Ethiopian Food and Drug Authority

Organization Job Description

June 2020

Addis Ababa

Introduction

In addition to securing universal economic and social development, our country is achieving excellent results in all areas of development. At the moment, the government is accelerating development and achieving the Millennium Development Goals to realize the prosperity of our country. This is visible in all areas of development. Therefore, in order to be successful in all areas of development, there must be a healthy, productive, productive and prosperous society. To make this effective, achieving the development of the health sector is an important and decisive task.

One of the institutions that play an important role in protecting public health in the health sector was the Ethiopian Food, Medicines, Health Care Administration and Control Authority (EFMHACA). Since its establishment by Proclamation 661/2009 and Regulation No. 299/2013, had been carrying out its mission to achieve excellent results in the health sector in the country.

In order for the office to carry out its assigned powers and responsibilities effectively, it is believed that there was a need to formulate a new product-oriented organization by thoroughly examining the existing organization and procedures of the institution using internationally accepted research methods, and conducting a study to facilitate the establishment of efficient and convenient organization. In accordance with the growth and technological development required by the times and the increasing needs of the society, the competent office of the Federal Democratic Republic of Ethiopia, the Food and Drug Administration of Ethiopia, has been re-established as the Food and Drug Control Proclamation 1112/2019 and Council of Ministers Regulation No. 531/2023. According to the authority and responsibility given to the authority, the EFDA is to control food safety, drug and medical device safety and quality, and tobacco products to prevent harm to public health. In order to carry out the tasks and responsibilities efficiently and effectively, it is necessary to have a system that can carry the work properly to achieve the intended goal, and to accommodate the amount and type of manpower planned according to theassesements done. Therefore, it was found necessary to prepare the organizatinal structure of the Federal office including its branch and entry and exit ports offices in a way that they can satisfy the implementation of the Authority mandates.

Assessment of the situation and the need for a new structure

According to the authority and responsibilities given to the authority, the office is known to be one of the institutions that plays an important role in the health sector in terms of protecting public health. When the work process change survey was studied and implemented, the main work process for quality control of health and health-related services and resources was designed and supported by Proclamation No. 661/2009 and has been implemented for the earlier 9 years. In order to achieve this, great efforts had been made to fulfill the responsibilities given in the sector by preparing a strategic plan for the health and health-related services and resources control sector and issuing proclamation, regulations, standards and guidelines.

As tried to explain above, the institution has achieved many results, but the existing organization was not based on the work processes and contained various setbacks becusee of congested tasks coming together, lacking focus to critical areas of attention. Therefore, the organization has revealed perceivedgaps in implementation of key objectives. On the other hand, following the speed of economic and social development created by the establishment of peace and security in the country, the high level of investment coming into the food and drug production sectors,could not manage the required flow of investment. In addition to this, it was necessary to pay attention to establish capable organization to manage the health products to the extent required from such an organization. On the other hand, the society has been suffering due to lack of organization and regulatory control of the illegal food, drug, medical device and cosmetic products that are spreading through outevery time, so that they do not harm the health of the society.

Due to the fact that the duties and responsibilities of this institution, given by the law, are extremely overlapping and complicated, it was not possible to achieve the desired results as observed under the supervisions. How can the quality control of national health and health related services and resources work so that the society can benefit from quality and safe health and health related services and resources? By using international indicators, it has been tried to identify the strengths and weaknesses of the control system, organization, and skills of the experts in the field, strategies to keep them in the institution, institutional culture and sustainable finance, and suggested solutions. The organizations that have conducted the study, including the best recommendations from the relevant stakeholders, the regional and federal regulatory sector and the health sector leaders and other countries experiences, came up with

four options for the organization that can be used to control the quality of health and health resources and services in our country, viz. 1) if the current organization at the state and federal level continues 2) if a national regulatory institution is established 3) if health professionals are independent and organize others together 4) if the control of food, medicine, medical equipment, cosmetic products and tobacco products is organized separately. After extensive discussions, it was decided to organize the authority office at the federal level taking the fourth option and drafting proclamation no.1112/ 2019 and enabling the work to be done according to the required standards. Following this, the Ethiopian Food and Drug Authority was established by Cabinet Regulation No. 531/2023, a federal institution that can implement the fourth option with Proclamation No. 1112/ 2019.

In order to carry out the tasks and responsibilities given by the newly established authority office efficiently and effectively, it was necessary to organize an organization based on sufficient assesement. Therefore it was tried to look at three options of what kind of arrangement would be applicable, the first option is organized according to the types of controlled products (Product based), the second option was functional, and the third option was geographic location based. It has been tried to see experiences and take it in a way that is beneficial to our country. Therefore, it is believed that if the institute is organized in the first option (product based), using the resources obtained from the managers and staff of the authority office, the customers of the sector and the experiences of the countries, this organization will be able to effectively fulfill the responsibilities given by proclamation No. 1112/ 2019 and that was prepared and presented.

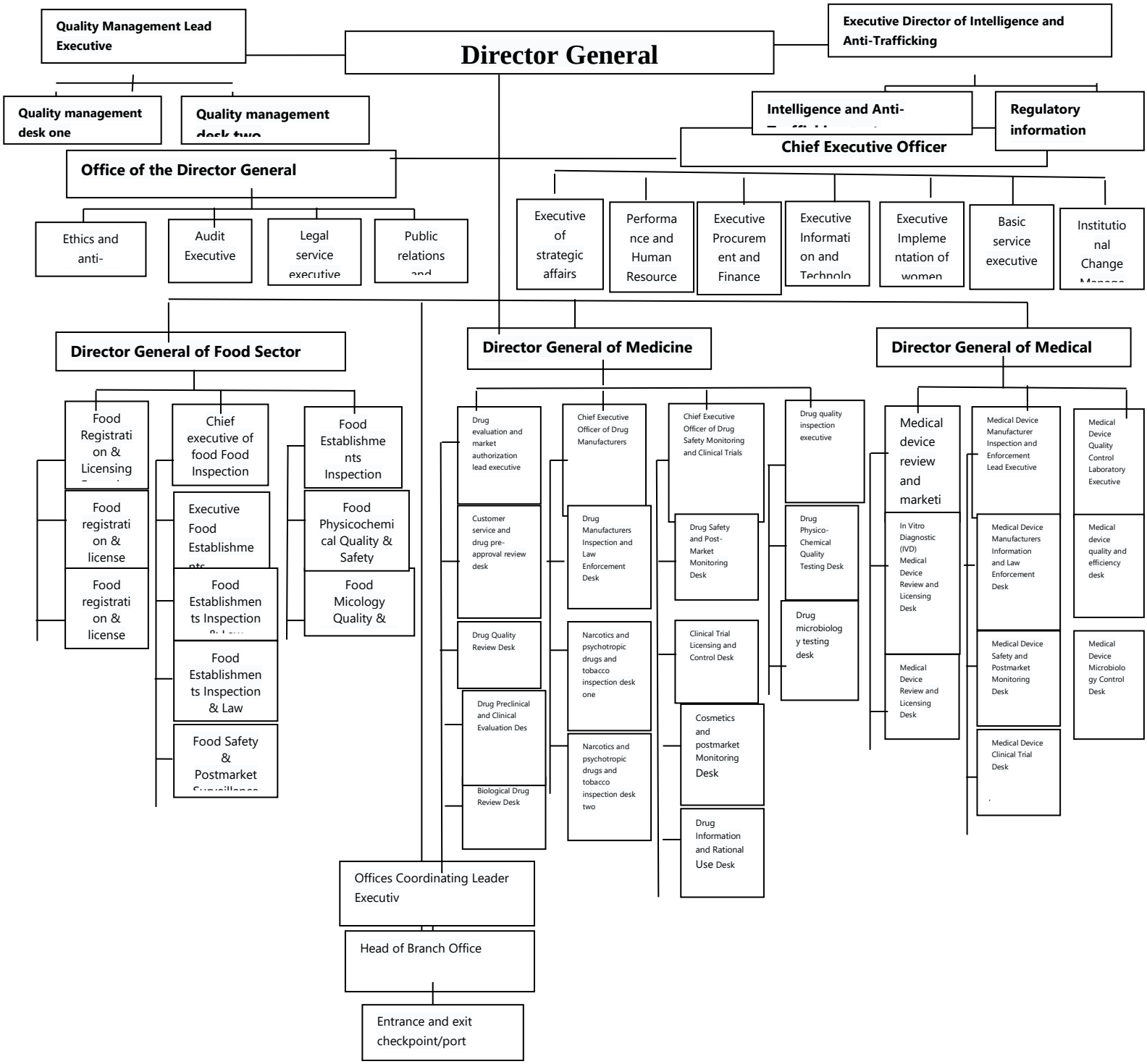
Therefore, the new organization has been prepared to achieve its newly designed vision, mission and objectives, and the authority office is led by an executive board, the director general and deputy director generals who managed the day-to-day operations and purpose-fulfilling directorates and supporting directorates have been organized. In addition to these, branch offices and entry and exit ports/checkpoints have been organized in different parts of the country so that the control work is accessible to the public and users.

Purpose

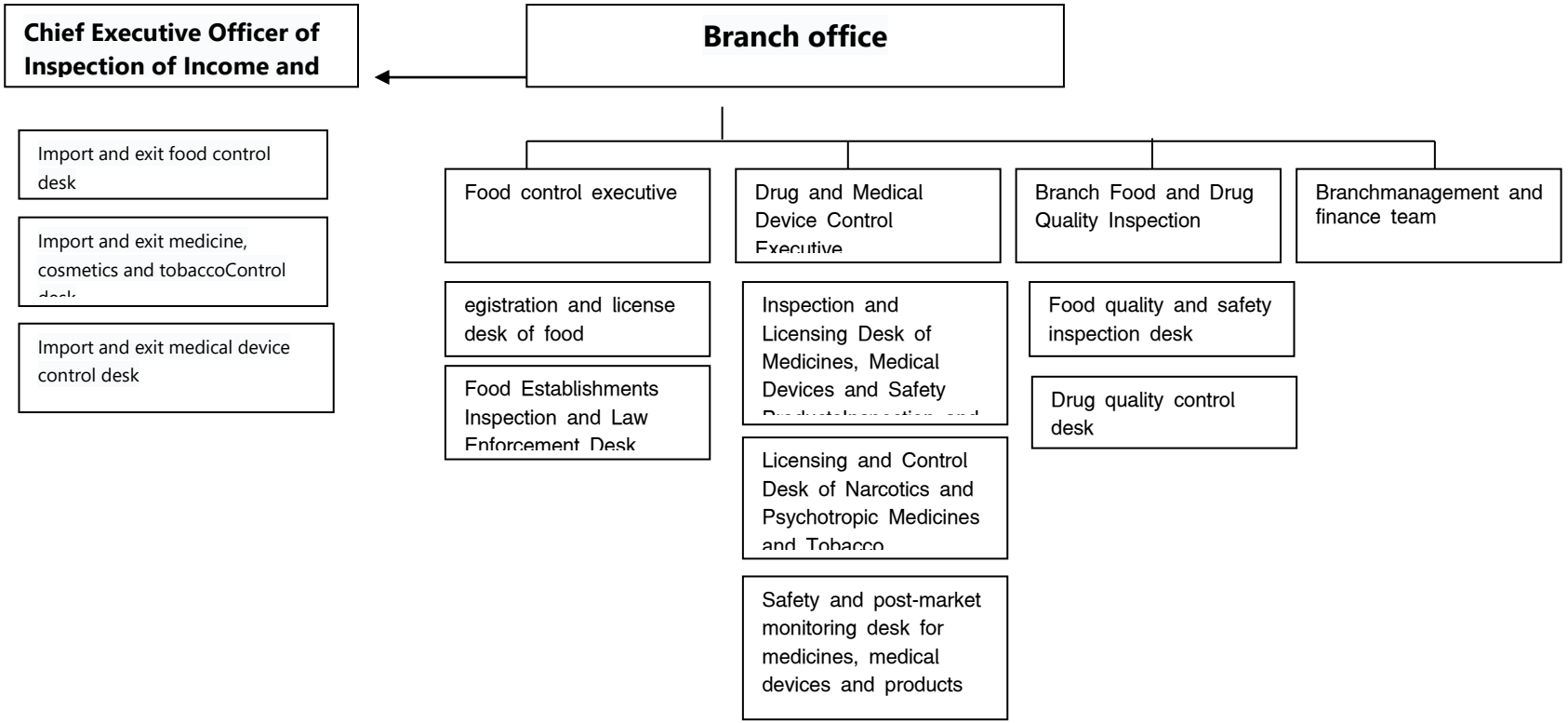
A new structure and procedures that take into account the weight, complexity, scope and national and international current and ongoing conditions of the responsibilities given to the

authority by proclamation no. 1112/2011, the scope of work of the work units, the type and number of manpower required and the expected results were clearly defined and stated.

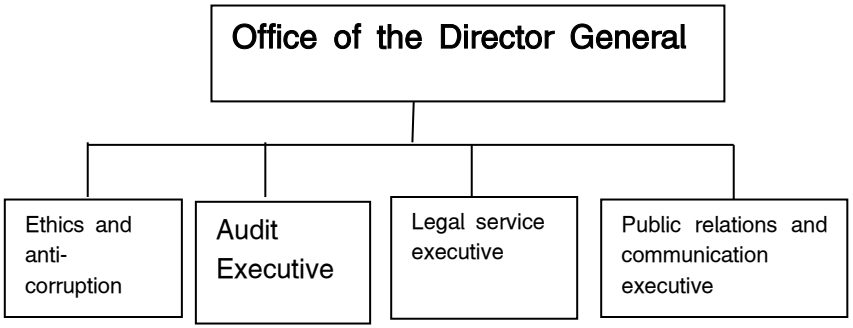
Organizational structure of Ethiopian Food and Drug Authority

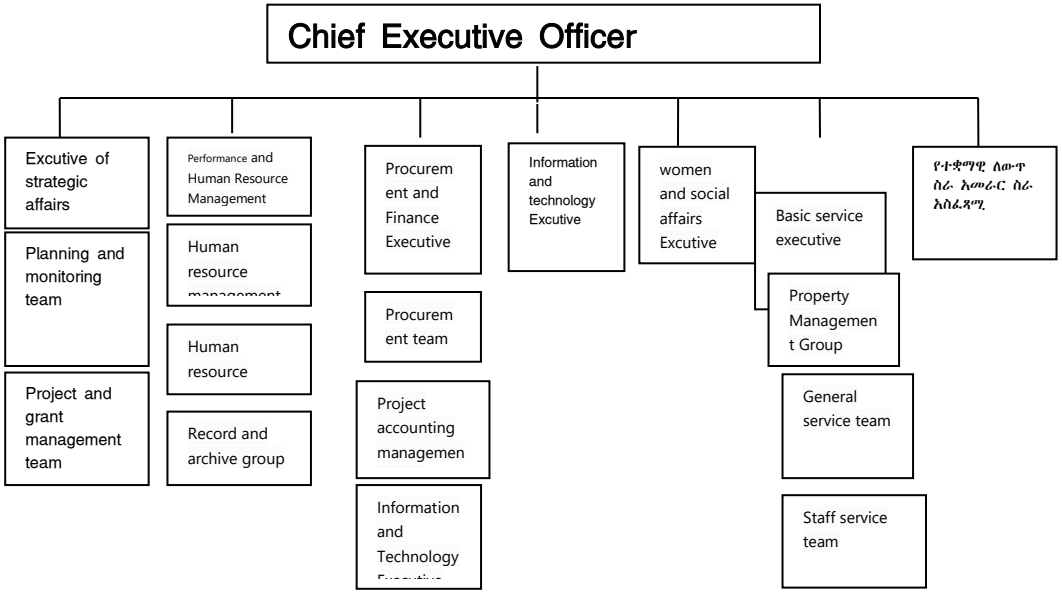


Organization of Ethiopian Food and Drug Authority branch offices and entry and exit ports



Ethiopian Food and Drug Authority Executive Director and Executive Organization





Quality Management Lead Executive

Purpose of establishment

The main purpose of the organization of the leading executive is to conduct physical tests on new registrations, consignments, post-market surveillance and suspected samples imported from abroad; Chemical, microbiological and toxicological testing, traditional medicine safety/efficacy and quality, as well as pesticide and cosmetic safety and quality assurance systems and procedures for public health services, control activities (local manufacturers, importers and wholesalers); Sample registration operations or events (Dossier (document) registration order, prescreening and evaluation, prepares the institution's vendor list, selection process and supervises the work to be done based on quality, evaluates, generates and implements ideas to implement process improvement, guides the entire work units of the office according to the quality management method; rules; uniform procedures; Qualification documents; compels technical and administrative documents to be prepared together with the relevant departments. Revises and manages revisions. He evaluates and manages evaluation; develops new procedures; studies the institution's internal and external complaints and provides feedbacks, analyzes and uses them for transparency; accountability and operational system improvement; conducts internal audits of the institution (all departments); provides qualified bidders.

Duties and Responsibilities

- Plans, organizes, directs and coordinates work for the executive;
- Monitors the implementation of the plan, provides a report on the implementation of the plan;
- Evaluates professional performance;
- Food and drug laboratory, control, documentation ensures that professionals are competent;
- Liaise with the instituitions superiors and stakeholders on behalf of the executive;
- Ensures that necessary resources are met for the lead executive;
- Summarizes and distributes experiences for the executive and turns them into a permanent operating system;
- By conducting user feedback and survey, designs the situation in which the quality control system of the food and drug institution can be improved, and monitors its implementation;
    - The overall lead executive directs operations, responds to timely decisions that require decision-making;

- Periodically measures, evaluates, and makes necessary adjustments to the performance of the lead executive;
- Development of quality control activities of food and drug control as well as branch office and regional regulatory unites in terms of quality management system.
- Develops international standards, laboratories (ISO/IEC17025/17, WHOGPPQCL and GLP); Control and registration (ISO/IEC 1720/2012 and ISO/IEC 9001/2015), vigilance and other parts of the institution, including international and national standards, the required quality management system (QUALITY MANAGEMENT SYSTEM). Accordingly, food and drug Quality control laboratories, control units, food and drug registration institutions and 11 food and drug branch institutions, including quality manuals, safety manuals, prepare food and drug quality management system guidelines, train them, and monitor their implementation.
- Coordinates the flow of work through different work unites in the institution, such as those who control, those who do sample quality testing, those who examine the sample scientific dossier or document, those who monitor the product survey and procedure, and coordinate the flow of work by creating coordination and integration in different operating systems or a uniform system. International supervisory institutes, supervisory research institutes, etc. will jointly develop new operational resources and apply them to the relevant departments.
- When there are new outbreaks of disease-causing bacteria that have changed their characteristics, or when there is a hint that they may occur, a system will be put in place to prevent this.
- Professionals working at the institute, international laboratories; Facility and Inspection; Food and Drug Registration Standards (ISO/IEC17025/17, WHOGPPQCL and GLP); ISO/IEC 1720/2012 and ISO/IEC 9001/2015; COMPETECY MATRIX works according to criteria. Qualified professionals are distinguished from unqualified professionals, by ensuring the competence of those who are not qualified by providing them with adequate training. This authorizes only qualified professionals to work in the relevant work units. This will schedule the competency tests for all the departments periodically. It will update the COMPETECY MATRIX.
- International standards (ISO/IEC17025/17, WHOGPPQCL and GLP) for all professionals of the institution; According to ISO/IEC 1720/2012 and ISO/IEC 9001/2015 standards, refresher training is provided to the professionals in the institution in each quality management system.
- Laboratory Design ensures that the working system of the laboratories is convenient. Different temperature and humidity measurement devices (Thermometer and Thermohygrometer) are located by doing Mapping operations.

