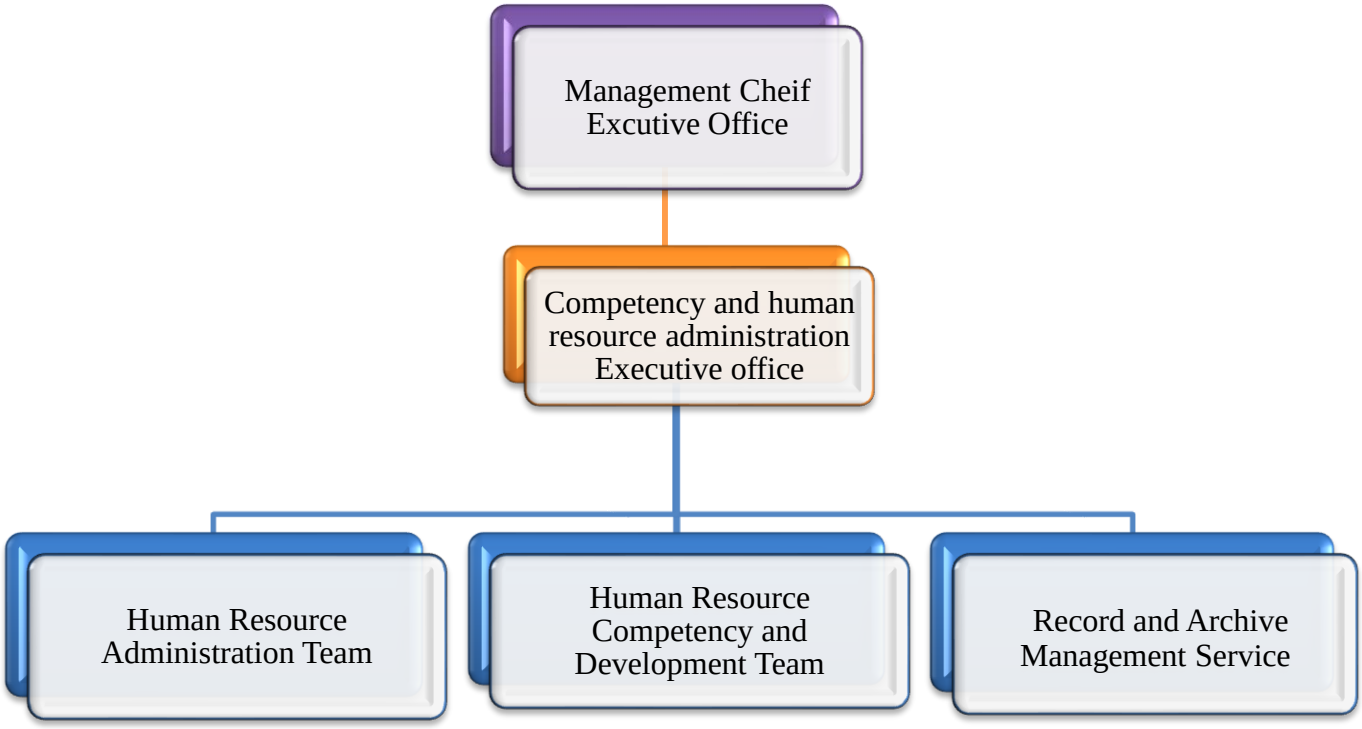


Fig 2.2.4.2: *Competency and Human Resource Administration Executive Office Organizational Chart*

c. Duties and Responsibilities of the Competency and Human Resource Administration Executive Office

- Prepare job descriptions and specifications.
- Advertise vacancies, screen, and interview candidates. and select, place the right person in the right job position.
- Identify training needs of employees.
- Plan and forecast workforce need
- Organize orientation for new staff.
- Provide skill development and capacity-building programs.
- Develop future leaders through succession planning.

- Monitor and evaluate employee performance.
- Conduct appraisals and provide feedback. And Reward high performers and manage under performance.
- Motivate employees through incentives and recognition programs.
- Maintain healthy employee–employer relationships.
- Handle grievances, complaints, and disciplinary actions.
- Promote teamwork, communication, and collaboration.
- Prevent and manage workplace conflicts.
- Ensure compliance with civil service laws and regulations.
- Develop and implement human resource policies and procedures.
- Enforce occupational health and safety standards.
- Manage contracts and employee records.
- Develop succession plans for key positions.
- Conduct human resource analytics for decision-making.
- Promote job satisfaction and motivation.
- Organize employee engagement activities.
- Support work-life balance and wellness programs.
- Reduce turnover and improve retention.

d. Duties and Responsibilities of the Human Resource Administration Team

- prepares an annual human resource plan according to the plan
- Identifying the necessary positions and preparing the job list.
- According to the guidelines issued to meet the required skills and human resources required for the open positions.
- For new employees who join the structure of the school, before they start work, according to the familiarization program, they will get an understanding of the school's general organization and procedures, labor management laws and human resource management policies.

- Monitors the performance evaluation results of employees to ensure that they are completed in a timely manner and submits a comprehensive report.
- Based on the results of the evaluation of the performance of the employees, the employees who will benefit the staff.
- Provides prompt response to various services provided by the employee, such as leave, termination of employment contract, pension, guarantee, medical experience and other services.
- Makes workers who are out of work to take the necessary steps in compliance with the government's regulations and directives.
- Investigates cases of disciplinary indiscipline and makes a decision based on the law.
- Identifying work areas that may cause accidents in the work area and monitoring the implementation by ensuring that the employees who are engaged in the work are provided with accident protective clothing and milk in a timely manner.
- In order to protect the health and safety of the school's employees and improve their work efficiency, the workplaces will be suitable for the employees, and the equipment and materials used for the safety and health of the work environment will be studied and completed.
- By giving appropriate awareness to the employees regarding safety and health at work and HIV AIDS prevention in the workplace.
- Organizes the staff information of the organization and makes it supported by integrate civil service management information system (ISCMIS)
- Open and keep personal profile by hard copy and system

e. Duties and responsibility of Human Resources Competency and Development Team

- Prepares a training plan and action plan.
- Conducting training needs survey, identify training needs
- Prepare manuals and modules to provide trainings and lessons that build leadership and executive skills.
- Develop the knowledge of employees and to provide timely services,

- Identify organization long-term training based on required job position tasks
- Evaluate the effectiveness of the trainings provided, and based on the evaluation, makes suggestions for improvement.
- Conducts training system improvement studies;
- Keep Training and education records according to the SOPs
- Designs a fundraising project for training; makes suggestions and develop a system that will enable them to work together with training institutes and universities in the country and abroad.
- Based on the results of the evaluation of the work performance of the employees, evaluates those with low results and helps them with training.

f. Duties and responsibility of Records and Archives Management Service

- Register, file, and index official documents for easy retrieval.
- Maintain accurate records of incoming and outgoing correspondence.
- Ensure security, confidentiality, and integrity of records.
- Identify records of long-term value and transfer them to archives.
- Implement proper storage systems to prevent damage, deterioration, or loss.
- Digitize physical records to ensure long-term accessibility.
- Provide authorized staff with timely access to required documents.
- Maintain a tracking system for borrowed or accessed files.
- Ensure records management practices comply with national laws, regulations, and organizational policies.
- Support legal and audit processes by providing accurate documentation when required.
- Implement data protection and privacy measures.
- Maintain a records retention schedule (how long records should be kept).
- Coordinate safe and authorized destruction of obsolete or non-essential records.
- Train staff on proper records creation, handling, and storage.
- Promote awareness of records management policies within the organization.
- Prepare reports on records management activities for management review.

- Keep an updated inventory of all records and archives.

2.2.4.3. Procurement and Finance Executive Office

a. Introduction

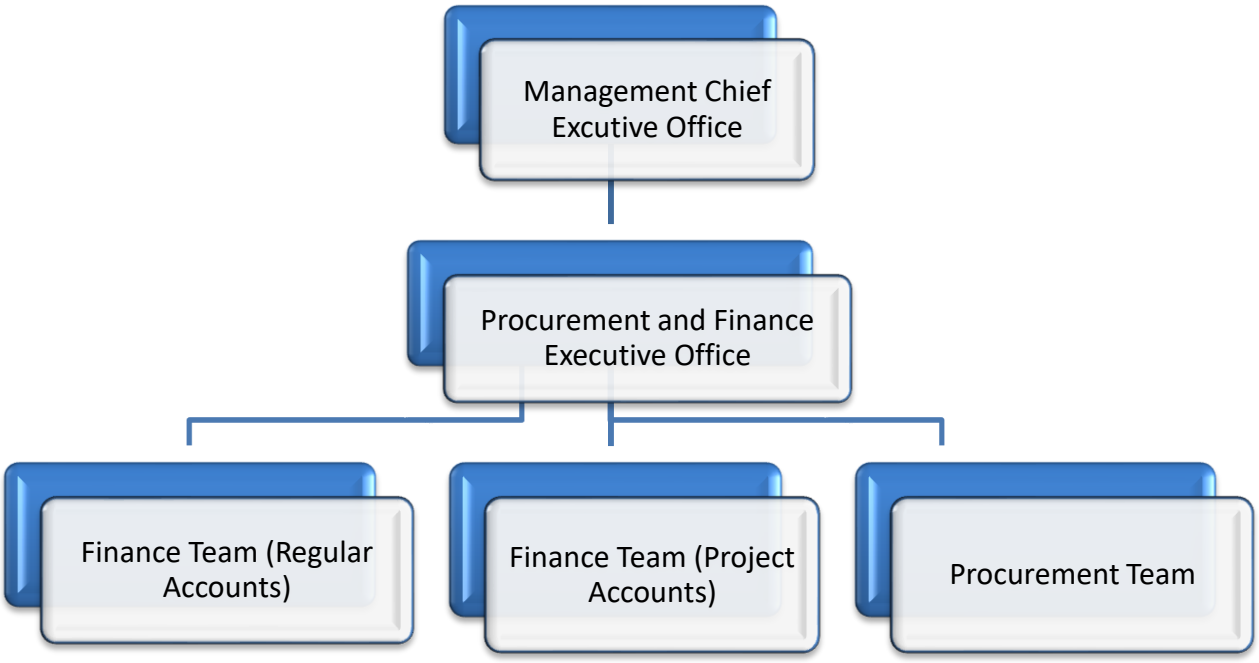
The main purpose of the Procurement and Finance Executive Office is to provide the necessary resources to effectively fulfill the organization's mission. To achieve this, it involves controlling the appropriate allocation and use of the allocated budget, as well as providing the necessary materials and services for various programs and activities in a timely manner. This office provides crucial support for the success of the organization by establishing a strong system for responsible and transparent management of money and assets, implementing financial and procurement guidelines, and regularly reviewing its operations.

Therefore, the work of this office ranges from paying employee salaries to large-scale construction and technology procurements. All tasks are carried out in compliance with laws and regulations. Overall, the financial and supply support provided by this department strengthens the organization's efforts to protect public health and safety by improving the quality and accessibility of services it provides to the community.

b. Organization and accountability

The Procurement and Finance Executive Office is accountable to the Management Chief Executive Office and it has the following three Team.

1. Finance Team (Regular Accounts)
2. Finance Team (Project Accounts)
3. Procurement Team



c. Duties and Responsibilities of the Procurement and Finance Executive office

- Ensures that the organization's procurement system is executed in accordance with procurement directives and related laws.
- Ensures that procurements made by the organization are aligned with its strategic and operational plans.
- Ensures that branch offices conduct procurements in compliance with laws and regulations, based on the authority delegated to them. The Executive also makes sure there is no redundant procurement at the headquarters and branch offices.
- Facilitates various opportunities for procurement experts to enhance their performance to make the procurement process swift, efficient, and cost-effective.
- Ensures the establishment of a database containing a list of suppliers and products related to the organization's work and monitors its performance over time.

- Ensures that information on suppliers who have not fulfilled their contractual obligations or have had performance issues is recorded. Appropriately forwards their details to the relevant federal institution for blacklisting.
- Ensures that clear and specific bidding documents are prepared for goods and services to be procured through bidding. Also ensures that bids are released, documents of bidders are evaluated, and the winner is identified. Handles complaints and grievances as appropriate, approves the bid winner, issues a work order, and ensures the procurement is executed by entering into a contract. Monitors and controls that the procurement is completed as per the contract.
- Ensures that bid bonds and performance guarantees are handled properly. Makes sure that the guarantees deposited by bidders who failed to meet their obligations are deposited into the organization's account before the deadline expires.
- Ensures that purchased goods meet the technical specifications or required quality standards as per the bidding document by establishing an inspection committee or using an expert, as appropriate.
- Monitors and ensures that the bidding process is conducted according to the established performance standards.
- Ensures that market research is conducted.
- Conducts regular discussions with suppliers to ensure that the procurements carried out by the organization are transparent, inclusive, and accountable. Informs them of the organization's annual procurement needs and focus areas. Collects constructive feedback from suppliers on bid documents and acts on it as appropriate.
- Works with the strategic affairs executive to prepare the organization's annual budget request. Together with the relevant departments, presents and clarifies the budget to the approving body to ensure its approval.
- Opens or closes the organization's bank account when necessary.

- Monitors and ensures that the organization's revenue is collected in a timely manner according to the plan and deposited into the bank. Ensures that a revenue report is prepared based on the approved revenue plan.
- Verifies that the budget is available before any payment is made under any budget line item and monitors and controls that the budget is used only for its intended purpose. Ensures that an expenditure and revenue report is prepared based on the approved budget.
- Ensures that the bank account is reconciled in a timely manner. If errors occur, ensures they are corrected before the bank's deadline expires.
- Monitors and ensures that revenue and expenditure account documents are recorded and maintained in a timely manner.
- Ensures that the organization's account reports are prepared and a financial summary is made in a timely manner. Submits the report to the relevant body.
- Ensures that payments are made after verifying the legality of any payment made by the organization.
- Ensures that the payroll for managers and employees is prepared in a timely manner through the strategic affairs executive and that payments are made. Ensures that pension contributions, employment tax, and other deductions are made in accordance with the law.
- Records accounts payable and receivable, including who to pay, when to pay, who to collect from, and when to collect. Monitors their performance over time.
- Ensures that financial documents are up-to-date and properly organized, reconciled in a timely manner, compiled, and that account adjustments are made.
- Monitors and ensures that the withholding tax, value-added tax, bid bond, performance bond, C.P.O, insurance, or bank guarantee deducted from suppliers during procurement are properly handled and that appropriate action is taken in accordance with the law and regulations.

d. Duties and Responsibilities of the Finance Team (Regular Accounts)

- Prepares an annual revenue plan and submits it to the relevant body for approval.

- Collects the organization's revenue in a timely manner according to the plan and deposits the collected amount into the bank. Prepares a revenue report based on the approved revenue plan and submits it to the work process.
- Monitors that working capital funds are sent to branch offices in a timely manner.
- Supports branch offices and monitors that their accounts are reconciled in a timely manner.
- Monitors the collection and deposit of service fees collected at branch offices and checkpoints, as per the approved service fee schedule.
- Verifies and monitors the payment of various service fees, procurements, per diem allowances, overtime, etc.
- Monitors, supports, and coordinates the performers under its supervision. Provides performance feedback.
- Executes, monitors, leads, and controls the organization's financial operations in accordance with laws, regulations, and directives.
- Submits a request to the directorate to open or close the organization's bank account when necessary and monitors its implementation.
- Prepares the organization's annual financial budget in collaboration with the relevant departments and plays its part in ensuring the budget is approved during the budget hearing.
- Submits a request to the executive based on current payments to avoid a cash shortage.
- Ensures that the payroll for managers and employees is prepared in a timely manner and that payments are made. Ensures that pension contributions, employment tax, and other deductions are made in accordance with the law.
- Ensures that the budget is available before any payment is made under any budget line item. Monitors and controls that the budget is used only for its intended purpose. Prepares an expenditure and revenue report based on the approved budget and submits it to the directorate.

- Ensures that the bank account is reconciled in a timely manner. If errors occur, ensures they are corrected before the bank's deadline expires.
- Makes payments for input procurements after verifying that the necessary documents are in place.
- Ensures that payments are made after verifying the legality of any payment made by the organization.
- Monitors and ensures that the withholding tax and value-added tax deducted from suppliers during procurement, as well as bid bonds, performance bonds, C.P.O, insurance, or bank guarantees, are properly handled and that appropriate action is taken in accordance with the law and regulations.
- Monitors bank account activity and ensure any problems are resolved in a timely manner.
- Ensures that financial documents are properly organized and provides information when requested.
- Arranges for the annual accounts to be audited by internal and external auditors and prepares a corrective action plan for any findings.
- Fills out performance evaluation for employees under its supervision in a timely manner.
- Submits the team's performance reports to the directorate and takes necessary action based on the information and feedback provided by the directorate.
- Performs other work-related duties as assigned by the directorate.
- Prepares monthly, quarterly, and annual budget disbursement plans, gets them approved by the relevant official, and submits them to the Ministry of Finance for approval. Notifies the relevant bodies when approved.
- Releases the budget for monthly salary payments by providing the necessary information/documents.
- Monitors, supports, and coordinates the performers under its supervision. Provides performance feedback.
- Executes, monitors, leads, and controls the organization's financial operations in accordance with laws, regulations, and directives.

- Prepares the organization's annual financial budget allocation and request in collaboration with the relevant departments and plays its part in ensuring the budget is approved during the budget hearing.
- Prepares payment request documents based on current payments and submits them to the department head to avoid a cash shortage.
- Ensures that the budget is available before any payment is made under any budget line item. Monitors and controls that the budget is used only for its intended purpose. Prepares an expenditure and revenue report based on the approved budget and submits it to the directorate.
- Monitors capital payments sent to branch offices and ensures they are reconciled. Performs account registration.
- Makes payments for various input and service procurements to be used for the project's work.
- Monitors and ensures that the withholding tax and value-added tax deducted from suppliers during procurement, as well as bid bonds, performance bonds, C.P.O, insurance, or bank guarantees, are properly handled and that appropriate action is taken in accordance with the law and regulations.
- Performs the registration of project expenditure and revenue accounts. Monitors that bank account reconciliations with ledger accounts are performed and ensures a report is submitted to the department head.
- Prepares a financial analysis based on the financial statements and submits it to the directorate.

e. Duties and Responsibilities of the Finance Team (Project Accounts)

- Prepares the organization's aid-related account reports on a monthly/timely basis and a financial summary, which it submits to the directorate.
- Monitors and controls that project financial documents are properly organized and kept separate.
- Monitors bank account activity and ensure any problems are resolved in a timely manner.

- Arranges for the financial revenue and expenditure accounts to be audited by internal and chief auditors on a monthly basis. Prepares an action plan based on the findings and submits it to the executive.
- Ensures that account adjustments and registration for donor organizations are performed during the budget year. Ensures that the account is reconciled in a timely manner and a report is prepared for the relevant bodies.
- Ensures that the organization's capital project account is closed in a timely manner.
- Works with the relevant teams to arrange for the annual accounts to be audited by internal and external auditors and prepares a corrective action plan for any findings.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Submits the team's performance reports to the directorate and takes necessary action based on the information and feedback provided by the directorate.
- Performs other work-related duties as assigned by the executive.

f. Duties and Responsibilities of the Procurement Team

- Prepares the team's plan, monitors its implementation, and evaluates its performance.
- Monitors, supports, and coordinates the performers under its supervision. Provides performance feedback.
- Executes the organization's procurement system in accordance with procurement directives and related laws.
- Ensures that the procurement is aligned with the organization's plan.
- Monitors that branch offices conduct procurements in compliance with laws and regulations, based on the authority delegated to them.
- Monitors appropriately to prevent redundant procurement at the headquarters and branch offices.
- Develops and implements strategic and operational plans for procurements at every level.
- Facilitates opportunities for procurement experts within the team to receive training to fill any knowledge and skills gaps they may have.

- Ensures that clear and specific bidding documents are prepared for goods and services to be procured through bidding.
- Monitors and ensures that the bidding process is conducted according to the established performance standards.
- Monitors and controls the collection of annual procurement needs from departments based on their budget.
- Conducts regular discussions with suppliers to ensure that the procurements carried out by the organization are transparent, inclusive, and accountable. Informs them of the organization's annual procurement needs and focus areas. Collects constructive feedback from suppliers on bid documents and acts on it as appropriate.
- Ensures the establishment of a database containing a list of suppliers and products related to the organization's work and monitors its performance over time.
- Conducts market research using various methods, such as information gathered from the Central Statistical Agency, the Procurement Agency, the market, government suppliers, peer organizations, the organization's past procurements, etc. Ensures that a price index for goods is prepared and approved and that it is kept up-to-date.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Submits the team's performance reports to the directorate and takes necessary action based on the information and feedback provided by the directorate.
- Performs other work-related duties as assigned by the directorate.
- Ensures that departments receive an up-to-date price index before their procurement request is submitted so they can align their annual procurement needs with their budget.
- Conducts procurements using various methods, such as bidding, limited bidding, request for quotation, direct procurement, etc.
- Ensures that information on suppliers who have not fulfilled their contractual obligations or have had performance issues is recorded. Appropriately forwards their details to the relevant federal institution for blacklisting.

- Ensures that bids are released, documents of bidders are evaluated, and the winner is identified. Handles complaints and grievances as appropriate, approves the bid winner, issues a work order, and ensures the procurement is executed by entering into a contract.
- Receives bid bonds and performance guarantees and ensures they are transferred to the finance support work process in a timely manner. Ensures that the guarantees deposited by bidders who failed to meet their obligations are deposited into the organization's account before the deadline expires.
- Ensures that purchased goods meet the technical specifications or required quality standards as per the bidding document by establishing an inspection committee or using an expert, as appropriate.
- Ensures that clear and specific bidding documents are prepared for goods and services to be procured through international open bidding, limited bidding, and direct procurement.
- Monitors and ensures that the bidding process is conducted according to the established performance standards.
- Obtains the necessary foreign currency approval, opens a letter of credit, and ensures that all related work is carried out in compliance with the procurement process to ensure inputs are provided.
- Receives inputs coming from abroad as donations or procurements by completing the necessary customs procedures.
- Reconciles foreign currency accounts that have been approved by the National Bank and used.
- Ensures the establishment of a database containing a list of suppliers and products related to the organization's work and monitors its performance over time.
- Conducts market research using various methods, such as information gathered from the Central Statistical Agency, the Procurement Agency, the market, government suppliers, peer organizations, the organization's past procurements, etc. Ensures that a price index for goods is prepared and approved and that it is kept up-to-date.

- Ensures that departments receive an up-to-date price index before their procurement request is submitted so they can align their annual procurement needs with their budget.
- Ensures that information on suppliers who have not fulfilled their contractual obligations or have had performance issues is recorded. Appropriately forwards their details to the relevant federal institution for blacklisting.
- Ensures that international bids are released, documents of bidders are evaluated, and the winner is identified. Handles complaints and grievances as appropriate, approves the bid winner, issues a work order, and ensures the procurement is executed by entering into a contract.
- Receives bid bonds and performance guarantees and ensures they are transferred to the finance support work process in a timely manner. Ensures that the guarantees deposited by bidders who failed to meet their obligations are deposited into the organization's account before the deadline expires.
- Monitors and controls that the procurement is completed as per the contract.
- Ensures that purchased goods meet the technical specifications or required quality standards as per the bidding document by establishing an inspection committee or using an expert, as appropriate.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Performs other work-related duties as assigned by the directorate.
- Submits the team's performance reports to the executive and takes necessary action based on the information and feedback provided.

2.2.4.4. Information Communication Technology Executive Office

a. Introduction

The Information Technology Executive Office (ICT EO), under the Management Chief Executive Office, oversees the organization's technology operations. Its core mandate is to plan, implement, and manage technological resources to support institutional ICT functions, drive digital transformation, maintain infrastructure, and promote innovation.

The ICT EO is responsible for directing and coordinating all ICT functions, including network management, software development, hardware maintenance, database and website management, systems administration, and security. Working closely with other LEOs and stakeholders, the ICT EO ensures a secure, efficient, and responsive technology environment. It plays a central role in shaping the Authority's technology strategy, aligning ICT initiatives with institutional goals, and driving operational excellence to support the Authority's long-term vision.

The office ensures that digital systems, communication tools, and information services effectively support the Authority's mission. It also leads digital transformation efforts, introduces emerging technologies, and enforces information security standards to ensure the delivery of secure and reliable digital services.

Additionally, the ICT EO is tasked with digitizing Authority services by developing and maintaining software, hardware, databases, and web systems to ensure seamless digital service delivery. This aligns with government priorities for administrative and service reforms, particularly the pillar of digitalization—ensuring public services are easily accessible, fully digital, paperless, and supported by organized systems for feedback and complaint management.

b. Organization and accountability

The Information Communication Technology Executive Office is accountable to the Management Chief Executive Office and it has the following two Team

1. Information Communication Technology Team
2. System Administrator Team

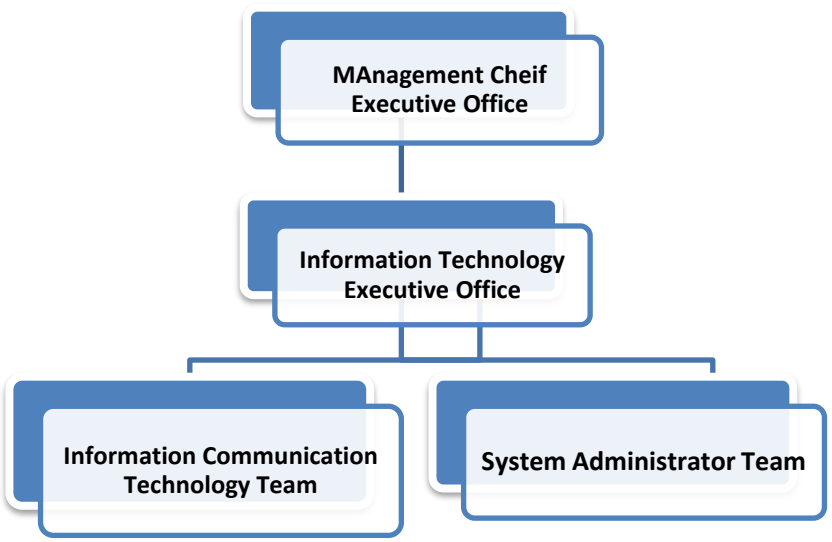


Fig 2.2.4.4: *Information Communication Technology Executive Office Organizational Chart*

c. Duties and Responsibilities of the Information Communication Technology Executive Office

- Provide strategic leadership in the application of information technology to advance the Authority's goals and objectives.
- Develop, manage, and safeguard the Authority's technology infrastructure, systems, and applications.
- Establish effective communication channels, oversee information management, and make informed decisions on technology services.
- Lead digital transformation initiatives aimed at enhancing operational efficiency and improving service delivery.
- Ensure full compliance with cybersecurity standards, data protection requirements, and applicable regulatory frameworks.
- Provide leadership in strategic planning and ICT governance to ensure alignment with the Authority's mandate and objectives.
- Oversee the management and maintenance of information and technology infrastructure, systems, and platforms.

- Implement and enforce measures to manage cybersecurity, mitigate risks, and safeguard digital assets.
- Lead digital transformation initiatives and promote the adoption of innovative technologies.
- Ensure the effective delivery of customer and user support services to enhance operational efficiency.
- Manage the acquisition, utilization, and lifecycle of technology assets and ICT equipment.
- Promote capacity building and professional development of ICT personnel and the remaining staff to strengthen institutional capability.

d. **Duties and responsibilities of Information Communication Technology Team**

- **Monitoring and Evaluation**
  - Monitor and evaluate the status of deployed ICT infrastructure and systems, ensuring timely corrective actions are taken to address deficiencies.
  - Assess and enhance the performance, reliability, and efficiency of ICT operations.
- **Technological Support and Tools**
  - Provide the necessary technological support to record sector developments and operational changes.
  - Select appropriate technological tools and provide professional support to work units.
  - Support the implementation and maintenance of databases developed by partner organizations.
- **Service Management and User Support**
  - Receive, track, and resolve complaints regarding ICT services from internal and external stakeholders.
  - Monitor and support necessary improvements in ICT service delivery.
  - Provide technical assistance to users in person or remotely, troubleshooting hardware, software, and network issues.
  - Prioritize and resolve technical issues while maintaining positive working relationships with users and stakeholders.