- The temperature and humidity of the tile determine the size (Specification). By monitoring their measurements every time, it ensures that they are within the specified temperature and humidity specifications. Plans/executes necessary corrective actions when temperature and humidity measurements are out of specification.
- In addition, prepares the institution's quality manual and necessary uniform operating instructions, which are necessary for the establishment of a quality management system in the institution, and coordinates the preparation.
- Monitors and controls that the sample testing equipment used in the laboratory, from its purchase, maintains its quality and is used for the intended purpose of the test.
- Develops quality equipment qualification (IQ, OQ, PQ, DO) system (Documentation System) in the laboratory, ensures the accuracy of the application of qualification (Qualification) of laboratory equipment.
- Schedules annual calibration of laboratory equipment. The program notifies the relevant department to carry out equipment characterization or calibration. Reviews and evaluates equipment calibration certificates. Permits the instrument to be used in accordance with the instrument calibration certificate reviewed.
- Develops an annual preventive maintenance program for laboratory equipment. The program notifies the relevant department and makes pre-breakdown operations of the equipment. Reviews preventive maintenance reports for equipment. Permits the device to be used based on the reviewed device pre-fault report.
- Opens the device history file of all devices available in the labs. It documents the entire history of the device from the purchase request to the current time.
- Develops/revises the Procedure for Laboratory Equipment Management. Ensures laboratory equipment is properly maintained and used in accordance with instructions. Maintains a database of all laboratory equipment. It prepares the database of control institutions and document registration according to the quality management system and forces it to be prepared; evaluates the prepared procedure; makes suggestions for improvement;
- Ensures the documents and uniform operating instructions (standard operating procedures, directives, guidelines, forms and formats, manuals) required for international recognition of regulatory and document registration institutions are completed and revised in a timely manner.
- Works to achieve and maintain international recognition in all Directorates of the institution. Answers any question regarding the laboratory during the laboratory audit from international

accreditation bodies. It works for the implementation of international recognition by monitoring during the audit. Corrects findings made during external audits and fixes them.

- Test Method Validation/Verification of the sample testing methods used by the laboratories will lead to a transition system for the test method validation/verification of local and foreign manufacturer's quality testing methods that pass through the control and registration institutions. It will strengthen the accuracy of testing methods by providing training to relevant experts on the accuracy of sample testing methods (Test Method Validation/Verification).
- An information system (Documentation System) will be established in all departments of the institution, and according to the information system, uniform operating procedures (SOP), quality manual, equipment qualification test results reports, training files of technical staff, etc. In order to strengthen the operational system, the technical training system for the institute's experts will be coordinated, prepared, and given training together with the relevant parties.

- Plans the internal quality audit of the institution. Distributes the plan to all the institutions (food and drug Directorates as well as branch and regional regulatory offices). According to the plan, conducts the internal audit of the laboratories (Laboratory Internal Quality Audit). Prepares an internal audit report for the Laboratory Internal Quality Audit and will send the report to the concerned. Plans corrective actions for non-conformities found in the audit report; performs; conducting a second audit will confirm that the defect has been cleared.
- Plans the institution's Management Review Meeting; circulates the plan to the concerned management members of the institution; conducts Management Review Meetings as per the plan; Introduces management review meeting agendas; participates in the meeting; takes minutes of the meeting; prepares and distributes management review meeting reports; makes certain decisions in management review meetings and make them happen or ensures that they are done within the specified time limit by monitoring.
- Establishes a customer complaint handling system; complaints will be received according to the established system. investigates complaints; notifies the complaining customer of the results of the investigation; plans appropriate corrective action if the complaint is valid; ensures that it is applied.
- Develops laboratory proficiency test plans; according to the scheme, it helps the laboratories to participate in proficiency Test in various tests; evaluates laboratory proficiency test results. Prepares a Formal Proficiency Testing Report and close-Out Report; distributes to laboratory

management. Plans corrective actions for non-conformities found in the results; Implements or ensures implementation.

- Controls that the handling and use of Sample and Reference Standard is being carried out by the established system; evaluates the application and organizes the documentation system in the institution. Preparation of documents;a review and approval system will be in place. Prepares the Document Master List of the documents in each work department and revises them periodically. Distributes important (Controlled) documents in important areas of the institution and removing obsolete documents from their place:
- Prepares necessary documents of the institution, i.e. approved signatories (Approved Signatories); Conflict of Interest Attestation, signs, and files a confidentiality declaration.
- Ensures that the work done in the institution is carried out in accordance with the quality policy and procedure guidelines described in the Quality Manual, and monitors it.
- According to the internal audit report, it points out the problems found and the corrections, monitors the correct implementation of the corrective measures.
- Proposes that the procedures that have caused problems in the work should be fixed and appropriate adjustments should be made by identifying the professionals who need technical training.
- Monitors that laboratory equipment is regularly pre-destroyed and calibrated according to the plan;
- Monitors that the technical experts and managers working in the institution are clearly defined and controls implemented;
- When asked for support and supervision from his colleagues, provides the necessary assistance and supervision.
- We will study the quality and efficiency of the institution's quality control system and monitor its effectiveness.
- Up to now, new and emerging scientific diagnostic methods with high-quality diagnostic equipment (Hi-tech) automated machines for cancer, genetics, electronic data management systems (e-mris, i-import, i-licence, LIMS, e- It will develop a system that can start operations using QMS, etc.
- Harmonization from other countries and institutions sets standards for equivalence and evaluates. Creating a source of income for the institution by providing training in QMS (Quality Management System) to IGAD Countries.

- The entry and exit ports located under the branch offices will develop a system of procedures to maintain the quality of the samples entering the regions at their respective ports, train and support them in the management of information (Documentation system).

Organization and accountability

The Chief Executive Officer of Quality Management is responsible to the Director General and has two desks under him.

1. Quality management desk one

2. Quality management desk two

The quality management desk will have the following tasks and responsibilities

- Plans, organizes, directs and coordinates the work of the desk.
- Monitors the implementation of the plan, submits a plan performance report to the Quality Management Directorate;
- Evaluates and registers the performance of quality management professionals
- Food and drug laboratory, control, documentation ensures that professionals are competent.
- Liaise with the Quality Management Lead Executive and stakeholders on behalf of the desk;
- Ensures necessary resources are met for the desk;
- Experiences for the desk will be compiled and distributed to be converted into a permanent operating system.
- By conducting user feedback and survey, he designs the situation in which the quality control system of the food and drug institution can be improved, and monitors its implementation.
- Manages the overall operations of the desk, provides timely responses to decision making; Periodically measures, evaluates and makes necessary adjustments for the performance of the desk
    - Establishes International standards for laboratories (ISO/IEC17025/17, WHOGPPQCL and GLP); the Quality Management System (QUALITY MANAGEMENT SYSTEM) required by international and national standards including control and registration (ISO/IEC 1720/2012 and ISO/IEC 9001/2015, vigilance and other parts of the institution).
    - Mandates, directs, approves and enforces the preparation of documents such as operational strategies, manuals, uniform work instructions and other documents for the physicochemical

and microbiological quality testing of medicines, cosmetics, food and medical devices, and oversees them to be implemented.

- Prepares and revises Method of analysis; Good Manufacturing Practice Guideline, Good Distribution Practice Guideline, Good Review Practice, medicines that do not have Good Review Practice, food, beauty care samples and service procedures from those concerned and the quality standards and methods of inspection of the work packages;
- Prepares for all the professionals of the institution, international standards (ISO/IEC17025/17, WHOGPPQCL and GLP); According to ISO/IEC 1720/2012 and ISO/IEC 9001/2015 standards, refresher training is provided to the professionals in the institution in each quality management system.
- Develops laboratory proficiency test plans. According to the scheme, helps the laboratories to participate in Proficiency Test in various tests. Evaluates laboratory proficiency test results. Prepares a Formal Proficiency Testing Report and close-Out Report; distributes to laboratory management. Plans corrective actions for non-conformities found in the results; Implements or ensures implementation.
- Develops updated and new and emerging scientific diagnostic methods with high-quality diagnostic equipment (Hi-tech) automated machines for cancer; genetics, electronic data management systems (e-mris, i-import, i-licence, LIMS, eQMS ,etc)) will establish a system that can start works, and will be developed by the institution by drawing on the experience of similar institutions from the relevant department.
- Establishes a system that allows for smooth communication between professionals in the team and efficient and effective work.
- Harmonization from other countries and institutions and sets standards of equivalence; evaluates. Creating a source of income for the institution by providing training in QMS (Quality Management System) to IGAD Countries.
- The entry and exit checkpoints located under the branch offices will develop a system of procedures to maintain the quality of the samples entering the regions at their respective checkpoints, train and support them in the management of information (Documentation system).
- Monitors that the technical experts and managers working in the institution are clearly defined and implemented. controls,

- Plans the internal quality audit of the institution. Distributes the plan to all the institutions (food and drug institutions as well as branch and regional regulatory offices). According to the plan, conducts the internal audit of laboratories. Prepares an internal audit report for the Laboratory Internal Quality Audit. He sends the report to the director. Plans corrective actions for non-conformities found in the audit report; performs; conducting a second audit will confirm that the defect has been cleared.
- Laboratory Design ensures that the working system of the laboratories is convenient. The location of different temperature and humidity (Thermometer and Thermohygrometer) measurement devices is identified by doing mapping operations: it places or verifies that they are placed. Determines the specification of the temperature and humidity of the building. By monitoring their measurements every time, it ensures that they are within the specified temperature and humidity specifications. Plans/executes necessary corrective actions when temperature and humidity measurements are out of specification.
- The necessary documents of the institution, i.e. approved signatories; Conflict of Interest Attestation Prepares, signs, and files a confidentiality declaration.
- According to the international standard of control and registration (ISO/IEC 9001/2015) including vigilance and other parts of the institution, according to the international and national standards, the Quality Management System (QUALITY MANAGEMENT SYSTEM) systems are set up.
- Mandates, directs, approves and enforces the preparation of operational strategies, manuals, uniform work instructions and other documents in accordance with the quality management system, which governs the reporting of medicines, cosmetics, food, and medical devices.
- The necessary documents of the institution, i.e. approved signatories (Approved Signatories); Conflict of Interest Attestation Confidentiality declaration for the number sector; Registration, payment for inspection and other 9001/2015-directed work payments prepares, signs, files.
- Plans the internal quality audit of the institution. Distributes the plan to all the institutions (food and drug control registration and similar institutions as well as branch and regional regulatory offices). According to the plan, the internal audit of control, registration and other work units will be conducted (Internal Quality Audit). Prepares an internal audit report for the Laboratory Internal Quality Audit. He sends the report to the director. Plans corrective actions for non-conformities found in the audit report; performs; conducting a second audit will confirm that the defect has been cleared.

- Electronic data management systems (e-mris, I-import, i-licence, LIMS, e-QMS, etc) will be used to set up a system that can start operations.
- The entry and exit checkpoints located under the branch offices will set up a system of procedures to ensure the quality, efficacy/efficiency, and safety of the samples entering their respective checkpoints.

Executive Director of Intelligence and Illegal Trade

Purpose of establishment

The main purpose of the chief executive officer, who is accountable to the director general, investigates corrupt practices and the controls activities carried out by the authority office; identifies and investigates the causes and chain of illegal trade. It is a working unit that is set up to investigate the sales chains of products whose quality and safety are not known and collects various information in general and ensure that appropriate action is taken by the relevant working unit.

Duty and responsibility

- To study the areas where illegal trade is carried out and the strategies used to do it,
- Creates a graphic document of the areas where illegal trade flourishes;
- Performs pre-surveillance activities to help in the study of the areas where illegal trade is carried out and the methods used in the products it controls;
- Recruits experts who are not employees of the Instituition for intelligence work, trains and assigns tasks and missions.
- Working conditions of foreign intelligence experts; monitors behavior and other related issues;
- Performs Market Assurance Review by identifying areas that require full surveillance operations.
- Uses various strategies and operational systems to prevent illegal activities
- Collecting information, analyzing, organizing and presenting it to the relevant parties by conducting a survey on areas identified as where illegal trade is carried out.
- Based on the information provided, will provide the necessary assistance to the relevant parties when they carry out operations;
- Prepares various strategies and operational systems to prevent illegal activities and implement them.

- Receives suggestions related to illegal trade and submits it to the relevant work Directorates after verifying the correctness of the suggestion;
- Coordinates with neighboring countries and international organizations (Interpol) to prevent controlled products before they harm public health.
- Designs and works together with relevant national institutions (Customs Commission, security agencies---) to work together to prevent illegal trade.
- Identifies entities that indicate data and provides training.
- Prepares a system of procedures in which individuals who point out illegal activities are encouraged and works to implement it.

Organization and accountability

The Chief Executive Officer is responsible to the Director General and has two desks under him:

1. Intelligence and Illegal Trade Desk

2. Regulatory Information Preparation and Distribution

Desk Duties and responsibilities of Intelligence and Illegal Trade Prevention Desk

- Creates a graphic document of the areas where illegal trade flourishes;
- Performs pre-surveillance activities to help in the study of the areas where illegal trade is carried out and the methods used in the products it controls;
- Recruits experts who are not employees of the Instituition for intelligence work; trains and assigns tasks and missions.
- Working conditions of foreign intelligence experts; monitors behavior and other related issues;
- Performs Market Assurance Review by identifying areas that require full surveillance operations;
- Collecting information, analyzing, organizing and presenting it to the relevant parties by conducting a survey on areas identified as where illegal trade is carried out.
- Prepares various strategies and operational systems to prevent illegal activities and submits them to be approved by the concerned parties and implements them.
- Receives suggestions related to illegal trade and carries out various intelligence activities to verify the necessary verification work and the validity of the suggestion;

- Coordinates with neighboring countries and international organizations (Interpol) to prevent controlled products before they harm public health.
- Coordinates and cooperates with relevant national institutions (Customs Commission, security agencies----) that work to prevent illegal trade, and provides professional support based on the sector;
- It provides to the relevant body to encourage individuals who have suggested illegal activities by verifying the accuracy of their suggestions.
- Creates various capacity building platforms that strengthen the capacity of the desk;
- Works in coordination with the surveillance team;

Office of the Director General

The authority is required to establish a system to ensure that the public health service is carried out in an appropriate manner and that the products used as resources for this service are being used for the desired public health purpose while ensuring their safety and quality.

The Office of the Director General is to established and coordinate activities to enable the Director General to focus on strategic and policy works by closely following the strategic activities to facilitate the work that needs an immediate response to facilitate the conditions and to monitor the implementation as well as closely follow up the implementation of the decisions made by the Management Committee to provide the necessary support for the effectiveness of the key duties carried out by the authority and the advisors of the Director General.

Duties and Responsibilities

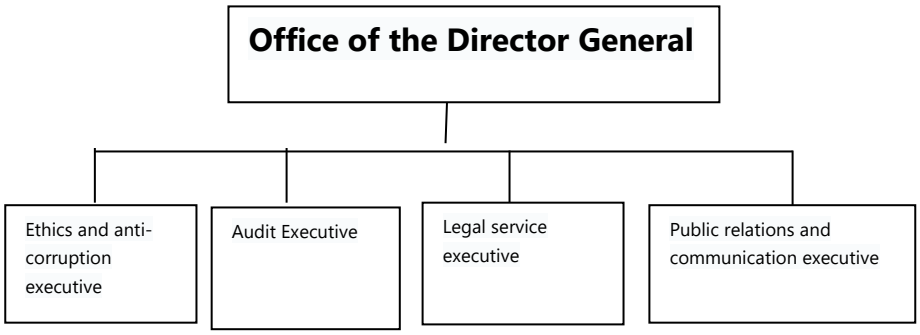
- Coordinating the office work organized under the office
- Coordinating the advisors of the director general
- Accepting issues identified by the Director General and providing the necessary response
- Preparing the necessary explanations and analyzes issues submitted to the Director General, and submits them to response by the Director General.
- In consultation with the Director General, he will set up a system where organizations and individuals who have been subject to administrative action by the authority can file a complaint, and will monitor its performance.

- Devising procedures and strategies for the authority to be led by the office
- The authority office works as the secretariat of the leadership and management committee.
- Monitoring and supporting the main strategic activities of the authority office
- Liaising and coordinating with stakeholders
- Facilitates a joint forum with the General Director or the concerned Directorates by inviting and hosting partners from partner organizations, international institutions and foreign stakeholders.

Organization and accountability

The head of the office is responsible to the director general and the office has five executives under it.

1. Executive of legal services
2. Ethics monitoring executive
3. Public relations and communication executive
4. Audit Executive
5. Implementation Executive for Women and Social Affairs



Legal Services Executive

Brief job description

The main purpose of the legal service executive is to prepare, promote and monitor the implementation of various legal frameworks required for the regulatory work, in order to provide legal advice and services to various departments of the authority, to represent the authority in legal matters, and to establish a system that upholds legality.

Duties and responsibilities:-

- Providing necessary support to regional regulatory bodies in drafting, approving and promoting laws;
- Participates in the preparation of nationally and internationally controlled standards, compiles standards to be issued and revised, and provides awareness training to the authority office and regional regulatory bodies.
- Prepares a National Pharmacopoea, in collaboration with relevant parties.
- Ethiopia accepted and supports international conventions and monitors their implementation;
- Submits requests to the appropriate body for the development and revision of new standards on regulated products, and generates ideas;
- Provides legal professional support by being physically present when operations are conducted based on surveillance findings:
- According to the request submitted by the inspection departments, will attend the institution where the inspection is conducted and provide legal professional support.
- Providing legal advice and opinion in terms of law before taking administrative action and ensuring that appropriate action is taken when violations of the law are confirmed.
- Terms of service and purchase; the authority prepares the documents of the memorandum of understanding with other international and national institutions and partner organizations, comments when they are prepared and submitted.
- Organizes the necessary evidence regarding court cases and argues on behalf of the official when the office is sued.
- Provides professional support to legal professionals at branch offices.

- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit.
- The authority conducts studies on legal issues related to the office, presents the results of the study to the relevant body and monitors its performance.
- Works as a member in the Complents Handling committee that will be established to investigate the complaints submitted by the organizations and individuals against whom administrative action has been taken.
- Facilitates the conditions for the relevant parties to discuss and contribute ideas on draft legal documents, and the document is developed and submitted for decision and provides awareness training after approval to the concerned parties.