- **Coordination and Collaboration**
  - Ensure a well-coordinated ICT system between work units and promptly address operational gaps.
  - Collaborate with relevant departments to build staff capacity in ICT competencies.
  - Coordinate and provide direction to ICT personnel, including computer maintenance technicians, network administrators, and technical support specialists.
- **ICT Planning and Policy Implementation**
  - Prepare and implement ICT strategy documents as required by the Authority.
  - Develop and enforce ICT guidelines and policies in collaboration with relevant work units.
  - Implement government-mandated ICT policies and regulations.
- **Infrastructure Development and Maintenance**
  - Improve and maintain the ICT infrastructure deployed across the Authority's offices.
  - Ensure newly established or rented offices are equipped with the necessary ICT infrastructure.
  - Provide ongoing maintenance and support for ICT infrastructure at branch offices and operational entry/exit points.
  - Monitor the electrical safety of computer and network equipment.
- **Systems Administration and Technical Operations**
  - Install, configure, and maintain computer hardware, operating systems, and software applications.
  - Monitor and support computer systems and networks to ensure smooth operations.
  - Troubleshoot system and network problems, diagnose hardware or software faults, and implement solutions.
  - Support the release and deployment of new applications and systems.
  - Prepare system documentation and reports to support ICT management and decision-making.
- **Innovation and Technology Assessment**

- Test and evaluate new technologies to ensure continuous improvement of ICT operations.
- Recommend and implement technological innovations to enhance service delivery and operational efficiency.

- **Team Composition and Scope**
  - The Desk includes maintenance staff, customer support personnel, network administrators, and ICT service professionals, working collaboratively to ensure seamless ICT operations.

e. Duties and Responsibilities of the System Administrator Team

- **Team Coordination and Leadership**
  - Coordinate and provide direction to systems analysts, software programmers, database administrators, and other core ICT staff, including Information Technology Cybersecurity Specialists and DevOps Specialists.
  - Guide team members in system deployment, application management, and security practices.
  - Foster collaboration between stakeholders, technical teams, and end-users to ensure system requirements are clearly understood and addressed.
- **Systems and Application Management**
  - Support the release, installation, configuration, and deployment of new applications and systems.
  - Maintain, upgrade, and optimize existing software and hardware to ensure compatibility and efficiency.
  - Develop alternative solutions to anticipated problems and adapt applications to new functional requirements.
  - Monitor system performance, utilization, and user access to optimize efficiency.
  - Prepare detailed system and application documentation, manuals, and reports for operational reference.
  - Promote user awareness and training on new applications and system updates.
- **Database Administration**

- Design, implement, and maintain database structures, including virtual mapping and storage planning.
- Install and test database management system (DBMS) updates and new versions.
- Monitor database usage, backups, and recovery procedures to ensure data integrity and consistency.
- Respond promptly to user issues and provide technical support for database operations.
- Ensure the security of databases through consultation with technical experts and application users.

- **Cybersecurity and Risk Management**
  - Develop, implement, and monitor information security programs, policies, procedures, and technical standards at all organizational levels.
  - Proactively identify security vulnerabilities in systems and networks, report issues, and develop remediation plans.
  - Design, maintain, and improve security infrastructure, including disaster recovery and alternative service delivery systems.
  - Monitor, detect, and respond to cyberattacks, intrusion events, unauthorized access, and malicious activities.
  - Evaluate security applications, verify provider certificates, and ensure systems comply with national and organizational security policies.
  - Prepare cybersecurity performance reports and inform technology stakeholders on system status and security events.
  - Conduct security awareness training for staff to promote proactive risk mitigation.
- **Systems Monitoring and Troubleshooting**
  - Monitor computer systems, networks, and application performance to identify potential improvements.
  - Troubleshoot hardware, software, and network issues, diagnose defects, and provide solutions.
  - Collect information from users to configure systems and assist in problem resolution.

- Test usability, evaluate success of applications, and recommend enhancements for operational effectiveness.

- **Documentation and Reporting**
  - Prepare system, database, and cybersecurity documentation, reports, and manuals for operational guidance.
  - Record findings, incidents, and preventive actions to strengthen future security and operational measures.
  - Provide regular reports on system performance, application deployments, and security audits to management and stakeholders.
- **Innovation and Continuous Improvement**
  - Work with development teams to ensure secure application architecture.
  - Identify and evaluate emerging technologies to improve system performance, reliability, and security.
  - Review and enhance cyber-attack prevention systems, processes, and overall IT resilience.
- **Compliance and Policy Enforcement**
  - Monitor the implementation of the Authority's ICT policies and procedures.
  - Ensure adherence to national and organizational regulations regarding ICT governance, cybersecurity, and data protection.
  - Advise management on risk management issues and implement appropriate mitigation measures.
- **Artificial Intelligence (AI) Integration and Emerging Technologies**
  - Explore, evaluate, and integrate AI solutions to enhance system automation, data analysis, and operational efficiency.
  - Collaborate with development and cybersecurity teams to ensure AI applications comply with security standards and organizational policies.
  - Monitor the performance and outcomes of AI systems, adjusting configurations to optimize accuracy, efficiency, and user experience.

- Identify opportunities for AI-driven innovation to support decision-making, predictive analytics, and proactive risk management.
- Provide guidance and training to staff on the adoption and responsible use of AI technologies.

2.2.4.5. Women's and Social Affairs Inclusive Implementation Executive Office

a. Introduction

The main objective of Women's and Social Affairs Inclusion Executive Office is to enhance the participation and representation of women, ensure gender equality, and create a suitable and equitable environment for everyone in the workplace. This office is responsible for designing and implementing strategies and programs that enable women and other disadvantaged groups to benefit from and contribute to the Authority's mission. The existence of this executive body guarantees fairness, inclusivity, and the protection of human rights within the Authority.

b. Organization and accountability

The Women's and Social Affairs Inclusion Executive Office is accountable to Management Chief Executive Office.

c. Duties and Responsibilities of the Women's and Social Affairs Inclusion Executive Office

- Policy Implementation and Monitoring: Monitoring, evaluating, and raising awareness about proclamations, policies, and directives issued for women, children, youth, people with disabilities, the elderly, and other vulnerable groups.
- Strengthening Women's and Youth Forums: Providing monitoring and support to strengthen the forums for female government employees and youth.
- Organizing a Children's Daycare Center: Working to ensure the children's daycare center is modern, comfortable and a preferred choice for children.
- Workplace Accessibility: Facilitating a comfortable working environment for employees with disabilities and for breastfeeding mothers.
- Social, Economic, and Political Support: Creating, supporting, and monitoring conditions that enable women and youth to solve their problems.
- Inclusive Planning and Reporting: Monitoring and evaluating the inclusion of multi-stakeholder issues (women, children, youth, people with disabilities, the elderly, HIV/AIDS, and environmental protection) in the strategies, laws, directives, plans, and reports issued by the Authority.

- Policy Preparation and Implementation: Preparing and monitoring the implementation of policies relevant to gender, women, children, youth, and people with disabilities.
- Capacity Building:
    - Strengthening mentorship programs for women and youth leaders.
    - Undertaking advocacy work to encourage women and youth to join leadership positions.
    - Organizing and providing training for employees on various topics (gender equality, life skills, reproductive health, and HIV/AIDS awareness).

- Access to Educational Opportunities: Working to ensure female, youth, and disabled employees can benefit from educational opportunities offered by government and private universities.
- Data Collection and Analysis: Collecting, consolidating, and analyzing specific data related to gender and disability.
- Working with Stakeholders: Exchanging shared experiences and strengthening coordinated work with the Ministry of Health and other similar institutions.
- Celebrating Holidays: Celebrating national and international holidays for women, people with disabilities, children, and youth through awareness campaigns and forums.

2.2.4.6. Basic Service Executive Office

a. Introduction

The primary purpose of the Basic Services Executive Office is to provide a comprehensive and efficient support system for the organization. This includes overseeing the overall security, cleaning, and grounds keeping of the premises, ensuring the safety of assigned vehicles and their proper use, and establishing a system for efficient vehicle dispatch to avoid interrupting the organization's work. The office is also structured to provide effective management and protection of the organization's assets, enabling it to fulfill its duties and responsibilities.

b. Organization and accountability

The Basic Executive Office is accountable to the Management Chief Executive Office and it has

the following seven team.

1. Property Management Team
2. General Service Team
3. Transport Deployment Service Team
4. Cafeteria service Team
5. Building Administration and Maintenance Team
6. Chemical Store Administration Team

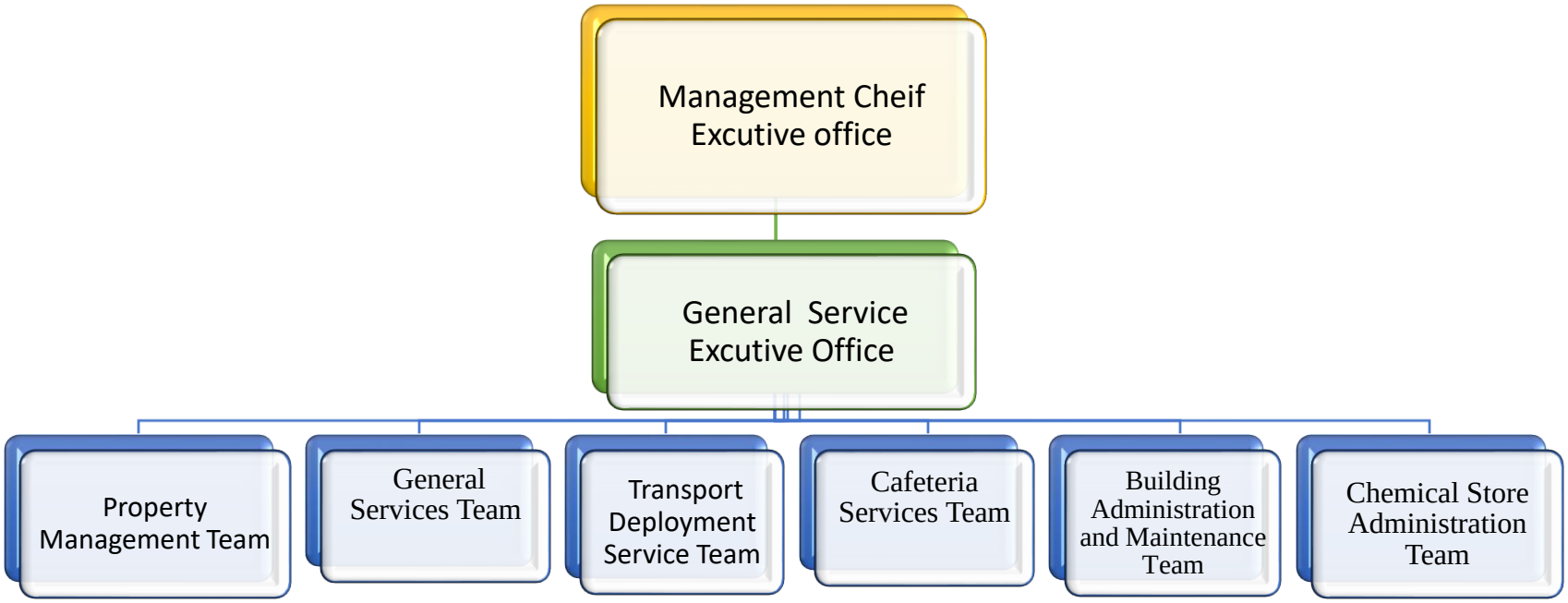


Fig 2.2.4.6: *Basic Executive Office Organizational Chart*

c. Duties and Responsibility of the Basic Service Executive Office

- Creates a conducive working environment by making building maintenance and office service tasks efficient and effective.
- Ensures that the authority's properties without land title deeds are provided with maps
- Establishes an effective operational system to ensure the security of the organization's assets so that the authority's services continue without interruption.
- Monitors the maintenance of the authority's buildings and office equipment.
- Fulfills the needs for fax, telephone, internet, etc., and monitors that monthly payments are made on time.
- Establishes and monitors a system for the cleaning and beautification of the organization's premises.
- Monitors the completion of annual vehicle fitness inspections and insurance renewals.
- Conducts a current fuel quota study by identifying the type of service and vehicle.
- Based on the organization's construction requests, prepares engineering estimates and carries out work such as access roads, warehouses, guard houses, towers, and fences using internal resources. For work assigned to third parties, the executive provides monitoring and supervision. The executive also verifies completed construction work and forwards it for payment.
- Installs and maintains electrical wiring and systems in a timely manner.
- Monitors the timely completion of legal and insurance procedures for vehicles involved in accidents.
- Identifies work to be done by a third party and transfers it for procurement.
- Monitors the timely handover of the construction site to the winning bidder and ensures that the work is performed according to the contract and within the specified timeline.
- Performs other work-related tasks as assigned by the sub-sector.

d. Duties and Responsibilities of the Property Management Team

- Plans, leads, coordinates, and controls work to ensure it is performed efficiently and properly. Allocates the necessary human resources, inputs, and budget to perform the work

in a timely, efficient, and proper manner.

- Manages the organization's assets based on government asset administration proclamations, directives, and manuals. Maintains complete records and provides information to requesting parties in a timely manner.
- Receives stores, manages, and controls assets acquired by the organization through purchase, third-party aid, or donation, ensuring that complete documents and quality standards are verified. Organizes and maintains records.
- Identifies vital items and chemicals, determines the minimum stock level, and, considering the movement of items, notifies the relevant work departments, procurement support process, and, as appropriate, the sectors and the chief executive officer before the minimum stock level is reached. The team also issues remaining items from the store with care and economy and monitors that a subsequent procurement is carried out.
- Receives assets that have been used and are returned. Differentiates between repairable and non-repairable items. Repairs and reuses repairable items. Takes appropriate action to dispose of non-repairable and unusable items in accordance with the law and operational procedures.
- Assigns stock numbers to the organization's assets and keeps a complete record.
- Arranges for asset counts to be conducted at the end of each budget year and whenever necessary.
- Based on the plans the organization has for each budget year and considering the existing stock, prepares a Material Requirement Plan and submits it to the procurement support process in a timely manner to ensure procurement is completed.
- Monitors the stock level of major assets monthly, keeping records of asset movement documents used by the primary users. It controls their distribution, ensures that the documents are completed and signed by the relevant officials, distributes the documents, and adjusts asset registration tasks.
- Submits a monthly report on the quantity of items in all warehouses to branch offices, major water and sanitation work processes, and other relevant departments.

- Receives expenditure, revenue, and other documents from each item store and enters them on a stock control card. The team improves the system and implements a modern asset management system supported by information technology and keeps it updated.
- Before purchasing a requested item, verifies whether it is already in stock. Then, based on its necessity, the team decides whether to keep it in stock.
- Records items that have been in storage for more than five years without use and submits the information to the relevant department.
- Identifies assets that have been out of use for a long time. In consultation with the sectors that use the assets, the team arranges for the assets to be disposed of.
- Closely monitors that asset remaining after use are collected from the work area/site and returned to the warehouse in a timely manner.
- When any employee is reassigned to a new work department due to promotion, transfer, or appointment, the team ensures that the employee hands over the assets they received in their previous work department before leaving.
- The team monitors those pipes, fittings, and related equipment purchased through the head office for water and sanitation line installation for branch offices are released from the head office stores and stored in their respective stores in a timely manner, based on the allocation made for them.
- When projects are completed, the team ensures that assets remaining from the project are deposited into the head office stores following the proper procedure.
- When a request is made to transfer stock items from a project to the head office or from the head office to a project office, it is implemented only after the sector has approved it and supporting documents have been provided.
- Provides technical/professional support for the disposal of unusable vehicles, vehicle spare parts, and other equipment.
- Matches the sea transit documents, packing list, and invoice documents sent by the supplier for items purchased from abroad with the organization's procurement request.
- Monitors the implementation of policies related to asset management and provides support.

Regularly studies and implements ways to improve procedures.

e. Duties and Responsibilities of the General Services Team

- Ensures that necessary tasks are included in the bid document preparation with third-party security service providers and monitors the process.
- Monitors that security services at all locations where third-party security is used are provided as per the contract. Ensures that appropriate action is taken against a security company that fails to fulfill its obligations.
- Ensures that necessary materials for security services are provided to permanent employees assigned to security work.
- Identifies work deficiencies encountered at security sites and takes corrective action. Submits a report.
- When property is stolen, the team gathers witnesses and evidence and submits it to legal services to file a lawsuit.
- Ensures that the appropriate payment is made after verifying that the security service has been provided as per the contract.
- Ensures that gate passes are properly handled and recorded at the head office, branch offices, and other premises of the organization.
- Monitors that vehicle parking and traffic flow are maintained at the head office and branch offices.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Submits the team's performance reports to the support work process and takes necessary action based on the information and feedback provided by the support work process.
- Performs other work-related tasks as assigned by the work process.
- Performs and maintains cleaning of the organization's offices, premises, and the surrounding area within a 50-meter radius.
- Monitors telephone, duplication, and photocopying services to ensure they are provided efficiently.

- Ensures a comfortable working environment by properly maintaining the security and aesthetic of the premises and offices and, in general, performs the organization's service work.
- Provides appropriate support to branch offices regarding service work.
- Monitors that restrooms, bathrooms, water, and sewage lines in the head office, branches, and any other service stations of the organization are functioning correctly. If a malfunction occurs, the team quickly repairs, replaces, or renovates them, etc.
- Conducts an annual building maintenance needs and survey study and prepares a budget.
- Carries out building maintenance by having an annual plan.
- Identifies work to be done by a third party and transfers it for procurement.
- Ensures that necessary tasks are included in the bid document preparation for third-party access road and building maintenance and participates in the process.
- Performs masonry, carpentry, electrical, and plumbing work using internal resources.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Performs other work-related tasks as assigned by the work process.

f. Duties and Responsibility of the Cafeteria Services Team

- Provide high-quality, hygienically prepared food and beverages at a reasonable price to the organization's employees and guests.
- Regularly prepare and update a diverse and balanced menu based on the preferences and needs of the employees.
- Regularly monitor that the cafeteria environment, cooking utensils, and food preparation process comply with health and safety standards.
- Ensure that necessary raw materials and other supplies for food preparation are procured in a timely manner, verifying their quality and quantity, and storing them properly.
- Coordinate, support, and monitor the work of employees under the team; also, to facilitate opportunities for them to acquire necessary skills.
- Properly maintain revenue and expenditure accounts, adjust prices, and prepare financial

reports.

- Receive and evaluate customer feedback and complaints and make necessary adjustments.

g. **Duties and Responsibilities of the Transport Deployment Service Team**

- Provides vehicle deployment based on transport requests sent from departments.
- Ensures the safety of vehicles by providing timely maintenance, service, and washing according to their schedule.
- Ensures that vehicles are covered by insurance and that annual vehicle safety inspections and roadworthiness certifications are completed in a timely manner.
- When a vehicle has a minor breakdown, the team arranges for it to be repaired within the organization. If the breakdown is major, the team arranges for it to be repaired according to the contract with a repair company.
- Organizes and maintains information about the type, quantity, year of manufacture, and other data for the organization's vehicles. Identifies old vehicles that have reached the end of their service life and disposes of them according to government asset disposal directives.
- Evaluates the competence and work performance of drivers and sends the results to the relevant department. Provides necessary support to branch offices on vehicle use and handling.
- Conducts a study on the organization's work scope and vehicle needs and submits a report to the executive for the allocation of additional vehicles. Establishes a system by adopting best practices from others to make vehicle dispatch and maintenance efficient and effective.

h. Duties and responsibility of the Building Administration and Maintenance Team

- Prepares the team's plan, monitors its implementation, and evaluates its performance.
- Monitors, supports, and coordinates the performers under its supervision and provides performance feedback.
- Based on the organization's construction requests, prepares engineering estimates and carries out work such as access roads, warehouses, guard houses, towers, and fences using internal resources. For work assigned to third parties, the team provides monitoring and supervision. The team also verifies completed construction work and forwards it for

payment.

- Monitors that restroom, bathrooms, electrical, water, and sewage lines, compressors, and air handling units in the head office, branches, and any other service stations of the organization are functioning correctly. If a malfunction occurs, the team quickly repairs, replaces, or renovates them, etc.
- Constructs restrooms for the organization's service stations that do not have them.
- Identifies and provides necessary inputs for the construction and maintenance of restrooms. Ensures that an adequate stock of materials is kept.
- Conducts an annual building maintenance needs and survey study and prepares a budget.
- Carries out building maintenance by having an annual plan.
- Identifies work to be done by a third party and transfers it for procurement.
- Ensures that necessary tasks are included in the bid document preparation for third-party access road and building maintenance and participates in the process.
- Hands over the site to be repaired or constructed to the winning bidder and monitors that the work is performed according to the contract and within the specified timeline.
- Conducts a handover when the construction work is completed and prepares a work completion report.
- Monitors the safety of the building and repairs it when renovation or maintenance is needed.
- Performs masonry, carpentry, electrical, mechanical, and plumbing work using internal resources.
- Fills out the performance evaluation for employees under its supervision in a timely manner.
- Submits the team's performance reports to the support work process and takes necessary action based on the information and feedback provided by the support work process.
- Performs other work-related tasks as assigned by the work process.
- Performs laboratory equipment maintenance

i. Duties and Responsibilities of the Chemical Store Administration Team

- Provides necessary information before the procurement of chemicals, reagents, and reference standards is initiated.
- Establishes a registration and control system for chemicals, reagents, and reference standards and properly maintains the data.
- Stores chemicals, reagents, and reference standards at the correct temperature and in a secure manner, following international standards and domestic regulations.
- Maintains Safety Data Sheets (SDS) to ensure the safety of chemicals, reagents, and reference standards.
- Provides chemicals, reagents, and reference standards to laboratory professionals according to the quantity and type they need.
- Continuously monitors the stock, flow, and use of chemicals, reagents, and reference standards.
- Identifies expired chemicals, reagents, and reference standards and those whose expiration dates are approaching and arranges for their proper disposal.
- Monitors and controls the cleanliness, safety, and temperature of the chemical store.
- Establishes a proper storage system (segregation) for different types of chemicals.
- Works closely with the procurement and finance teams to prevent supply issues for chemicals, reagents, and reference standards.
- Uses Personal Protective Equipment (PPE) to ensure safety when providing chemicals, reagents, and reference standards.
- Regularly monitors and ensures that the materials and equipment used for chemical storage and supply are in service.
- Takes appropriate medical and protective measures when hazardous chemicals spill or an accident occurs.
- Prepares and submits detailed reports to managers on the overall movement and stock of chemicals, reagents, and reference standards.
- Provides training to employees who handle, use, and distribute chemicals, reagents, and reference standards.

2.2.4.7. Organizational Change Management Executive Office

a. Introduction

The Organizational Change Management Executive Office is established to facilitate the application of change management tools across all departments and branch offices, ensuring that service delivery is fair, efficient, impartial, transparent, and accountable. It is mandated to prepare service delivery standards, provide monitoring and support, and develop solution strategies for good governance challenges identified through research, while following up on their implementation. Furthermore, the office coordinates and oversees the development of service taxonomy to track service delivery against established standards, ensuring accountability and transparency, while also monitoring the introduction of new procedures and institutional changes. In addition, it is tasked with supporting, verifying, and facilitating corrective actions to strengthen good governance within the institution.

b. Organization and accountability

The Organizational Change Management Executive Office is accountable to the Management Chief Executive Office and it has the following two Team;

1. Organizational Reform Team
2. Service Complaints Grievance Hearing Team

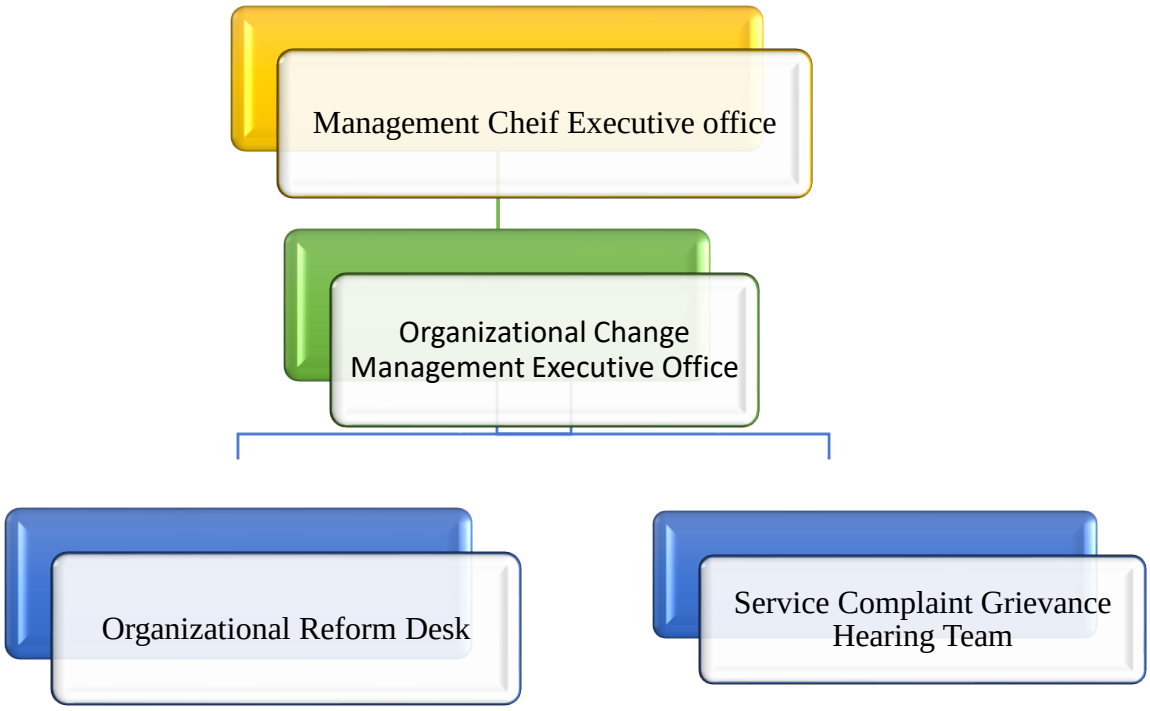


Fig 2.2.4.7: *Organizational Change Management Executive Office Organizational Chart*

c. Duties and responsibilities of the Organizational Change Management Executive Office

- Ensures that fundamental business process change studies are conducted, and upon completion and implementation, facilitates necessary adjustments through continuous monitoring.
- Monitors and supports the institution's strategic plan to ensure its alignment with the Balanced Scorecard methodology.
- Oversees the development and effectiveness of the change agent network within the work unit and across the institution.
- Evaluates and determines the performance of business processes related to change and good governance implementation.
- Identifies, documents, and shares best practices within the institution.
- Coordinates and delivers short awareness-raising trainings for internal business processes and executives on change management and good governance.

- Identifies governance challenges faced by the institution's internal and external stakeholders and facilitates their resolution through short-, medium-, and long-term plans.
- Facilitates the preparation and implementation of the institution's citizens' charter, and monitors compliance with established service standards.
- Provides support and oversight for the activities and participation of the institution's public wing common platform.
- Facilitates the rollout of systems aimed at improving service delivery and monitors their implementation.
- Oversees and supports the process for conducting customer satisfaction surveys.
- Receives and manages complaints from internal and external sources, ensuring proper handling and follow-up until resolution.
- Collaborates with other departments to implement operational systems that foster a customer-service-oriented culture, while providing ongoing monitoring and support.
- Prepares and submits change and good governance performance reports to the Reform and Good Governance Sector, and ensures that provided feedback is implemented.

d. Duties and Responsibilities of Organizational Reform Team

- Identifies, synthesizes, and disseminates best practices within the institution;
- Provides and coordinates short awareness trainings for internal work processes and implementers regarding change and good management;
- Submits the institution's change and good governance performance reports to the reform and good governance sectors, implements the information and feedback provided;

e. Duties and Responsibilities of Service Complaint Grievance Handling Team

- Identifies the good management problems of the internal and external customers of the institution, and prepares short-, medium- and long-term plans to solve them;
- prepares and implements the institution's citizen's charter, monitors and ensures that it is Being provided according to the standard set by the service provision;
- Establishes various systems to improve service delivery; Monitors their implementation;
- Monitors and supports the way customer satisfaction surveys are conducted;

- Receives complaints from both outside and inside the institution, handles them appropriately and monitors the way they are resolved;

2.2.5. Branch Coordination Lead Executive Office

a. Introduction

The Branch Coordination Lead Executive Office (BCLEO) of EFDA serves as a central office coordinating the strategic and operational activities of the EFDA branch offices, and support of Regional Regulatory bodies (RRBs). This role ensures effective communication, standardization, and policy and legal frameworks enforcement across all branches. Working closely with top leadership, the BCLEO supports evidence-based decision-making, planning and performance monitoring of the branch offices. It also fosters collaboration between EFDA and RRBs.

b. Organization and Accountability

The BCLEO is accountable to Director General of EFDA. The BCLEO serves as a liaison between top leadership and branch operations. It holds authority to coordinate, monitor, and support branches offices. It manages and coordinates seven branch offices and 17 POEs. The detail organization structure of branch offices is depicted in 2.6.