Organization and accountability

The executive director of legal services is accountable to the Director General.

Duties and Responsibilities

- Participates in drafting and revising laws, ie decrees, rules and regulations.
- Providing legal advice and opinion in terms of law before administrative action is taken for matters outside of control activities;
- Ensures that appropriate action is taken when violations of the law are confirmed.
- Terms of service and purchase; prepares the documents of the memorandum of understanding with other international and national institutions and partner organizations, comments when they are prepared and submitted.
- When the office sues and is sued for civil cases, the office shall compile the evidence and take the case to the judicial body and carries out the appropriate activities.
- Provides professional support to legal professionals at branch offices.
- Prepares the necessary guidelines, operating manuals and standard operating procedures (SOP) for the team.
- The official participates in studies on legal issues related to the office
- Provides awareness training to the office staff on various legal issues.
- Identifying the role of the different operational guidelines prepared and implemented by the authority, exploring their implementation results and presenting further improvement ideas to the relevant body.

- Prepares, revises, approves, promulgates, and monitors implementation of regulatory laws, such as proclamations, rules, and regulations.
- Provides necessary professional support to regional regulatory bodies in preparing laws regarding food control;
- Participates in the preparation of national and international controlled food standards, compiles standards, and provides awareness training to the authority office and regional regulatory bodies.
- Submits requests to the appropriate body for the development and revision of new standards on controlled food products, and generates ideas;
- Provides legal professional support by being physically present when operations are conducted based on surveillance findings in the food sector:
- According to the request submitted by the food inspection departments, he will attend the institution where the inspection is conducted and provide legal professional support.
- Providing legal advice and opinion in terms of law before taking administrative action based on the findings of food inspection; to ensure that appropriate action is taken when violations of the law are confirmed.
- In relation to food control, organizes the necessary evidence related to court cases and argues on behalf of the authority when the office is sued.
- Provides professional support to legal professionals at branch offices.
- Prepares the necessary guidelines, operating manuals and standard operating procedures (SOP) for the team.
- Conducts studies on legal issues related to food control, presents the results of the study to the relevant body and monitors the performance.
- Facilitates conditions for relevant parties to discuss and contribute ideas on food control draft legal documents, and prepares the document for decision.
- Provides awareness training to the concerned parties on the approved food control legal documents.

Executive for Ethics monitoring

Brief JobDescription

Organized under the Office of the Director General, the main purpose of the Executive of Ethics Monitoring is to establish operational systems to prevent corruption and malpractices, create favorable conditions for their implementation, enact laws and ensure their implementation, monitor ethical issues, enhance transparency and accountability, and establish a control system free from theft and malpractices. This is to put in place a system that ensures EFDA service provision is fair, efficient and that the human resources engaged in the sector have better ethical practices.

Duties and responsibilities:-

- To enhance ethical practice in the authority, to develop a sense of servitude, to carry out various awareness-raising activities about the damaging image and harmfulness of fraud and to have an employee who hates theft;
- Ensure that the officers and employees of the authority have sufficient understanding of anti-corruption policies, laws, rules and regulations;
- Studying and identifying procedures that open the door to theft and corruption, proposing solutions and monitoring them to be implemented;
- Designs a strategy to prevent theft and corrupt practices and monitors its implementation;
- Investigating theft and corrupt practices and coordinating with the relevant parties to ensure that appropriate measure is taken;
- Identify and encourage leaders and workers who are leading and role models in combating theft or corrupt practices;
- Provides support to branch offices ethics officers;
- Guides the personal property registration of supervisors and staff of the authority
- The executive will submit plans and current reports to the Director General of the authority and the Federal Ethics and Anti-Corruption Commission.

Public Relation and Communication Executive

Brief Job Description

Public Relations and Communication Executive is organized under the Office of the Director General, the main purpose of it is to act as spokes person of the authority, to provide up-to-date and recent information to the public and other parties concerned by using various communication methods, and to receive the opinions and needs of the public regarding the regulatory system, so that corrective actions can be taken.

Duties and Responsibilities:-

- Prepares and conducts consultation and discussion forums that help to create transparency in the institution's policies, guidelines and regulations, and national issues;
- Serves as a bridge of information between the government, the public and the government, lead, coordinat, monitor the implementation;
- Creates working relationship with the institution and customers as well as local and foreign media, strengthens communication exercises;
- Attending bilateral and beyond signing ceremonies at the institution and holds media briefing;
- Acts as spokesperson for the authority;
- Carries out media monitoring activities regarding the authority;
- Prepares various programs on radio, television and various media;
- Preparation of press conference on the institution's work and performance as well as future directions;
- Works in collaboration with other sections strives in achieving the institution's vision and mission and to enhance image of the authority;
- Prepares articles and reports about the institution and distributes them through private and government media and social media;
- Conducts local surveys to collect opinions from stakeholders and the community on the activities of the authority.

Public relations and communication team

- Prepares and conducts consultation and discussion forums that help to create transparency in the institution's policies, guidelines and regulations, national issues;

- Serves as a bridge of information between the government, the public and the government, leading, coordinating, and monitoring their implementation;
- Creates working relationship with the regulatory and customer as well as local and foreign media, strengthen communication work;
- Attending bilateral and beyond signing ceremonies at the institution and holds media briefing;
- Acts as spokesperson for the authority;
- Carries out media monitoring activities regarding the institution;
- Preparing various programs on radio, television and various media;
- Preparation of press conference on the institution's work and performance as well as future directions;
- Works in collaboration with other sections strives in achieving the institution's vision and mission and to enhance image of the authority;
- Prepares articles and reports about the authority and disseminate them through private and government media and social media;
- Conducts local surveys to collect opinions from stakeholders and the community on the activities of the authority;
- Provides up-to-date and new information about the authority's activities to the public through documentary films, press releases and media;
- Makes activities done by the authority are accessible to the public in a standardized and transparent manner and documents the necessary information;
- Dissemination of information in various ways/print as well as electronic media;
- Preparing a standardized documentary film about the main activities of the authority;
- Organizes library and monitoring its service delivery;
- Providing library services to customers;
- Provides customer information desk service;
- Serves as a bridge of information between the government, the public and the government, leading, coordinating, monitoring their implementation;
- Prepares various programs on radio, television and various media.

Audit Executive

Brief job description

The audit executive is directly responsible to the Office of the Director General, and is established to carry out the financial and operational audit work of the authority in accordance with the financial management proclamation, regulations and Directives issued by the federal government and the authority, as well as the implementation of the strategic plans and policies to achieve the purpose for which the office was established.

Duties and Responsibilities

- The authority oversees the implementation of the strategic plans and policies of the office to achieve the purpose of its establishment, monitors, controls, and ensures its validity;
- The office assesses whether the operating system is effective in achieving its goals and identifies the weak and strong points and gives the necessary suggestions and recommendations for improvement;
- Facilitating the conditions for operational audits to be conducted in accordance with the orders given by the head of the Instituition other than the regular operational audits that are planned;
- To evaluate the contribution of the projects implemented in the office and the budget allocated to them in terms of the country's development level, and proposes improvements;
- Ensuring that the government's resources and assets are spent for the intended purpose by doing the authority's general financial and property audit work;
- Identifying weaknesses in internal control and compiling risk and control information and providing advice, monitoring performance;
- To improve the rules and guidelines that have implementation problems in terms of audit procedures;
- Facilitating special accounting and property audits in accordance with the orders given by the head of the instituition, apart from regular audits that are carried out according to plan;
- Facilitates situations by preparing audit proposals that should be done in every work process according to the financial management proclamations, rules and regulations issued by the federal government and other relevant laws.
- Oversees the implementation of the strategic plans and policies of the office to achieve the purpose of its establishment, monitors, controls, and ensures its validity.

- The office assesses whether the operating system is effective in achieving its goals and identifies the weak and strong points and gives the necessary suggestions and recommendations for improvement.
- Facilitating the conditions for operational audits to be conducted in accordance with the orders given by the head of the Instituition other than the regular operational audits that are planned.
- Assessing the contribution of the projects implemented in the office and their contribution to the development of the country by implementing the budget allocated to them and proposing improvements.
- Ensuring that the government's resources and assets are spent for the intended purpose by doing the authority's general financial and property audit work.
- Identifying weaknesses in internal control and compiling risk and control information and providing advice, monitoring performance.

Management Lead Executive

Brief Job Description

The Chief Executive Officer plans, organizes, directs, supervises and supports, coordinates, provides operational and policy directions, and formulates strategies to build the capacity of the subordinate executives to make them effective; Makes decisions on matters beyond the executive's control; Communicates decisions and directions as an authority; Designs the next management procedures and strategies of the authority; Creates ownership and partnership by introducing and creating awareness about management to the society and stakeholders; Works on behalf of the office to establish effective and sustainable cooperation and is organized to assist the Director General by ensuring that operations are being carried out properly.

The Chief Executive Officer shall have the following duties and responsibilities subject to the duties assigned by the Director General:

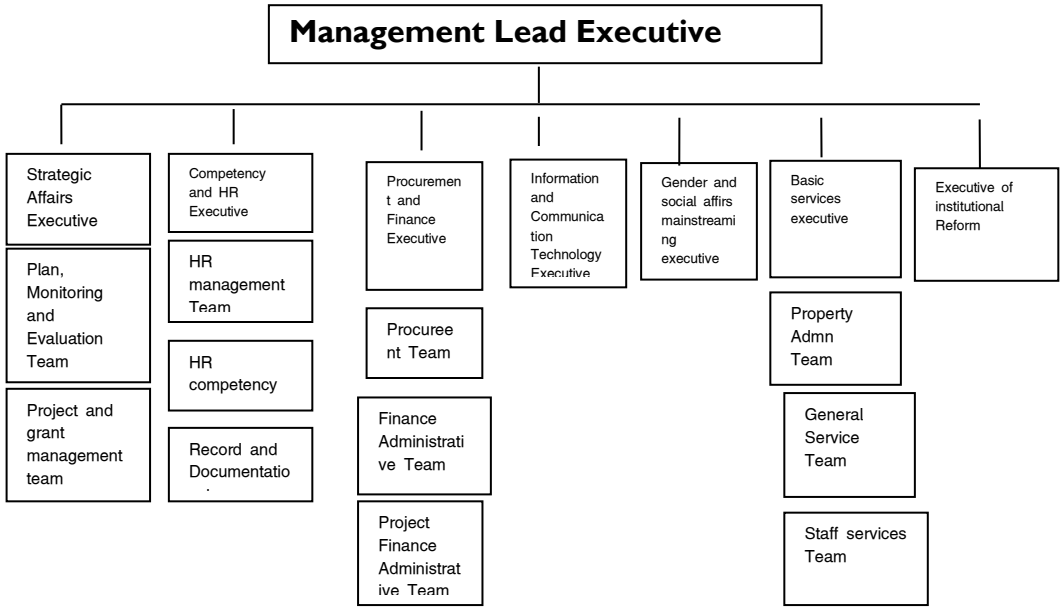
- Coordinates the development of strategies, programs that guide the strategies of the management.
- Supervises the daily activities of the management
- By identifying the legal gap of the management, guide the development rules and regulations by the relevant sections.

- Ensures that policies, laws, operating instructions and standards issued by subordinates are properly implemented;
- Ensures that sufficient budget is allocated for the operations of the executives, and monitors the appropriate use of the allocated budget.
- Supports, monitors and coordinates the subordinates to do effective work
- Creates a strong working relationship and coordination between the business executives and to take corrective action by quickly evaluating gaps when they arise.
- Reviews periodically and confirms their effectiveness of performance indicators seted to measure the effectiveness and efficiency of the executives.
- Designs implementation capacity strategies and programs for professionals in the executive to improve their performance, and monitors their implementation.
- Design and monitor the implementation motivational strategies that enable professionals who record effective performance to be motivated;
- Create ownership and partnership by promoting and creating awareness of the executive's strategies and procedures to the community and stakeholders.
- In relation to the executive, he works to establish effective and sustainable cooperation with international and national institutions on behalf of the office.

Structure and Governance

The Chief Executive Officer is directly responsible to the Director General of the authority and there are seven executives under him. Namely;

1. Executive of strategic affairs
2. Procurement and Finance Executive
3. Competency and Human Resource Management Executive
4. Information and Communication Technology Executive
5. Gender and social affirs mainstreaming executive
6. Executive of institutional Reform
7. Basic services executive



Executive of strategic affairs

Brief job description

The main purpose of the strategic affairs executive is to coordinate the activities of the health control sector and the authority office in preparing long, short and medium term plans, monitoring and evaluating their performance, preparing performance reports, formulating various programs and projects, collecting resources, monitoring and evaluating.

Duties and Responsibilities:-

- Preparation of 5- and 10-year strategic plans and annual plans for the health control sector up to the district level and the authority's office.
- Making the projects needed for the execution of the works and making them practical
- Preparation of the authority's work plan implementation report
- Preparation of planning and reporting summary forms
- Plan implementation and evaluation
- Preparing short term and long term programs and projects
- Seeking resources from supporting bodies for approved programs and projects
- Monitoring the utilization of the resources obtained from the supporting bodies, evaluating the results;

- Compilation of regulatory sector information and make it serve as a resource for studies and research.
- Preparing the program budget, monitoring and evaluating the performance
- Proposes policy proposals and improves them
- Develop performance measurement indicators; He revises and monitors the execution of scheduled works in the time and amount set, and makes corrections
- Collects necessary information in time to measure performance according to the set criteria and checks the quality of the information
- Annual; Prepares six-monthly, quarterly and monthly performance reports.
- Identifies the tasks that should be given attention and support and presents them for decision
- Establishes periodic plan performance review forums (Executive, GSC, etc.)
- Prepares support and follow-up programs independently and in a coordinated manner, provides follow-up and support, prepares the feedback of the visit and distributes the document to all concerned.
- Monitoring and Evaluation Manual; It prepares a system for reporting and performance monitoring and monitors the performance
- Coordinates indicator performance studies at the institution. It will use the results of the study for planning input. He also owns the report.
- Provides awareness to the community of the institution on planning and reporting
- Compilation of regulatory sector information and make it serve as a resource for research
- Solves problems by conducting survey and proposes to turn them into a project.
- Prepares medium and short term projects
- Prepares strategies to collect wealth and accordingly he works to find and collect wealth
- Monitors the use of the collected resources and reports to the relevant department
- Monitors the performance of projects; It evaluates. Prepares a performance report and submits it to the Ministry of Finance and relevant development partners
- Coordinates construction projects; Monitors the performance process and submits a report to the relevant body

Organization and accountability

The Executive Director of Strategic Affairs is directly accountable to the Chief Executive Officer and has two working groups under him.

They are:

1. Plan and budget preparation, monitoring and evaluation team

2. Project management, partnership and resource acquisition team

Planning and budget preparation, monitoring and evaluation team

Duties and Responsibilities

- Develops the team's plan, monitors its implementation, evaluates its performance;
- Monitors, supports, coordinates and provides performance feedback to subordinates;
- Proposes policy proposals and improves them
- Prepares the long-term and short-term strategic plan of the regulatory sector
- Prepares the annual plans of the regulatory sector and the institution
- Based on evaluation, when a plan revision is necessary, a revision is made (both the strategic plan and the annual plan).
- Prepares and distributes modules and formats used for planning
- Training is provided on the preparation of the plan
- Creates awareness for all parties involved in the plan
- Monitors that the plan is properly cascaded down and gives feedback if there is any correction.
- Prepares a 3-year program budget plan
- Prepares the annual budget demand according to the ceiling given by the government
- After the budget of the institution is approved, budget allocation is done for each department and branch
- Prepares annual program budget action plan
- Annual. He prepares the quarterly and monthly cashflow and submits a request to the Ministry of Finance
- Monitors the use of the budget
- When there is an additional budget request, he prepares and submits it to the top management for decision
- Requests for budget transfer, when approved, budget transfer will be done
- Prepares a quarterly budget utilization report and sends it to the Ministry of Finance
- Evaluates the compliance of budget utilization with results and submits a report

- Develops performance measurement indicators; He revises
- Supports the preparation of the annual plan action plan
- Monitors the execution of scheduled works in the time and amount set, and makes corrections
- Collects necessary information in time to measure performance according to the set criteria
- Checks the quality of the information together with others
- Annual; Prepares six months, quarterly and monthly performance reports
- Conducts performance analysis: distributes or informs the results obtained to the concerned party
- Identifies the tasks that should be given attention and support and presents them for decision
- Establishes periodic plan performance review forums (Executive, GSC, etc.)
- Prepares quarterly support and monitoring programs and provides monitoring and support
- Prepares an integrated monitoring and support program that reaches up to the district;
- Coordinates and participates in joint visits. He prepares the feedback of the visit and distributes the document to everyone concerned
- Monitoring the performance of each department, branch and region every month provides timely feedback
- Provides input to the planning department by preparing information for planning
- Prepares a system for reporting and performance monitoring
- Prepares a monitoring and evaluation manual and monitors the performance
- Coordinates indicator performance studies at the institution. It will use the results of the study for planning input. He also owns the report.
- Preparation of report summary forms
- In the formats; It provides information on reporting and indicators

Project Management, Partnerships and Sourcing Team Duties and Responsibilities

- Develops the team's plan, monitors its implementation, evaluates its performance;
- Monitors, supports, coordinates and provides performance feedback to subordinates;
- Solves problems by conducting survey and proposes to turn them into a project

- Prepare medium and short-term projects in collaboration with other executive bodies
- Presenting projects to the Planning Commission for approval
- Prepares strategies to collect wealth and accordingly he works to find and collect wealth
- Prepares and distributes the grant management manual
- Monitors the use of the collected resources and reports to the relevant department
- Gives confirmation to the budget team for the use of the collected resources¬ Monitors and evaluates the performance of projects
- Prepares project performance reports and submits them to the Ministry of Finance and relevant development partners
- Prepares and evaluates the evaluation platform of projects.
- Creates a forum for partners
- Prepares mutual understanding documents
- Prepares a strategic document for resource gathering and revises it regularly
- Coordinates construction projects; Monitors the performance process and submits a report to the relevant body.

Finance and Procurement Executive

Brief job description

The main purpose of the procurement and finance executive is to ensure that the authority properly allocates the budget needed to carry out various work programs according to the plan, monitor its use, purchase temporary and permanent items needed for the Instituition and prepare monthly salaries for employees. By establishing a system and conducting regular research and implementation, the office was established to provide the necessary support in terms of supply and payment to fulfill the assigned tasks and responsibilities.

Financial and procurement executive functions and responsibilities

- Ensures that the authority's procurement system, procurement guidelines and related laws are followed;
- Ensures that procurements carried out by the Instituition are aligned with the authority's strategic and operational plan;

- Ensures that the branch offices follow the laws and regulations and make purchases according to the delegation; Makes appropriate monitoring to prevent overlapping purchases at the center and branch offices;
- Facilitates various situations in which the performance of procurement professionals is developed so that the procurement process is fast, efficient and cost-effective;
- Establishes a database containing a list of suppliers and products related to the instituitions work; He also monitors his performance regularly.
- They did not fulfill their contract; Maintain records of suppliers with performance issues; Transfers their details to the appropriate federal institution so that they can be blacklisted;
- To make the procurement of goods and services to be purchased by auction, prepare a tender document with clear criteria, issue a tender, review the documents of the bidders who participated in the auction and identify the winner, and if there are any complaints and complaints, he will do the appropriate and justify the winner of the auction; He issues work orders, contracts and executes procurement; Monitors and controls whether the purchase is done according to the contract.
- Ensures that the bid enforcement and good performance guarantees are kept properly, and the guarantees booked by defaulting bidders are deposited into the office account before the time limit expires.
- According to the tender documents, the goods to be bought and imported meet the technical requirements or the required quality standards by establishing an inspection committee or by an expert as appropriate;
- Monitors whether the bidding process is carried out according to the set performance standards;
- Conducts current market research. Transparency of procurements carried out by the instituition;
- Regularly engages with suppliers to ensure they are engaged and accountable; communicates the instituitions annual procurement needs and focus; collects constructive comments from suppliers on tender documents;
- Prepares the instituitions annual financial needs budget, together with the relevant work departments, it is presented to the body that approves the budget, and the budget is approved by explaining and justifying it.
- To open or close the bank account of the Instituition when necessary;

- Monitors whether the instituitions income is collected in accordance with the plan and deposited in the bank, and prepares an income report according to the approved income plan.
- Ensures that there is a budget before any payment is made for any of the budget topics, monitors and controls whether the budget is spent only for the intended purpose, prepares an expenditure and income report according to the approved budget;
- Reconciles the bank account in a timely manner, and if there are any errors, will be corrected before the deadline of the bank.
- Monitors whether income and expenditure accounting documents are regularly recorded.
- The instituitions financial reports are prepared in a timely manner, financial summaries are prepared, and reports are submitted to the relevant parties.
- Ensures the legality of any payments made by the Instituition and ensures that the payments are made;
- Ensures timely preparation of payroll documents for officers and employees and ensures payment is made, pension contributions, work agriculture and other deductions etc. are made in accordance with the law.
- Keeps records of accounts payable and receivable, to whom they will be paid, when they will be paid, when they will be collected and from whom they will be collected, and will regularly monitor their performance.
- Ensures that financial documents are organized, timely, compiled and adjusted.
- When the office makes a purchase, the withholding tax deducted from the suppliers, value added tax, bid enforcement, good work performance, CPO, insurance or bank guarantee are properly handled, monitors and verifies that the appropriate execution is done according to the laws and regulations.

Organization and accountability

- The executive is accountable to the chief executive and has three working groups under him. They are:

  1. Finance Group (Regular Account)
  2. Finance Group (Project Account)
  3. Procurement team Finance team (regular accounting) functions and responsibilities Prepares an annual income plan and submits it to the relevant body for approval;

- The income of the Instituition is collected according to the plan according to the season; Deposits the collected money into the bank, and prepares an income report according to the approved income plan and submits it to the work process;
- Monitors the sending of operating funds to the branch offices on time;
- Supports branch offices and supervises them to bet their accounts on time;
- Monitors the collection and income of service fees collected by branches and checkpoints according to the approved service rate;
- Checks and monitors the payment of various service, purchase, final allowance, overtime etc. payments;
- Monitors, supports, coordinates and provides performance feedback to subordinates;
- Performs the financial activities of the Instituition in accordance with the law, rules and regulations: monitors, directs, controls;
- Submits a request to the directorate to open or close the instituitions bank account when necessary, monitors its implementation;
- Prepares the instituitions annual financial budget together with the relevant departments and contributes to the approval of the budget during the budget hearing;
- Submits the request to the manager based on current payments so that there is no shortage of cash;
- Ensures timely preparation of payroll documents for officers and employees and ensures payment is made, pension contributions, work agriculture and other deductions etc. are made in accordance with the law.
- Ensures that there is a budget before any payment is made in any of the budget topics, monitors and controls whether the budget is spent only for the intended purpose, prepares an expenditure and income report according to the approved budget and submits it to the directorate.
- Reconciles the bank account in a timely manner, and if there are any errors, it will be corrected before the deadline of the bank.
- Makes payments for the purchase of inputs by ensuring that the necessary documents are kept;
- Ensures the legality of any payments made by the Instituition and ensures that the payments are made;

- When the office makes a purchase, it monitors and verifies that the withholding tax and value added tax deducted from the suppliers, bid security, good work performance, CPO, insurance or bank guarantee are properly held, as per the laws and regulations.
- Monitors the activity of bank accounts and if there is any problem, it will be solved in time.
- Ensures proper organization of financial documents, provides information when requested;
- Conducts annual accounts audits for internal and external auditors and prepares corrective feedback on findings;
- Fills in the performance results of subordinates in a timely manner.
- Submits the team's performance reports to the directorate, takes necessary action based on the information and feedback from the directorate.
- Performs other duties related to the work assigned by the directorate.
- Prepare annual, quarterly and monthly budget disbursements and submit to the Ministry of Finance for approval and approval by the concerned head.
- Releases budget by providing necessary information/documents for monthly salary payment;
- Monitors, supports, coordinates and gives performance feedback to the performers under the team;
- Performs the financial activities of the Instituition in accordance with the law, rules and regulations: monitors, directs, controls;
- Prepares the instituitions annual, financial budget allocation and requests together with the relevant departments and contributes to the approval of the budget during the budget hearing;
- To avoid shortage of cash, prepares payment request document based on current payments and submit it to the head of the work department;
- Ensures that there is a budget before any payment is made in any of the budget topics, monitors and controls whether the budget is spent only for the intended purpose, prepares an expenditure and income report according to the approved budget and submits it to the directorate.
- Follows up the capital payments sent to the branch offices;

- Makes payment for the procurement of various resources and services used for the works carried out by the project;
- When the office makes a purchase, monitors and verifies that the withholding tax and value added tax deducted from the suppliers, bid security, good work performance, CPO, insurance or bank guarantee are properly held, as per the laws and regulations.
- Performs the registration of project expense and income accounts, bank account reconciliation with the record account, monitors the work done and submits a report to the head of the work department;
- Prepares financial analysis based on financial statements and presents it to the directorate.

Finance team (project accounting) duties and responsibilities

- Prepares monthly/seasonal financial reports of the instituition, prepares financial summary and submits it to the directorate.
- Monitors and supervises that project finance documents are properly organized separately.
- Monitors the activity of bank account and if there is any problem, it will be solved in time
- Audits financial income and expenditure accounts monthly for internal audit and main audit and prepares an action plan based on the findings and submits it to the manager;
- In the fiscal year, the accounting adjustment and registration of the donor organizations is done, the account is settled in a timely manner and a report is prepared for the concerned parties.
- Ensures timely closure of the instituitions capital project account;
- Conducts annual audits for internal and external auditors in collaboration with relevant teams and prepares corrective feedback on findings;
- Fills in the performance results of subordinates in a timely manner.
- Submits the team's performance reports to the directorate, takes necessary action based on the information and feedback from the directorate.
- Performs other tasks related to the work assigned by the executive.

Procurement team functions and responsibilities

- Develops the team's plan, monitors its implementation, evaluates its performance;

- Monitors, supports, coordinates and provides performance feedback to subordinates;
- Executes the authority's procurement system, procurement guidelines and related laws.
- Ensures that the procurement is in line with the authority's plan.
- Monitors whether the branch offices have made purchases in accordance with the law and regulations according to the delegation.
- Makes appropriate monitoring to prevent overlapped procurement at the center and branch offices;
- Develops strategic plans and operational plans for procurements at any level and implements them;
- When there is a knowledge and skill gap for procurement professionals in the group, it facilitates the training to fill this gap;
- Prepares a tender document with clear criteria for the procurement of goods and services to be purchased by auction;
- Monitors and verifies that the bidding process is carried out according to the set performance standards.
- Monitors and supervises the collection of budget-based annual procurement requirements from departments.
- Transparency of procurements carried out by the instituition; regularly engages with suppliers to ensure they are engaged and accountable; Communicates the instituitions annual procurement needs and focus; Collects constructive comments from suppliers on tender documents;
- Establishes a database containing a list of suppliers and products related to the authority's work; also monitors his performance regularly.
- Using different methods from Central Statistical Authority; froms the procurement unit with data collected from the market; froms government providers; froms peer organizations; prepares the price index of the goods by conducting a market research of the instituitions previous purchases, etc. and will be updated regularly.
- Fills in the performance results of subordinates in a timely manner.
- Submits the team's performance reports to the directorate, takes necessary action based on the information and feedback from the directorate.
- Performs other duties related to the work assigned by the directorate.

- The current price list will be received before the submission of the purchase request so that the work units can align their annual purchasing needs with the budget.
- Makes purchases using methods such as auctions, limited bids, price submissions, direct purchases, etc.
- They did not fulfill their obligations according to the contract; maintains records of suppliers with performance issues; transfers their details to the appropriate federal institution so that they can be blacklisted;
- Makes a tender; reviews the documents of the bidders who participated in the auction, and will identify the winner; If there is a complaint or petition, will do what is appropriate and justify it; issues work orders, contracts and executes procurement;
- Accepts bid enforcement and good performance guarantees and transfers them to the financial supporter in a timely manner, ensures that the guarantees of defaulting bidders are deposited into the office's account before the end of the deadline.
- According to the tender documents, the goods to be bought and imported meet the technical requirements or the required quality standards by establishing an inspection committee or by an expert as appropriate;
- Prepares a tender document with clear criteria for the procurement of goods and services that are internationally open, limited auction and directly purchased;
- Monitors and verifies that the bidding process is carried out according to the set performance standards;
- Opens a letter of credit by approving the required foreign currency, and ensures that all the related works are kept in the procurement process and supplies are provided;
- Receives inputs from foreign countries as gifts and purchases by performing the necessary customs procedures.
- Bets on foreign currency accounts approved and used by the National Bank;
- Establishes a database containing a list of suppliers and products related to the authority's work; He also monitors his performance regularly.
- Using different methods ie from Central Statistical Authority; from the procurement agency; with data collected from the market; froms government providers; from peer organizations; prepares the price index of the goods by conducting a market research of the instituitions previous purchases, etc. and will be updated regularly.

- The current price list will be received before the submission of the purchase request so that the work units can align their annual purchasing needs with the budget.
- If they did not fulfill their obligations according to the contract; maintains records of suppliers with performance issues; transfers their details to the appropriate federal institution so that they can be blacklisted;
- When international tender will be issued; reviews the documents of the bidders who participated in the auction, and will identify the winner; If there is a complaint or petition, will do what is appropriate and justify it; issues work orders, contracts and executes procurement;
- Accepts bid enforcement and good performance guarantees and transfers them to the financial supporter in a timely manner, ensures that the guarantees of defaulting bidders are deposited into the office's account before the end of the deadline.
- Monitors and controls whether the purchase is done according to the contract.
- According to the tender documents, the goods to be bought and imported meet the technical requirements or the required quality standards by establishing an inspection committee or by an expert as appropriate;
- Fills in the performance results of subordinates in a timely manner.
- Performs other duties related to the work assigned by the directorate.
- Submits the group's performance reports to the executive, and takes necessary action based on the information and feedback provided.

Competency and Human Resource Management Executive

Brief job description

The main purpose of the organization of competence and human resource management is to enable the office to provide efficient, effective and continuous services, to acquire, allocate, develop and use resources as required, and to attract and retain qualified human resources to the institution, to improve methods of payment and compensation, by studying and implementing short and long-term trainings and occupational safety and health protective equipment and clothing, was established to develop a strong human resource development and management system and to make it effective in the supply and deployment of human resources.

Duties and Responsibilities:

- Develops long and short term HR strategy plans;
- The Executive formulates an organization to carry out the assigned tasks and responsibilities, identifies job positions, prepares a job list, evaluates and levels the work and sends it to the relevant body for approval.
- Recruiting and developing manpower according to the education, work experience, knowledge and skills required for open positions. Deploys in fulfilling work through transfer and assignment.
- Organizes the staff information of the Instituition and makes it supported by modern information technology.
- By supporting and monitoring the performance and service delivery of the human resources management of the offices, corrective measures will be taken;
- Provides various services (pension, insurance, leave, work experience and others) required by the Instituition staff in accordance with the law;
- Develops and implements an operating system that protects the safety and health of the workers' working environment;
- In order to ensure the effectiveness of human resources, studies employee benefit and retention strategy and submits it to the relevant body and approves it.
- Designs long and short term training and education systems, implements them, and makes continuous improvements;
- Conducting training needs survey, based on the capacity gap, prepares modules to provide trainings and lessons that build leadership and executive skills, formulates a program, and provides training.

Organization and accountability

- The chief executive of competency and human resource management is responsible to the Management Lead Excutive and will have two groups and one service, namely:-
  1. Human resource management team
  2. Human resource competency and development team
  3. Record and archive management service

Tasks and responsibilities of the human resource management team

- Based on the instituitions vision and mission, it prepares a long-term and short-term human resources strategy plan, and prepares an annual human resource plan according to the plan: Based on the organization of the institution, by identifying the necessary positions and preparing the job list in a format suitable for evaluation, will have approved by the concerned party.
- According to the guidelines issued to meet the required skills and human resources required for the open positions, the work schedule will be provided.
- For new employees who join the structure of the instituition, before they start work, according to the familiarization program, they will get an understanding of the instituitions general organization and procedures, labor management laws and human resource management policies.
- Provides appropriate support and supervision to the branch offices in human resource planning and management activities, and monitors the proper execution of assigned tasks.
- Monitors the performance evaluation results of employees to ensure that they are completed in a timely manner and submits a comprehensive report by ensuring that they are completed in an appropriate manner.
- Based on the results of the evaluation of the performance of the employees, the employees who will benefit from the biennial salary increase will be identified and will receive the increase in time.
- Provides prompt response to various services provided by the employee, such as leave, termination of employment contract, pension, guarantee, medical experience and other services.
- In order to ensure the effectiveness of human resources monitors the implementation of the employee benefits allowed by law, studies the retention strategy and submits it to the relevant party for approval.
- Makes workers who are out of work to take the necessary steps in compliance with the government's regulations and directives.
- Investigates the cases of disciplinary indiscipline and makes a decision based on the law.
- Coordinates the establishment of various social committees by studying social services that can help employees in the institution.
- Provides support and follow-up for the branch offices in the performance of employee services and benefits.

- 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 instituitions 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 Instituition and makes it supported by modern information technology.
- Opens personal file of the Instituition staff in their names and keep the information that should be stored in the file carefully.
- Organizes the information of the employees of the Instituition by their names in modern /IT/ information management and provides the necessary personnel information services to the users and customers.
- The entry and exit time of employees will be modernized/printed/controlled so that it can be provided for the appropriate performance.
- Provides support and monitoring of branch offices' HR information management and reporting.

The main functions of the human resources competency and development team

- Prepares a training plan and action plan based on the institution's human resource strategic plan, evaluates the program,
- Conducting training needs survey, identify training needs and gaps and prepare manuals and modules to provide trainings and lessons that build leadership and executive skills in a method that is suitable for training.
- Based on the instituition's strategic plan, to develop the knowledge of employees and to provide timely services, it will identify institutions that provide long-term professional development education and education and educate employees.
- Identifying the Instituition professionals who have experience and knowledge who can provide training and make them available to TOT so that they can provide training in a coordinated manner;
- Evaluates the benefits of the trainings provided, and based on the evaluation, makes suggestions for improvement.

- Conducts training system improvement studies;
- Designs training curriculum.
- 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.

Information Communication Technology Executive

Brief job description

The main purpose of the information communication technology executive is to organize information network technology, software development and hardware maintenance, database and website preparation and management to work, lead and coordinate information and communication technology issues.

Duties and Responsibilities

- To study and implement the information technology infrastructure needs of the authority;
- Developing and managing information technology infrastructure;
- Renovating and repairing information technology equipment so that they can provide complete services while being safe.
- To provide training for users in the use of information technology infrastructure
- Designing, implementing and improving information technology-related operating systems
- Identification of information communication tools, networking activities.
- Doing software development and management tasks,
- To ensure strong and reliable security of the prepared network lines.
- Electronic database management
- Preparing a website, keeping it up-to-date and doing the necessary expansion work (doing website development work)

Basic service executive

Brief job description

The main purpose of the organization of the basic service executive is to ensure that the vehicles assigned to be used by the authority's office are safe and provide appropriate service, that the general security, cleaning and yard beautification services of the Instituition are carried out appropriately, and that there is an efficient and timely supply of property management and maintenance free from waste.

Duties and Responsibilities

- Managing the official's vehicles and machinery in compliance with the government's laws and regulations (providing vehicle distribution, annual vehicle inspection, timely monitoring of third party and appropriate total insurance coverage and doing all the appropriate things);
- Creating a comfortable work environment by making building maintenance and office service operations efficient and effective;
- To have a map of the authority's holdings for those who do not have title deeds,
- Establishing an effective operating system to ensure the safety of the institution's assets by providing reliable protection and to ensure that the officer's services continue without interruption;
- Monitoring the maintenance of the authority's office buildings and office equipment;
- Meeting the needs of fax, telephone, internet, etc. and monitoring the monthly payment so that it is paid on time.
- Supervise the establishment of a system for cleaning and beautifying the Instituition grounds;
- Annual vehicle inspection, follow up on insurance renewal;
- Identifying service and vehicle type; To study current fuel quota;
- According to the institution's construction request, making an engineer's estimate, carrying out the works of access roads, property warehouses, guard houses, towers, fences, etc. by oneself, and monitoring and controlling the works given to a third party, verifying the completed construction works and forwarding them for payment.
- Conducting and monitoring current electrical installation and maintenance;
- Monitoring the current legal and insurance activities for the vehicle involved in the collision.
- Identifying works done by 3rd parties and transferring them for purchase.

- Timely handover of the site to the successful bidder and work in accordance with the contract; Tracks the execution of a set of Gizmodo cards.
- Performs other tasks related to the work assigned by the sub-sector.