1. South East Addis Ababa Branch Office
2. Mekelle Branch Office
3. Hawassa Branch Office
4. Jimma Branch Office
5. Bahirdar Branch Office
6. Diredawa Branch Office
7. Kombelcha Branch Office

c. Duties and Responsibilities

- Ensure the proper implementation of licensing, regulatory inspection and port release activities, and enforcement actions at branch offices.
- Coordinate the implementation and enforcement of Good Distribution Practices (GDP), Good Storage Practices (GSP), Good transport practices and Good Documentation Practices at Importers and wholesalers.

- Coordinate and oversee the implementation of EFDA science-based tools such as laws, strategies, guidelines, across all branch offices.
- Ensure alignment of branch-level activities with the strategic goals and mission of the authority.
- Facilitate effective communication and reporting between headquarters and branches.
- Plan, monitor and evaluate branch performance and provide regular updates to top leadership.
- Support capacity building and training initiatives at branch levels.
- Identify operational gaps and recommend corrective actions or adjustments.
- Organize periodic coordination meetings and review sessions with branch managers.
- Prepare consolidated reports on branch activities, challenges, and achievements.
- Coordinate and support regional regulatory bodies

2.3. Medicine Sector Deputy Director General

a. Introduction

The Medicine Sector Deputy Director General (DDG) is one of three DDGs, responsible for providing strategic leadership and oversight to ensure the safety, quality, and efficacy of medicines in Ethiopia. The DDG makes high-level decisions beyond the scope of lead executive officers, sets strategic, operational and policy directions, and formulates future strategies for the sector. The DDG coordinates the Lead Executive Offices, public and stakeholders, fostering national and international partnerships and collaboration, and representing EFDA in matters related to medicine regulation. The DDG also supports the Director General in ensuring sector activities aligned with the Authority's mission and mandate.

b. Organization and Accountability

The Deputy Director General of Medicine Sector is accountable to the Director General and manages the following Four Lead Executive Offices.

1. Medicine Evaluation and Market Authorization (MEMA) Lead Executive Office
2. Medicine Manufacturers Inspection and Enforcement (MMIE) Lead Executive Office
3. Pharmacovigilance and Clinical Trial (PVCT) Lead Executive Office
4. Medicine Quality Control (MQC) Lead Executive Office

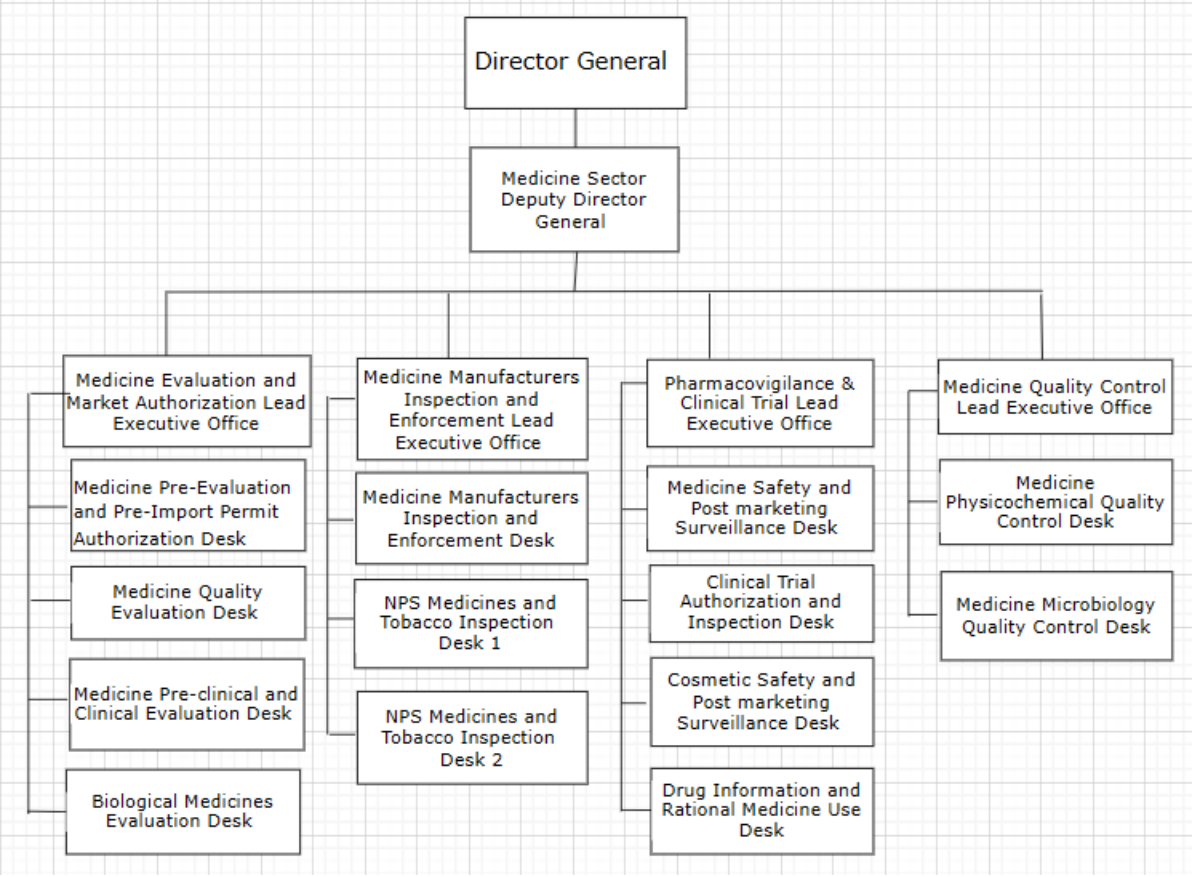


Fig 2.3: *Medicine Sector Deputy Director General Organizational Chart*

c. Duties and Responsibilities

- Assists the Director General in planning, organizing, directing and coordinating the activities of the Authority,
- Coordinates the development of policies, strategies, programs and plans for medicine regulation;
- Coordinates and ensures the implementation of ratified international agreements and conventions related with medicine regulation;
- Supervises the day-to-day activities of the medicine sector;
- Ensures that sufficient resources are allocated for the operations of the medicine sector, and monitors that the allocated resources are utilized properly;
- Supports, supervises and coordinates the work units under him to do effective work;

- creates a strong working relationship and coordination between work departments and to take corrective action by quickly evaluating gaps when they arise;
- Ensures their applicability by periodically evaluating the performance parameters set to measure the effectiveness and efficiency of the sector;
- Ensures that the policies, laws, operating instructions and standards issued for the sector are properly implemented by the subordinate working units;
- Designs strategies and programs to improve the performance of experts in the field, monitors their implementation;
- Designs motivational strategies that enable professionals who record effective performance to be encouraged, monitors its implementation;
- Creating ownership and partnership by introducing and creating awareness of sector strategies and practices to the society and stakeholders;
- Works to establish effective and sustainable cooperation with international and national institutions on behalf of the authority;
- Perform other activities specifically assigned to him by the Director General,
- Perform duties of Director General in his absence

2.3.1. Medicine Evaluation and Market Authorization Lead Executive Office

a. Introduction

The Medicine Evaluation and Market Authorization Lead Executive (MEMA LEO) is mandated by Article 20 of Proclamation No. 1112/2019, which requires that all medicines be registered and granted market authorization before they can be placed for use by the public in the territory of Ethiopia.

In fulfilling its mandate, the MEMA LEO undertakes a broad scope of responsibilities. These include preparing and implementing regulatory strategies, guidelines, and manuals; coordinating and managing the assessment of medicine dossiers; and evaluating scientific evidence on quality, pre-clinical, and clinical studies to determine whether medicines produced locally or abroad can be authorized for market use; oversees post-approval activities, including variations, renewals, and monitoring of authorized medicines, as well as taking regulatory actions such as suspension or

cancellation of market authorization certificates of safety, efficacy, or quality concerns;

The MEMA LEO review the promotional and advertising materials are scientifically sound, accurate, and consistent with the approved product information. To promote transparency, the office has also established an official platform for publishing SPC-like information, including the Summary of Product Characteristics (SPC), Package Information Leaflets (PILs), and approved labeling for all authorized medicines. This ensures that healthcare professionals, patients, and the public have access to reliable, up-to-date, and officially approved information on medicines.

The office is also responsible to authorize the pre-import permit medicines to be used for different medical (such as during emergency) and investigational purposes after reviewing the safety evidence.

b. Duties and Responsibilities of MEMA LEO

- Develops the annual operational plan for the Lead Executive Office (LEO) in alignment with the Authority's strategic plan; oversees its effective implementation; monitors and evaluates performance against set objectives; and prepares and submits comprehensive performance reports on a quarterly, biannual, and annual basis to the relevant governing bodies for review and decision-making.
- Serves as Secretary to the National Drug Advisory Committee (NDAC) of EFDA and acts as the liaison between the NDAC and the Authority. Coordinates and facilitates NDAC operations, including the scientific review of non-clinical and clinical data for new molecules and other critical products, and ensures timely submission of meeting reports to the Authority. Integrates the NDAC's recommendations as key inputs in the decision-making process for granting market authorization, particularly when the benefits of a new molecule outweigh the risks.
- Preparing, approving and monitoring the implementation of operational strategies, manuals, guidelines and other documents that guide medicine evaluation and markets authorization in the country.
- Initiate the development and revision of directive that serve the activities related to medicine evaluation and market authorization.

- Compiles and implements international experiences in the field of medicine evaluation and market authorization system in a way that benefits the country.
- Plans, executes, coordinates, manages, monitors and supports activities related to medicine evaluation and market authorization.
- Ensure personnel working in MEMA LEO follow Good Review Practices (GRevPs) while reviewing of application and issuing of market authorization.
- Evaluates current performances and provides feedback, compiles performance reports and submits them to relevant parties.
- Evaluates the results of quality, pre-clinical and clinical scientific studies and researches for medicines produced in the country or abroad and requires market approval, and confirms the quality, safety and authenticity of the medicine submitted for registration.
- Ensure the functionality of pharmaceutical products traceability including existence of a barcode during assessment of application.
- Grants medicines market authorization for new (including new molecular entities, generic medicine, biological and biosimilar applications), post approval variations, and renewal applications that meet the respective requirements.
- When any confirmed concerns arise on safety, efficacy and quality of medicines that have been granted market authorization certificate, the lead executive officer may suspend and cancel the market authorization certificate and notify the relevant LEOs and stakeholders.
- Evaluates and approves medicine promotional materials to ensure they are balanced and consistent within information submitted during market authorization.
- Issue Certificate Pharmaceutical Products for locally manufactured products intended for export.
- Oversees the activities of the respective MEMA desks related to marketing authorization.
- Poster a strong collaboration and partnership with countries and international institutions experienced in medicine evaluation and market authorization.
- Represents EFDA at national and international conferences on pharmaceutical regulation.

- Formulate strategies to strengthen the capacity of the LEO, make decisions on issues beyond the mandate of the desks, and ensure the implementation of decisions and directions made as an institution.
- Establish a system to enhance effective communication and promote efficient work across the respective MEMA desks
- Facilitate the preparation of necessary instructions, guidelines, manuals and SOP for the lead executive office work.
- Established an official platform for publishing SPC-like information—comprising the SPC, PILs, and approved labeling—for all approved medicines to ensure that healthcare professionals, patients, and the general public have access to reliable, up-to-date, and officially approved information about medicines.
- Grants pre-import permits for the importation or use of medicines under non-routine procedures in compelling circumstances, in accordance with Article 20 (5) of Proclamation No. 1112/2019.

c. Organization and accountability

The MEMA LEO is accountable to the Deputy Director General of the Medicine Sector and has four desks. They are:

1. Medicine Quality Evaluation Desk
2. Medicine Pre-Clinical and Clinical Evaluation Desk
3. Biological Medicines Evaluation Desk
4. Medicine Pre-Evaluation and Pre-import Permit Authorization desk

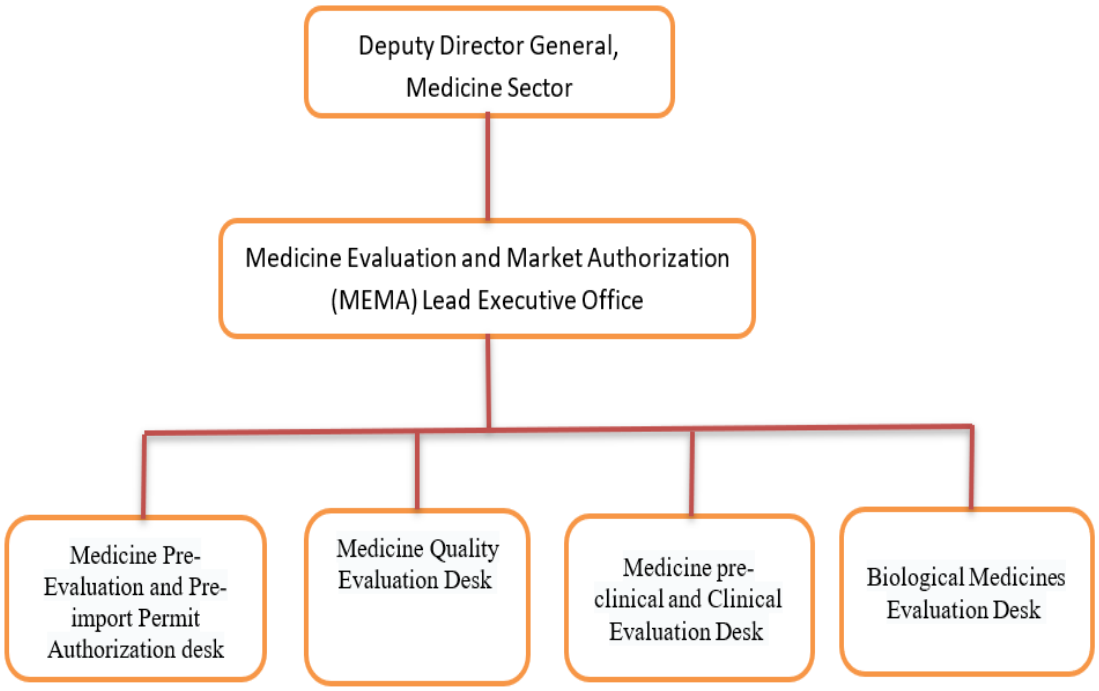


Fig 2.3.1: MEMA LEO Organizational Chart

d. Duties and Responsibilities of Medicine Quality Evaluation Desk and Medicine Pre-clinical and Clinical Evaluation Desk

- Prepares the desk's annual operational plan in alignment with the LEO's plan and cascades it into individual work plans for team members. Oversees the implementation of these plans, monitors and evaluates performance against set objectives, and prepares comprehensive quarterly, biannual, and annual reports for submission to the LEO.
- Ensure the safety, efficacy and quality of medicines through the thorough evaluation of scientific documents in the quality, preclinical, and clinical sections of medicine dossiers.
- Coordinates all preparatory activities for NDAC meetings, including notifying members in advance, distributing relevant documents, and accurately recording minutes. Prepares and presents evaluation summaries to the NDAC, ensures the Committee's recommendations are well documented, and incorporates them into final reports for submission to the

Authority. Requests additional information or study reports from applicants as needed, and continues evaluations upon receipt of responses.

- Prepares, reviews and implements necessary instructions, manuals, guidelines, SOPs, checklists and other documents used for medicine quality, preclinical, and clinical sections of medicine dossiers in line with the strategies and directives of MEMA LEO.
- Compiles, harmonizes and applies international best practices in the assessment of the quality, preclinical, and clinical sections of medicine dossiers.
- Plans, executes, coordinates, monitors and supports activities related to medicine quality and clinical evaluation.
- Ensure assessors follow GRevPs while reviewing of medicine applications.
- Providing feedback by evaluating current performance, compiling performance reports, and submitting them to the relevant parties.
- Review the quality data and clinical study results submitted by both domestic and international pharmaceutical companies, including active pharmaceutical ingredient's synthesis route and critical control parameters, finished pharmaceutical product and product information, bioequivalence study reports, and other preclinical and clinical study reports.
- Prepare and submit the assessment outcome for approval when the submitted dossier is found complete.
- Prepare and submit the assessment report including the proposed additional information or study reports required from the applicant, along with the necessary explanations to the applicants.
- Evaluate applicant responses to queries and submit the corresponding evaluation report for consideration; Identify issues for inspection and communicate them clearly to the inspectors.
- Use evaluation reports issued by assessors, GMP compliance reports and as appropriate, laboratory test results for recommendation for approval.
- Review the Certificate of Pharmaceutical Product (CPP) for locally manufactured products intended for export and recommend to MEMA LEO for final review and approval.

- Publishing SPC-like information comprising the SPC, PILs, and approved labeling for all approved medicines to ensure that healthcare professionals, patients, and the general public have access to reliable, up-to-date, and officially approved information about medicines.
- Receives requests for changes to the registered medicines, determines the type of change, conducts evaluation; prepares an evaluation report and notifies the concerned party.
- Receive renewal application requests; check the Good Manufacturing Practice (GMP) compliance status and confirm whether there are any changes or other quality findings in the manufacturing of the medicine and submits a final report with recommendations for decision.
- Evaluate and recommend for approval of medicine promotional materials to ensure they are balanced and consistent within information submitted during market authorization.
- Review and ensure the accuracy of the tasks performed by the respective desk.
- Designs a strategy to build the capacity of the desk; makes decisions on matters beyond the competence of assessors; implements decisions and directions of MEMA LEO and EFDA management.
- Establish a system to enhance effective communication within the desk and promote efficient work within the desk
- Organize and strengthen the Electronic Registration Information System (eRIS) and improve the procedures, conducts a post-market survey and identify issues, requests to upgrade the information system; Designs new operating systems based on new methods found in scientific research, new technologies that come out regularly, best practices in other sectors and countries, and service needs that are constantly provided.

e. Duties and Responsibilities of Biological Medicine Evaluation Desk

- Prepares the desk's annual operational plan in alignment with the LEO's plan and cascades it into individual work plans for team members. Oversees the implementation of these plans, monitors and evaluates performance against set objectives, and prepares comprehensive quarterly, biannual, and annual reports for submission to the LEO.
- Prepares, reviews and implements vaccine, biosimilar and other biological medicines evaluation and registration manuals, guidelines, checklists and other documents used for

assessment quality, preclinical, and clinical sections of the biological medicine dossiers in line with the strategies and directives of MEMA LEO.

- Compiles, harmonizes and applies international best practices in the evaluation and authorization of vaccines and other biological medicine applications.
- When any confirmed concerns arise on safety, efficacy and quality of vaccines, biosimilar and other biological medicines that have been granted market authorization certificate, provide recommendations to suspend and cancel the market authorization certificate and notify the relevant LEOs and stakeholders.
- Coordinates all preparatory activities for NDAC meetings, including notifying members in advance, distributing relevant documents, and accurately recording minutes. Prepares and presents evaluation summaries to the NDAC, ensures the Committee's recommendations are well documented, and incorporates them into final reports for submission to the Authority. Requests additional information or study reports from applicants as needed, and continues evaluations upon receipt of responses.
- Ensure assessors follow GRevPs while reviewing of biological medicine applications.
- Plans, executes, coordinates, monitors and supports activities related to vaccine, biosimilar biological drug evaluation and registration.
- Evaluates current performances, providing feedback by evaluating current performance, compiling performance reports, and submitting them to the MEMA LEO.
- Evaluates quality, clinical and other important scientific research and research data for biological medicines that are manufactured domestically or abroad and require market approval.
- Prepare and submit the assessment outcome for approval when the submitted dossier is found complete.
- Prepare and submit the assessment report including the proposed additional information or study reports required from the applicant, along with the necessary explanations to the applicants.
- Evaluate applicant responses to queries and submit the corresponding evaluation report for consideration;

- Receives requests for changes to the registered biological medicines, determines the type of change, conducts evaluation; prepares an evaluation report and notifies the concerned party.
- Receive renewal medicine application requests; check the GMP compliance status and confirm whether there are any changes or other quality findings in the manufacturing of the medicine and submits a final report with recommendations for decision.
- Review and ensure the accuracy of the tasks performed by the desk.
- Poster a strong collaboration and partnership with countries and international institutions experienced in biological medicine evaluation and market authorization.
- Designs a strategy to build the capacity of the desk; makes decisions on matters beyond the competence of assessors; implements decisions and directions of MEMA LEO and EFDA management.
- Establish a system to enhance effective communication within the desk and promote efficient work within the desk
- Prepare necessary instructions, guidelines, manuals and SOP for the desk.

f. Duties and Responsibilities of Medicine Pre-Evaluation and Pre-import Permit Authorization desk

- Prepares the desk's annual operational plan in alignment with the LEO's plan and cascades it into individual work plans for team members. Oversees the implementation of these plans, monitors and evaluates performance against set objectives, and prepares comprehensive quarterly, biannual, and annual reports for submission to the LEO.
- Conduct pre-assessment verification to ensure the completeness of modern and traditional medicine applications for market Authorization; advise applicants to provide any missing documents; issues written notification regarding payment of service fees in line with the current regulations; and verifies that the payment has been received.
- Reviews applications for pre-import permits for the importation or use of medicines under non-routine procedures in compelling circumstances, and recommends for approval in accordance with Article 20 (5) of Proclamation No. 1112/2019.

- Ensures that pre-import permit requests submitted through eRIS are complete, requests applicants to complete those that have not been completed, and authorizes those that have been completed through the information system.
- Plans, executes, coordinates, monitors and supports activities related to medicine pre-evaluation and pre-import authorization.
- Ensure assessors follow GRevPs while screening of medicine applications and other activities within the desk.
- Evaluates current performances, providing feedback, compiling performance reports, and submitting them to the MEMA LEO.
- Receives requests for changes to registered medicines used for public health, verifies that they are complete, informs the concerned party for assessment.
- Verify renewal medicine application requests, verifies that they are complete and submit it to the relevant body for assessment.
- Review and ensure the accuracy of the tasks performed by the desk.
- Designs a strategy to build the capacity of the desk; makes decisions on matters beyond the competence of experts; implements decisions and directions of MEMA LEO and EFDA management.
- Establish a system to enhance effective communication within the desk and promote efficient work within the desk
- Prepare necessary instructions, guidelines, manuals and SOP for the desk.
- When found necessary, such as during an emergency, orphan medicine, for clinical trial purpose, the desk reviews risk-benefits of pre-import permit applications; when found to be complete, authorize importation of unregistered medicines to be used for different medical and investigational purposes after reviewing the safety evidence.
- Gather and verify information on medicines that are in short supply (unmet need) at the country level; differentiates, monitors the information and updates according to the actual situation of the country and submits for approval.
- Creates a list of drugs that do not have a supplier or importer; consults stakeholders refines the list and submits for approval.

- Collects and analyzes information on the quality, safety and efficacy of medicines imported and used without registration during Emergency Situations in the country using the survey methods and decides the next step to be followed.

2.3.2. Medicine Manufacturer Inspection and Enforcement Lead Executive Office

a. Introduction

The Medicine Manufacturers Inspection and Enforcement Lead Executive Office (MMIE LEO) is a core regulatory arm within the EFDA, mandated to ensure that pharmaceutical and biopharmaceutical products manufactured locally or imported for local use meet national and international Good Manufacturing Practice (GMP) standards. Through its regulatory oversight, the office helps to ensure that Ethiopia's pharmaceutical sector remains competitive, globally recognized, and aligned with international standards, benefiting both local and international markets.