Organization and accountability

The basic service executive is directly responsible to the chief executive and has one work group and three services under him. They are:

1. Property management team
2. General Service
3. Cafeteria service
4. Transportation distribution service

Functions and Responsibilities of Transport Service

- According to the request of transport needs sent from the work units, the deployment of vehicles is provided.
- Vehicles will be safe by providing timely maintenance, service and washing services according to the plan;
- Ensures that they get insurance coverage and that annual safety inspections and vehicle renewals are carried out in a timely manner;
- When there is a breakdown in vehicles and if the breakdown is minor, the Instituition will repair it, if the breakdown is major, it will be repaired according to the contract with the repair companies.
- Organizes and maintains the type and number of vehicles, the date of manufacture and other information, separates old vehicles that have finished their service and disposes of them in accordance with the government's property disposal guidelines.
- Evaluates the performance and performance of the drivers, sends the result to the relevant department, and provides the necessary support to the branch offices in the use and handling of vehicles.
- Conducts a study of the instituitions scope of work and vehicle needs and submits a report to the respondent to allocate additional vehicles, and develop a procedure by taking other experiences to make vehicle deployment and maintenance work efficient and effective;

Tasks and responsibilities of the general service

- During the preparation of tender documents with 3rd party security service providers, ensures that necessary activities are included and monitors the process.
- Monitors the performance of the security services in accordance with the contract in all areas that receive security services from a third party, and takes the necessary action against security organizations that do not fulfill their obligations.
- Ensures that materials needed for security services are provided to permanent employees assigned to security work;
- Corrective action is taken by identifying work defects encountered in the security areas, andsubmits a report.
- When a property is found stolen, it collects evidence and information and submits it to the law for prosecution.
- Ensuring that security services are provided in accordance with the contract and ensuring that appropriate payment is made;
- Ensuring that exit documents are properly kept and recorded in the main office, sub-offices and other premises of the institution;
- Monitor the establishment of cars and traffic system in the main office and sub-offices.
- Fills in the performance results of subordinates in a timely manner.
- Submits the team's performance reports to the supporting workflow, performs the necessary based on the information and feedback provided by the supporting workflow;
- Performs other tasks related to the job as assigned by the work process.
- Cleaning and maintaining the instituitions offices, premises and the environment within 50 meters;
- Telephone service, duplicator and photocopier monitoring to provide efficient service.
- Ensures the proper maintenance and beauty of the premises and office, and provides a comfortable working environment.
- Gives appropriate support to the branch offices on service staff.
- Monitoring that the toilets, showers, water and sewage lines in the main office, branches and any service stations of the institution are providing proper service and in the event of a malfunction, repair, change, renew, etc.
- Prepares a budget by conducting a survey of the year's building maintenance needs;
- Carrying out building maintenance with an annual plan;

- Identifies works done by 3rd parties and forwards them for purchase;
- To ensure that the necessary activities are included in the preparation of the tender document for the maintenance of the access road and building by the 3rd party and participate in the process;
- Self-powered building; does carpentry, electrical and plumbing work;
- Fills in the performance results of subordinates in a timely manner.
- Performs other tasks related to the job as assigned by the work process.

Property management team duties and responsibilities

- Plans, directs, coordinates, supervises and allocates the manpower, resources and budget needed to carry out the work in a timely, efficient and proper manner.
- Manages the property of the office based on the government property management decree, guidelines and manuals, completes and maintains information, and provides timely information to those who request it.
- The office receives stores, manages, supervises, organizes and keeps information on the assets it receives from third parties through grants and donations, ensuring that their complete documents and quality standards are verified.
- Identifies vital items and chemicals, determines the minimum stock level, takes into account the movement of items before they reach the minimum stock level, informs the relevant departments, purchasing support work process, the importance of the item or chemical to the departments and the main manager, and what remains in the treasury, spends carefully and sparingly, and follows up to ensure that purchases are made;
- Receives serviceable assets, separates those that can be repaired and those that cannot be repaired, repairs those that can be repaired and puts them to work, and disposes of those that cannot be repaired and cannot be serviced, according to the law and operating system.
- Gives a stock number for the instituitions assets, records and keeps complete information.
- At the end of every fiscal year and in the periods when it is deemed necessary, conducts an inventory of assets;
- Every fiscal year, the institution prepares a Material Requirement Plan (Material Requirement Plan) based on the plans sent by the institution and taking into account what is in stock, and submits it to the purchasing support process so that the purchase can be completed in time.
- The amount of inventory of major assets, every month, keeps the asset movement documents in the center for the assets that are mainly used and controls their distribution.

- Submits monthly reports on the amount of inventory in the entire treasury to the branch offices, water and sewage business processes and other relevant departments.
- Receives the income and expenditure documents from each warehouse and places them on the stock control card, improves the system and implements a modern asset management system supported by information technology, and updates it regularly.
- Before purchasing the item requested for purchase, it first checks whether the requested item is in stock or not, and then orders it in stock considering its demand.
- Registering goods stored for more than 5 years without activity (without service) and submits the information to the relevant department.
- Identifies assets that have not been used for a long time without service, disposes of the assets in consultation with the sectors that use the assets;
- Makes strict monitoring to ensure that decommissioned assets are timely collected from the work place/site and returned to the treasury.
- When any employee is given employment from one work unit to another work unit due to promotion, transfer or assignment, hands over the property received by the previously assigned work unit.
- For the offices, the pipes and fittings used for the construction of water and sewerage lines, as well as related equipment, which have been procured by the W/M, will be monitored so that they can be stored in their treasuries at the time of expenditure from the W/M's treasuries.
- When the projects are completed, the assets left over from the project will be transferred to the head office offices, following the proper procedures.
- When a request is made to transfer stock items from the project to the main office, from the main office to the project office, it will be implemented if it is first approved by the sector and evidence is presented.
- Provides technical/professional support for disposal of unserviceable vehicles, vehicle spare parts and other equipment;
- The sea transit, document sent from the supplier company for goods purchased from abroad; Cross-checking of packing list and invoice documents with the instituitions purchase requisition:
- Monitors and supports the implementation of policies related to asset management and regularly studies and implements the improvement of procedures.

Institutional change executive

Brief job description

The main purpose of the institutional change executive accountability to the chief executive officer is to ensure that the change-making tools of the office are implemented in all departments and offices, that the service delivery is fair, efficient and implemented in a manner that ensures fairness, transparency and accountability, and that good governance is implemented in the institution. It was established to enable corrections to be made by doing support and verification work.

Duties and Responsibilities;

The institution ensures that the basic work process change study is conducted, after the study is completed and implemented, if there are any required calibration works, it will be carried out by regular monitoring.

- Conducts the necessary monitoring and support activities so that the institution's strategic plan is planned following the Balanced Scorecard planning method;
- Monitors and supports the status of the change army in the workplace and the institution;
- Evaluates the performance status of work processes in terms of change and good management;
- 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;
- 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;
- He 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;
- The public wing of the institution provides appropriate support and monitoring regarding the event and participation status of the common forum;
- 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;
- Works together with other work departments, monitors and supports them in order to establish the necessary operating system so that the attitude and activities of rent collection are improved;
- Submits the institution's change and good governance performance reports to the reform and good governance sectors, implements the information and feedback provided;

Food Sector

Food Regulatory Sector Deputy Director General

Brief Description

The Deputy Director General of FoodRegulatory Sector is one of the three Deputy Director Generals under the Director General. Plans, organizes, directs and coordinates the authority's activities in the food sector, as well as supervises and supports the sections under his authority. Formulates strategy to build capacity of sections; makes decisions on matters beyond the scope of executives; communicates decisions by participating in the decisions and directions decided by the authority;design the country's food control procedures and strategies, creates ownership and partnership by promoting and creating awareness about the sector to the society and stakeholders, works to establish effective and sustainable cooperation with international and national institutions regarding the food control sector. In general, it is structured to help the Director General by ensuring that the operations of the sector are being done properly

The Deputy General Director of the sector will have the following duties and responsibilities, subject to the duties assigned by the General Director.

- Coordinates the development of strategies, programs and strategies to guide the food control sector.
- Solves the problems encountered during food control together.
- Supervises the daily activities of the food control sector
- Allocates the necessary resources and sufficient budget for the sector's operations, and monitors the appropriate use of the allocated budget.
- Supports and supervises subordinate work units to do effective work.

- To create a strong work relationship and coordination between work departments and to take corrective action by quickly evaluating when gaps are created.
- Ensures their applicability by periodically evaluating the performance parameters set to measure the effectiveness and efficiency of the sector.
- Ensures that the policies, laws, operational guidelines and standards issued for the sector are properly implemented by the subordinate working units.
- Designs strategies and programs to improve the performance of job openings and professionals in the sector, and monitors their implementation.
- Creates ownership and partnership by promoting and creating awareness of strategies and practices in the food control sector to the community and stakeholders.
- Works to establish effective and sustainable cooperation with international and national institutions regarding the food control sector on behalf of the authority.

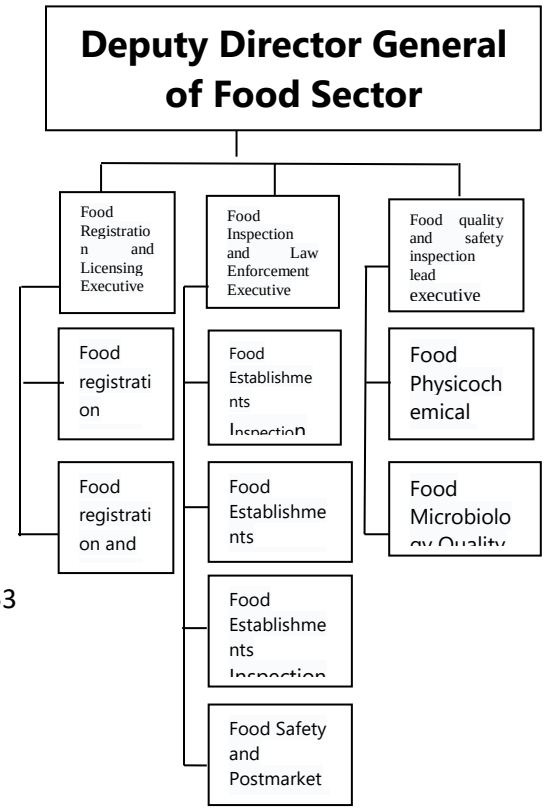
Organization of Food Sector D/Director General

The Chief Executive Officer reports to the Chief Executive Officer and directs the following three executive officers.

1. Food Registration and Licensing Executive

2. Food Inspection and Law Enforcement Executive

3. Food quality and safety inspection lead executive



Food Registration and Licensing Executive

Brief job description

The main purpose of the Food Registration and Licensing Executive is to conduct pre-licensing inspections for local institutions engaged in food production, to provide certification of competence, to register localally produced and imported food products and obtain market licenses.

Duties and Responsibilities:

- In order to be registered in accordance with the guidelines issued by the office, the authority shall issue marketing license, renew and approve changes in registration of processed and packaged food products, food additives and nutrients imported into the country in accordance with the guidelines issued by the office.
- Facilitates the necessary prerequisites for GMP inspection on selected foods for foreign manufacturers.
- According to the guidelines issued by the office, the authority grants market permission for certain products to enter the market only by informing the country.
- Conducting pre-licensing inspections for establishments engaged in food production, issues new qualification certificates or change permits, renews them, and makes the list of licensed establishments known to the relevant parties at the time.
- Based on the results of the inspection received from the inspection department, the registered food, the institution that has been certified will block and cancel it based on the law and inform the relevant parties.
- Prepares the guidelines for the transmission of food promotions, informs the relevant parties and monitors the performance;
- Ensures the correctness of the registration and license issued by the chief executive.
- 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 executive capacity; 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 at the executive desks.
- Supports the branch offices to provide professional support to the food registration and licensing work unit and strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit;
- Organization and accountability The Chief Executive Officer of Food Registration and Licensing has been appointed as the Director General of Food Control Sector and will have the following two desks under his authority. They,

    1. Food registration and license desk

    2. Food establishments' registration and license desk

Food registration and license desk duties and responsibilities

- In order to be registered in accordance with the guidelines issued by the office, the authority will issue market licenses, renew and change registrations by evaluating and ensuring the safety of processed and packaged food products, food additives and nutrients imported from abroad and imported into the country.
- According to the instructions issued by the office, the authority grants market permission for certain products to enter the market only by informing the country.
- Facilitates the GMP/Good Manufacturing System (GMP) inspection work on selected foods for foreign manufacturers in cooperation with the head of the department.
- Based on the results of the inspection received from the inspection department, the registered food will be suspended and canceled based on the law and will inform the relevant parties.
- Works in coordination with the relevant departments to prepare guidelines for food promotions; He ensures that the relevant parties are informed and monitors the performance.
- According to the guidelines issued by the authority, the authority will give market permission for certain products to be produced in the country only after notification.
- Based on the results of the inspection received from the inspection department, the registered food will be suspended and canceled based on the law and will inform the relevant parties.
- Works in coordination with the relevant departments to prepare guidelines for food promotions; He ensures that the relevant parties are informed and monitors the performance.

- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, it works by presenting them to the chief executive so that decisions can be made so that they can be implemented.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- It provides professional support to branch offices for food registration and licensing, and exchanges information;
- Recommends and prepares guidelines, operating manuals and standard operating procedures (SOP):

Functions and responsibilities of Food Establishments Registration and Licensing Desk

- According to the guidelines issued by the office, the authority will conduct document verification and pre-licensing inspection for establishments engaged in food production, issue new qualification certificates or change licenses to those who meet the requirements, make renewals, and inform the relevant parties of the list of licensed establishments at the time.
- Based on the results of the inspection received from the inspection department, the institute that has been given the certificate of qualification will be suspended or canceled based on the law and will inform the relevant parties.
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, he presents them to the chief executive so that decisions can be made and implemented.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support and information exchange to branch offices for licensing of food production facilities;
- Proposes and prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Food Inspection and Law Enforcement Executive

Brief job description

Food Inspection and Law Enforcement Executive

The main purpose of the organization is to regulate local animal and animal husbandry, plant extract, beverage producers. It is a leading executive established to carry out post-licensing inspections, ensure that products on the market meet national standards, food safety and post-market monitoring, and to ensure consistency in the national food control system in general.

Duties and responsibilities

Food Inspection and Law Enforcement Executive

- Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents to guide food inspection and law enforcement in the country.
- Conducts good management control as necessary on producers who export their products as foreign food production organizations.
- Conducting national level food safety monitoring activities.
- Based on food safety monitoring and post-market surveillance, based on the results of the surveillance report, he will take legal action against institutions and foods that need to be acted upon and inform the relevant parties of the performance;
- When a sudden food outbreak occurs, he will be present at the site and take appropriate action based on the result, and will inform the relevant parties about the performance.
- ensures that the amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants found in the food on the market do not exceed the standards set by national or international standards and take action based on the results.
- In relation to food, when it is suggested that food products that may cause serious damage to public health may be produced and placed on the market or are on the market, as well as food products that are being transported into the country, it will be arrested before any damage is caused to the public or inform the relevant parties to take action.
- When requesting a health certificate for food exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:

- Monitors and verifies that there are no health problems related to food safety and early warning as well as prohibited products on the market at the international level.
- 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 production facilities that have been granted qualification certification and informs the relevant parties of the results.
- Based on the information received from the surveillance and illegal prevention work unit, appropriate legal action will be taken and the performance will be notified to the relevant parties.
- Designs and works together with relevant national institutions (Customs Commission, security agencies, etc.) to prevent illegal trade.
- The Chief Executive will work in conjunction with the Directorate of Legal Affairs as necessary in carrying out inspection activities.
- Any legal action taken by the controlled institution, such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- The CEO 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.
- A system will be established to ensure smooth communication and efficient and effective work at the executive desks.
- To provide professional support to the branch offices and regional food inspection and information work units and to strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit;

Organization and accountability

As the Chief Executive Officer of Food Inspection and Law Enforcement, he will be the Director General of the Food Control Sector and will have the following four desks under his authority. They are,

- Animal Product and Nutrition Inspection and Law Enforcement Desk
- Plant and plant product inspection and law enforcement desk
- Liquor Inspection and Law Enforcement Desk
- Food safety and post-market monitoring desk

Duties and Responsibilities of Animal Product Nutrition Inspection and Law Enforcement Desk

- Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents to guide the inspection and law enforcement of animal products in the country.
- Conducts good management control as necessary on producers who export their products to the country as foreign animal product producing organizations.
- Assists in animal production safety monitoring activities carried out at the national level.
- Based on animal product safety monitoring and post-market surveillance, based on the results of the surveillance report, will take legal action against institutions and foods that need to be acted upon and inform the relevant parties of the performance;
- When a sudden food outbreak occurs, will be present at the site and take appropriate action based on the results, and inform the relevant parties about the performance.
- Ensuring that the residual amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants that can harm human health in the animal products on the market do not exceed the standards set by national or international standards and takes action based on the results.
- In connection with the production of animal products, which may cause serious harm to the health of the public, when it is brought to the market or it is on the market, and when it receives a suggestion about the food products that are being transported into the country, it will be arrested before any harm is caused to the public, or it will inform the relevant parties to take action.
- When requesting a health certificate for an animal by-product exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:
- Monitors and verifies the absence of health problems and early warnings related to the safety of animal products on the international level, as well as products that are prohibited from being used on the market.
- Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents to be guided by the country's nutritional inspection and law enforcement;
- As necessary, good management controls the producers who export their products to the country as foreign food producing organizations.
- Assists in monitoring activities of nutritional food safety carried out at the national level.

- Based on the results of the monitoring of food safety and post-market surveillance, take legal action against institutions and foods that should be acted upon according to the results of the surveillance report and inform the concerned parties of the performance;
- When a sudden food outbreak occurs, will be present at the site and take appropriate action based on the results, and will inform the relevant parties about the performance.
- Ensuring that the residual amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants that can harm human health in the nutritional food on the market do not exceed the standards set by national or international standards and takes action based on the results.
- When there is a suggestion of food products that may cause serious harm to the health of the public, or they are on the market, and they are being transported into the country, they will arrest them before harming the public or inform the relevant parties to take action.
- When requesting a health certificate for a nutritious food to be exported, a certificate is issued by confirming that it meets the necessary requirements:
- Monitors and ensures that there are no healths problems related to nutritional food safety and early warning as well as prohibited products on the market at the international level.
- Monitors and takes action to ensure that there are no animal derivative products on the market that have similar problems, misleading descriptive text, etc.
- Conducts post-licensing inspections on animal product manufacturing facilities that have been granted a qualification certificate and informs the relevant parties of the results.
- Based on the information received from the surveillance and illegal prevention work unit, appropriate legal action will be taken and the performance will be notified to the relevant parties.
- Designs and works together with relevant national institutions (Customs Commission, security agencies, etc.) to prevent illegal trade.
- The desk will work in conjunction with the Legal Affairs Executive as necessary while carrying out inspection activities.
- Any legal action taken by the controlled institution, such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.

- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the working groups, it is presented to the chief executive so that decisions can be made and implemented.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- To provide professional support to the branch offices and regional food inspection and information work units and to strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Plant and Plant Product Inspection and Law Enforcement Tasks and Responsibilities

- Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents to guide the inspection and law enforcement of plants and plant products in the country.
- As necessary, it will conduct good management control on the producers who export their products to the country as foreign plant and plant production companies.
- Assists in plant and plant product safety monitoring activities carried out at the national level.
- Based on the results of plant and plant and product safety monitoring and post-market research, take legal action against institutions and foods that should be taken action based on the results of the surveillance report and inform the relevant parties of the performance;
- When a sudden contamination of plants and plant products (Food outbreak) occurs, will be present at the site and take appropriate action based on the results, and will inform the concerned parties about the performance.
- Ensuring that the residual amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants that can harm human health in plants and plant products on the market do not exceed the standards set by national or international standards and takes action based on the results.
- In connection with the production of plants and plant products, which may cause serious damage to the health of the public, when it is suggested that they may be produced and put on the market or are on the market, as well as food products that are being transported into the country, it will be arrested before any damage is caused to the public, or it will inform the relevant parties to take action.

- When requesting a health certificate for plants and plant products to be exported, a certificate will be issued by confirming that it meets the necessary requirements:
- Monitors and verifies the absence of health problems and early warnings related to the safety of plants and plant products on the international level, as well as the absence of prohibited products on the market.
- Monitors and takes action to ensure that there are no plants and plant extracts on the market that have problems such as imitations, misleading descriptive text, etc.
- Conducts post-licensing inspections on plant and plant extract production facilities that have been granted a qualification certificate and informs the relevant parties of the results.
- Based on the information received from the surveillance and illegal prevention work unit, appropriate legal action will be taken and the performance will be notified to the relevant parties.
- Designs and works together with relevant national institutions (Customs Commission, security agencies, etc.) to prevent illegal trade.
- The desk will work in conjunction with the Legal Affairs Executive as necessary while carrying out inspection activities.
- Take any legal action in the controlled institution, such as documents, receipts, electronic records, samples, photographs or videos, etc.
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, it is presented to the executive for a decision and works to be implemented.

- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- To provide professional support to the branch offices and regional food inspection and information work units and to strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.
- Functions and Responsibilities of Beverage Products Inspection and Law Enforcement Desk Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents to guide the country's beverage products inspection and law enforcement;

- Conducts good management control as necessary on producers who export their products to the country as foreign beverage product manufacturing companies.
- Assists in national level safety monitoring of beverage products.
- Based on the results of the surveillance report on the safety of beverage products and post-market research, legal action will be taken against institutions and foods that need to be acted upon, and the performance will be notified to the relevant parties;
- When there is a food outbreak, will be present at the site and take appropriate action based on the results, and will inform the concerned parties about the performance.
- Ensuring that the residual amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants that can harm human health in the drinking products on the market do not exceed the standards set by national or international standards and takes action based on the results.
- In connection with drinking products, which may cause serious harm to the health of the public, when it is suggested that they may be produced and put on the market or that they are on the market, as well as food products that are being transported into the country, it will be arrested before harm is done to the public, or it will inform the relevant parties to take action.
- When requesting a health certificate for beverage products exported to a foreign country, a certificate is issued by confirming that it meets the necessary requirements:
- Monitors and verifies that there are no healths problems related to the safety of beverage products and early warning as well as prohibited products on the market at the international level.
- Monitors and takes action to ensure that drinks products with similar problems, misleading descriptions and similar problems are not on the market.
- Conducts post-licensing inspections on beverage product manufacturing facilities that have been granted qualification certification and informs the relevant parties of the results.
- Based on the information received from the surveillance and illegal prevention work unit, appropriate legal action will be taken and the performance will be notified to the relevant parties.
- Designs and works together with relevant national institutions (Customs Commission, security agencies, etc.) to prevent illegal trade.
- The desk will work in conjunction with the Legal Affairs Executive as necessary while carrying out inspection activities.

- Any legal action taken by the controlled institution, such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- 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 chief executive so that decisions can be made and implemented.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- To provide professional support to branch offices and regional food inspection and law enforcement departments and to strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.
- Duties and responsibilities of food safety monitoring and post-market monitoring desk Preparing, approving and implementing operational strategies, manuals, protocols and other documents to be guided by the country's food safety monitoring system.
- Coordinates national level food safety monitoring activities;
- Based on the results of food safety monitoring, he informs the concerned parties about the foods that need to be acted upon and monitors the performance;
- Conducting national post-market monitoring to ensure food safety at the national level;
- Based on the results of post-market monitoring of food, he informs the concerned parties about the foods that need to be acted upon and monitors the performance;
- The team works and coordinates with food manufacturers and importers to conduct post-market research.
- To monitor and ensure that the amount of fertilizers, chemicals, pesticides and animal medicine, radiation and other pollutants that can harm human health in the foods on the market do not exceed the standards set by national or international standards and to take action based on the results.
- Based on the results of the food aftermarket research, it will carry out continuous awareness activities for the society and stakeholders to protect themselves from health problems and be part of the control.

- Monitors the presence of foods with similar problems, misleading descriptive text and similar problems in the market, and when found, informs the relevant parties and monitors the performance.
- The team supports and coordinates with food producers and importers to report problems encountered in food safety.
- When a sudden food outbreak occurs, he will be present at the site to conduct the necessary monitoring and collect information, analyze it and inform the relevant parties so that appropriate action can be taken based on the results, and monitor the performance.
- In relation to food, when there is a suggestion that food products that may cause serious damage to public health may be produced and put on the market or are on the market, as well as food products that are being transported to enter the country, it will establish a system of procedures to arrest them before they cause harm to the public.
- To protect the society from health problems related to food safety, it will carry out continuous awareness activities.
- Monitor, collect, distribute to the relevant parties and ensure the implementation of health problems related to food safety at the international level and early warning as well as information on prohibited products.
- Coordinates food post-market surveillance activities with the offices and regional regulatory bodies.
- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, presents them to the directorate so that decisions can be made and implemented.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support and information exchange to the food safety risk and incident management team of branches;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Chief executive of food quality and safety inspection

Brief job description

- The main purpose of the Food Quality and Safety Inspection Executive is to coordinate physicochemical and microbiological quality inspection activities to ensure the quality of food produced locally and imported from abroad, and to ensure the safety of food products used in the market with the support of branch offices and laboratories of regional regulatory bodies.

Duties and Responsibilities:-

- Preparing, approving and monitoring the implementation of operational strategies, manuals, protocols and other documents that guide the activities of food quality testing.
- Performs quality inspection of food produced in the country and imported from abroad;
- Ensures that existing and new diagnostic methods are working correctly using various advanced analytical methods.
- Compiles 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 inspection on behalf of the authority.
- The food safety testing laboratory works to gain international recognition.
- Prepares technical specifications for laboratory equipment and materials necessary for food quality testing; Performs a technical review when purchased and delivered, ensuring they are handled properly;
- To conduct quality inspection for the purpose of registration of food produced in the country or imported from abroad as necessary; will inform the relevant parties about the results.
- Conducts post-market quality inspection on localally and abroad produced and marketed food, and also conducts necessary quality inspection on suspect samples; will inform the relevant parties about the results.
- Conducting the necessary quality inspection of consignments imported from foreign countries; and inform the relevant parties of the results,
- Ensures that the equipment used for food quality testing is working properly
- Receives laboratory samples ensuring they meet the required standards and handles them appropriately.

- Establishes procedures for the handling and use of backup samples, samples that survive quality testing and expired samples, and monitors performance;
- Formulates strategy to build leadership capacity; makes decisions on matters beyond the scope of the desks; as an institution, works to implement the decisions and directions.
- A procedure will be established to ensure smooth communication and efficient and effective work at the executive's desks.
- Provides training, professional support and supports the strengthening of information exchange for branches and regional food quality inspection departments;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit.

Organization and accountability

The Chief Executive Officer of Food Quality and Safety Inspection is the Deputy Director General of Food Inspection and has two desks under him. And they

1) Food physicochemical quality testing desk

2) Food microbiological quality testing desk

Function and responsibility of food physicochemical quality inspection desk

- Conducting physicochemical tests to ensure the quality of food produced in the country and imported from abroad.
- Develops/revises new food physicochemical quality analysis methods (Method of Analysis).
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, it is presented to the chief executive so that decisions can be made and implemented.
- Conducting physicochemical quality testing of localally produced and imported foods for the purpose of registration as necessary; will inform the relevant parties about the results.
- Conducts post-market physicochemical quality testing on foods produced and marketed in the country and abroadand also performs necessary quality testing on suspect samples; will inform the relevant parties about the results.

- Conducting inspection of consignment physicochemical quality of foods produced in foreign countries and imported into the country as necessary; and inform the relevant parties of the results,
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- It supports the strengthening of the exchange of information and professional support for the branch offices and regional food quality inspection departments.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Main functions of food microbiology quality inspection desk

- Performs microbiological tests to ensure the quality of food produced in the country and imported from abroad
- Developing/revising new food microbiological quality analysis methods (Method of Analysis),
- To carry out microbiological quality testing for the purpose of registration as necessary for food produced in the country and imported from abroad; will inform the relevant parties about the results.
- Conducts post-market microbiological quality testing on foods produced and marketed in the country and abroadand also performs the necessary quality testing on suspect samples; He will inform the relevant parties about the results.
- Conducting consignment microbiological quality inspection of food produced abroad and imported into the country as necessary; and inform the relevant parties of the results,
  - Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, he presents them to the directorate so that decisions can be made and implemented.
  - A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
  - It supports the strengthening of the information exchange to provide professional support to the branch offices and regional food quality inspection departments;
  - Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Drug control sector

Deputy Director General of Drug Control Sector

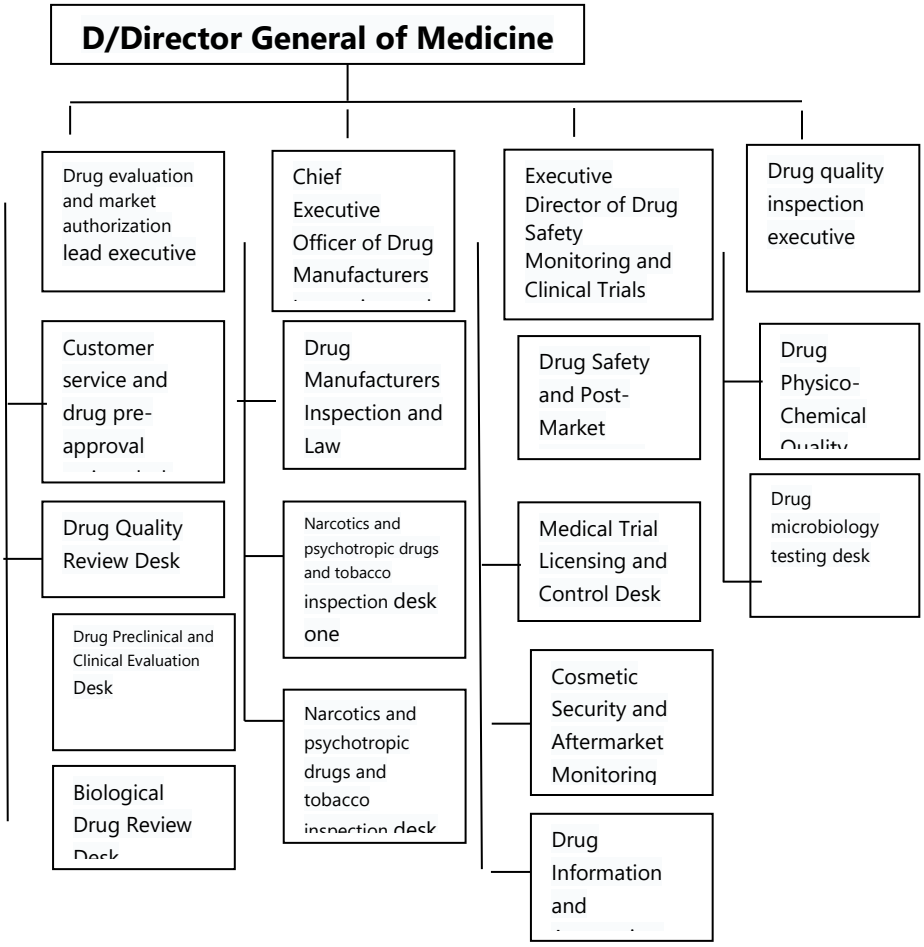
Brief job description

The Director General of the Drug Control Sector is one of the four Deputy Director Generals under the Director General and makes decisions on matters beyond the scope of work units; communicates decisions and directions as an institution; designs the next procedures and strategies of the country's drug control sector, creates ownership and partnership by promoting and creating awareness about the sector to the society and stakeholders, works to establish effective and sustainable cooperation with international and national institutions regarding the drug control sector on behalf of the office, and is organized to help the director/director by ensuring that the operations of the sector are carried out properly.

The Deputy General Director of the sector will have the following duties and responsibilities,

- subject to the duties assigned by the general director, coordinates the development of strategies, programs and strategies for the sector;
- Ensures the implementation of the international agreements (conventions) accepted by the country for the sector;
- Supervises the day-to-day activities of the sector;
- Ensures that sufficient budget is allocated for the operations of the sector, and monitors that the allocated budget is properly used;
- 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;



Organization and accountability

The Drug Control Sector/Directorate is accountable to the authority office as the Director General and there are sixty-six working units/directorates. They are:

1. Drug Evaluation and Licensing Executive

2. Drug Manufacturers Inspection and Law Enforcement Executive

3. Drug Safety Monitoring and Clinical Trial Executive

4. Chief Executive Officer of Drug Quality Testing

Drug Evaluation and Registration Executive

Purpose of establishment

The main purpose of the Drug Evaluation and Licensing Executive is to ensure the quality, safety and efficacy of traditional and modern medicines and ensure their use for medical purposes. To ensure the quality, safety and efficacy of new drugs to be used by the society, to increase the supply of alternative drugs without registering or with assistance, and to recognize the benefits and harms of drugs imported for medical use, and to give special permission for them to be used for medical purposes.

Executive duties and responsibilities of drug review and approval leader

- Preparing, approving and monitoring the implementation of operational strategies, manuals and other documents that guide drug evaluation and registration in the country.
- Compiles and implements international experiences in the field of drug evaluation and registration system in a way that is beneficial to the country
- Plans, executes, coordinates, manages, monitors and supports activities related to drug evaluation and registration.
- 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.
- During drug registration, to ensure the functionality of Pharmaceutical Products Traceability Implementation, it verifies the existence of a barcode and gives the market license identification number;
- Grants re-registration market authorization for drugs that meet the renewal criteria;
- When it is confirmed that there are defects in the quality, safety and healing properties of drugs that have received market permission, the market license will be suspended and canceled and the relevant parties will be notified;
- Receives, evaluates and evaluates the results of studies and research submitted to the community for pesticides, grants market licenses, renews, suspends and cancels when there is a problem with the product;
- Evaluates whether drug promotion information is balanced and based on the medical information you have registered; Provides product promotion and promoter license, (if done by drug information department)
- A certificate stating that the drug exported abroad is used in the local market.
- Ensures the correctness of marketing licenses and activities given by the desks under the supervision.
- Works to maintain a strong relationship with experienced countries and international institutions related to drug evaluation and registration process.
- Participates on behalf of the institution in national and international conferences related to pharmaceutical and public health pesticide issues; report,
- Formulates strategy to build executive capacity; makes decisions on matters beyond the scope of the desks; as an institution, it works to implement the decisions and directions.
- Establishes a system to facilitate communication and efficient and effective work at the executive desks;
- Prepares necessary instructions, guidelines, manuals and standard operating procedures (SOP) for the work unit;

Organization and accountability

The Executive Director of Drug Evaluation and Licensing is the Director General of the Drug Control Sector and has four desks.

They are,

1. Drug Quality Review Desk
2. Biological Drug Evaluation Desk
3. Drug pre-clinical and clinical evaluation desk
4. Customer service and drug pre-authorization evaluation desk Drug Quality and Clinical

Review Desk Tasks and Responsibilities

- Ensuring the efficacy and safety of medicines by thoroughly evaluating the scientific documents of quality and clinical research to register modern medicines;
- Making new drugs available for medical use;
- Ensuring the effectiveness of social pesticides used for public service and enabling them to be used
- Ensuring the quality, safety and efficacy of traditional and modern medicines so that they can be used for medical purposes;
- Ensuring the effectiveness of pesticides used for public health services and ensuring their use;
- Bringing drugs used for medical purposes into the country without being registered with a special license, realizing the benefits and harms of the drugs and making them use them for medical purposes;
- Prepares, approves, and implements manuals and operational guidelines used for drug quality evaluation based on the operational guidelines and strategies that guide drug evaluation and approval;
- Compiles and implements international experiences regarding the quality and clinical.
- Plans, executes, coordinates, monitors and supports activities related to drug quality and clinical evaluation.
- Evaluates current performances and provides feedback, compiles performance reports and submits them to relevant parties.
- Quality and clinical research results that are studied and presented by pharmaceutical manufacturer compony to be given market license both locally and abroad; Production of medicinal raw materials; It prepares a quality assessment report by analyzing the interactions of light medicine with other compounds and evaluating the scientific studies and research

questions (Evaluate active pharmaceutical ingredient route of sysnthis and critical control parameters, Evaluate finished pharmaceutical product and product information) regarding the correctness of the production; In addition, the results of studies and researches that should be presented will be presented to June along with the necessary explanation. When it is decided, it will be delivered to the manufacturer. When the response is submitted, will conduct the necessary review; submits an evaluation report in June; makes a presentation to the inspectors by identifying issues that should be examined during the inspection.