The office's mission extends beyond compliance monitoring to include pharmaceutical guidance, collaboration with international partners, regional and global drug regulatory bodies. These efforts are aimed at strengthening the domestic pharmaceutical sector and aligning regulatory practices with global standards. Its overarching role is to safeguard public health by ensuring the quality, safety, and efficacy of medicines through effective regulatory oversight of pharmaceutical manufacturing facilities.

b. Organization and accountability

The **MMIE LEO** is structured into two key desks, each responsible for specific duties and responsibilities. The office is accountable to the Deputy Director General of the Medicine Sector**.** The two desks under this office are:

1. Medicine Manufacturers Inspection and Enforcement Desk
2. Narcotic and Psychotropic Drug Control & Tobacco Control Desk

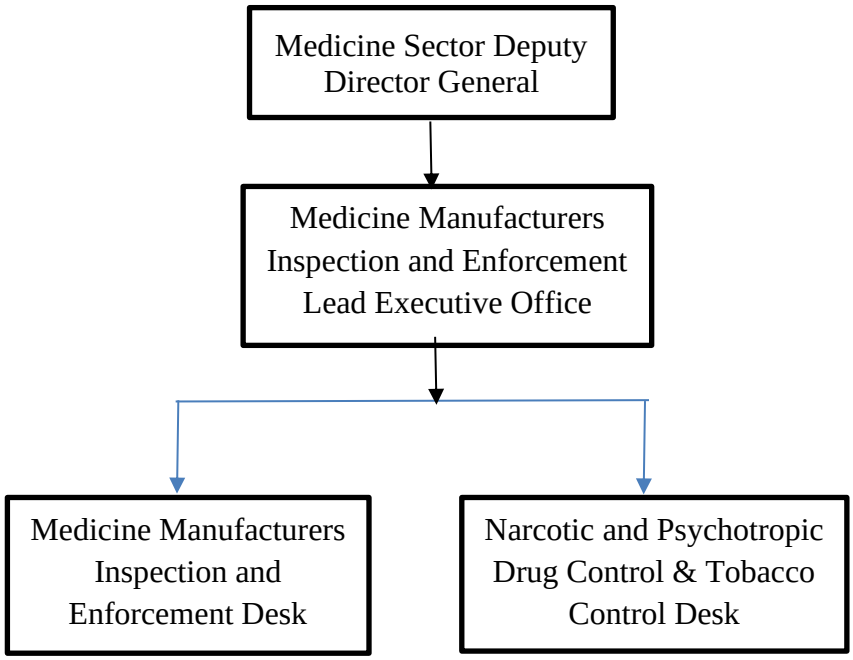


Fig 2.3.2: *MMIE LEO Organizational Chart*

c. Duties and Responsibilities of MMIE LEO

- Plan and manage human resources and budget for Good Manufacturing Practice (GMP) inspection and enforcement initiatives, ensuring optimal resource allocation and operational efficiency;
- Identify and seek funding opportunities for market control projects and other enforcement activities, including grants, donations, and partnerships;
- Ensure the timely procurement of necessary resources, tools, and materials for the effective implementation of GMP inspections activities and enforcement programs;
- Plan, oversee and conduct regular, risk-based inspections of pharmaceutical manufacturing facilities to ensure adherence to GMP standards.
- Develop, review, and oversee the implementation of operational strategies, GMP guidelines, manuals, and related documentation to guide GMP inspection and enforcement activities;

- Develops and implements systems and strategies to build the capacity of GMP inspectors, ensuring continuous improvement in operations, efficiency, and overall effectiveness;
- Conducts regular and risk-based inspections of pharmaceutical manufacturing facilities to ensure compliance with GMP standards. When deficiencies are identified, the office works with manufacturers to ensure that appropriate CAPA is taken;
- Plays a critical role in leading and collaborating with other Lead Executive Offices of EFDA as well as regional and global regulatory bodies to ensure that only safe, effective, and high-quality medicines reach the market. The office oversees the entire supply chain and addresses any gaps that could jeopardize public health, including the presence of substandard and falsified medicines and communicate such information to all concerned bodies including the general public;
- Review the local medicine manufacturer design layout and concept note to ensure to national and international GMP standards and provide technical feedback and recommendations;
- Supports and encourages local pharmaceutical manufacturers to continuously enhance their manufacturing facilities, equipment, and quality management systems in accordance with cGMP standards;
- Provides industry guidance to help local pharmaceutical manufacturers meet international standards and improve their competitiveness in the global market;
- Provide reliable, evidence-based information to support regulatory decisions for Medicine market Authorization;
- Evaluate and issues medicine manufacturing license, medicine packing and labelling licenses, by ensuring that the facilities meet regulatory requirements;
- Issuing GMP compliance certificate to those pharmaceutical manufacturing facilities that meet the required standards;
- Fosters effective and sustainable collaboration with national and international institutions (PICs, IGAD, AMA, WHO) on behalf of the authority to regulate drug manufacturers;

- Strengthens EFDA's credibility as trusted regulatory authority through consistent enforcement actions and active precipitation in international collaboration. This recognition facilitates the entry of Ethiopian pharmaceutical products into global markets, promoting international trade and ensuring access to high-quality medicines;
- The office ensures that all the regulatory actions are consistent, timely, and transparent. It takes appropriate enforcement measures in cases of non-compliance, such as issuing warning or suspending manufacturing licenses or GMP compliance certificate, and follow-up to verify corrective and preventive actions (CAPA) are successfully implemented;
- Maintain detailed inspection reports and communicate findings clearly through appropriate channels to stakeholders;
- Train GMP inspectors and continuously develop the regulatory capacity of EFDA;
- Contributes to the development of pharmaceutical industry policies and provides technical advice.
- Ensure the effective execution of inspection programs by establishing clear objectives and aligning team efforts with EFDA's mission and regulatory requirements.
- Oversee the implementation of regulatory actions to ensure that narcotic and psychotropic substances are used only for legitimate medical, scientific, and industrial purposes.
- Monitor compliance with national regulations governing the production, importation, distribution, and use of controlled substances.
- Take enforcement actions when non-compliance is detected, including issuing warnings, suspending licenses, and collaborating with law enforcement agencies for further investigation.
- Issuing especial import permit for Narcotic and Psychotropic Substances as well as precursor chemicals for the legal distribution and ensuring these are only used for medical or scientific purposes in line with Ethiopian and international laws (e.g. INCB)
- Conduct regular inspections and monitor to detect any illegal activities, such as diversion or illicit trafficking of these substances, and taking enforcement actions as necessary;

- Promoting awareness campaigns, providing training and resources, and supporting the development of regulatory capacity within the health and law enforcement sectors;
- Estimation and forecasting the national demand for narcotic and psychotropic substance, competing accurate consumption data, and submitting annual report to the INCB on usage, import, export, and controlled substances to ensure compliance with international agreements;
- Responsible for ensuring compliance with national and international tobacco control laws and international treaties (e.g. WHO framework convention on tobacco control (FCTC));
- Safeguard public health by promoting awareness about the risk of tobacco use. It coordinates anti-tobacco campaigns, implements tobacco products warning labels, and ensure that tobacco related health risk information is accessible to the public.

d. Duties and Responsibilities of Medicine Manufacturers Inspection and Enforcement Desk

- Lead the development, review, and implementation of operational strategies, GMP guidelines, manuals, and related documentation to guide inspection and enforcement activities;
- Oversee the incoming applications through the Electronic Regulatory Information System (eRIS);
- Assign applications to GMP inspectors, Ensure proper assignment and prioritization of applications for medicine manufacturing licenses, GMP inspections, and related regulatory approvals.
- Monitors the processing of applications to ensure timely and accurate evaluations in accordance with EFDA’s standards;
- Oversee and conduct regular, risk-based inspections of pharmaceutical manufacturing facilities to ensure adherence to GMP standards;
- Ensures that prompt corrective and preventive actions, and/or implementation evidence, are submitted by the manufacturer within the stipulated timeframe, reviewed, and that appropriate regulatory decisions are made in a timely manner.

- Lead and collaborate with Medicine sectors of EFDA's other Lead Executive Offices, as well as regional and global regulatory bodies, to ensure that only safe, effective, and high-quality medicines enter the market
- Monitor the entire pharmaceutical supply chain, identifying and addressing any gaps that could compromise public health, such as presence of substandard or falsified medicines.
- Monitor the review of the medicine manufacturers design layouts and concept notes submitted by local pharmaceutical manufacturers and submit the review report and recommendation for decision to LEO.
- Provide technical feedback and recommendations to help manufacturers improve their operations, ensuring alignment with regulatory requirements.
- Lead the evaluation and issuance of medicine manufacturing licenses, including those for packing and labeling, ensuring that facilities meet all regulatory requirements.
- Oversee the issuance of GMP compliance certificates to facilities that meet the required standards, ensuring a consistent and transparent process.
- Receive market complaints or reports related to drug product quality defects.
- Assign a GMP inspector for a cause investigation, ensuring a prompt and thorough review of the complaint or defect report.
- Facilitate the logistics and resource requests necessary for conducting inspections, investigations, ensuring the availability of required materials and support.
- Monitor and follow-up on the investigation process, ensuring that it progresses effectively and efficiently.
- Review the findings of the investigation report and submit it for regulatory decision-making.
- Ensure that the implementation of corrective actions from the investigation is monitored and completed in a timely manner.
- Ensure all regulatory actions are timely, consistent, and transparent.
- Follow-up with manufacturers to verify that corrective and preventive actions are implemented in a timely manner.

- Lead training programs for GMP inspectors, ensuring the continuous development of EFDA's regulatory capacity.
- Promote knowledge sharing and best practices within the team to enhance inspection capabilities and overall efficiency.
- Maintain comprehensive inspection reports and communicate findings to stakeholders in a clear and timely manner.
- Ensure that inspection and enforcement actions are properly documented and communicated to relevant authorities, maintaining transparency and accountability.
- Implements decisions and directions given by the lead executive office, ensuring that policies, strategies, and directives are carried out effectively and efficiently.
- Makes decisions on matters beyond the competence of experts, exercising authority to address complex issues and ensure alignment with regulatory goals.

e. Duties and Responsibilities of Narcotic and Psychotropic Drugs Control & Tobacco Control Desk

- Lead the development, review, and implementation of strategies, guidelines and operational plans for the regulation and control of narcotic and psychotropic substances.
- Ensure that the team's goals and activities align with EFDA's mission, national policies, and international regulations, including the Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.
- Lead coordination with national and international regulatory bodies, including the International Narcotics Control Board (INCB), the WHO, and other relevant agencies.
- Ensure that Ethiopia's narcotic and psychotropic drug control efforts align with international best practices and conventions, fostering global cooperation to combat misuse and trafficking.
- Oversee inspections of facilities involved in the importation, storage, and distribution of narcotic and psychotropic substances.
- Ensure that facilities comply with established guidelines and that substances are stored and distributed in a secure, controlled environment to prevent misuse or diversion.

- Develop and implement training programs for experts involved in the inspection, regulation, and enforcement of narcotic and psychotropic substances as well as precursor chemicals.
- Continuously enhance the capacity of the desk by fostering professional development and knowledge-sharing among team members and stakeholders.
- Lead initiatives to raise public awareness regarding the risks of misuse of narcotic and psychotropic substances.
- Collaborate with health professionals, law enforcement agencies, and educational institutions to educate the public and stakeholders about the legal and health risks associated with these substances.
- Monitor the national consumption, production, and distribution trends of narcotic and psychotropic substances including precursor chemicals, ensuring that these activities are in line with national needs and international treaties.
- Prepare and submit regular reports on the status of narcotic and psychotropic substance control, including data on regulatory actions, compliance, and enforcement.
- Contribute to the development and review of national policies and regulations governing narcotic and psychotropic substances.
- Provide expert technical advice to EFDA leadership on the issues related to narcotic and psychotropic drug control, ensuring that polices are aligned with international standards;
- Ensure that all applications are reviewed thoroughly and in timely manner incompliance with the national laws and international agreements.
- Oversee the evaluation and approval of applications for especial import permit and distribution of narcotic and psychotropic substances as well as precursor chemicals.
- Lead investigations into incidents of illegal trafficking, diversion, or misuse of narcotic and psychotropic substances.
- Collaborate with law enforcement agencies to ensure proper legal action is taken against violations, including seizures and prosecutions.

- Lead responses to crises or emerging threats related to narcotic and psychotropic substances, including public health risks or significant incidents of diversion.
- Develop strategies for mitigating the risks associated with the misuse or illicit trade of controlled substances, working closely with other government agencies and stakeholders.
- Lead, guide, and oversee the tobacco control team, ensuring effective and coordinated efforts toward the implementation of national tobacco control policies and strategies.
- Supervise the planning, implementation, and evaluation of tobacco control programs and initiatives in alignment with EFDA's mission and strategic objectives.
- Ensure that the team complies with EFDA's standards and regulatory frameworks in executing their responsibilities.
- Provide expert advice on tobacco control policies, legislative measures, and regulatory frameworks to senior management and key stakeholders.
- Advocate the implementation of comprehensive tobacco control programs in line with international guidelines such as FCTC.
- Act as a liaison between EFDA, governmental bodies, non-governmental organizations, and international agencies in tobacco control efforts.
- Oversee the enforcement of tobacco control regulations, including those concerning tobacco product packaging, labeling, advertising, and sales.
- Monitor compliance with tobacco control regulations among manufacturers, importers, and distributors, ensuring adherence to national laws and international standards.
- Conduct risk assessments and evaluate the impact of tobacco control regulations.
- Oversees and regulates the production of shisha, electronic nicotine delivery devices (ENDS), and other similar tobacco-related products, ensuring compliance with national standards and regulatory frameworks
- Lead the development of data collection systems for tobacco-related indicators, including smoking prevalence, tobacco product sales, and the economic impact of tobacco use.
- Prepare and present regular reports, statistical analyses, and policy briefs to senior management, policymakers, and stakeholders.

- Develop and implement public awareness campaigns to reduce tobacco use and educate the public on the risks associated with smoking and second-hand smoke exposure.
- Coordinate with other health agencies, community organizations, and educational institutions to promote tobacco-free environments.
- Oversee the development and dissemination of educational materials, media campaigns, and health promotion activities related to tobacco control.
- Build and maintain partnerships with national and international organizations involved in tobacco control and public health.
- Represent EFDA in meetings, workshops, and conferences related to tobacco control, ensuring the Authority's interests are well-represented.
- Collaborate with law enforcement agencies to address the illegal trade of tobacco products and enforce existing regulations.

2.3.3. Pharmacovigilance and Clinical Trial Lead Executive Office

a. Introduction

The Pharmacovigilance and Clinical Trial Lead Executive Office (PVCT LEO) is responsible for monitoring the safety, efficacy and quality of medicines and cosmetic products including modern, traditional, and alternative medicines, as well as biologicals, vaccines, blood and blood products, and radiopharmaceuticals and continue to uphold these standards throughout their use in the market.

The office reviews new clinical trial applications, evaluates safety and progress reports submitted from authorized trials, and conducts Good Clinical Practice (GCP) inspections to ensure the rights, safety, and well-being of participants are protected, while also ensuring the credibility and integrity of generated data. Additionally, the office is tasked with coordinating risk-based quality Post Market Surveillance (PMS), drug information and promoting rational and appropriate use of medicines across the health system.

b. Organization and accountability

The Lead Executive Office for Pharmacovigilance and Clinical Trial is accountable to Deputy

Director General of the Medicines Sector and is responsible for overseeing four desks under the office. Each desk reports to the Lead Executive Officer. These include:

1. Medicines Safety and Post Marketing Surveillance Desk
2. Clinical Trial Authorization and Inspection Desk
3. Drug Information and Rational Medicine Use Desk
4. Cosmetics Safety and Post Marketing Surveillance Desk

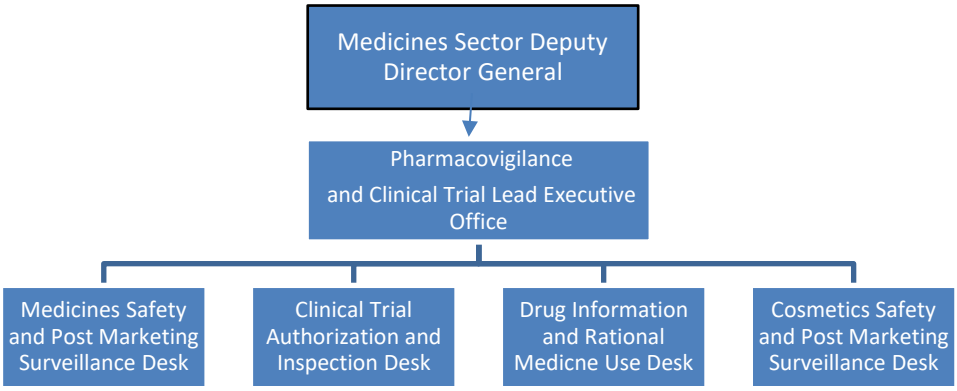


Fig 2.3.3: *PVCT LEO Organization Chart*

c. Duties and responsibilities of PVCT LEO

- Ensures that the quality, safety, and effectiveness of medicines are maintained after they enter the market, in line with the standards approved during their registration.
- Oversees system of Adverse Drug Event (ADE) monitoring, including collecting reports on Adverse Drug Reactions (ADRs), product quality defects, and medication errors, assessing and analyzing the reports, compiling the analysis results, recommending appropriate measures, and sharing the reports with the WHO.
- Ensures and monitors that manufacturers, importers, and distributors establish and maintain medicines safety monitoring system.
- Directs medicines manufacturers and importers to conduct post-market surveillance on their own.

- Instructs and monitors medicines manufacturers and importers to independently conduct post-market surveillance of their products.
- Provides appropriate solutions to medicine-related problems received nationwide from healthcare facilities and professionals, through systematically organizing, analyzing, and interpreting of the collected information.
- In the event of a sudden or serious medicine-related incident, facilitate and coordinate that activities are carried out to promptly respond by visiting the site to carry out necessary investigation, collecting and analyzing relevant data. Ensures that thorough assessment is conducted and recommendations are provided to appropriate stakeholders based on the findings, and follows up to ensure effective implementation of those recommendations.
- Works to strengthen the technical capacity of regional investigation task forces, facilitates training, and ensures the efficient investigation of serious adverse events.
- Coordinates and facilitates the causality assessment of serious adverse events by the National Pharmacovigilance Advisory Committee, ensures timely communication of recommendations to relevant public health programs and stakeholders, and monitors the implementation of these recommendations.
- Ensures and Coordinates provision of awareness and trainings to healthcare professionals to enhance their ability to promptly identify and report any medicine-related problems.
- Monitors and follows the conduct of continuous awareness-raising activities for the public and stakeholders to protect them from health risks related to the safety, quality, and effectiveness of medicines, and to promote the prevention of medicine-related issues.
- Collaborates with national, regional, continental, and international organizations on matters related to the quality, safety, and efficacy of medicines, working on behalf of the authority to carry out joint activities and exchange relevant information.
- Monitors, collects, and analyzes data from national, regional and international sources related to medicine quality, safety, and efficacy alerts, including early warnings and notifications about products prohibited for use. Ensures that this information is

communicated to relevant stakeholders and follows up to monitor the implementation of appropriate actions.

- Establishing relationships with international organizations and exchanging information when faced with medicines safety, quality and efficacy related problems occurring in the country.
- Supports and coordinates for the establishment of Medicines safety monitoring centers in selected health institutions at the sub-national level;
- Works in collaboration with bodies that work towards ensuring the proper use of medicines.
- Ensures the Preparation of timely and accurate medicine related information and dissemination using appropriate channels to reach the public, and coordinate and monitor for the information to be used for the desired purpose.
- Oversee the conduct of risk-based PMS on medicines by collecting product samples from the market and submission for laboratory testing. Based on the test results, identifies non-compliant products, informs the relevant stakeholders for appropriate regulatory action, and follows the implementations of the actions.
- Confirms Preparation the Essential Medicines List and shares information on registered medicines with health facilities and other stakeholders; develops and issues the National Medicines Formulary; categorizes medicines according to different levels of healthcare and updates these classifications as needed.
- Monitors activities related to antimicrobial resistance (AMR) and works in collaboration with research and academic institutions to support the prevention and containment of AMR.
- Supports and ensures the implementation of Antimicrobial Stewardship Programs in all hospitals and promotes collaborative efforts to strengthen their effectiveness.
- Monitors the safety and quality of cosmetic products, and performs risk-based post marketing surveillance on cosmetic products.

- Approves Review results and feedback on new clinical trial applications, amended submissions, and responses to requests for additional information, ensuring compliance with applicable guidelines and standards.
- Ensures the conduct of risk based GCP inspection and approve results.
- Issues clinical trial authorization certificates for applications that have been reviewed and found to be in compliance with applicable regulatory requirements and ethical standards
- Maintains a national database to document and register information on ongoing clinical trials conducted within the country
- Supervises the conduct of studies to assess whether the legal frameworks established to ensure the proper use of medicines are being effectively implemented at the national level, and, based on the findings, informs the relevant stakeholders to take appropriate actions and monitor implementation.
- Evaluates, approves, and ensures implementation of guiding documents, such as strategies, manuals, protocols, and related materials, for medicines and cosmetics safety and post-marketing surveillance, drug information and rational medicine use, and clinical trial authorization and inspection systems.
- Conduct periodic performance evaluations and provide feedback to desks.
- Designs strategies to build the capacity of experts within the executive office, makes decisions on matters beyond the scope of individual desks, and implements the decisions and guidance issued by the authority.
- Develops a system to ensure smooth communication, as well as efficient and effective operations, across the desks under the Lead Executive Office.
- Develops a system to ensure smooth communication across the desks under the Lead Executive Office, supporting efficient and effective operations.
- Devices ways to support branch offices in the medicine sector by facilitating technical assistance on medicines safety and quality monitoring, and strengthening information exchange

- Ensures the availability and implementation of necessary guidelines, operating manuals and SOPs for the executive office.

d. Duties and Responsibilities of Medicines Safety and Post Marketing Surveillance Desk

- Ensures that all medicines (including biologicals, vaccines, blood products, and radiopharmaceuticals) in the Ethiopian market continue to meet the safety, quality, and efficacy standards established at the time of registration, through conduct of post marketing surveillance by sample collection, and submitting for laboratory testing.
- Conducts risk-based PMS on medicines by collecting product samples from the market and submit for laboratory testing. Based on the test results, identifies non-compliant products, informs the relevant stakeholders for appropriate regulatory action, and follows the implementations of the actions.
- Conduct post-authorization safety studies (PASS) and effectiveness studies.
- Issues public alerts on substandard, or falsified medicines and advice for initiating of product recall procedures when necessary.
- Issuing of Drug Safety Alerts and Dear Healthcare Provider letters.
- Disseminating updated product information and safety labelling changes.
- Develop, submit for approval and implement documents such as strategies, manuals, protocols and other documents that govern the medicines post-market surveillance system.
- Performs and coordinates medicines post-market surveillance activities at the national level.
- Coordinates and collaborates with pharmaceutical manufacturers and importers to carry out post-marketing surveillance activities.
- Monitoring of Adverse Event Following Immunization (AEFI) for vaccines that are being used in the country and placed in the market.
- Conducts ADE monitoring, including collecting reports on ADRs, product quality defects, and medication errors, assessing and analyzing the reports, compiling the analysis results, recommending appropriate measures, and sharing the reports with the WHO.

- Ensures, coordinates and monitors that manufacturers, importers, and distributors establish and maintain medicines safety monitoring system.
- Based on findings from medicine safety monitoring, informs relevant stakeholders of necessary regulatory actions and monitors their implementation.
- In the event of a sudden or serious medicine-related incident, promptly responds by visiting the site to carry out necessary investigation, collecting and analyzing relevant data. Participates and ensures that thorough assessment is conducted and recommendations are provided to appropriate stakeholders based on the findings, and follows up to ensure effective implementation of those recommendations.
- Coordinates and provides awareness and trainings to healthcare professionals to enhance their ability to promptly identify and report any medicine-related problems.
- Performs periodic review and monitoring of safety update reports, Risk assessment and Risk communication plan and provide feedback.
- Ensuring that manufacturers and importers meet Pharmacovigilance obligations such as submitting Periodic Safety Update Reports, Risk Management Plan.
- Reviewing Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs).
- Supporting regulatory inspections or audits related to PV systems.
- Conducts and collaborates active surveillance on selected medicines
- Analyze and assess for potential signals on reported adverse events in collaboration with the National Pharmacovigilance Advisory Committee as needed.
- Facilitates and participates as necessary in the investigation of serious adverse events, coordinates conduct of causality assessment classification by the national Pharmacovigilance Advisory committee.
- Monitors, collects, and analyses data from international sources related to medicine quality, safety, and efficacy alerts, including early warnings and notifications about products prohibited for use. Ensures that this information is communicated to relevant stakeholders and follows up to monitor the implementation of appropriate actions.

- Establishing relationships with Regional and international organizations and exchanging information when faced with medicines safety, quality and efficacy related problems occurring in the country.
- Participating in regional pharmacovigilance initiatives (e.g., AU-AVAREF, AUDA-NEPAD, WHO PV networks and others).
- Supports and coordinates for the establishment of Medicines safety monitoring centres in selected health institutions at the sub-national level;
- Conducts continuous awareness-raising activities for the public and stakeholders to protect them from health risks related to the safety, quality, and effectiveness of medicines, and to promote the prevention of medicine-related issues.
- Conduct periodic performance evaluations and provide feedback, compile performance reports and submit them to the lead Executive Officer.
- Ensures the correctness of the activities performed by the desk;
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, present to the lead executive Officer so that it can be implemented.
- Develops system to ensure smooth communication and efficient and effective work within the desk.
- Prepare necessary guidelines, operating manuals and SOPs for the desk.

e. Duties and Responsibilities of Clinical Trial Authorization and Inspection Desk

- Establish a system for clinical trial oversight. Prepares, revises, and implements guidelines and standard operating procedures.
- Receives and reviews clinical trial applications, authorizing those with public health benefit and rejecting those that pose safety risks.
- Evaluates clinical trial protocols involving investigational products by assessing the chemical properties and potential human risks based on pre-clinical animal studies and data from similar substances, and ensures the inclusion of appropriate preventive measures in the protocol.

- Evaluates whether the investigators responsible for the protocol and clinical trial conduct possess adequate expertise in clinical research and foundational health sciences, and implements authorization decisions accordingly.
- Evaluates requests for amendments to authorized clinical trial protocols and approves or not accept revisions based on justified evidence indicating that the existing methodology/design is not scientifically sound.
- Reviews interim data submitted for ongoing clinical trials conducted under an approved protocol and makes decisions on trial termination when results indicate failure to meet study objectives.
- Monitors and inspects the conduct of clinical trials to ensure compliance with GCP and the approved study design and methodology. Trials found to be conducted by unlicensed researchers or in violation of the approved protocol may be suspended or terminated and referred to the legal department for further action.
- Ensures that the subjects of the clinical trial are recruited voluntarily without any pressure or deception, and that they can terminate the trial at any time.
- Confidentially monitors and investigates ethical or safety concerns raised by clinical trial participants. Where non-compliance or participant risk is identified, recommends corrective actions up to and including trial suspension.
- Requests scientific justification from the Principal Investigator for adverse events occurring during the clinical trial; collects, analyzes, and interprets safety data; and takes appropriate actions, including requesting protocol amendments or early termination to prevent further risk to participants.
- Conducts interim data reviews and monitoring progress of clinical trial being conducted as per authorized protocol.
- Reviews and validates clinical trial results upon study completion to ensure the credibility of findings.

- Conducts inspections and monitoring of clinical trial sites to verify compliance with GCP; issues, renews, suspends, or revokes site authorization based on adherence to applicable standards.
- Plans, executes, coordinates, manages, monitors and supports activities related to clinical trial protocol review and approval.
- Conduct periodic performance evaluations and provide feedback, compile performance reports and submit them to the lead Executive Officer.
- Ensures the correctness of the activities performed by the desk;
- Designs strategies to build the capacity of the desk, forward decision for issues that are beyond the capacity of the experts, executes decisions and directions from the lead executive officer.
- Develops system to ensure smooth communication and efficient and effective work within the desk.
- Prepare necessary guidelines, operating manuals and SOP for the desk
- Adopts and integrates international best practices related to clinical trial application review and authorization systems, tailoring them to align with national regulatory priorities.

f. Duties and Responsibilities of Drug Information and Rational Medicine Use Desk

- Ensure that registered and marketed medicines contain correct information on the use, handling and disposal of medicines as per stated during registration.
- Conducts and coordinates therapeutic efficacy studies in collaboration with health institutions to verify that antimicrobial drugs including modern, traditional, and alternative medicines marketed in Ethiopia meet the therapeutic claims made at the time of registration, and to identify those suitable or unsuitable for national use.
- Work in collaboration with academic and research institutions related to research on AMR to assess the national resistance profile, support prevention and containment efforts, and inform evidence-based corrective actions.
- Prepares and promotes Essential Medicines List taking into account the prevalence of health problems in the country.

- Prepares and promotes National Medicines Formulary to provide easy access of medicines information for health care professionals, categorize medicines in different levels, revises the category as necessary.
- Inform the list of registered medicines to the public through various means of communication.
- Provision of training and awareness creation sessions for key stakeholders (Regional Regulatory Bureaus, Hospital Pharmacies, Community Pharmacies, Healthcare Providers) about Rational Drug use and Rational Medicine Use Directive.
- Provide training on AMR for federal hospitals and regional Health Bureaus.
- Participating in the Advisory Committee of AMR prevention and containment, evaluate the status of the AMR prevention and containment Strategy and set the next direction.
- Collecting and analysing the National antimicrobial consumption (AMC) data and report to WHO GLASS.
- Supports and ensures the implementation of Antimicrobial Stewardship Programs in all hospitals and promotes collaborative efforts to strengthen their effectiveness.
- Support regions to conduct Medicine Use Evaluation (MUE) and antimicrobials consumption survey in Hospitals through trainings, meetings for one unified report
- Support medicine information centres in hospitals.
- Promote and strengthen implementation of community pharmacy standards.
- Prepare timely and accurate medicine related information and disseminate using appropriate channels to reach the public, and coordinate and monitor for the information to be used for the desired purpose.
- Provide information to the public using different appropriate channels on rational and appropriate use of medicines.
- Assess whether the legal frameworks established to ensure the proper use of medicines are being effectively implemented at the national level, and, based on the findings, informs the relevant stakeholders to take appropriate actions and monitor implementation.

- Prepares, submit for approval, and implements guiding documents, such as strategies, manuals, protocols, and related materials for drug information and rational medicine use activities.
- Participates in, coordinates and monitors activities to prevent the antimicrobial resistance at the national level and support regional AMR coordinating committees.
- Work in collaboration with the concerned stakeholders in activities to promote the proper use of medicines.
- Conduct periodic performance evaluations and provide feedback, compile performance reports and submit them to the lead Executive Officer.
- Ensures the correctness of the activities performed by the desk;
- Designs strategies to build the capacity of the desk, forward decision for issues that are beyond the capacity of the experts, executes decisions and directions from the lead executive officer.
- Develops system to ensure smooth communication and efficient and effective work within the desk.
- Prepare necessary guidelines, operating manuals and SOP for the desk.

g. Duties and Responsibilities of Cosmetics Safety and Post Marketing Surveillance Desk

- Prepare, submit for approval and monitor the implementation of operational strategies, manuals, SOPs and other documents to be managed by the cosmetic safety and post-market surveillance desk.
- Compiles and implements international experiences around the post-market surveillance system of cosmetic products
- Conduct and coordinate national safety monitoring and post-market surveillance on cosmetic products available in the market; take measures or recommends measures to be taken based on the findings.
- Carry out assessments based on reports of defective cosmetic products such as those with misleading claims or regulatory non-compliance and, when confirmed, issues appropriate corrective or regulatory actions and monitors their implementation.