- ❖ It is used to finalize drug manufacturing inspection reports and laboratory test results;
- ❖ After confirming that there is no manufacturing change in the registered drug, re-registration license is issued;
- ❖ When requesting a certificate of pharmaceutical product stating that it has been used in the local market for a drug exported abroad, it is given by confirming that it meets the necessary requirements;
- ❖ Produces a package report by combining drug quality and clinical evaluation report; sends measured questionnaires to the manufacturer in a single questionnaire; sends clarifications and additional study and research results to the drug quality review desk or to the pre-clinical and clinical desk, as appropriate; monitors evaluation process; drug quality by receiving reports. A report will be prepared showing the safety and remedial status; submits a report to the relevant body; final decision will be implemented;
- ❖ Receives requests for changes to the prescribed medication; determines the type of changeand evaluates; prepares an evaluation report; notifies the concerned party;
- ❖ Accepts re-registration requests; checks the Good Manufacturing practice Inspection Report and whether there are any changes or other quality findings in the manufacturing of the medicine; submits a final proposal report to the relevant body;
- ❖ Receives pesticide registration documents for public health services he evaluates. Once they are met, a marketing license will be issued. Requests additional clarifications when additional information is needed; when a response is submitted, hesubmita a final proposal to the relevant party. Uses laboratory test results as needed;
- ❖ Ensures the correctness 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 as Chief Executive Officer;

- A system will be developed to ensure smooth communication in the desk and efficient and effective work;
- Prepares necessary instructions, guidelines, manuals and standard operating procedures (SOP) for the desk;

Duties and Responsibilities of the Biological Drug Review Desk

- Prepares, approves, and implements biological drug evaluation and registration manuals and operational guidelines based on operational strategies that guide drug evaluation and approval;
- Compiles and implements international experiences regarding the evaluation and authorization of biological drugs;
- When it is confirmed that there are defects in the quality, safety and efficacy of the biological drugs that have received a market license, the market license will be suspended, cancelled, and notified to the relevant parties;
- Evaluates the results of studies and research done on new biological drugs; prepares a summary report; presents to Medicines Advisory Board for discussion; using the comments as input, a final report will be submitted to the concerned body; If there is additional required information, it will be done and presented; when the response is submitted, it continues the evaluation in the same manner. When the benefit of the drug is greater than the risks, makes a decision to register the drug and use it on the market, and implements the final decision;
- Plans, executes, coordinates, monitors and supports activities related to biological drug evaluation and registration;
- Evaluates current performances and provides feedback, compiles performance reports and submits them to the directorate;
- Plans, executes, coordinates, monitors and supports activities related to the evaluation and registration of biological drugs;
- Evaluates quality, clinical and other important scientific research and research data for biological drugs that are manufactured localally or abroad and require market approval; In addition, it issues questions that need to be studied or clarified, sends them to the manufacturer, and evaluates the accuracy of the research and research results that are studied and presented. If approved, submit a proposal for a marketing authorization; If it is not accepted, it will prepare a report containing a reasonable explanation and submit it to June; Applies the specified limits, receives and evaluates requests for change registrations on registered biological drugs; If accepted, submits a proposal

for registration; If it is not accepted, will submit a report containing a professional recommendation stating that the market license will not be granted, or prepare a report containing a professional analysis stating that further research and research should be conducted and the results will be presented, and send it to the manufacturer; valuates when a response is submitted. Provides professional advice for the granting of an approved marketing authorization;

- Renews the marketing authorization for biological drugs that meet the renewal criteria; When it is confirmed that there are defects in the quality, safety and efficacy of the biological drugs that have received market license, the market license will be suspended, cancelled, and notified to the relevant parties;
- Performs the correct verification of the activities performed by the desk;
- Works to maintain a strong relationship with experienced countries and international institutions related to biological drug evaluation and registration process;
- Designs a strategy to build the capacity of the desk, makes decisions on issues beyond the capacity of experts; Implements decisions and directions as directed by the Directorate;
- A procedure will be established to ensure smooth communication in the desk and efficient and effective work;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;

Tasks and responsibilities of drug pre-evaluation and facilitation desk

- Performs pre-assessment verification of the completeness of documents submitted for the registration of modern and traditional medicines, informs the subject to complete and submit incomplete documents, makes payment of service fee: notifies in writing that service fee is to be paid in accordance with the regulations, confirms that it has been done;
- Performs pre-checking that the information of the documents of pesticides used for public health is complete.
- Submitting to June to the head of the work department, confirming that the requests to be given a special drug injection license have been completed and submitted;
- Ensures that procurement requests submitted through the electronic control information system are complete, completes those that have not been completed, and authorizes those that have been completed through the information system;
- Coordinates and monitors evaluation activities in the evaluation process.

- Plans, executes, coordinates, monitors and supports activities related to drug pre-evaluation work;
- Evaluates current performances and provides feedback, compiles performance reports and submits them to relevant parties;
- Receives requests for changes to registered traditional and alternative medicines and medicines used for public health, verifies that they are complete, informs the concerned party;
- Verify the validity of requests for traditional and alternative medicine and public health services submitted for re-registration, and submit it to the relevant body for review;
- Ensures the correctness of the tasks performed by the desk;
- Designs a strategy to build the capacity of the desk, makes decisions on issues beyond the capabilities of experts, implements decisions and directions as a leading executive;
- Establishes a system to facilitate communication and efficient and effective work in the desk;
- Prepares necessary instructions, guidelines, manuals and standard operating procedures (SOP) for the desk;

Chief Executive Officer of Drug Inspection and Law Enforcement

Purpose of establishment

The main purpose of the Drug Inspection and Law Enforcement Executive is to make the local drug industry competitive nationally and internationally by carrying out the control activities required by the local drug manufacturing industry and to ensure that the products they produce are accepted by other countries by implementing a proper control system. It is for the society to have full confidence in the use of local medicinal products and to overcome the associated health problems associated with production. In addition, this Directorate of Intelligence and Anti-Illegal Traid; carries out special information activities with the information received from security and post market and other international institutions.

Duties and Responsibilities of Drug Inspection and Law Enforcement Leader

- Preparing, approving and monitoring the implementation of operational strategies, manuals and other documents to be guided by drug inspection and information in the country.
- Conducts quality control for local and foreign drug manufacturers who wish to sell their products in the local market, and informs the relevant parties of the results.

- Based on drug safety monitoring and post-market surveillance as well as the results of surveillance reports, will take legal action against institutions and drugs that need to be acted upon and inform the concerned parties of the performance;
- When there is a suggestion that drugs are being produced that can cause serious harm to the health of the public, checks before they cause harm, takes the necessary measures and informs the relevant parties.
- The Chief Executive will work in conjunction with the Directorate of Legal Affairs as necessary in carrying out inspection activities.
- Quality of production documents for the establishment of new local manufacturing companies; Evaluates, integrates safety and remediation; provides technical recommendations;
- Studying and solving the causes of complaints submitted in connection with the inspection of quality control and quality control; record and analyze complaints; Prepares operational adjustments
- Any legal action taken by the controlled institution, such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary.
- Works to maintain a strong relationship with countries and international institutions that have experience in controlling the good production of medicines.
- Works to establish effective and sustainable cooperation with international and national institutions on behalf of the authority regarding the control of drug manufacturers.
- Prepares various documents to help strengthen the capacity of local manufacturing company inspectors; Training is also provided
- The procedure of Mutual Recognition prepares various documents to accept the conditions.
- Participates in various policies and strategic plans related to GMP Inspection; Provides technical advice.
- Contributing to the authority's work to become a member of the Convention by implementing the requirements of the International Inspection Convention (Pharmaceutical Inspection Convention, PIC's) and fulfilling other conditions; ensures continuity of membership.
- Identifies problems by conducting internal control inspection (Internal Audit); evaluates the methods and procedures by which the problems are solved; coordinates;
- Formulates strategy to build executive capacity; makes decisions on matters beyond the scope of the desks; As an institution, he works to implement the decisions and directions;

- A procedure will be established to ensure smooth communication and efficient and effective work at the executive's desks;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit; performs quality assurance activities; he works for international recognition.

Organization and accountability

The Chief Executive Officer of Drug Inspection and Law Enforcement holds three desks under his responsibility and is responsible to the Deputy Director General of the Drug Control Sector.

They are,

1. Drug Manufacturers Inspection and Law Enforcement Desk

2. Narcotic and psychotropic drug control desk

3. Tobacco Control Desk

Duties and Responsibilities of Drug Manufacturers Inspection and Law Enforcement Desk

- Prepares, approves, and implements the manuals and operational guidelines for the inspection of local drug manufacturers based on operational strategies that govern the inspection and law enforcement of drug manufacturers.
- The local pharmaceutical manufacturer will conduct quality control for the manufacturers who want to use their products in the local market, and will inform the relevant parties of the results.
- Based on drug safety monitoring and post-market surveillance as well as the results of surveillance reports, will take legal action against institutions and drugs that need to be acted upon and inform the concerned parties of the performance;
- When there is a suggestion of drug products that may cause serious harm to the health of the public, when produced and released on the market or they are being transported into the country, will be checked before they cause harm, and will take the necessary measures and inform the relevant parties.
- In case of quality of production documents for the establishment of new local manufacturing companies; evaluates, integrates safety and remediation; provides technical recommendations;

- Studying and solving the causes of complaints submitted in connection with the inspection of quality control and quality control; record and analyze complaints and prepares operational adjustments;
- The Desk will work closely with the Directorate of Legal Affairs as necessary while carrying out inspection enforcement duties;
- Any legal action taken by the controlled institution, such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken, organized and kept, and given to the appropriate parties when deemed necessary;
- Statically organizes, compiles, and presents information related to good production control to the team;
- On behalf of the directorate, works to establish effective and sustainable cooperation with international and national institutions regarding the control of drug manufacturers;
- Together with the Investment Commission and other bodies, participates in strategies and similar documents prepared to strengthen the local manufacturing process;
- Ensures the correctness of the activities 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 as lead executive;
- A system will be developed to ensure smooth communication and efficient and effective work in the desk;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit; performs quality assurance activities and works for international recognition.

Narcotic and Psychotropic Drug Control Desk

- Develops a control system for psychotropic substances and precursor chemicals, prepares operational strategies, master plans, guidelines and procedures, revises, approves, implements;
- Implements Narcotic drugs control; coordinates, monitors the international agreements and national laws accepted by the country regarding the control of psychotropic substances and precursor chemicals;
- It compiles and implements international experiences in the Narcotic drugs control system, psychotropic substances and precursor chemicals;

- Provides special pre-entry permits for Narcotic drugs, psychotropic substances and precursor chemicals, and compiles information;
- Prints prescriptions for narcotic and psychotropic drugs and issue them when requested by relevant health institutions, ensure and control their proper use;
- Collecting information on the demand for narcotic drugs, psychotropic substances and precursor chemicals from various institutions and conducting an assessment of the country's needs and organizing the information and sending it to the International Narcotic Control Board (INCB) in time;
- Collects information, reports on used narcotic drugs, psychotropic substances and precursor chemicals from various institutions and regional regulatory bodies and organizes the information and sends it to the International Narcotic Control Board (INCB) in time;
- Receives questions from the World Narcotics Control Board regarding the control of narcotic drugs, psychotropic substances and precursor chemicals, responds in a timely manner, and implements;
- Monitors the handling, storage, distribution, distribution and disposal of narcotic drugs, psychotropic substances and precursor chemicals, verifies the appropriateness of the usage system, and takes action as necessary;
- Monitors and supervises the use of narcotic drugs, psychotropic substances or precursor chemicals approved for the purposes of institutions outside the health sector;
- Maintains National narcotic medicine information, psychotropic substances, precursor chemicals, coordinates the collection of reports;
- Supports Narcotic drug at national level; participates in setting up committees to strengthen the control of psychotropic substances and precursor chemicals;
- Works to raise awareness on Narcotic medicine among health professionals, importers and distributors so that the proper use of psychotropic substances and precursor chemicals can be spread;
- Regarding illegal narcotic drugs, psychotropic substances and precursor chemicals, the desk works in cooperation with the relevant parties;
- 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 desks, it is presented to the chief executive so that decisions can be made and implemented;

- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work;
- Provides professional support and exchange of information for narcotic and psychotropic drug and tobacco control desk for branch offices;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Tobacco Control Desk

- Establishes a tobacco control system, prepares operational strategies, guidelines and procedures, revises, approves, implements;
- Implements, coordinates, monitor and supervise the proper implementation of the international agreements and national laws accepted by the country regarding tobacco control;
- Combines and implements international experiences in tobacco control system;
- Supports and participates in setting up committees to strengthen tobacco control;
- Organizes information about tobacco control and sends it to the Secretariat of the World Health Organization Framework Agreement on Tobacco Control in timely manner;
- To prevent and control the health, social and economic problems that are happening to the society due to tobacco production, will carry out awareness activities for the society; In relation to illegal tobacco trade, the desk works in cooperation with the relevant parties;
- For establishments engaged in tobacco production, importation or wholesale distribution, issues special licenses by conducting pre-license inspections, renews them, and conducts post-license inspections, and appropriate action is taken based on the results;
- Monitors and controls the production of shisha, electronic nicotine delivery devices and other technology similar to cigarettes;
- Ensures the correctness of the activities performed by the desk;
- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, presents them to the executive and makes decisions to be implemented;
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work;
- Provides professional support and exchange of information for narcotic and psychotropic drug and tobacco control desk for branch offices;

- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Pharmacovigilance and Clinical Trial Lead Executive Officer

Objective

The main purpose of Pharmacovigilance and clinical TrialLead Executive Office is to ensure that medicines (modern, traditional and alternative, biologicals, vaccines, blood and blood products, radiopharmaceuticals, etc.) are at the level of quality, safety and efficacy they have been registered on the market and that they contain accurate drug information. It was also established to ensure and enforce the proper use of medicines and to monitor and combat availability of illegal drugs on the market.

Duties and responsibilities of Pharmacovigilance and clinical Trial Lead Executive Officer

- Ensures that the quality, safety and efficacy of medicines after entering the market maintained their level during registration.
- To monitor and ensure that correct information on the use of medicines market as per the level of registration,
- To monitor and control the presence of unregistered illegal medicines.
- Prepares a Essential MedicinesList, informs the list of registered drugs to stakeholders, health institutions, Issues national data on drug use, Categorize medicines into different levels, revises the category as necessary;
- Regulate the Antimicrobial Resistance (AMR), works in collaboration with research and educational institutions to prevent and control the AMR.
- Support/enforce the organization and implementation of Antimicrobial StewardshipProgram in all hospitals, encourage integrated system
- Solving medicines-related problems nationwide by collecting, organizing, analyzing and interpreting information from various health institutions and health professionals.
- Adverse Drug Event management, i.e. collection, monitoring and analysis of adverse drug reactions, product quality defects, efficacy failure of medicines, and medication error reports, data management, administrative measure to be taken based on the results, and reporting to the World Health Organization:

- Direct, monitor and coordinate manufacturers, importers and distributors to establish medicines safety monitoring system.
- Directmedicines manufacturers and importers to conduct post-market surveillance on their own.
- Conducting post-market surveillanceon the quality of medicines and collecting samples to carry out quality testing in the laboratory and based on the results of the study, informs the concerned parties about the medicines that should be taken action and monitors the performance;
- Monitors the presence of medicines with illegal drug advertisements, misleading leaflets and drug information problems in the market, and when found, informs the relevant parties and monitoritsexecution.
- Monitors whether narcotic drugs and psychotropic substances are being sold to patients in the country's market legally and only with its special prescription.
- Proper use of narcotic drugs and psychotropic substances by providing information to the society in a different way and widely, to prevent drug poisoning associated with improper use and save the society from unnecessary addiction, mental and social crisis.
- In relation to drugs, when there is a suggestion of drug products that may cause serious harm to the public health, they may be manufactured and put on the market or they are on the market, as well as drug products that are being transported into the country, it will establish a system of procedures to arrest them before they cause harm to the public.
- When there is a sudden problem related to medicine, he will be present at the site and conduct the necessary monitoring and investigation, collect data, analyze and inform the relevant parties so that appropriate action can be taken based on the results, and monitor the execution.
- Provide and coordinate the necessary awareness so that health professionals can report problems related to drug safety and quality in a timely manner;
- Carries out continuous awareness raising activities to protect the society and partners from health problems related to the safety, quality and therapeutic deficiencies of medicines.
- In relation to drug safety, quality and efficacy, the office works on behalf of the authority with national, continental and international institutions and exchanges information.

- Monitoring, collecting and analyzing data on health problems and early warnings related to drug safety, quality and healing, as well as products that are prohibited from being used, will be distributed to the relevant parties and ensure their execution.
- Establishing relationships with international institutions and exchanging information when faced with drug safety, quality and medicinal problems occurring in the country.
- Establish, supports and coordinates the establishment of Medicines safety monitoring centers in selected health institutions at the sub-national level;
- It works in collaboration with the bodies that work to ensure the proper use of drugs.
- Prepare andmonitors timely and quality information, make accessible to the public using various distribution methods, and coordinating for the desired purpose;
- Conducts a study to see if the legal frameworks issued to ensure the appropriate use of drugs are being properly implemented at the national level, and based on the results of the study, informs the relevant parties so that the necessary action is taken.
- Preparing, approving and implementing documents such as operational strategies, manuals, protocols and other documents that govern medicines safety monitoring and post-market surveillance, drug information and appropriate use system;
- Design strategy to build capacity of the executive office professionals; Makes decisions on issues beyond the scope of working groups; 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.
- Support the branch offices to provide professional support to the sections under medicine sector in the field of medicines safety and quality monitoring and to strengthen the exchange of information;
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit.

Structure and governance

The Lead Executive Officer of Pharmacovigilance and Clinical Trials be answerable to the Medicines Sector Deputy Director General and will have four desks under him.

1. Medicines Safety Monitoring (Pharmacovigilance) and Post-Market Surveillance Desk
2. Clinical Trial Licensing and Control Desk
3. Drug Information and Proper Use Desk
4. Cosmetics safety monitoring and post-market monitoring desk

Medicines Safety Monitoring (Pharmacovigilance) and Post-Market Surveillance Desk

- Verify thequality all medicine used in the Ethiopian market (modern, traditional and alternative, vaccines, biologicals, radiopharmaceuticals, etc.) by collecting samples from the market and conducting quality tests as to maintaining the quality level when registered by the authority.
- By ensuring that there are no drugs/pseudo-drug products of unknown origin in the market, informs the public about drugs whose quality, safety and efficacy are not established, and collects them from the market.
- Collect samples from the market to evaluate the recording on the proper use, handling and disposal of registered medicines by the Drug Information and Proper Use desk, and takes the necessary measures based on the findings.
- Focusingof reduction of Antimicrobial Resistance, coordinates the collectionof samples and conducting quality control tests of selected Antimicrobials toensure their quality
- Develop, submit for approval and implement documents such as strategies, manuals, protocols and other documents that govern the medicines post-market surveillancesystem;
- Performs and coordinates drug post-market surveillance activities at the national level
- Works and coordinates with pharmaceutical manufacturers and importers to carry medicines post-market surveillance
- Monitoring Adverse Event Following Immunization of vaccines that have been put on the market.
- Adverse Drug Event management, i.e. collection, monitoring and analysis of reports of Adverse Drug Reactions, Product Quality Defects and Medication Errors; managing data,

facilitating administrative measures based on the results and reporting to the World Health Organization:

- Monitor and coordinate the establishment of pharmacovigilance system. By manufacturers, importers and distributors,
- Based on the results of medicines safety monitoring, informs the concerned parties about the drugs that measures should be taken and monitors the execution;
- Monitor the availability of counterfeit medicines, misleading labels/leaflets and similar problems in the market, and when found, informs the relevant parties and monitor itsexecution.
- Establish system to detain suspicious products as suggested are available in the market or transported into the country or manufactured or in process of manufacturing that may otherwise cause serious harm to the public health.
- When there is aemergency medicine safety issue, present at the site and carry out the necessary monitoring and investigation, collect data, analyze and inform the relevant parties so that appropriate action can be taken based on the results, and monitor the execution.
- Provide and coordinate the necessary awareness so that health professionals can report problems related to drug safety and quality in a timely manner;
- Conduct continuous awareness raising activities to protect the society and partners from health problems related to the safety and quality of medicines.
- Periodic medicines safety report monitoring, medicines safety risk monitoring, medicines safety risk communication.
- Signal detection and casual assessment of drug adverse event reports sent from different entities and active surveillance.
- Monitor, collect and analyze information on health problems and early warnings related to medicines safety and quality, as well as products prohibited from being used, and distribute them to the relevant parties and ensure execution.