- In the event of a cosmetic product-related incidents, responds promptly by conducting on site investigation activities, collects and analyzes relevant data, informs appropriate stakeholders of the findings, and oversees the implementation of necessary corrective measures.
- Plans and executes continuous public awareness activities to protect the community and stakeholders from health risks associated with adulterated or contaminated cosmetic products.
- Monitors, collects, and analyzes data from national and international sources on health problems and early warnings related to the safety of cosmetics as well as products that are prohibited from being used and communicates the information.
- Conduct periodic performance evaluations and provide feedback, compile performance reports and submit them to the lead Executive officer.
- Ensures the correctness of the activities performed by the desk;
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, present to the lead executive so that it can be implemented.
- Develops system to ensure smooth communication and efficient and effective work within the desk.
- Provides professional support to branch offices on conducting cosmetics safety monitoring and post-market activities and ensure smooth exchange of information.
- Prepare necessary guidelines, operating manuals and SOP for the desk

2.3.4. Medicine Quality Control Lead Executive Office

a. Introduction

The Medicine Quality Control (MQC) Lead Executive Office (LEO) is established as a Lead Executive Office to carry out the required quality control testing to ensure that active pharmaceutical ingredients, excipients and finished pharmaceutical products meet quality specifications. Throughout the process of assuring the quality of medicines both before market authorization and after marketed in the country, MQC LEO acts as an active technical wing for EFDA.

In addition, MQC LEO performs quality control tests on cosmetics, antiseptics and disinfectants, traditional medicine, vaccine, biological products etc. Concerning other quality control and quality assurance aspects, MQC LEO collaborates with other EFDA LEOs in the assessment of quality section of the dossier and inspections of pharmaceuticals, bio-analytical centers and pharmaceutical manufacturing companies for their compliance as per the national and international standards. The main purpose of medicine quality control is for carrying out physical, chemical, and microbiological tests on products from both local and foreign origin on samples for new registrations, consignments, post-market surveillance and suspicious cases;

By, conducting the tests, establishes safety and quality of modern and traditional medicines as well as the safety and quality of and cosmetic products used for public health were.

b. Organization and Accountability

The Lead Executive Officer of Medicines Quality Control is accountable to the Medicines Sector Deputy Director General and has two desks under it.

1. Medicines Physicochemical Quality Control Desk
2. Medicines Microbiology Quality Control Desk

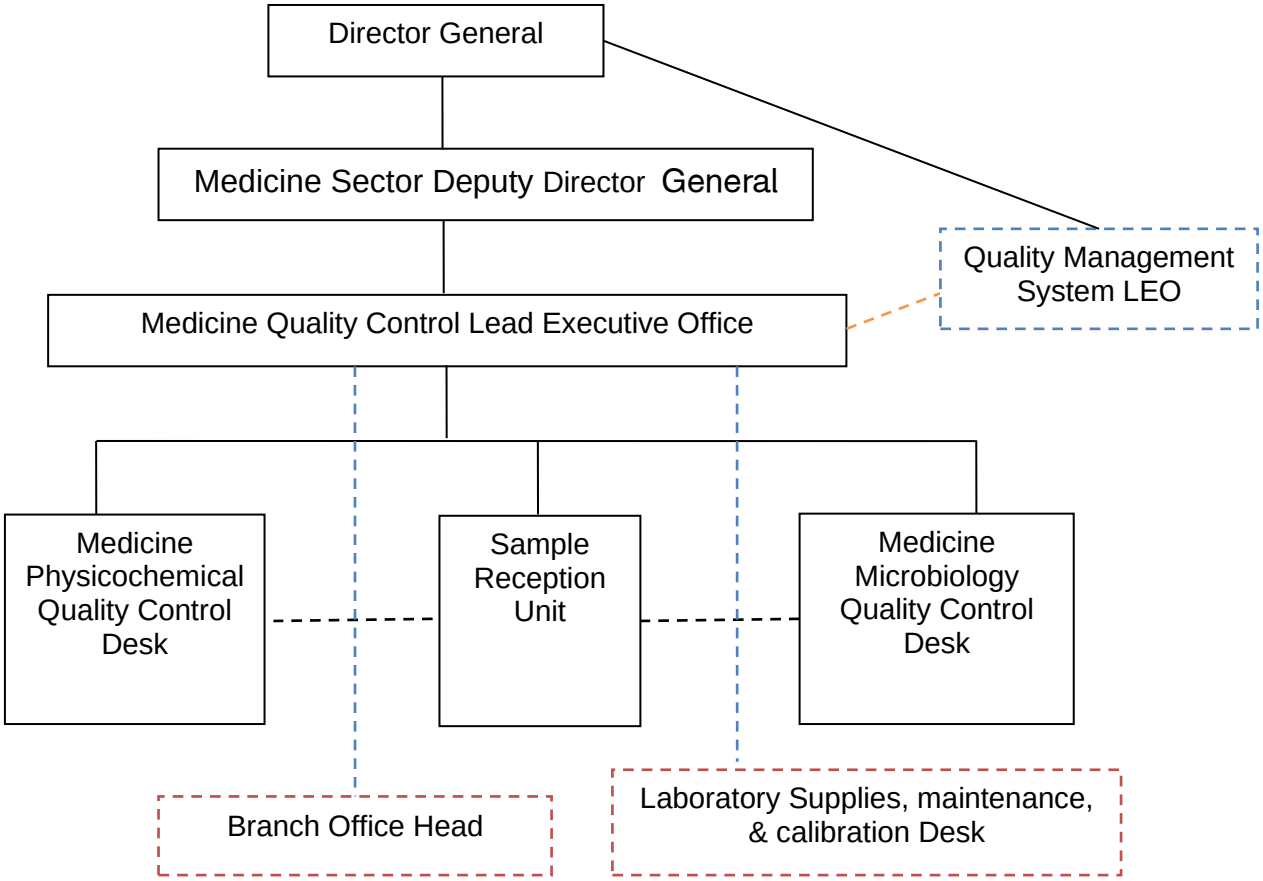


Fig 2.3.4: *MQC LEO Organizational Chart*

c. Duties and Responsibilities of MQC LEO

- Prepare, submit for approval and monitor the implementation of scientific documents such as operating strategies, manuals, standard operating procedures, which guide the quality testing of medicines, and cosmetic products used for public health.
- Prepare in-house method by generating and researching the method of analysis and quality standard for testing the samples of medicines, and cosmetic products that do not have a quality testing method.
- Compile and implement international experiences in quality testing of medicines, and cosmetic products used for public health.

- Works on behalf of the authority to establish effective and sustainable cooperation with international and national institutions regarding the quality testing of medicines, and cosmetics used for public health.
- Collaborate with other National Regulatory Agencies (NRAs) and rely on accredited or prequalified laboratories for supplementary testing when necessary
- Ensures that professionals have the required technical skills of the period; when competence gap observed, facilitates local and abroad training to improve their skills.
- Work for proficiency testing of samples with accredited labs and ensure proper execution of same.
- Maintain and expand scope of accreditations for quality testing obtained by international laboratory accreditation organizations, as well as work to obtain and maintain accreditations from local accreditation bodies.
- Create income generation for the authority by providing quality testing services from other countries and institutes.
- Validation of existing and new quality testing methods using various advanced analytical methods.
- Conduct necessary quality control testing on modern and traditional medicines used for public health, whether produced in the country or imported from abroad before registration and inform the result to relevant parties.
- Conduct risk based post-market quality control testing on medicines, and cosmetics produced and marketed in the country or abroad, conduct the necessary quality control test on suspect samples; and inform the results to the relevant parties.
- Carry out quality control test on necessary consignments samples (taken from entry and exit ports before entering the market) of medicines produced abroad and imported into the country, and cosmetics used for public health; and inform the results to relevant parties,
- Prepare and/or make available reference standards for physico-chemical testing using international methods.

- Ensure all laboratory equipment is qualified, calibrated, and maintained according to predefined schedules to support reliable testing
- Develop technical specifications for laboratory equipment and materials necessary for quality testing of pharmaceuticals, and cosmetics for public health; submit for approval of the spec, conducts a technical evaluation when they are purchased and delivered, verifies that they comply with the prepared technical specifications (standards);
- Implement an operational system that allows the drug quality control testing system to be supported by modern information and communication technology (LIMS); Monitors sustainability.
- In the event of a national emergency epidemic disease, conduct the necessary quality testing on medicines that should prevent the epidemic.
- Develop mechanisms for maintain meticulous records of all testing activities, from sample receipt and analysis to data interpretation and reporting.
- Receive laboratory samples ensuring they meet the required standards and handles them appropriately.
- Establishes procedures for the handling and use of retention samples, samples leftover from quality testing and expired samples, and monitors execution;
- Design strategy to build capacity of the executive office professionals; Makes decisions on issues beyond the scope of desks; executes the decisions and directions of the authority.
- Develop system to ensure smooth communication and efficient and effective work in the desks under the lead executive.
- Provide training, professional support and support the strengthening of the exchange of information to the desks that carry out quality testing of medicines, and cosmetics for public health services;
- Provide training and support to ports of entry and exit (structured under the branch offices) on the necessary quality control of medicines for public health services, and cosmetics.
- Prepare necessary guidelines, operating manuals and SOPs for the desks.

d. Duties and Responsibilities of Medicine Physicochemical Quality Control Desk

- Prepare, submit for approval and monitor the implementation of operational strategies, manuals, standard operating procedures and other documents that govern the physicochemical quality testing of medicines and cosmetics.
- Develop a new Analytical Method (Method Development) and a new analytical method for testing samples of medicines and cosmetics that do not have a physicochemical quality testing method.
- Monitor of the environmental condition and cleanness of the test areas to be as per the international standard requirements
- Participate in proficiency testing of samples with accredited labs and ensure proper execution of same.
- Validation/verifying of existing and new quality testing methods using various advanced analytical methods.
- Conduct physicochemical quality test necessary for registration of locally produced and imported medicines: traditional medicines and cosmetics; inform the results to relevant parties.
- Conduct post-market physicochemical quality testing on medicines and cosmetics produced and marketed in the country and abroad, and performs the necessary physicochemical quality testing on suspect samples; inform the results to relevant parties.
- Conduct necessary physicochemical quality testing of consignments medicines and cosmetics of imported products; and inform the results to relevant parties,
- Prepare and/or make available reference standards for physico-chemical testing using international methods.
- Develop technical specifications for laboratory equipment and materials necessary for physicochemical quality testing of drugs and cosmetics; Performs a technical review of purchased and delivered products to ensure compliance with specifications;
- Verify proper functioning and regularly calibrated, verified, and maintained of physicochemical equipment used for quality testing of pharmaceuticals and cosmetics.

- Formulate strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, present it to the lead executive so that decisions can be made so that they can be implemented.
- Develop mechanisms for maintain meticulous records of all testing activities, from sample receipt and analysis to data interpretation and reporting.
- Develop procedure to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support to branch offices and sections conducting quality control activities.
- Prepare necessary guidelines, operating manuals and SOPs for the desk;

e. Duties and Responsibilities of Medicines Microbiology Quality Control Desk

- Prepare, play role in approval and monitor the implementation of operational strategies, manuals, unified work instructions and other documents that govern the microbiology quality testing of medicines and cosmetics.
- Develops a new Analytical Method Development (Method of analysis) and a new analytical method for testing samples of medicines and cosmetics that do not have a microbiology quality testing method.
- Suitability or Validation of existing and new quality testing methods using various advanced analytical methods.
- Conform the suitability of microbiological test areas for the specific test to be conducted
- Monitor the environmental condition and cleanness of the microbiological test areas to be as per the international standard requirements
- Participate in proficiency testing of samples with accredited labs and ensure proper execution of same.
- Conduct microbiological test necessary for registration of locally produced and imported medicines: traditional medicines and cosmetics; inform the results to relevant parties.

- Conduct risk based post-market microbiological quality testing on medicines and cosmetics produced and marketed in the country and abroad and performs the necessary microbiological quality testing on suspect samples; inform the results to relevant parties.
- Conduct necessary microbiological quality testing of consignments medicines and cosmetics of imported products; and inform the results to relevant parties,
- Develop technical specifications for laboratory equipment and materials necessary for microbiological quality testing of drugs and cosmetics; Performs a technical review of purchased and delivered products to ensure compliance with specifications;
- Develop mechanisms for maintain meticulous records of all testing activities, from sample receipt and analysis to data interpretation and reporting.
- Verify proper functioning, regularly calibrated, verified and maintained of microbiological equipment used for quality testing of pharmaceuticals and cosmetics.
- Formulate strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, present it to the lead executive so that decisions can be made so that they can be implemented.
- Develop procedure to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support to branch offices and sections conducting quality control activities.
- Prepare necessary guidelines, operating manuals and SOPs for the desk

2.4. Medical Device Sector Deputy Director General

a. Introduction

The Deputy Director General of the Medical Device Sector, as one of the three Deputy Directors General plans, organizes, directs, monitors, supports, and coordinates medical device control activities. He/she provides operational and policy direction, formulates strategies to build the capacity of subordinate units, and makes decisions on matters beyond the capacity of those units. The Deputy Director General for Medical Device Sector also develops policies and strategies for the national medical device regulatory system, issues institutional decisions and directions, and promotes awareness among the public and stakeholders to foster ownership and partnership in the sector.

In addition, the Deputy Director General for Medical Device Sector works to establish effective and sustainable cooperation with national and international institutions, and supports the Director General in ensuring that all sector activities are carried out efficiently and in alignment with the Authority’s mandate.

b. Organization and Accountability

The Medical Device Sector Deputy Director General is accountable to the Director General and consists of three Lead Executive Offices:

1. Medical Device Quality Control Lead Executive Office
2. Medical Device Manufacturers Inspection and Enforcement Lead Executive Office
3. Medical Device Evaluation and Marketing Authorization Lead Executive Office

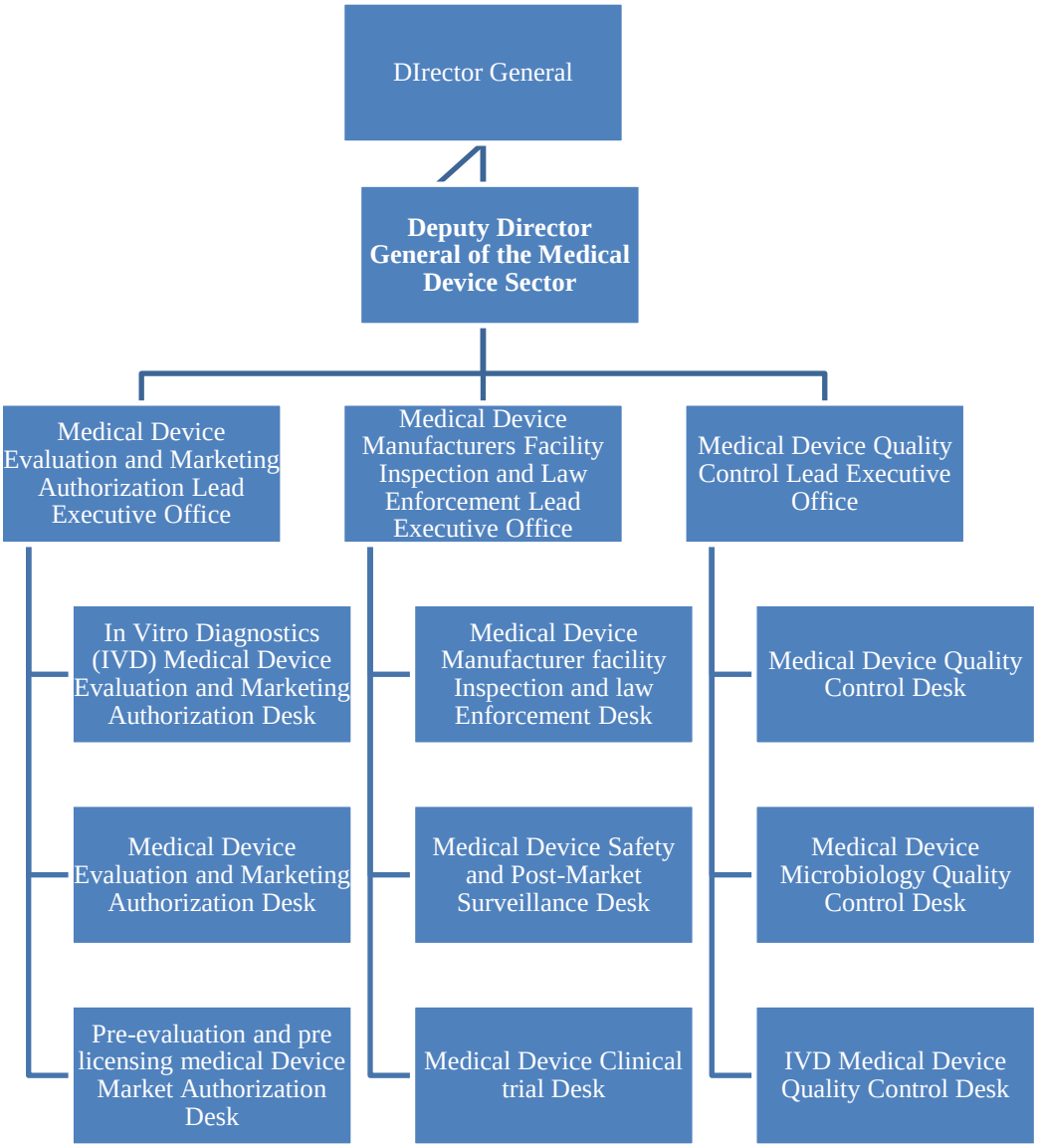


Fig 2.4: *Medical Device Deputy Director General Organizational Chart*

c. Duties and Responsibilities of the Medical Device Deputy Director General

- Coordinate the development of strategies, programs, and methods for the sector.
- Supervise the daily activities of the sector.
- Identify legal gaps in the sector and ensure that regulations and guidelines are implemented by the relevant work units.

- Ensure that the policies, laws, operating guidelines, and standards issued for the sector are properly implemented by subordinate work units.
- Ensure that the budget required for the sector is allocated and that the allocated budget is used effectively.
- Support, monitor, and coordinate subordinate work units to ensure effective performance.
- Ensure strong coordination and working relationships among work units, and take corrective action when gaps arise by promptly assessing them.
- Ensure that performance indicators set to measure the sector's effectiveness and efficiency are periodically reviewed and implemented.
- Develop strategies and programs to improve the performance of professionals within the sector, and monitor their implementation.
- Develop incentive strategies to encourage professionals who demonstrate effective performance, and monitor their implementation.
- Promote awareness and create partnerships among the community and stakeholders to build ownership of the sector's strategies and practices.
- Represent the Authority in establishing effective and sustainable collaboration with international and national institutions related to the sector.

2.4.1. Medical Device Evaluation and Market Authorization Lead Executive Office

a. Introduction

According to proclamation number 1112/2019, article 20 sub article (1-7) and article 21 sub-article (1-2), the main objective of Medical Device Evaluation and market authorization Lead Executive office is to review the dossiers of medical devices and IVD medical devices manufactured domestically and abroad and issue market Authorization. It reviews, approves, when there are changes and renews market authorization of medical devices. It cancels the medical device marketing authorization based on the non-compliance results of the post-market surveillances or medical device safety report on medical devices that have been approved for sale on the market.

b. Organization and accountability

The Medical Device Evaluation and Marketing Authorization Lead Executive Office is

accountable to the Deputy Director General of Medical Device Sector and operated through three specialized desks:

1) In Vitro Diagnostics (IVD) Medical Device Evaluation and Marketing Authorization Desk
2) Medical Device Evaluation and Marketing Authorization Desk
3) Pre-Evaluation and Pre-Licensing Medical Device Market Authorization Desk

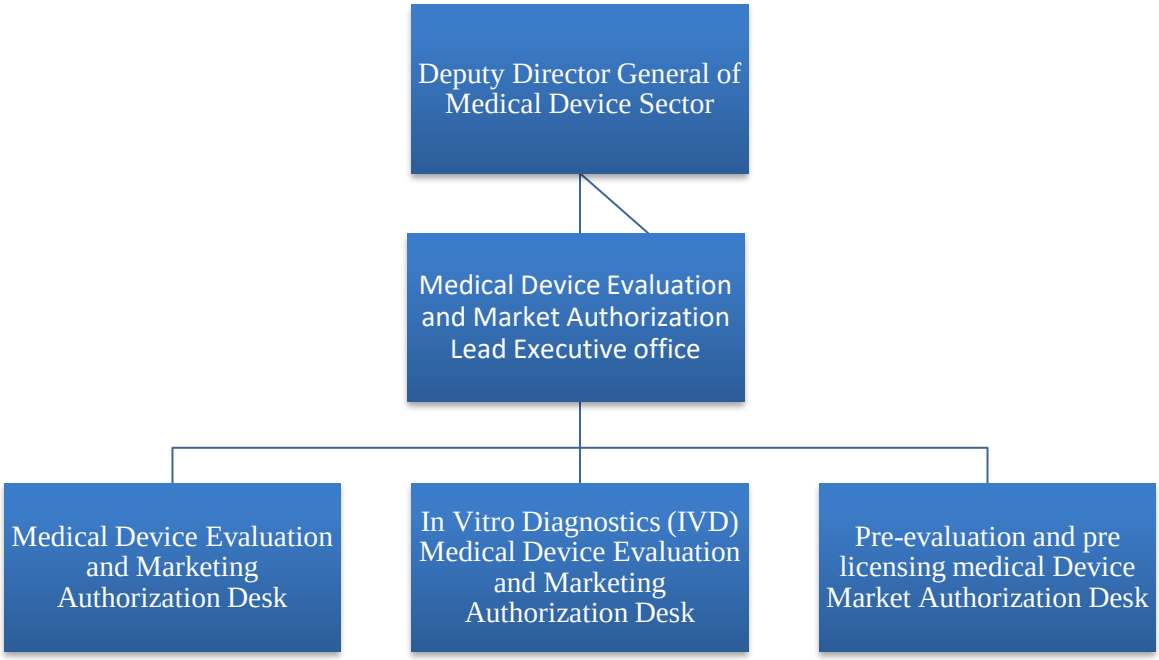


Fig 2.4.1: *Medical Device Evaluation and Marketing Authorization Lead Executive Office Organizational Chart*

a. Duties and Responsibilities of Medical Device Evaluation and Marketing Authorization Lead Executive Office

- Preparing, approving and implementing operational strategies, manuals and related documents governing the evaluation and market authorization of medical devices in the country;
- Compile and apply international experiences around the medical device evaluation and market authorization in a manner that beneficial to the country.

- Plan, implements, coordinates, manages, monitors and supports activities related to medical device evaluation and market authorization.
- Review current performance, compile performance reports, and provide feedback to relevant desks.
- Review and records scientific data on the quality, safety, and performances of medical devices manufactured domestically and abroad that requires marketing authorization, reviews and approves changes, and issues marketing authorizations.
- Issue marketing authorizations for domestically manufactured, imported, remanufactured, or refurbished medical devices, after reviewing the necessary documentation.
- Identify medical devices eligible for market entry without detailed review, establish a notification procedure, and issue market authorizations accordingly.
- Renew market authorizations for medical devices that meet the re-renewal requirements
- Cancel market authorizations and notify relevant authorities if deficiencies in quality, safety, or effectiveness are identified in approved medical device.
- Issuing a Free Sale Certificate for medical devices manufactured in the country for exported medical device.
- Identify operational gaps and provide directives to address them.
- Ensure accuracy and consistency in market authorization activities across the desks.
- Build strong collaborations with countries and international organizations experienced in medical device evaluation and market Authorization.
- Develop strategies to build institutional capacity, make decisions beyond the authority of the desks, and ensure implementation of directives.
- Establish systems to enhance communication and efficiency across the Executive Office.
- Prepare guidelines, operating manuals, and standard operating procedures (SOPs) required for the department

b. In Vitro Diagnostics (IVD) Medical Device Evaluation and Marketing Authorization Desk.

- Prepare, approve, and implement manuals and operating guidelines for IVD evaluation and marketing Authorization, aligned with national strategies.
- Compile and adapt international best practices in IVD evaluation and marketing Authorization for national use.
- Review and record scientific data on the quality, safety, and performance of IVDs manufactured domestically or abroad; review and approve changes; and issue marketing authorizations
- Issue marketing authorizations for domestically manufactured, imported, remanufactured, or refurbished IVDs after reviewing the required documentation.
- Suspend or revoke authorizations if deficiencies in quality, safety, or performance are identified, and notify relevant authorities.
- Ensure accuracy of authorization processes handled by desk experts.
- Maintain strong collaboration with countries and international institutions engaged in IVD regulation.
- Establish procedures for effective communication and workflow among desk professionals.
- Prepare guidelines, manuals, and SOPs required for desk operations.

c. Medical Device Evaluation and Marketing Authorization Desk

- Prepare, approve, and implement manuals and operating guidelines for medical device evaluation and marketing authorization, based on national strategies.
- Compile and apply international best practices in medical device regulation for national benefit.
- Review and record scientific data on the quality, safety, and performance of medical devices manufactured domestically or abroad; approve changes and issue authorizations
- Cancel authorizations and notify relevant authorities when devices are found to have quality, safety, or performance deficiencies.
- Strengthen relations with countries and international institutions engaged in medical device regulation.

- Ensure accuracy of authorization processes handled by desk experts.
- Establish procedures to ensure smooth communication and workflow among desk professionals.
- Prepare guidelines, manuals, and SOPs required for desk operations.
- Review and take action on post-authorization complaints regarding device quality, safety, or performance, in collaboration with relevant departments.

d. Pre-Evaluation and Pre-Licensing Medical Device Market Authorization Desk

- Develop, revise, and monitor the implementation of new techniques, guidelines, and procedures to make the pre-notification process for low-risk medical devices and the one-time pre-import permit process for unmet-need medical devices efficient, effective, and transparent.
- Ensure that international and up-to-date product notification and licensing procedures are established and complied with in the pre-notification and licensing of low-risk medical devices.
- Facilitate awareness-raising and training sessions for stakeholders regarding pre-import permit and licensing of low-risk medical devices; participate in meetings, workshops, and seminars.
- Renew marketing authorizations for all medical devices that meet re-registration requirements.
- Evaluate promotional materials for compliance with regulations and issue product promotion and promoter licenses.
- Evaluate low-risk medical devices for compliance with regulations and issue notifications for market authorization.
- Address operational challenges and product quality complaints from team members and customers; recommend improvements to operational procedures and guidelines in line with international standards.

2.4.2. Medical Device Manufacturers Inspection and Enforcement Lead Executive Office

a. Introduction

As mandated under Proclamation 1112/2019, Article 25 sub article (1-5) and article 27 sub article (1-11), the main objective of the Medical Device Manufacturers Inspection and Enforcement Lead Executive Office is to conduct inspections of domestic and foreign medical device manufacturers, to control the harm caused to the public by medical devices that do not meet their quality and safety standards, to take legal measures, and to ensure the competence of domestic medical device manufacturers.

b. Organization and Accountability

The Lead Executive Office of Medical Device Inspection and Enforcement is accountable to the Medical Device Sector Deputy Director General and three work desks fall under this office:

1. Medical Device Manufacturers Inspection and Enforcement Desk
2. Medical Device Safety and Post-Market Surveillance Desk
3. Medical Device Clinical Trial Desk

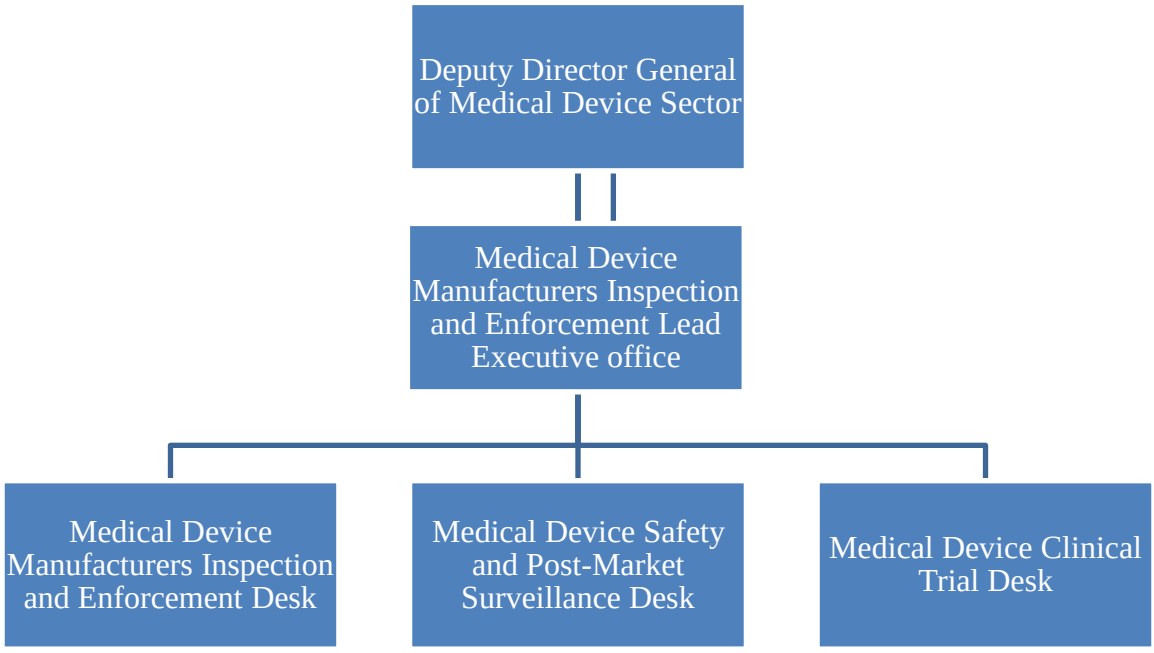


Fig 2.4.2: *Medical Device Manufacturers Inspection and Enforcement Lead Executive Office Organizational Chart.*

c. Duties and responsibilities of Medical Device Manufacturers Inspection and Enforcement Lead Executive Office.

- Preparing, approving and monitoring the implementation of operational strategies, manuals and other documents that guide the implementation of the Medical Device Inspection and enforcement.
- Conduct physical inspections of domestic and foreign manufacturers seeking to market products locally, ensuring compliance with Good Manufacturing Practices (GMP) or Quality Management Systems (QMS), and report findings to responsible body.
- Perform pre-licensing inspections of domestic manufacturers and submit reports to the responsible bodies.
- Take legal action against institutions and medical devices when safety monitoring or post-market surveillances study reports indicate the need, and notify to responsible bodies
- Investigate and take necessary action when unsafe medical devices that may cause serious harm are identified, and inform relevant bodies.
- Collaborate with legal executive office as necessary during inspection and enforcement.
- Collect, preserve, and provide evidence (documents, receipts, electronic records, samples, photographs, videos) to responsible body as permitted by law.
- Foster relationships with countries and international institutions involved in medical device good manufacturing systems or quality management systems oversight.
- Establish sustainable cooperation with national and international institutions for controlling medical device manufacturers.
- Build executive capacity, make decisions on matters beyond the scope of desk-level responsibilities, and ensure implementation of organizational directions.
- Facilitate effective communication between work desks for smooth operations.
- Prepare guidelines, operational manuals, and SOPs as required.

d. Duties and Responsibilities of Medical Device Manufacturer Inspection and Enforcement

Desk.

- Conduct facility inspections before issuing manufacturing licenses and submit findings to the lead executive office.
- Conducts renewal inspections of manufacturers who have been granted manufacturing certificates of competency as needed.
- Prepare, approve, and implement manuals and operational guidelines for inspections.
- Conduct physical inspections before manufacturers obtain market approval to confirm compliance with GMP and submit reports.
- Evaluate corrective and preventive actions (CAPAs), monitor their effectiveness, and re-inspect when necessary.
- Collaborate with the Legal Affairs Executive as necessary when conducting inspection activities.
- Collect and preserve evidence during inspections in compliance with legal requirements.
- Establish training and documentation systems to understand manufacturing processes, covering quality, safety, and performance
- Utilize global information sources, follow scientific and technological developments, and implement new methods.
- Take legal action against unsafe or substandard medical devices identified through inspections or post-market surveillance.
- Enforce compliance with advertising and promotional guidelines.
- Investigate devices with unverified safety or unknown sources and withdraw them from the market if necessary.
- Recommend administrative actions in consultation with Legal Affairs when inspection findings warrant them.
- Take preventive action against harmful medical devices before they enter or circulate in the market.
- Evaluate proposals for new domestic manufacturing facilities in collaboration with relevant government agencies and oversee GMP compliance during construction.

- Monitor desk performance, build staff capacity, and ensure smooth communication within the desk.
- Prepare guidelines, manuals, and SOPs as required.

e. Duties and Responsibilities of Medical Device Safety and Post-Market Surveillance Desk

- Prepare, approve, and implement post-marketing surveillances manuals, instructions, and related documents.
- Conducts post marketing surveillances on any manufacturer, importer, distributor and. health institution
- Coordinate with stakeholders to implement post-market surveillance and field safety corrective actions.
- Conduct nationwide post-market studies and annual market surveys.
- Inform stakeholders about devices requiring corrective actions and monitor their implementation.
- Raise public and professional awareness about medical device safety and quality issues.
- Provide professional support to branch offices on safety monitoring and research.
- Investigate risks, report findings, and disseminate actions taken.
- Manage adverse device event reports, analyze data, and recommend corrective actions.
- Monitor counterfeit, substandard, or misleading medical devices, and notify authorities.
- Establish systems to prevent harmful devices from reaching the market or entering the country.
- Promote proper reporting systems for adverse events by health professionals.
- Monitor global safety alerts and banned products and ensure timely dissemination.
- Conduct research to ensure effective enforcement of safety regulations.
- Detect signals in adverse event reports, conduct causality assessments, and implement active surveillance.
- Prepare guidelines, operating manuals, and SOPs as required.
- Develops strategies to build the capacity of the desk, and when issues beyond the capacity of the desk arise, presents them to the lead Executive Office for decision-making and implementation.
- Establishes a system that ensures smooth communication between professionals in the desk and efficient and effective work.

f. Duties and Responsibilities of Medical Device Clinical Trial Desk

- Prepare, approve, and implement clinical trial manuals and related documents.
- Review and license medical trial requests and ensure they benefit the community.
- Review applications for clinical evaluations, investigations, and follow-up studies conducted in Ethiopia.
- Issue licenses for modified medical devices subject to necessary controls.
- Monitor and regulate trials in compliance with Good Clinical Practice (GCP); suspend or terminate unsafe trials.
- Investigate complaints about clinical trials, particularly regarding ethics and safety.
- Support the introduction of modern diagnostic methods and removal of ineffective technologies.
- Build team capacity and escalate matters beyond desk-level authority to the lead Executive Office.
- Ensure clinical trials undergo ethical and scientific review by an authorized committee.
- Review adverse events and assess benefit-risk balance of devices under trial.
- Prepare guidelines, manuals, and SOPs as required.
- Establishes a system that ensures smooth communication between professionals in the desk and efficient and effective work.

2.4.3. Medical Devices Quality Control Lead Executive Office

a. Introduction

According to proclamation number 1112/2019 article 4, sub article (5), the Medical Device Quality Control Lead Executive Office has established with the main objective of ensuring safety and quality of domestically manufactured and imported medical devices through quality control testing for market authorization, consignment, post-market surveillances studies, and suspected devices.

b. Organization and accountability

The Medical Device Quality Control LEO is accountable to the Medical Device Sector Deputy Director General and has three desks within it. They are:

1. Medical Device Quality Control Desk
2. IVD Medical Device Quality Control Desk
3. Medical Device Microbiology Quality Control Desk

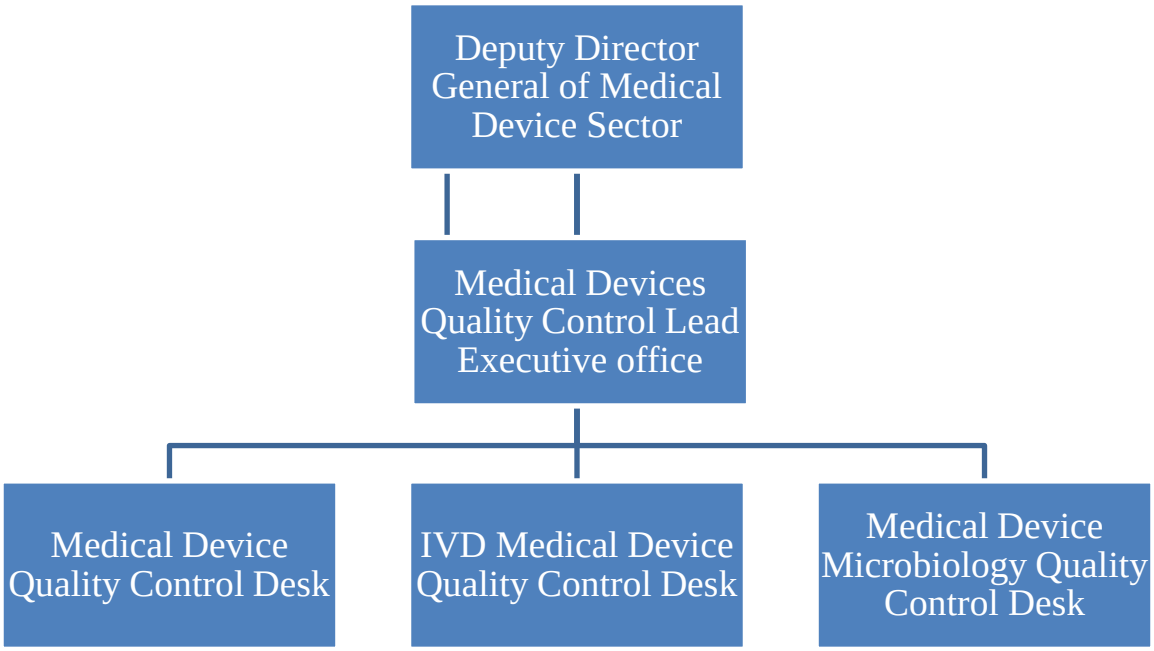


Fig 2.4.3: *Medical Device Quality Control Lead Executive Office Organizational Chart*

c. Duties and Responsibilities of Medical Device Quality Control Desk

- Develop, approve, and implement testing manuals, SOPs, and related documents.
- Establish analytical methods and quality criteria for devices lacking standard methods.
- Validate existing and newly developed testing methods.

- Conduct quality inspections of domestic and imported devices and report results.
- Carry out post-market and consignment quality inspections, as required.
- Conduct pre-market quality control testing of imported devices as necessary.
- Conducts consignments of medical devices manufactured in the country before they are put on the market, as required.
- Develop technical specifications for laboratory equipment and ensure functionality.
- Properly dispose of biological and non-biological test samples according to guidelines.
- Build staff capacity, escalate major issues to the lead Executive Officer, and establish efficient communication systems.
- Prepare guidelines, manuals, and SOPs as required

d. Duties and Responsibilities of IVD Medical Device Quality Control Desk

- Develop, approve, and implement testing manuals, SOPs, and related documents.
- Establish analytical methods and quality criteria for devices lacking standard methods.
- Validate existing and newly developed testing methods.
- Conduct quality inspections of domestic and imported IVD medical devices and report results.
- Carry out post-market and consignment quality inspections, as required.
- Conduct pre-market quality control testing of imported IVD medical devices as necessary.
- Conducts consignments of IVD medical devices manufactured in the country before they are put on the market, as required.
- Develop technical specifications for laboratory equipment and ensure functionality.
- Properly dispose of biological and non-biological test samples according to guidelines.
- Build staff capacity, escalate major issues to the lead Executive Officer, and establish efficient communication systems.
- Prepare guidelines, manuals, and SOPs as required

e. Duties and Responsibilities of Medical Devices Microbiology Quality Control Desk

- Develop and implement microbiology testing manuals, guidelines, and related documents.

- Establish analytical methods and quality criteria for devices lacking microbiological testing methods.
- Validate and verify microbiological testing methods.
- Request, manage, and release resources for microbiological testing.
- Conduct microbiological testing for pre-market, post-market surveillances, consignments, and suspected samples, and report result for domestically manufactured and imported medical device.
- Issue certificates for noncompliant devices and notify stakeholders promptly.
- Ensure compliance with international microbiological testing standards.
- Prepare technical specifications and evaluate laboratory equipment for microbiology testing.
- Ensures that equipment used for microbiological testing of medical devices is functioning properly;
- Properly dispose of microbial samples according to guidelines.
- Build desk capacity, escalate critical issues, and establish effective communication systems.
- Prepare manuals, guidelines, and SOPs as required.

2.5. Food Sector Deputy Director General

a. Introduction

The Food Sector Deputy Director General (DDG) is one of three DDGs, responsible for providing strategic leadership and oversight to ensure the safety and quality food. The DDG makes high-level decisions beyond the scope of lead executive officers, sets strategic, operational and policy directions, and formulates future strategies for the sector. The DDG coordinates the Lead Executive Offices, public and stakeholders, fostering national and international partnerships and collaboration, and representing EFDA in matters related to food regulation. The DDG also supports the Director General in ensuring sector activities aligned with the Authority's mission and mandate.

b. Organization and Accountability

The Deputy Director General of Food Sector is accountable to the Director General and manages the following three Lead Executive Offices.

1. Food Registration and Licensing Lead Executive Office
2. Food Inspection and Law Enforcement Lead Executive Office
3. Food Quality and Safety Control Laboratory Lead Executive Office

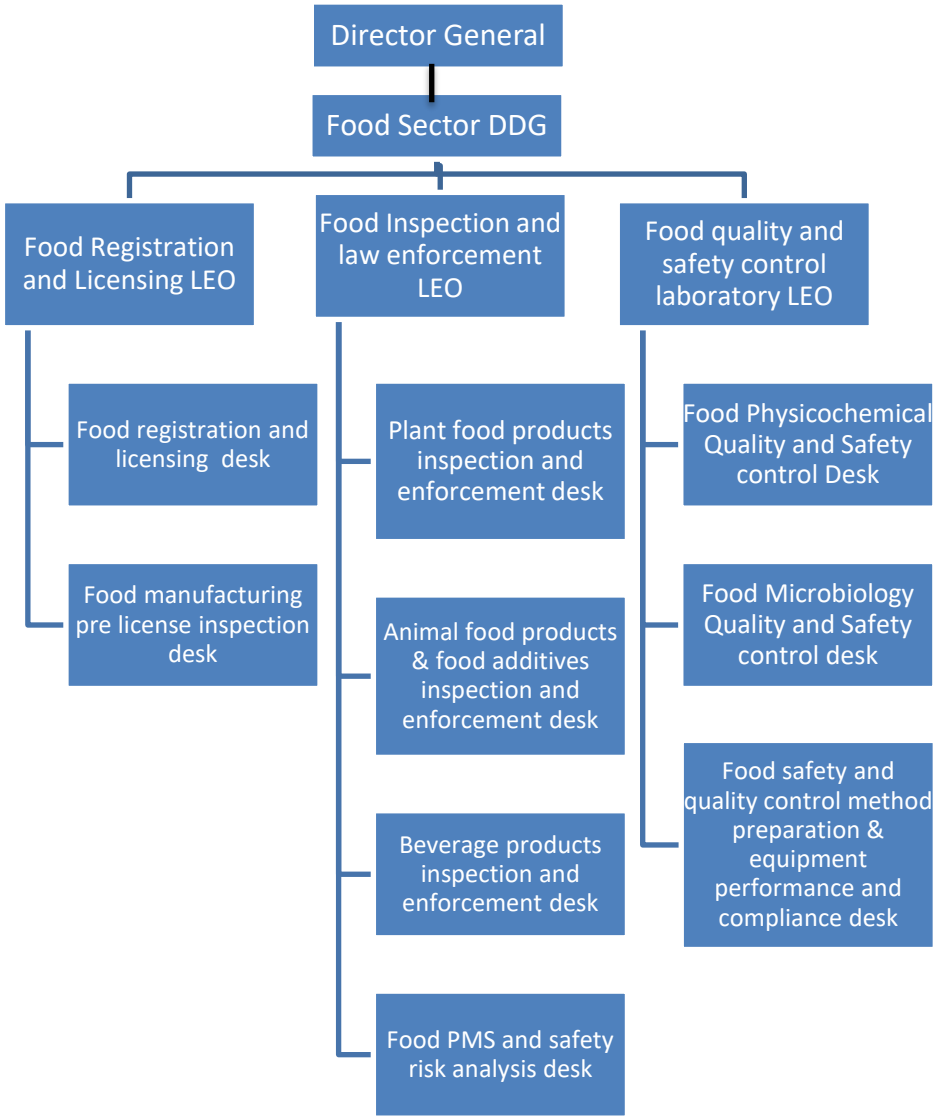


Fig 2.5: *Deputy Director General of Food Sector Organizational Chart*

2.5.1. Food Registration and Licensing Lead Executive Office

1. Introduction

The main purpose of the Food Registration and Licensing Lead Executive Office is to conduct pre-license inspections on local food manufacturers engaged in food production and provide certification of competence, register domestically produced and imported food products and Issue Market Authorization certificate.

2. Organization and accountability

The Food Registration and Licensing Lead Executive Office is accountable to the Food Sector Deputy Director General and has the following two desks;

1. Food registration and license desk
2. Food manufacturing pre-license inspection desk

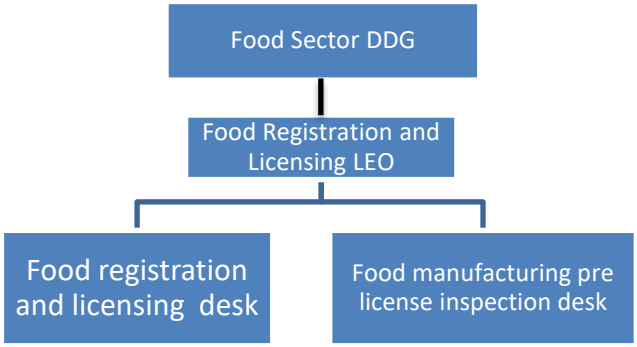


Fig 2.5.1: *Food Registration and Licensing Lead Executive Office Organizational Chart*

3. Duties and Responsibilities of Food Registration and Licensing Lead Executive Office

- In accordance with the guidelines issued by the Authority, issue marketing license, renew and approve changes in registration of processed and packaged food products, food additives and nutrients locally produced and imported into the country using scientific methods to evaluate and ensure their safety.
- Facilitates the necessary prerequisites for GMP inspection on selected foods for foreign manufacturers.
- According to the guidelines issued by the Authority, grants market authorization for certain products to enter the market through notification registration process.

- Conducting pre-licensing inspections for establishments engaged in food production, issues new certificate of competency, or change permits, renews them, and makes the list of licensed establishments known to the relevant parties.
- Based on the results of the inspection received from the inspection and enforcement lead executive office, suspend or revoke certificate of competence and cancel market authorization of food registration, based on the law and inform to the relevant parties.
- Prepares the guidelines for the transmission of food promotions, informs the relevant parties and monitors its implementation;
- Ensures the correctness of the registration and license issued by the Lead Executive Officer;
- Works to maintain a strong relationship with countries that have experience in food registration and licensing of production facilities; compiles the recommendations and lays out the plans for the future, and provides the necessary monitoring and support for their implementation.
- Formulates strategy to build leadership capacity of lead executive office; makes decisions on issues beyond the scope of working groups; as an institution, works to implement the decisions and directions.
- A system will be established to ensure smooth communication and efficient and effective work among the desks under the executive office.
- Supports the branch offices to provide professional support to the food registration and licensing work team and strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and SOPs for the work unit;

4. Duties and responsibilities of Food Registration and License Desk

- In accordance with the guidelines issued by the authority, issue market authorization, renew and change registrations by evaluating and ensuring the safety of processed and packaged food products, food additives and nutrients produced locally and imported into the country.
- According to the guidelines issued by the Authority, grants market authorization for certain products to enter the market through notification registration process.

- In collaboration with the Lead Executive Officer facilitates the necessary prerequisites for GMP inspection on selected foods for foreign manufacturers.
- Based on the results of the inspection report received from the inspection LEO, suspended and canceled the registered food based on the law and will inform to the relevant parties.
- Works in coordination with the relevant departments to prepare guidelines for food advertisement; ensures that the relevant parties are informed and monitors its implementation.
- According to the guidelines issued by the authority, give market authorization for certain products to be produced in the country through notification.
- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, presenting them to the chief executive officer so that decisions can be made so that they can be implemented.
- Developed procedure to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support and exchanges information to branch offices of food registration and licensing team, and;
- Recommends and prepares guidelines, operating manuals and SOPs for the desk:

5. Duties and responsibilities of Food Establishments' Registration and License Desk

- According to the guidelines issued by the Authority, conduct document verification and pre-licensing inspection for establishments engaged in food production; issue new certificate of competency; renew or change licenses to those who meet the requirements, and inform the list of licensed establishments to the relevant parties.
- Based on the results of the inspection report received from the inspection section, suspended or revoke the certificate of competency of the institution that has been granted before; based on the law and will inform to the relevant parties.
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk; presents them to the lead executive officer so that decisions can be made and implemented.

- Develop procedure to ensure smooth communication between the professionals within the desk and to do efficient and effective work.
- Provides professional support and information exchange to branch offices of food manufacturing facility licensing team;
- Proposes and prepares necessary guidelines, operating manuals and SOPs for the desk.

2.5.2. Food Inspection and Law Enforcement Lead Executive Office

a. Introduction

Food Inspection and Law Enforcement Lead Executive Office is established mainly for the purpose of conducting post licensing inspection on plant-based food products, animal-based food products and food additives and beverages. The lead executive office also conducts post market surveillance and market assessment to ensure products on the market are safe and meet national standards. In general, the LEO is established to make the food control system consistent nationally.

b. Organization and accountability

The Food Inspection and Law Enforcement Lead Executive Office is accountable to Food Sector Deputy Director General and has the following four desks:

1. Animal Food Products and Food Additive Inspection and Law Enforcement Desk
2. Plant Food Product Inspection and Law Enforcement Desk
3. Beverage Inspection and Law Enforcement Desk
4. Food Post-marketing Surveillance and Safety Risk Analysis Desk

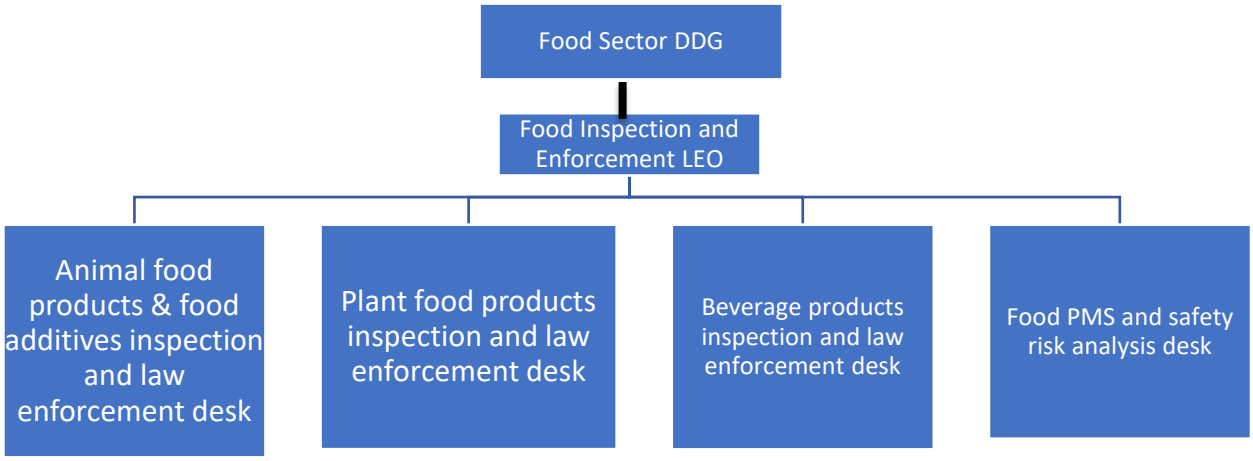


Fig 2.5.2: *Food Inspection and Enforcement Lead Executive Office Organizational Chart*

c. Duties and Responsibilities of Food Inspection and Law Enforcement Lead Executive Office

- To develop, endorse and implement national food inspection and enforcement strategies, manuals and protocols and to monitor its implementation.
- To conduct good manufacturing practice inspection on foreign manufacturers who export their product to domestic market as necessary.
- Monitor the implementation of national food safety activities.
- Based on reports from intelligence and illegal trade prevention lead executive office, the food inspection and enforcement lead executive office will take legal measures on those non-compliant manufacturers and products and notify its implementation for concerned bodies
- When a sudden food outbreak occurs, the LEO will take appropriate measures based on the result and will inform the performance the relevant/concerned bodies.
- Ensures that the amount of fertilizers, chemicals, pesticides and drug residue, radiation and other pollutants found in the food on the market do not exceed the limits set by national or international standards and take action based on the results.
- In case it is suggested that food products that may cause serious damage to public health are placed on the market or being transported into the country, the LEO will take

appropriate action before any damage is caused to the public or inform the relevant body to take action.

- When food exporters request a health certificate for food exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:
- When problems related to food safety warnings occur at the global level, the LEO Monitor and ensure prohibited products are not on the market.
- Monitors and takes action to ensure that there are no counterfeit, misleading descriptive text and other problematic foods on the market.
- Conducts post-licensing inspections on food manufacturing facilities that have been granted certificate of competence and informs the relevant bodies the inspection results.
- Based on reports from intelligence and illegal trade prevention lead executive office, appropriate legal measures will be taken and the performance will be notified to the relevant parties.
- When conducting inspection, the LEO will collaboratively work with Legal Service Executive office.
- Any legal action within the institution under control that the authority believes is necessary, including documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- The LEO formulates a strategy to build capacity; makes decisions on matters beyond the scope of the desk; As an institution, it works to implement the decisions and directions.
- Establish a system that ensure smooth communication between the desks for efficient and effective work.
- Provide professional support to the branch offices and regional food inspection bodies. And work to strengthen the exchange of information between regional inspection bodies and branch offices.
- Develop necessary guidelines, operating manuals and SOPs for the work.

d. Duties and Responsibilities of Animal Food Products and Food Additive Inspection and Law Enforcement Desk

- To develop, endorse and implement national food inspection and enforcement strategies, manuals and protocols and to monitor its implementation.
- To conduct good manufacturing practice inspection on foreign manufacturers who export their product to domestic market as necessary.
- Assist in monitoring animal-based food product safety activities carried out at the national level.
- Based on reports from intelligence and illegal trade prevention lead executive office on animal-based food product safety defect surveillance, the animal food products and food additive inspection and enforcement desk will take legal measures on those non-compliant manufacturers and products and notify its implementation for concerned bodies
- When a sudden food outbreak occurs, the desk will take appropriate measures based on the result and will inform the performance the relevant/concerned bodies.
- Ensures that the amount of fertilizers, chemicals, pesticides and drug residue, radiation and other pollutants found in the animal based-food product on the market do not exceed the limits set by national or international standards and take action based on the results.
- In case it is suggested that animal-based food products that may cause serious damage to public health are placed on the market or being transported into the country, the desk will take appropriate action before any damage is caused to the public or inform the relevant body to take action.
- When food exporters request a health certificate for animal-based food products exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:
- When problems related to animal-based food product safety warnings occur at the global level, the desk Monitor and ensure prohibited products are not on the market.
- Monitors and takes action to ensure that there are no counterfeit, misleading descriptive text and other problematic foods on the market.
- Conducts post-licensing inspections on food manufacturing facilities that have been granted certificate of competence and informs the relevant bodies the inspection results.

- Based on reports from intelligence and illegal trade prevention lead executive office, appropriate legal measures will be taken and the performance will be notified to the relevant bodies.
- To control illegal trade the desk will collaboratively work with relevant stakeholders such as customs authority and others.
- When conducting inspection, the desk will collaboratively work with Legal Service Executive office.
- Any legal action within the institution under control that the authority believes is necessary, including documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- The desk formulates a strategy to build capacity; makes decisions on matters beyond the scope of the desk; As an institution, it works to implement the decisions and directions.
- Establish a system that ensure smooth communication between the desks for efficient and effective work.
- Provide professional support to the branch offices and regional food inspection bodies. And work to strengthen the exchange of information between regional inspection bodies and branch offices.
- Develop necessary guidelines, operating manuals and SOPs for the work.

e. Duties and Responsibilities of Plant food Product Inspection and Law Enforcement Desk

- To develop, endorse and implement national food inspection and enforcement strategies, manuals and protocols and to monitor its implementation.
- Conduct good manufacturing practice inspection on foreign manufacturers who export their product to domestic market as necessary.
- Assist in monitoring plant food product safety activities carried out at the national level.
- Based on reports from intelligence and illegal trade prevention lead executive office on plant food product safety defect surveillance, the plant food products inspection and enforcement desk will take legal measures on those non-compliant manufacturers and products and notify its implementation for concerned bodies

- When a sudden food outbreak occurs, the desk will take appropriate measures based on the result and will inform the performance the relevant/concerned bodies.
- Ensures that the amount of fertilizers, chemicals, pesticides and drug residue, radiation and other pollutants found in the plant food product on the market do not exceed the limits set by national or international standards and take action based on the results.
- In case it is suggested that plant food products that may cause serious damage to public health are placed on the market or being transported into the country, the desk will take appropriate action before any damage is caused to the public or inform the relevant body to take action.
- When food exporters request a health certificate for plant food products exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:
- When problems related to plant food product safety warnings occur at the global level, the desk Monitor and ensure prohibited products are not on the market.
- Monitors and takes action to ensure that there are no counterfeit, misleading descriptive text and other problematic foods on the market.
- Conducts post-licensing inspections on food manufacturing facilities that have been granted certificate of competence and informs the relevant bodies the inspection results.
- Based on reports from intelligence and illegal trade prevention lead executive office, appropriate legal measures will be taken and the performance will be notified to the relevant bodies.
- To control illegal trade the desk will collaboratively work with relevant stakeholders such as customs authority and others.
- When conducting inspection, the desk will collaboratively work with Legal Service Executive office.
- Any legal action within the institution under control that the authority believes is necessary, including documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- The desk formulates a strategy to build capacity; makes decisions on matters beyond the scope of the desk; As an institution, it works to implement the decisions and directions.

- Establish a system that ensures smooth communication between the desks for efficient and effective work.
- Provide professional support to the branch offices and regional food inspection bodies. And work to strengthen the exchange of information between regional inspection bodies and branch offices.
- Develop necessary guidelines, operating manuals and SOPs for the work.

f. Beverage Products Inspection and Enforcement Desk

- Prepare and approve operational strategies, manuals, protocols and other documents that guide the inspection and enforcement of beverage products in the country, and monitor the implementation.
- Conduct good manufacturing practice inspection, as necessary, for foreign beverage manufacturing companies that import their products in the country.
- Support beverage product safety monitoring activities at the national level.
- Based on the results of beverage product post-marketing surveillance and safety risk analysis, and intelligence and Illegal trade prevention lead executive office report take legal action to the manufacturers and foods that require action, and notifies to the relevant sectors.
- When a sudden outbreak occurs on beverage products, conduct inspection and take appropriate action based on the results, and inform to the relevant sectors.
- To ensure that the levels of fertilizers, chemicals, pesticides, radiation and other contaminants that may harm human health in beverage products do not exceed the national or international standards and take action based on the results;
- When receiving information about the presence of beverage products in the market, products being transported to the country and suspected beverage products which are ready to manufacture and distribute to the market that may cause serious harm to health of the public, take action or inform to the relevant sectors.
- When requesting a health certificate for export beverage products, a certificate is issued confirming that the necessary requirements have been met.

- Monitoring and ensuring that there are no food safety related problems and warnings on the beverage products on the international level, as well as products that are prohibited from use on the market.
- Monitoring and taking action for the counterfeit products, misleading description, or similar problems on the market.
- Conduct post-license inspection on beverage product manufacturers that have been granted a certificate of competency and notifies to the relevant sectors.
- Based on the information received from the intelligence and Illegal trade prevention lead executive office, appropriate legal action will be taken and the relevant sectors will be informed of its implementation.
- Develop systems and working together with relevant national institutions (Customs Commission, security agencies, etc.) to prevent illegal trade.
- The desk will collaboratively work with the Legal service executive office as necessary when conducting inspection activities.
- During inspection any evidence deemed necessary for any legal action within the manufacturing site such as documents, receipts, electronic records, samples, photographs or videos, etc., shall be taken, organized and retained in accordance with the law, and shall be provided to the appropriate sectors when deemed necessary.
- Develops strategies to build the capacity of the desk, and when issues beyond the capacity of the desk arise, presents them to the lead Executive Office for decision-making and works to implement them;
- A system will be established to ensure smooth communication among the inspectors in the desk and to ensure efficient and effective work.
- Provide professional support to branch offices and regional food inspection and law enforcement sectors to strengthen information exchange;
- Prepare necessary guidelines, operating manuals and SOPs for the desk.

g. Duties and Responsibilities of Food Post-Marketing Surveillance and Safety Risk Analysis Desk

- Preparing, approving and implementing operational strategies, manuals, protocols and other documents to guide food post-marketing surveillance and safety risk analysis in the country.
- Coordinate post marketing surveillance activities carried out at the national level.
- Based on the results of post-marketing surveillance and safety risk analysis, notify the relevant sectors of any food products requiring action, and monitor the implementation of these actions.
- Conducting national post-marketing surveillance to ensure food safety at the national level
- The desk conducts post-marketing surveillance collaboratively with Food manufacturers inspection desk and Food Importers, Exporters and Distributors Desk.
- Monitoring and ensuring that the levels of fertilizers, chemicals, pesticides, veterinary drugs, radiation, and other contaminants that may harm human health in foods on the market do not exceed the standards set by national or international standards, and notify to the relevant sectors to taking the action based on the results.
- Based on the results of food post market surveillance, it conducts continuous awareness activities for the community and stakeholders to protect themselves from health problems and to be part of the control.
- Monitor the availability of counterfeit products, foods with misleading descriptions, and other problems on the market, notify to relevant sectors when they are found, and monitors their implementation.
- The desk supports and coordinates the food manufacturers and importers to report food safety related problems.
- When a sudden food outbreak occurs, conducting the necessary monitoring, collecting and analyzing information, and informing to the relevant sectors that appropriate action can be taken based on the results, and monitors its implementation.
- Establish and monitor the implementation of a system to prevent food-related products from being introduced into the market or being transported into the country, which may cause serious harm to the health of the public, and to prevent them from being brought into the market;

- Conducts continuous awareness creation activities for the community to protect itself from health problems associated with food safety.
- Monitoring, collecting and disseminating information on health problems and early warnings related to food safety at the global level, as well as information on products prohibited from use, and ensuring their implementation to relevant bodies
- Coordinating the branch offices and regional regulatory bodies to conduct food post-marketing surveillance.
- Develop strategies to build the capacity of the desk, and when issues that arise beyond the capacity of the desk, it will present to the directorate for decision-making.
- Establish a system to ensure smooth communication among the professionals in the desk and to ensure efficient and effective work.
- Provide professional support and information exchange to the food safety risk and incident management team for branch offices.
- Prepare the necessary guidelines, operating manuals and SOPs for the desk.

2.5.3. Food Safety and Quality Control Laboratory Lead Executive Office

a. Introduction

The main purpose of the Food Safety and Quality Control Laboratory Lead Executive Office (FSQCL LEO) is to coordinate physicochemical and microbiological quality testing activities to ensure the quality of food produced domestically and imported, and to ensure the quality of food products used in the market with the support of branch offices and laboratories of regional regulatory bodies.

b. Organization and accountability

The Lead Executive Office of Food Safety and Quality Control Laboratory is accountable to the Deputy Director General of the food sector and has three desks under it.

1) Food Physicochemical Safety and Quality Control Desk
2) Food Microbiology Safety and Quality Control Desk
3) Food Safety and Quality Control Laboratory Method Preparation and Equipment Performance Compliance Desk

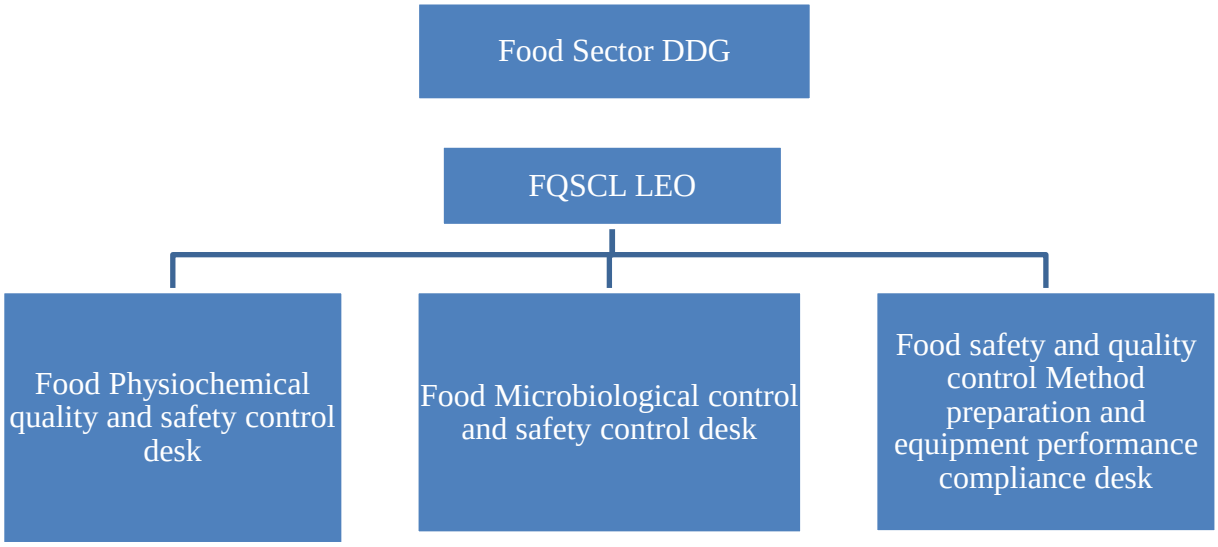


***Fig 2.5.3**: Food Safety and Quality Control Laboratory Lead Executive Office Organizational Chart*

c. Duties and Responsibilities Food Safety and Quality Control Laboratory Lead Executive Office

- Preparing, approving and monitoring the implementation of Quality manuals, Method validation and verification protocols, Method validation and verification report protocol, SOP and other documents that guide food quality and safety control laboratory activities.
- To perform quality testing of food products produced from in the country or locally and imported foods.
- To ensure that existing and new standard operational methods are working properly using advanced analytical methods.
- Ensure and implements national and international experiences in food safety testing
- Works to establish effective and sustainable cooperation with international and national institutions regarding food safety testing on behalf of the authority.
- The food quality and safety laboratory works to gain international recognition.

- Prepares technical specifications for laboratory equipment and materials necessary for food quality testing activities.
- Performs a technical review after purchased and delivered the equipment and materials, ensuring they are handled properly entered in to the laboratory.
- To conduct quality testing for the purpose of registration of food products produced in the country or imported and we will inform the results to relevant bodies.
- Conducts post market quality testing on domestically produced and imported food products and also conducts necessary quality testing on suspected samples and we will inform the results for relevant bodies.
- Conducting the necessary quality testing of consignment imported samples and inform the results for relevant bodies.
- Ensures that the food quality and safety control laboratory equipment is working properly.
- Receiving laboratory samples by ensuring they meet receiving sample procedures and handles properly.
- Establishes procedures for handling and use of backup samples, Retention samples and expired samples and also monitor their performance.
- Develops strategy to build leadership capacity, make decisions on matters beyond the scope of the desks and as an institution works to implement the decision and directions.
- A procedure will be established to ensure smooth communication and efficient and effective work at the head of desks.
- Provides training, professional support and supports strengthening of information exchange for branches food quality and safety control laboratory and regional food quality testing laboratory.
- Prepares necessary guidelines, quality manuals and SOPs for food quality and safety control laboratory.

d. Duties and Responsibilities of Food Physicochemical Quality and Safety Control Desk

- Conducting physiochemical tests to ensure the quality of food produced in domestically and imported food products.

- To develop and revise new food physiochemical quality analysis method (Standard operating procedures).
- Develops strategies to build the capacity of the desk, when there are issues that are beyond the scope/ability of the of desks it is reported to the lead executive officer for that decisions can be made and implemented.
- Conducting physiochemical quality testing of domestically produced and imported foods for the purpose of registration and we will inform the results to the relevant bodies/clients.
- Conducts post-market physiochemical quality testing on foods produced and marketed in domestically and imported and also performs quality testing on suspected samples and we will inform the results to the relevant bodies/clients.
- Conducting consignment physiochemical quality testing of foods produced in foreign countries and imported into the country and also, inform the results to the relevant bodies/clients.
- A procedure will be developed or established to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Supports strengthening of information exchange for branches food quality and safety control laboratory and regional food quality testing laboratory.
- Prepares guidelines, quality manuals and SOP for Food Physicochemical Quality and Safety Control Desk.

e. Duty and Responsibilities of Food Microbiology Quality and Safety Control Desk

- Conducting microbiological tests to ensure the quality of food produced in domestically and imported food products.
- To develop and revise new food microbiological quality analysis method (Standard operating procedures).
- Performs microbiological quality testing of domestically produced and imported foods for the purpose of registration and we will inform the results to the relevant bodies/clients.
- Conducts post-market microbiological quality testing on foods produced and marketed in domestically and imported and also performs quality testing on suspected samples and we will inform the results to the relevant bodies/clients.

- Conducting consignment microbiological quality testing of foods produced in foreign countries and imported into the country and also, we will inform the results to the relevant bodies/clients.
- Develops strategies to build the capacity of the desk, when there are issues that are beyond the scope/ability of the of desks it is reported to the lead executive officer for that decisions can be made and implemented.
- A Procedure will be developed or established to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Supports strengthening of information exchange for branches food quality and safety control laboratory and regional food quality testing laboratory.
- Prepares guidelines, quality manuals and SOPs for Food Physicochemical Quality and Safety Control Desk.

f. Duties and Responsibilities of Food Safety and Quality Control Laboratory Method Preparation and Equipment Performance Compliance Desk

- To develop and search a new method to analyze the laboratory activities.
- Validate and verify the validity of test methods developed by international organization
- Prepares scientific and technical specifications for laboratory equipment and supplies and also follow up the calibration and verification of the instrument
- Performs technical evaluation of the tender documents submitted for purchase and requires high technical skills to compare them.
- Published research results on journals based on laboratory results
- To build the capacity of the laboratory professional in different trainings
- Prepare and revise different laboratory guidelines, manuals, sops and other documents associate with the international recognition.
- To do the preventive maintenance by supplier or other bodies and to work by our capacity.
- Monitoring and follow up of the laboratory activities properly recorded
- Performs operational researches and performs the find of the study for the relevant bodies.

- Installs new advanced equipment (e.g., LCMSMS, GCMSMS, ICPMS, and others) in main and branch laboratories, ensures proper installation, verifies IQ/OQ/PQ certification, and facilitates.

2.6. Branch Offices

a. Introduction

Pursuant to Article 3 of Proclamation No. 1112/2011, the mandate to control regulated products at the national level is vested in the EFDA. To ensure effective implementation of these responsibilities, branch offices are established as operational arms of the Authority. Accordingly, the branch office regulates importers, distributors, and exporters of food, medicines, medical devices, cosmetics, and tobacco used for public health, and other regulated products. It also oversees cosmetics manufacturers by granting and renewing certificates of competence based on pre-license inspections, conducting post-license inspections, and taking corrective measures on establishments and products as necessary. Furthermore, the branch office registers food and cosmetic products under the notification scheme and issues market authorization, conducts post-market quality and safety monitoring, and enforces regulatory measures. In addition, it provides regulatory services at ports of entry and exit and coordinates with regional regulatory bodies to ensure effective oversight.

b. Organization and accountability

The Branch Offices are accountable the Branch Coordination Lead Executive Office

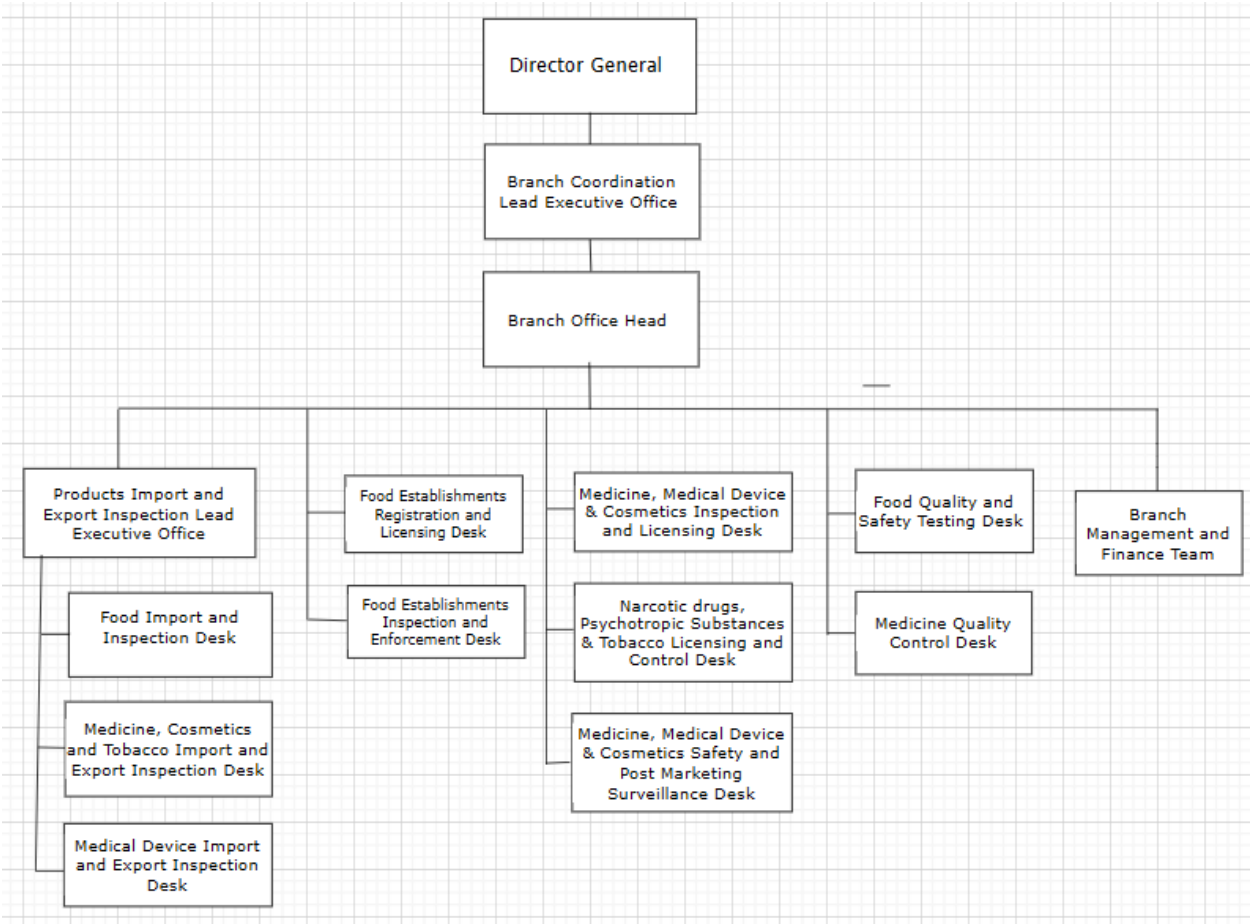


Fig 2.6: *Branch offices Organizational Chart*

c. Duties and Responsibilities of the Branch Offices

- Allowing market entry for both locally produced and imported food and cosmetic products by completing a prior notification process and registering notifications before the products can be placed on the market.
- Conducting pre-license inspections and issuing, renewing, or amending certificates of competency for establishments involved in manufacturing food, cosmetics, and medical devices, as well as for establishments engaged in the export, import, and distribution of food, medicine, medical devices, cosmetics, tobacco, pesticides used for public health, and other controlled products. Additionally, notifying the relevant parties of the list of licensed establishments.
- Conducting post-licensing inspections of licensed manufacturers of food, medical devices, and cosmetics, as well as licensed exporters, importers, and distributors of food, medicine,

medical devices, cosmetics, tobacco, pesticides used for public health, and other regulated products. Implementing appropriate administrative regulatory measures on non-compliant licensed establishments and products, and communicating the results to the relevant parties.

- Safeguard public health by ensuring compliance with Good Distribution Practices (GDP) and Good Storage Practices (GSP) within the supply chain of pharmaceuticals, medical devices, and health related products, while actively monitoring the market to prevent the circulation of substandard or falsified products;
- Conducts safety monitoring activities at national level for food, medicine, medical devices, and cosmetics in coordination with the head office.
- Conducts post-market surveillance at the national level for food, medicines, medical devices, and cosmetics in collaboration with the head office.
- Taking administrative measures on establishments and products based on the results of safety monitoring and post-market surveillance of food, medicine, medical devices, and cosmetics and ensuring notification of relevant parties about the actions taken.
- In the event of food outbreak occurs, conducts onsite investigation and take appropriate action based on the results, and shall inform the relevant parties about the actions.
- If evidence suggests that a food, drug, medical device, or cosmetic product whether domestically produced, already on the market, or in transit for import could seriously harm public health, it must take countermeasures. This includes detaining the products to prevent harm and notifying concerned parties to take action.
- Upon request, issue a health certificate for food and cosmetic products intended for export by verifying compliance with the necessary requirements.
- Implement market controls to prevent the availability of counterfeit or falsified, or mislabeled food, medicine, medical devices, and cosmetics. Take appropriate legal action against any violations.
- Take appropriate administrative measures against regulated products based on evidence from intelligence and illegal trade prevention team and notify relevant parties of all actions taken.
- When necessary, collect, organize, and securely store evidence including documents, invoices, electronic records, samples, photographs, and videos from regulated institutions,

in accordance with established procedures. This evidence might be provided for appropriate parties when deemed necessary.

- Collaborate with legal experts during inspections as necessary.
- Establishes procedures to collaborate and coordinate with relevant institutions such as the customs commission and security agencies to prevent illegal trade within its jurisdiction.
- As appropriate, coordinates and collaborates with manufacturers, importers, distributors, and exporters of food, medicine, cosmetics, and medical devices on safety monitoring and post-market surveillance activities.
- Conducts public awareness campaigns to protect consumers from health risks associated with food, medicine, cosmetics, and medical devices.
- Conducts post-market quality monitoring by collecting samples of all locally manufactured and imported foods, medicines, medical devices, and cosmetics, in addition sample suspected products and conduct testing. The test results shall be communicated to the relevant stakeholders.
- Collects and tests samples of imported food, medicines, medical devices, and cosmetics for consignments as necessary, and communicates results to the relevant parties.
- Shall timely request the procurement of laboratory equipment, reagents, and chemicals, and shall ensure their proper utilization.
- Control activities pertaining to narcotic drugs, psychotropic substances, and precursor chemicals
- Implements public awareness campaigns to address and mitigate the health, social, and economic harms caused by tobacco products within the community.
- Develop and execute a capacity-building strategy; render decisions on matters exceeding desk-level authority; and implement all decisions and directives issued by the central Authority.
- Facilitates effective coordination among desks within the office, with ports of entry and exit as well as with other lead executive offices at the head quarter.
- Establish and implement standardized procedures for coordination with regional regulatory bodies, and shall actively support the strengthening of information exchange mechanisms.

- In coordination with the Head Office, shall ensure the proper and rational use of medicines and medical devices and facilitate the ongoing exchange of relevant information.
- Timely planning and formal request of necessary personnel, financial, and other resources and subsequently directs, manages, and ensures the utilization of these resources.
- Conduct awareness campaigns to promote ethical practices and prevent misconduct, take necessary corrective actions in cases of ethical violations, and inform relevant stakeholders as appropriate.
- Develop all necessary guidelines, operating manuals, and standard operating procedures required.

d. Roles and Responsibilities of Desks and Administration units of Branch offices

4.1. Food Registration and Licensing Desk

The desk shall have the following duties and responsibilities:

- The desk grants market authorization for imported foods that can be authorized through notification scheme in accordance with the directive issued by the authority,
- Monitors and controls the implementation of notification schemes for imported foods, and facilitates the exchange of relevant information for it.
- Issues market authorization for eligible locally manufactured foods through the notification scheme, as mandated by the authority's directive.
- Suspends or cancels market authorization through notification upon receiving safety problem or defect reports from relevant parties concerning approved food products on the market and informs to the relevant parties about the actions taken.
- Issues new, renew or change certificates of competence to qualifying small-scale manufacturers of non-perishable foods based on document verification and pre-license inspection, and distributes updated lists of licensed establishments to relevant parties.
- Issues new renew or change certificates of competence to qualifying food exporters, importers and distributors based on document verification and pre-license inspection, and distribute updated lists of licensed establishments to relevant parties.
- Based on inspection findings received from the Inspection Department, the Branch Office shall suspend or revoke an establishment’s certificate of competency in accordance with the law and shall notify the relevant parties of such actions.

- Develop strategies to enhance the capacity of its desks, report matters that exceed the desks' authority to the Head of branch Office for decision-making, and implement the decisions accordingly.
- Communicate and exchange information within desk-level experts, Ports of Entry and Exit food sections, and the relevant Lead Executive Offices of the Food Control sector at Head offices
- Coordinate with regional food inspectors, provide necessary support, and facilitate the exchange of relevant information.
- Establish procedures to ensure effective relation among desk professionals, promoting effective and efficient work outcome.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop SOPs for the desk.

4.2. Food Inspection and Enforcement Desk

The desk shall have the following duties and responsibilities:

- Through post-license inspections, shall take the necessary administrative measures against licensed food manufacturers, importers, and wholesalers, as well as products that do not comply with regulations, and shall notify the relevant parties of the actions taken for appropriate decision-making.
- Conducts safety monitoring activities at national level for food in coordination with the head office.
- Taking administrative measures on establishments and products based on the results of safety monitoring and post-market surveillance of food, ensuring notification of relevant parties about the actions taken.
- In the event of food outbreak occurs, conducts onsite investigation and take appropriate action based on the results, and shall inform the relevant parties about the actions.
- If evidence suggests that a food, product whether domestically produced, already on the market, or in transit for import could seriously harm public health, it must take countermeasures. This includes detaining the products to prevent harm and notifying concerned parties to take action.

- Upon request, issue a health certificate for food and products intended for export by verifying compliance with the necessary requirements
- Implement market control measures to prevent the circulation of counterfeit, falsified, or mislabeled food products, and take appropriate legal actions against any violations.
- When necessary, collect, organize, and securely store evidence including documents, invoices, electronic records, samples, photographs, and videos from regulated food institutions, in accordance with established procedures. This evidence might be provided for appropriate parties when deemed necessary.
- Collaborate with legal experts during inspections as necessary.
- Establishes procedures to collaborate and coordinate with relevant institutions such as the customs commission and security agencies to prevent illegal food trade within its jurisdiction.
- As appropriate, coordinates and collaborates with manufacturers, importers, distributors, and exporters of food on safety monitoring and post-market surveillance activities.
- Conducts public awareness campaigns to protect consumers from health risks associated with food.
- Conducts safety monitoring activities at national level for food in coordination with the head office.
- In the event of a sudden food borne outbreak, conduct onsite monitoring, collect and analyze relevant information, take appropriate regulatory measures, and notify the concerned parties.
- Coordinate, monitor, and enforce the development and implementation of food safety monitoring procedures by food importers, exporters, and distributors.
- Develop strategies to enhance the capacity of its desks, report matters that exceed the desks' authority to the Head of branch Office for decision-making, and implement the decisions accordingly.
- Conduct continuous public awareness activities to enable public to protect themselves from food safety–related health risks

- Communicate and exchange information within desk-level experts, Ports of Entry and Exit food sections, and the relevant Lead Executive Offices of the Food Control sector at Head offices
- Coordinate with regional food inspectors, provide necessary support, and facilitate the exchange of relevant information.
- Establish procedures to ensure effective relation among desk professionals, promoting effective and efficient work outcome.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop SOPs for the desk.

4.3. Medicine, Medical Device and Cosmetics Inspection and Enforcement Desk

The main objective of the Desk is to safeguard public health by ensuring the quality, safety, and efficacy of medicines, medical devices, and cosmetics. This is achieved through pre-license control and the issuance of certificates of competence, as well as post-market inspection to identify and remove defective products and enforce appropriate administrative measures. In addition, the Desk implements national and international regulations and policies, including those related to narcotic and psychotropic substances (NPS), to strengthen regulatory compliance and protect the community. The desk shall have the following duties and responsibilities:

- Issue licenses for medicine and medical device importers, exporter and wholesaler by conducting pre-license inspections
- Safeguard public health by ensuring compliance with Good Distribution Practices (GDP) and Good Storage Practices (GSP) within the supply chain of pharmaceuticals, medical devices, and health related products, while actively monitoring the market to prevent the circulation of substandard or falsified products;
- Through post-license inspections, shall take the necessary administrative measures against licensed medicine and medical device importers, and wholesalers, as well as products that do not comply with regulations, and shall notify the relevant parties of the actions taken for appropriate decision-making.
- Taking administrative measures on establishments and products based on the results of safety monitoring and post-market surveillance medicine and medical devices and ensuring notification of relevant parties about the actions taken

- If evidence suggests that a medicine and medical device product whether domestically produced, already on the market, or in transit for import could seriously harm public health, it must take countermeasures. This includes detaining the products to prevent harm and notifying concerned parties to take action. The Desk gives special regulatory attention to psychotropic and narcotic medicines.
- Implement market controls to prevent the availability of counterfeit or falsified, or mislabeled medicine, medical devices. Take appropriate legal action against any violations.
- Takes appropriate legal action on and tobacco products based on the information received from the surveillance and illegal prevention unit, and notify relevant parties about the actions.
- When necessary, collect, organize, and securely store evidence including documents, invoices, electronic records, samples, photographs, and videos from regulated medicine and medical device institutions, in accordance with established procedures. This evidence might be provided for appropriate parties when deemed necessary.
- Collaborate with legal experts during inspections as necessary.
- Establishes procedures to collaborate and coordinate with relevant institutions such as the customs commission and security agencies to prevent illegal medicine and medical device trade within its jurisdiction.
- The Desk carries out its activities in coordination with regional regulatory authorities and actively supports the strengthening of information exchange mechanisms.
- Conducting pre-license inspections and issuing, renewing, or change certificates of competency for establishments engaged in the export, import, and distribution of medicine. Additionally, notifying the relevant parties of the list of licensed establishments.
- It suspends or cancels certificate of competence in accordance with legal requirements and notify actions taken to all relevant parties
- Confirm that defective, expired, or illegally seized narcotic drugs, psychotropic substances, and precursor chemicals have been properly segregated, securely stored, and disposed of in compliance with the international disposal system as well as the directives issued by the Authority and issued certificate as official confirmation of the completion of the disposal process.

- Ensure and monitor the proper utilization of NPS prescription papers
- Develop strategies to enhance the capacity of its desks, report matters that exceed the desks' authority to the Head of branch Office for decision-making, and implement the decisions accordingly.
- Communicate and exchange information within desk-level experts, Ports of Entry and Exit food sections, and the relevant Lead Executive Offices of the Food Control sector at Head offices
- Collecting information on the demand and use of narcotic drugs, psychotropic substances and precursor chemicals from various institutions and reporting to the main office on time;
- Ensures and approves the proper use of narcotic and psychotropic drugs.
- Regulates proper management, storage, distribution, prescription and dispensing of narcotic drugs, psychotropic substances and precursor chemicals and takes action as necessary.
- Takes appropriate legal action on narcotic and physcotropic medicines based on the information received from the surveillance and illegal prevention unit, and notify relevant parties about the actions.
- When necessary, collect, organize, and securely store evidence including documents, invoices, electronic records, samples, photographs, and videos from regulated narcotic and psychotropic medicines institutions, in accordance with established procedures. This evidence might be provided for appropriate parties when deemed necessary.
- Establishes procedures to collaborate and coordinate with relevant institutions such as the customs commission and security agencies to prevent illegal medicine and medical device trade within its jurisdiction.
- Carry out continuous public awareness activities to protect the public from the health problems associated with the safety of narcotic and psychotropic drugs
- Communicates with the experts in the desk, as well as with the other Medicine, medical equipment and cosmetics regulating units at the head office, and exchanges information.
- Establish procedures to ensure effective relation among desk professionals, promoting effective and efficient work outcome.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for the desk.

- Implements and coordinates the implementation of international agreements accepted by the country and national laws in relation to tobacco control, conducts studies in coordination with the main office and regions to ensure that laws are properly implemented, and informs the concerned parties of the results.
- Regulates and supervises institutions outside the health sector to ensure proper use of narcotic drugs, psychotropic substances or precursor chemicals for intended purpose only
- With regard to the regulation of NPS, precursor chemicals, and tobacco control, compile relevant information and submit it to the head office in a timely manner.

4.4. **Cosmetics and tobacco inspection and enforcement desk**

The main objective of the desk is to strengthen the regulation of cosmetics and tobacco products by addressing quality defects on cosmetics, ensuring proper health warning labeling on tobacco, and taking appropriate administrative measures against non-compliant these products. The desk also aims to raise public awareness about the risks associated with these products and to ensure the implementation of relevant policies and laws declared at both national and international levels. The desk shall have the following duties and responsibilities:

- Conducting pre-license inspections and issuing, renewing, or change certificates of competency for establishments engaged in the export, import, and distribution of cosmetics. Additionally, notifying the relevant parties of the list of licensed establishments.
- Through post-license inspections, shall take the necessary administrative measures against licensed cosmetics and tobacco importers, and wholesalers, as well as products that do not comply with regulations, and shall notify the relevant parties of the actions taken for appropriate decision-making.
- Taking administrative measures on establishments and products based on the results of safety monitoring and post-market surveillance cosmetics and ensuring notification of relevant parties about the actions taken
- Implement market controls to prevent the availability of counterfeit or falsified, or mislabeled cosmetics. Take appropriate legal action against any violations.
- Establishes procedures to collaborate and coordinate with relevant institutions such as the customs commission and security agencies to prevent cosmetics trade within its jurisdiction

- Based on the inspection of a certified establishment, the desk may suspend or cancel its certification and, when necessary, notify the relevant stakeholders
- Monitors the implementation of the international agreements accepted by the country and national laws regarding tobacco control; conducts studies in coordination with the main office and the regions and inform the concerned parties of the results.
- Regulates, monitors, and enforces compliance to ensure that health warnings on tobacco product packaging, highlighting the dangers of tobacco, are displayed in accordance with the law
- Carries out public awareness activities to prevent and control the health, social and economic problems that are happening to the society due to tobacco products.
- Ensures proper surveillance of non-smoking areas; works in cooperation with relevant judicial and regional regulatory bodies; monitors parties involved in the illegal business so that they can be brought to justice;
- Monitors whether awareness creation activities are being carried out to prevent smoking in public out-of-door areas and public gathering places
- Evaluates information regarding tobacco product trafficking, including illegal tobacco trade.
- Collaborate with legal experts during inspections as necessary
- Develop strategies to enhance the capacity of its desks, report matters that exceed the desks' authority to the Head of branch Office for decision-making, and implement the decisions accordingly.
- Communicates with the experts in the desk, port of entries as well as with the other cosmetics and tobacco regulating units at the head office, and exchanges information.
- Coordinates and collaborates with regional medicine and tobacco regulatory inspectors, facilitating the sharing of relevant information
- Establish procedures to ensure effective relation among desk professionals, promoting effective and efficient work outcome
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop SOPs for the desk.

4.5. Medicine, Medical Device, and Cosmetic Products Post-Market Surveillance Desk

The main objective of the desk is to strengthen post-licensing control by ensuring that products circulating in the market meet the required standards. This is achieved through the removal of products with identified quality issues, conducting inspections to verify compliance, monitoring adverse effects that may arise from product use, and carrying out continuous market surveillance to safeguard public health. The Roles and Responsibilities of the Desk are:

- In addition, the desk leads and coordinates activities aimed at preventing antimicrobial resistance.
- Collects samples of selected drugs to conduct quality testing and provides the results to the relevant body.
- Ensures and coordinates that drugs and medical devices available on the market continue to meet the quality, safety, and efficacy standards under which they were registered
- Conducts surveys to check for the presence of illegally marketed drugs and reports the findings to the relevant department.
- Identifies drugs and medical devices for post-market studies, considering their current quality status, international recommendations, and risk-based control. It then provides this information to the relevant head office departments.
- Carries out and coordinates national-level drug and medical device safety surveillance in collaboration with the head office.
- Manages Adverse Drug Events by collecting and sending reports on harmful drug characteristics and quality defects to the head office.
- Provides and coordinates necessary awareness campaigns to help health professionals promptly report problems related to the safety and quality of drugs and medical devices.
- Manages Adverse Device Events by collecting and sending reports on harmful medical device characteristics and quality defects to the head office.
- Works with the head office on national-level post-market studies for drugs and medical devices.
- Establishes, evaluates, and coordinates a system for receiving, organizing, analyzing, and submitting core information, experiences, and knowledge from any member of the safety surveillance and post-market study team to the appropriate body.

- Conducts strategic safety surveillance and post-market studies by compiling information from regional regulatory bodies, the World Health Organization, and other national and international institutions and evaluates the results.
- Coordinates the body that covers the cost of post-market studies and ensures, in accordance with the law, that they share the expenses.
- Analyzes safety issues with drugs and medical devices collected from various pharmacology centers, studies the root causes of the issues, and informs the body responsible for taking action.
- Analyzes trends in annual post-market study reports and ensures that a report on required procedural improvements for drug manufacturers is sent to the relevant department.
- Identifies skill gaps among professionals based on best practices and existing conditions and conducts capacity-building activities.
- Reviews specifications for various purchases needed for drug and medical device safety surveillance and post-market studies and submits them for approval.
- When there is a tip-off about products that are manufactured, already on the market, or in transit that could cause significant harm to public health (drugs and medical devices), the desk informs the relevant bodies to take action and contain them before harm occurs.
- Monitors the market for counterfeit drugs and medical devices, those with misleading labels, and other similar problems. When found, it informs the relevant body to take action.
- Coordinates and works in collaboration with medical device manufacturers, as well as drug and medical device importers, exporters, and distributors, to conduct safety surveillance and post-market studies.
- Monitors whether medical device manufacturers and drug/medical device importers, exporters, and distributors are conducting the necessary quality and safety surveillance on their products.
- Conducts continuous public awareness campaigns to help the public protect itself from health problems caused by a lack of safety in drugs and medical devices.
- Prepares reliable, up-to-date, and high-quality information about drugs and medical devices and makes information prepared by the head office accessible to the public through various distribution channels.

- Issues market authorization for cosmetic products that are locally manufactured or imported and are allowed to enter the market with a notification process, in accordance with the authority's guidelines.
- Conducts post-licensing inspections on cosmetic product manufacturers, exporters, importers, and distributors that have been granted a Certificate of Competence. When necessary, it takes action against the institution and/or the product and reports the results to the relevant bodies.
- Carries out and works in collaboration with the head office on national-level cosmetic safety surveillance activities.
- Strengthens risk-based control by classifying cosmetic product manufacturers, importers, exporters, and distributors by category.
- Works with the head office on national-level post-market studies for cosmetic products.
- Based on surveillance reports on cosmetic safety surveillance and post-market studies, it takes legal action against institutions and products that need it and reports the implementation to the relevant bodies.
- When a tip-off is received about cosmetic products that are being manufactured, are already on the market, or are in transit and could cause significant harm to public health, it takes control of them or informs the relevant bodies to take action before harm occurs.
- Monitors the market for counterfeit cosmetic products, those with misleading labels, and other similar issues, and takes action when they are found.
- Based on information received from the surveillance and illegal trade prevention departments regarding cosmetic products, it takes appropriate legal action and informs the relevant bodies of the implementation.
- During inspections of cosmetic establishments, it takes and organizes any evidence it deems necessary in accordance with the law, such as documents, receipts, electronic records, samples, photos, or videos. It provides this evidence to the appropriate bodies when needed.
- Works with legal professionals when necessary to carry out inspection work.
- Collaborates and exchanges information with relevant institutions (e.g., Customs Commission, security forces) that work to prevent the illegal trade of cosmetic products.

- Works with and coordinates cosmetic product manufacturers, importers, exporters, and distributors to conduct safety surveillance and post-market studies.
- Conducts continuous awareness campaigns to help the public protect itself from health problems caused by unsafe cosmetic products.
- Develops strategies to build the desk's capacity and, when issues arise that are beyond the desk's capacity, presents them to the head of the office for a decision to be made and implemented.
- Facilitates smooth communication and establishes a system for efficient and effective work among desk professionals, entry and exit checkpoints, and relevant head office departments that work on cosmetic control.
- Works with and provides support and exchanges information with regional regulators.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for the desk.
- Based on the operating strategies for medical device post-market study and clinical trial control, it prepares, approves, and implements medical device post-market study manuals, a uniform operating procedure, and other such documents.
- Conducts post-market surveys on any manufacturer, importer, distributor, or health institution.
- Carries out national-level medical device post-market study activities.
- Works with and coordinates medical device manufacturers and importers to conduct medical device post-market studies.
- When there is a problem with the safety, quality, and effectiveness of medical devices in use, it performs and coordinates Field Safety Corrective Actions.
- The authority conducts annual post-market surveys on any manufacturer, importer, distributor, and health institution.
- Based on the results of the medical device post-market study, it informs the relevant bodies about which medical devices need action and monitors the implementation.
- Conducts continuous awareness campaigns to protect the public and partner organizations from health problems related to a lack of safety and quality in medical devices.

- Analyzes the risk of medical devices, informs the relevant department of the results, and distributes information and actions taken to all relevant bodies.
- Based on tips, reports, and study findings from users or other parties, it verifies the accuracy and ensures the necessary action is taken.
- Carries out and coordinates national-level medical device safety surveillance activities.
- Manages Adverse Device Events by collecting, monitoring, and analyzing reports of adverse medical device events, quality defects, and medical device use errors. It manages the data, ensures administrative action is taken based on the results, and reports to the relevant bodies.
- Ensures, monitors, and coordinates that medical device manufacturers, importers, and distributors establish a medical device safety surveillance system.
- Based on the results of medical device safety surveillance, it informs the relevant bodies about which medical devices need action and monitors the implementation.
- Monitors the market for counterfeit, substandard, or misleadingly labeled medical devices. When found, it informs the relevant bodies and monitors the implementation.
- When a tip is received about medical devices that are being manufactured, are on the market, or are in transit and could cause significant harm to public health, it establishes a system to contain them before harm occurs and monitors its implementation.
- Provides and coordinates necessary awareness to help health professionals promptly report problems related to the safety and quality of medical devices.
- Provides continuous awareness to the public and partners to help them protect themselves from health problems related to a lack of medical device safety and quality and encourages them to report such issues.
- Monitors current medical device safety reports, medical device safety risks, and communicates about medical device safety risks.
- Works with organizations that work to ensure the appropriate use of medical devices.
- Conducts studies to ensure that legal frameworks issued to ensure the appropriate use of medical devices at a national level are properly implemented. Based on the study results, it informs the relevant bodies to take the necessary action and monitors it.

- Performs signal detection to identify the source of medical device adverse event reports sent by various bodies, conducts casual assessment, and performs active surveillance work.
- Monitors, collects, and analyzes information about health problems and early warnings related to medical device safety and quality at an international level, as well as information on products that are banned from use. It then distributes this information to the relevant bodies and ensures it is implemented.
- Develops strategies to build the desk's capacity and, when issues arise that are beyond the desk's capacity, presents them to the lead executive for a decision to be made and implemented.
- Provides professional support and exchanges information with branch offices regarding medical device safety surveillance and post-market studies.

4.6. Food Quality and Safety Control Desk

- Conducts physicochemical tests on both locally manufactured and imported foods to ensure their quality as needed.
- Conducts post-market physicochemical tests on foods manufactured locally or abroad that are on the market. It also performs the necessary quality tests on suspicious samples and informs the relevant bodies of the results.
- Conducts consignment physicochemical tests on foods imported from abroad as needed and informs the relevant bodies of the results.
- Establishes a system to ensure smooth communication among desk professionals for efficient and effective work.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for the desk.
- Conducts microbiological tests on both locally manufactured and imported foods to ensure their quality.
- Conducts post-market microbiological tests on foods manufactured locally or abroad that are on the market. It also performs the necessary quality tests on suspicious samples and informs the relevant bodies of the results.
- Conducts consignment microbiological tests on foods imported from abroad as needed and informs the relevant bodies of the results.

- Develops strategies to strengthen its operational capacity and, in cases where issues exceed its mandate or capability, refers them to the head of the office for appropriate decision-making and implementation.
- The desk shall support and strengthen professional collaboration and information exchange with regional departments responsible for food quality testing.

4.7. Medicine Quality Control Desk

- Conducts physicochemical quality tests on both locally manufactured and imported drugs and cosmetic products and informs the relevant bodies of the results.
- Conducts post-market physicochemical tests on drugs and cosmetic products manufactured locally or abroad that are on the market.
- Performs necessary physicochemical tests on suspicious samples submitted by regional regulatory bodies, authority inspectors, or other legal entities, and informs the relevant bodies of the results.
- Conducts necessary consignment physicochemical tests on drugs and cosmetic products imported from abroad and informs the relevant bodies of the results.
- Conducts necessary microbiological quality tests on both locally manufactured and imported drugs and cosmetic products and informs the relevant bodies of the results.
- Conducts post-market microbiological quality tests on drugs and cosmetic products manufactured locally or abroad that are on the market.
- Performs necessary microbiological quality tests on suspicious samples submitted by regional regulatory bodies, authority inspectors, or other legal entities, and informs the relevant bodies of the results.
- Conducts necessary consignment microbiological quality tests on drugs and cosmetic products imported from abroad and informs the relevant bodies of the results.
- Develops strategies to strengthen its operational capacity and, in cases where issues exceed its mandate or capability, refers them to the head of the office for appropriate decision-making and implementation.
- The desk shall support and strengthen professional collaboration and information exchange with regional departments responsible for food quality testing

- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for the desk.

4.8. Ports of Entry and Exit

a. Introduction

The port of entry (POE), under the branch office, is structured to regulate imported food, medicines, medical devices, cosmetics, tobacco, and public-use pesticides for the protection of public health, as well as raw materials of regulated products, excluding tobacco raw materials and certain other regulated products.

b. Organization and Accountability

The Ports of Entry and Exit is accountable to the Branch Office Head and is headed by a Lead Executive Officer, overseeing three operational desks

1. Food Import and Export Control Desk
2. Medicine, Cosmetics, and Tobacco Import and Export Control Desk
3. Medical Devices Import and Export Control Desk

c. Roles and responsibilities of Ports of Entry and Exit

- Issues entry release permits for regulated products entering the country, ensuring they meet all necessary requirements, and shares relevant information with the concerned bodies.
- Upon request, issues exit release certificates for all regulated products after verifying compliance with applicable requirements
- If an imported product fails to meet the necessary requirements, directs its return to the country of origin or takes other appropriate administrative actions on the regulated product.
- Work in coordination with other bodies (customs, police, etc) working at the ports of entry and exit station;
- As necessary, collects samples of regulated products imported into the country, submits them to the laboratory for analysis, and takes appropriate action based on the test results.
- Disposes of regulated products detained at entry and exit ports that do not meet requirements, in collaboration with the appropriate parties, and notifies the relevant stakeholders accordingly

- Collects information on regulated products that are subjected to control at ports of entry and exit, analyzes it and informs the relevant parties.
- Carries out inspections and rapid testing of imported regulated products as necessary, and takes appropriate action based on the results.
- Requests, directs and manages the planning of necessary personnel, financial and other resources for the port of entry and exit.
- Conducts awareness programs on ethical conduct to prevent corrupt practices at ports of entry and exit, takes appropriate measures in cases of ethical violations, and informs the concerned parties as necessary.
- Makes decisions on issues beyond the capacity of the desk; and implements decisions and directions decided as a branch office;
- Ensures effective communication between the desk at entry and exit ports and the branch office.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for port of entries.
- Monitors timely completion and submission of performance evaluation, and reviews the filled performance evaluation and send to the appropriate person.
- Communicates rules, instructions, and circulars issued by the government to the work units and ensures their proper implementation
- Takes necessary actions and measures, in accordance with government regulations, regarding workers who are absent from duty.
- Provides prompt response to various services requested by the employee, such as leave, termination of employment contract, pension, guarantee, medical experience and other services.
- Prepares and submits the annual financial requirements of the port of entry and exit to the head of the branch office.
- Prepare detailed income plan of the port of entry and exit.
- Monitors the timely collection of approved income in line with the plan, verifies its deposit into the bank, and submits reports to the relevant authority.
- Approves daily service charges collected and ensures they are deposited into the bank.

- Authorizes payments for miscellaneous service charges.
- Register the fixed assets of the branch office and distinguish the ones in the hands of the users, and keep them registered with a card opened in the users' name.
- Receives requests for fixed and non-permanent items required by work units and ensures their timely distribution.
- Ensure that all incoming and outgoing letters are promptly delivered to the relevant parties and properly archived for future reference.
- Coordinate with relevant stakeholders to address illegal trade of regulated products
- Conduct inspections of warehouses customs and others at port of entry and take administrative measures in cases of non-compliance.
- Receive and respond to appropriate decisions regarding complaints.

4.8.1. Duties and Responsibilities Products Import and Export Inspection Lead Executive Office

- Monitors and takes appropriate corrective action to ensure that release permits are properly issued for any controlled products entering or leaving the country.
- Monitors and takes appropriate administrative action, such as returning products to their country of origin, if any controlled product entering the country does not meet the necessary standards.
- Coordinates with other authorities at the entry and exit stations, such as Customs and Police.
- As necessary, collects samples of regulated products imported into the country, submits them to the laboratory for analysis, and takes appropriate action based on the test results
- Ensures that products seized at the entry and exit station that do not meet standards are disposed of in collaboration with the relevant bodies, and reports the implementation to the concerned parties.
- Keeps and analyzes data on controlled products at the entry and exit points and reports it to the relevant bodies.
- Carries out inspections and rapid testing of imported regulated products as necessary, and takes appropriate action based on the results.

- Timely requests, directs, and manages the necessary human resources, finance, and other resources for the entry and exit station.
- Conducts awareness programs on ethical conduct to prevent corrupt practices at ports of entry and exit, takes appropriate measures in cases of ethical violations, and informs the concerned parties as necessary.
- Makes decisions on matters beyond the capacity of the desks; works to implement decisions and directions issued by the branch office.
- Ensures effective coordination and a harmonious working relationship among the operational desks at the entry and exit port.
- Participate in the preparation of necessary guidelines and operational manuals by the Branch Office, and develop standard operating procedures (SOPs) for port of entries.
- Monitors that performance evaluations are filled out and submitted on time, and reviews, approves, and sends them to the relevant body when submitted.
- Communicates rules, instructions, and circulars issued by the government to the work units and ensures their proper implementation
- Takes necessary actions and measures, in accordance with government regulations, regarding workers who are absent from duty.
- Provides prompt response to various services requested by the employee, such as leave, termination of employment contract, pension, guarantee, medical experience and other services.
- Prepares and submits the annual financial requirements of the port of entry and exit to the head of the branch office.
- Prepare detailed income plan of the port of entry and exit.
- Monitors the timely collection of approved income in line with the plan, verifies its deposit into the bank, and submits reports to the relevant authority.
- Approves daily service charges collected and ensures they are deposited into the bank.
- Authorizes payments for miscellaneous service charges.
- Register the fixed assets of the branch office and distinguish the ones in the hands of the users, and keep them registered with a card opened in the users’ name.

- Receives requests for fixed and non-permanent items required by work units and ensures their timely distribution.
- Ensure that all incoming and outgoing letters are promptly delivered to the relevant parties and properly archived for future reference.
- Coordinate with relevant stakeholders to address illegal trade of regulated products
- Conduct inspections of warehouses customs and others at port of entry and take administrative measures in cases of non-compliance.
- Receive and respond to appropriate decisions regarding complaints.

4.8.2. Food Import and Export Inspection Desk

- Issues entry release permits for regulated products entering the country, ensuring they meet all necessary requirements, and shares relevant information with the concerned bodies.
- Upon request, issues exit release certificates for all regulated products after verifying compliance with applicable requirements
- If an imported food fails to meet the necessary requirements, directs its return to the country of origin or takes other appropriate administrative actions on the regulated product.
- As necessary, collects samples of food products imported into the country, submits them to the laboratory for analysis, and takes appropriate action based on the test results.
- Disposes of food products detained at entry and exit ports that do not meet requirements, in collaboration with the appropriate parties, and notifies the relevant stakeholders accordingly
- Collects information on regulated food products that are subjected to control at ports of entry and exit, analyzes it and informs the relevant parties.
- Carries out inspections and rapid testing of imported regulated products as necessary, and takes appropriate action based on the results.
- Notifies the lead executive officer of issues beyond the desk's capacity to get a decision, and implements the decision accordingly; works to implement decisions and directions issued by the branch office.
- Ensures effective coordination and a harmonious working relationship within desk
- Coordinate with relevant stakeholders to address illegal trade of regulated products

- Conduct inspections of warehouses customs and others at port of entry and take administrative measures in cases of non-compliance.
- Receive and respond to appropriate decisions regarding complaints

4.8.3. Medicine, Cosmetics, and Tobacco Import and Export Inspection Desk

- Issues entry release permits for medicine, cosmetics, tobacco, public health pesticides, precursor chemicals, and medicine/cosmetics raw materials entering the country, ensuring they meet all necessary requirements, and shares relevant information with the concerned bodies.
- Upon request, issues exit release certificates for any medicine, cosmetics, or tobacco to be exported, after verifying compliance with applicable requirements
- If an imported medicine, cosmetics, or tobacco entering fails to meet the necessary requirements, directs its return to the country of origin or takes other appropriate administrative actions on the regulated product.
- As necessary, collects samples from medicines and cosmetics imported into the country, submits them to the laboratory for analysis, and takes appropriate action based on the test results
- Ensures that medicines, cosmetics, precursor chemicals, and tobacco seized at the entry and exit station that do not meet standards are disposed of in collaboration with the relevant bodies, and reports the implementation to the concerned parties.
- Keeps and analyzes data on controlled products at the entry and exit points and reports it to the relevant bodies.
- Carries out inspections and rapid testing of imported medicine and cosmetics as necessary, and takes appropriate action based on the results.
- Notifies the lead executive officer of issues beyond the desk's capacity to get a decision, and implements the decision accordingly; works to implement decisions and directions issued by the branch office.
- Ensures effective coordination and a harmonious working relationship within desk
- Coordinate with relevant stakeholders to address illegal trade of regulated products

- Conduct inspections of warehouses customs and others at port of entry and take administrative measures in cases of non-compliance.
- Receive and respond to appropriate decisions regarding complaints.

4.8.4. Medical Devices Import and Export Inspection Desk

- Issues entry release permits for any medical device entering the country, ensuring they meet all necessary requirements, and shares relevant information with the concerned bodies.
- Upon request, issues exit release certificates for any medical device to be exported, after verifying compliance with applicable requirements.
- If an imported medicine, cosmetics, or tobacco entering fails to meet the necessary requirements, directs its return to the country of origin or takes other appropriate administrative actions on the regulated product.
- As necessary, collects samples from medical device imported into the country, submits them to the laboratory for analysis, and takes appropriate action based on the test results
- Ensures that medical device seized at the entry and exit station that do not meet standards are disposed of in collaboration with the relevant bodies, and reports the implementation to the concerned parties.
- Keeps and analyzes data on medical devices at the entry and exit points and reports it to the relevant bodies.
- Carries out inspections and rapid testing of imported medical devices as necessary, and takes appropriate action based on the results.
- Notifies the lead executive officer of issues beyond the desk's capacity to get a decision, and implements the decision accordingly; works to implement decisions and directions issued by the branch office.
- Ensures effective coordination and a harmonious working relationship within desk
- Coordinate with relevant stakeholders to address illegal trade of regulated products
- Conduct inspections of warehouses customs and others at port of entry and take administrative measures in cases of non-compliance.
- Receive and respond to appropriate decisions regarding complaints.