- Establish relationships with international institutions and exchanging information when faced with drug safety and quality problems in the country.
- Design, implement, support and coordinate the establishment of Pharmacovigilance centers in nationally selected health institutions;
- Based on the results of medicinespost-market surveillance, informs the concerned parties about the medicinesthat measures should be taken and monitors execution;
- Conducts continuous awareness raising activities to protect thesociety and partners from health problems related to the safety and quality of medicines.
- 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.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support to branch offices for drug safety monitoring and post-market desk and exchange of information.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;

Duties and Responsibilities of Drug Information and Rational Use Desk

- Ensure that registered and marketed medicines contain correct information on the use, handling and disposal of medicines asperstatedduring registration.
- Disseminating information to the public about drugs/pseudo-drug products of unknown origin through various means of media and increasing the awareness of the public.
- Any anti-microbial drug (modern, traditional and alternative medicine) on the market in Ethiopia will be verified by studies conducted by medical institutions to confirm the level of therapeutic in line with theirclaim during registration by the authority, and identify those that should be used and should not be used at the national level.
- Conducting joint research with various health research and educational institutions on the antimicrobialresistance and taking corrective action by realizing the state of resistance of antimicrobials at the national level.

- Giving information to the society in a different form and widely about the appropriate use of narcotic drugs and psychotropic substances.
- Prepare aEssentialMedicines List that takes into account the prevalence of health problems of the country.
- Through various means of communication inform the list of registered drugs to the public.
- Prepare the National Medicines Formulary to provide easy access of medicines information for health professionals
- Prepare, present for approval and implement operational strategies, manuals, and other documents that guide the drug information and appropriate use system.
- Prepare EssentialMedicines List, promote the list of registered drugs to the public, issues a national Medicines Formulary, categorize medicines in different levels, revises the category as necessary;
- Work in collaboration with the bodies to ensure the proper use of drugs.
- Preparecurrent,reliable and quality information, make the information accessible to the public using various distribution methods, coordinate and monitor the implementation of desired purpose;
- Conduct study to review properly implementation of the legal frameworks issued at the national level to ensure the appropriate use of drugs, and based on the findings, inform the relevant parties for taking the necessary measure.
- Coordinate activities to prevent the antimicrobialresistance at the national level.
- 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.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;

Duties and Responsibilities of Cosmetics safety monitoring and post-market monitoring desk

- Prepare, submit for approval and monitor the implementation of operational strategies, manuals, Standard Operation Procedures 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 cosmeticproducts
- Conduct and coordinate national safety monitoring and post-market surveillance on cosmetic products available in the market; takes measures based on the findings.
- Monitors the absence of cosmetics products with problems such as imitations, misleading descriptions, etc., and when found, informs the relevant bodies and monitors the execution.
- When there is an emergency related to cosmetic products, reach the site to conduct the necessary monitoring and investigation, collect data analyze and inform the relevant parties so that appropriate measure can be taken based on the finding, and monitor the execution.
- Conducts continuous awareness raising activities to protect the society and partners from the health problems associated with adulterated and contaminated cosmetics.
- Monitor, collect and analyze data on health problems and early warnings related to the safety of cosmetics at the national and international level, as well as products that are prohibited from being used.
- Conduct and coordinate national safety surveillance and post-market surveillance on cosmetic products available on the market;
- 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.
- A procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provides professional support to branch offices for drug safety monitoring and post-market desk and exchange of information.

- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;

Duties and Responsibilities ofClinical Trial Authorization and Control Desk

- Establish a system for clinical trial protocol review and approval, prepare, revise, and implement guidelines.
- Compile and implement international experiences in terms of clinical trial protocol review and approval system in a way that is beneficial to the country.
- Receives requests for clinical trials, evaluates research protocols and authorize if it is useful to the society and the country, and rejects it if it is not useful and endangers the society (intent for biological terrorism).
- If the clinical trial involves investigational products, the chemical properties of the substances and the harm they can cause to humans will be evaluated from pre-clinical animal studies and consideration of similar chemicals, the protocol will also evaluated for the inclusionof preventive measures.
- Evaluates whether the researchers who prepared the protocol and intend to conduct the clinical trial have the appropriate knowledge and skills in clinical trial and knowledge on basic health science, and decidesaccordingly.
- Evaluate and allow or deny for request of revision in the approved research method based on thejustifiableevidence that the approved protocol does not work according to the scientific principles,
- Evaluate the scientific data provided and make decision for application of termination for not producing the desired results (interim data review) which is being carried out as per the approved protocol.
- Plan, execute, coordinate, manage, monitor and support 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.
- 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.
- Develop system to ensure smooth communication and efficient and effective work in the desk.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;
- Compile and implement international experiences around the clinical trial monitoring system in a way that is beneficial to the country
- Monitor and supervise that the clinical trial is conducted according to the good clinical trial procedure system, if it is not being conducted by licensed researchers according to the approved clinical trial study method (Study Design and Methodology), it will be suspended/terminated, and will be directed to the legal department;
- Ensure 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.
- Monitor and investigate in a confidential manner whether there are ethical and safety complaints of people undergoing medical experiments, and if there are any problems, forward decision up to the point of suspension or corrective action.
- For adverse events that occur during clinical trials, request scientific reasons from the Principal Investigator, collect, analyze, interpret the results, and adjusts the trial process or terminate it before causing serious problems.
- Interim data review and monitoring of the process when the clinical trial is performed as authorized.
- When the clinical trial is completed as approved, evaluate the results of the research and verify the credibility of the findings;
- Conduct inspection and monitoring of centers where medical experiments are conducted, grants licenses, renews them, and suspends and revoke if nonconformanceto the appropriate standards.

Medicine Quality ControlLead Executive Officer

Objective of establishment

The main purpose of medicine quality control is for carrying out physical, chemical, microbiological and toxicological tests on products from both local and foreign originon samples for new registrations, consignments, post-market surveillance and suspicious cases; By, the conducting the tests, establishes safety and quality of modern and traditional medicines as well as the safety and quality of pesticides and cosmetic products used for public health were.

The lead executive of medicine quality testing will have the following duties and responsibilities

- 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, pesticides 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, pesticides and cosmetic products that do not have a quality testing method.
- Compile and implement international experiences in quality testing of medicines, pesticides 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, pesticides and cosmetics used for public health.
- Initiate the testing of new biological drugs and non-scientific diagnostic methods using high-quality (Hi-tech) diagnostic equipment.
- Ensures that professionals have the required technical skills of the period; When competence gap observed, facilitates local and abroad training to improved 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 and pesticides used for public health, whether produced in the country or imported from abroad before registration and inform the result to relevant parties.
- Conduct post-market quality control testing on medicines, pesticides 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, pesticides and cosmetics used for public health; and inform the the results to relevant parties,
- Prepare reference standards for physico-chemical testing using international methods.
- Develop technical specifications for laboratory equipment and materials necessary for quality testing of pharmaceuticals, pesticides 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.

- Verifies the proper functioning of the equipment used in the quality testing of medicines, pesticides and cosmetics for public health services.
- 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, pesticides and cosmetics for public health services;
- Provide training and support to portsof entry and exit (structured under the branch offices)on the necessary quality control of medicines for public health services, pesticides and cosmetics.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desks.

Structure and governance

The Lead Executive Officer of Medicines quality control laboratory is answerable to the Medicines Sector Deputy Director General and will have four desks under him.

1. Medicines Physicochemical quality control lab desk
2. Medicines microbiology laboratory Desk

Duties and Responsibilities of Physicochemical Quality Testing 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.
- Participatein proficiency testing of samples with accredited labs and ensure proper execution of same.
- Validation 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, andperforms 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 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 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 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 standard operating procedures (SOP) for the desk;

Duties and Responsibilities of Medicines microbiology laboratory Desk

- Prepare, palay 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.
- Validation of existing and new quality testing methods using various advanced analytical methods.
- Participatein 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 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;

- Verify proper functioning 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 standard operating procedures (SOP) for the desk;

Medical Device Sector

Medical Device Sector Deputy Director General

Brief Job Description

As one of the four Deputy Director Generals under the Director General, the Deputy Director General of Medical Device Plans, organizes, directs, monitors and supports, coordinates, provides operational and policy directions, and formulates strategies to build the capacity of the process units under him; Makes decisions on matters beyond the scope of work units; Communicates decisions and directions as an authority; It will design the procedures and strategies of the country's medical device regulatory sector, creates ownership and partnership by promoting and creating awareness about the sector to the society and stakeholders, works to establish effective and sustainable cooperation with international and national institutions regarding the medical device control sector on behalf of the authority, it is organized to help the director general by ensuring that the sector's operations are being carried out properly.

The Deputy Director General of the sector will have the following duties and responsibilities, subject to the duties assigned by the General Director:

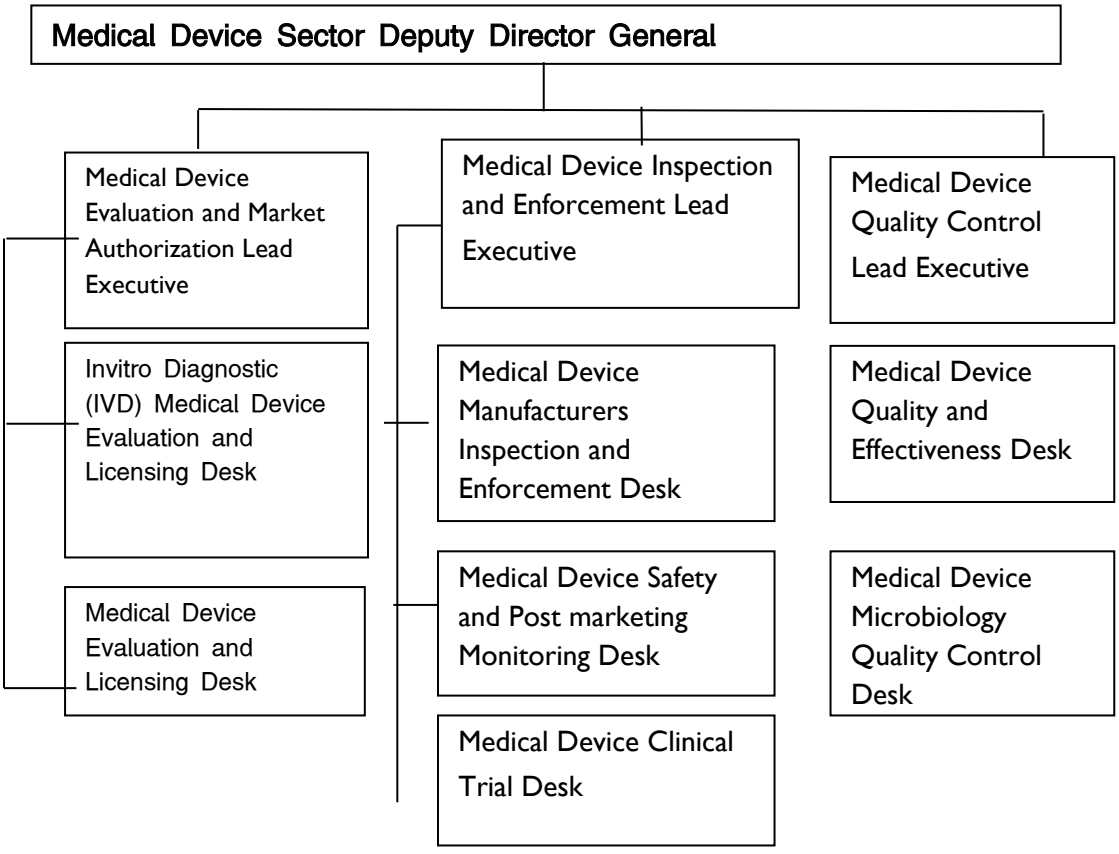
- Coordinates the development of strategies, programs and strategies to guide the sector.
- Supervises the day-to-day activities of the sector
- By identifying the legal gaps in the sector, regulations and guidelines will be prepared by the relevant work department
- Ensures that the policies, laws, operational guidelines and standards issued for the sector are properly implemented by the subordinate process units.
- Ensures that sufficient budget is allocated for the operations of the sector, and monitors that the allocated budget is properly used
- Supports, supervises and coordinates the work units under him to do effective work
- create a strong work relationship and coordination between work departments and to take corrective action by quickly evaluating when gaps are created.
- Ensures their applicability by periodically evaluating the performance parameters set to measure the effectiveness and efficiency of the sector.

- ❖ Designs strategies and programs to improve the performance of professionals under the sector, and monitors their implementation.
- ❖ Designs motivational strategies that enable professionals who record effective performance to be encouraged, monitors its implementation;
- ❖ Create ownership and partnership by promoting 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.

Organization and accountability

Medical Device Control Sector M/General Directorate is called as the General Director of the authority office and there are four directorates under it. And they

1. Medical Device Registration Licensing Lead Executive
2. Medical Device Quality Control Lead Executive
3. Medical Device Inspection and Enforcement Lead Executive



Medical Device Evaluation and Market Authorization Lead Executive

Brief Job Description

The main objective of Medical Device Evaluation and Market Authorization Lead Executive is to evaluate locally manufactured and imported medical devices and IVD medical device documents/dossiers and issue new market authorization, review, approve, and renew when there are changes. Based on the results of the post-market quality control or medical device safety monitoring report on the medical devices allowed to be placed on the market, the medical device market authorization will be suspended and revoked.

Duties and responsibilities of the lead executive for medical device Evaluation and Market authorization

- Prepare, approve and monitor the implementation of operational strategies, manuals and other documents governing the registration and licensing of medical devices in the country.
- Compiles and implements international experiences in the medical device registration and licensing system in a way that is beneficial to the country
- Plans, executes, coordinates, manages, monitors and supports activities related to medical device registration and licensing.
- Evaluates and records scientific data on the quality, safety and effectiveness of medical devices manufactured locally or imported and requires market approval.
- Issue the market authorization for medical devices manufactured locally or imported, remanufactured or refurbished, after evaluating the necessary information;
- Identifies medical devices that are allowed to be used on the market without document review, establishes a market authorization/notification system and issues market authorization;
- Renew market authorization for medical devices that meet re-registration criteria;
- When the quality, safety and effectiveness of the medical devices that have received market authorization are confirmed by the relevant bodies, the market authorization will be suspended and canceled followed by notification to the relevant bodies.
- Issuance of free sale certificate for medical device manufactured in the country and exported;
- Identifies operational gaps and attempt the preparation of guidance by the relevant section
- Works to ensure the correctness of market authorization activities given by the desks located at the root.

- Works to maintain a strong relationship with experienced countries and international institutions related to the registration and licensing of medical devices.
- Formulates strategy to build executive capacity; Makes decisions on matters beyond the scope of the desks; As an institution, it works to implement the decisions and directions.
- A system will be established to ensure smooth communication and efficient and effective work at the executive desks.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work unit;

Structure and governance

The Lead Executive of evaluation and market authorization of medical devices is answerable to the Medical Device Sector Deputy Director General and have two desks under him.

1. Invitro Diagnostics (IVD) Medical Devices Evaluation and Marketing Authorization Desk
2. Medical Device Evaluation and Market Authorization Desk

Invitro Diagnostics (IVD) Medical Devices Review and Marketing Authorization Desk

Prepares, approves, and implements the manuals and operational guidelines governing the registration and licensing of IVD medical devices based on operational strategies governing medical device registration and licensing.

- Compiles and implements international experiences in the registration and licensing system of IVD/invitro diagnostic medical device in a way that is beneficial to the country.
- Evaluate and record the quality, safety and effectiveness scientific data of the extracorporeal human body sample diagnostic medical device (IVD) produced locally or imported and requests a market authorization.
- After evaluating the necessary information, market authorization is issued for IVD medical devices manufactured locally or abroad, remanufactured or refurbished;
- Renew the market license for IVD devices that meet the re-registration criteria.
- When the quality, safety and effectiveness of the IVD medical device that has received a market license is confirmed by the relevant bodies, the market license will be suspended and canceled and the relevant bodies will be notified.
- Evaluates IVD/Promotion information for legal compliance and registration information; Provides product promotion and promoter licensing;
- Ensures the correctness of the activities of the marketing license given by the experts under the supervision.

- Works to maintain a strong relationship with countries and international institutions that have experience in connection with the registration and licensing of in vitro diagnostic medical devices (IVD).
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the working groups, it is presented to the executive for a decision and works to be implemented.
- Procedure will be developed to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;

Medical Device Evaluation and Licensing Desk

- Prepare, approve and implement manuals and operational guidelines for medical device registration and licensing based on operational strategies governing medical device registration and licensing.
- Compile and implement international experiences in the medical device registration and licensing system in a way that is beneficial to the country.
- Evaluate scientific data on the quality, safety and effectiveness of medical devices submitted for market authorization of locally manufactured or imported products and decides on approval.
- After evaluation of the necessary information issue market authorization for medical devices manufactured locally or imported, remanufactured or refurbished;
- Renew market authorization for medical devices that meet the re-registration criteria;
- When defect of quality, safety and effectiveness of a registered medical device is confirmed by relevant bodies, the market authorization will be suspended or canceled and the relevant bodies will be notified.
- Evaluate whether promotion information of medical device complies with the law and is based on the registration information; provides license for product promoters;
- works to maintain a strong relationship with countries and international institutions that have experience in the process of registration and licensing of medical devices.
- Supervise and verify the validity of market authorization activities done by the experts.

- Formulates strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desks, presents it to the executive and execute the decisions.
- Establish procedure to ensure smooth communication between the professionals in the desk and to perform efficiently and effectively.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk;
- Take necessary measures on registered products by evaluating with relevant sections the complaints submitted on quality, safety and efficiency products.

Medical Device Manufacturers Inspection and Enforcement Lead Executive

Purpose of establishment

The main purpose of the Medical Device Manufacturers Inspection and Law Enforcement Executive is to conduct inspections of local and foreign medical device manufacturers, regulate unsafe medical devices from harming the public, take legal measures and ensure the competence of local medical device manufacturers.

Duties and Responsibilities Lead Executive Officer of Medical Device Manufacturers Inspection and Law Enforcement

- Preparing, approving and following up on the implementation of operational strategies, manuals and other documents to guide medical device inspection and law enforcement.
- For local and foreign medical device manufacturers who want to market their products in the country, conducting a physical inspection for compliance of the manufacturers on Good Manufacturing Practices or Quality Management System by verify the findings, and the inspection report will be notified to the relevant bodies.
- Conduct pre-licensing inspections of local medical device manufacturers and submit the inspection findings to relevant bodies.
- Based on the results of medical device safety monitoring and post-market surveillance reports, legal action will be taken against institutions and medical devices, and the measures will be notified to the relevant parties.
- When there is a suggestion that medical devices are being produced that can cause serious harm to the health of the public, investigate it before causing harm, takes the necessary measures, and informs the relevant parties.

- The Lead Executive will work closely with the Legal Affairs Executive as necessary when performing inspection and enforcement activities.
- Exhibits such as documents, invoices, electronic records, samples, photographs or videos, etc., is taken in accordance with the law, organized and maintained, and given to the appropriate parties when deemed necessary.
- Works to maintain a strong relationship with experienced countries and international institutions related to the control of the Good Manufacturing Practices or Quality Management System of medical devices.
- Works to establish effective and sustainable cooperation with international and national institutions regarding the control of medical device manufacturers.
- Formulates strategy to build internal capacity; Makes decisions on matters beyond the scope of the desks; executes the decisions and directions of the authority.
- Develop system to ensure smooth communication and efficient and effective work at the executive desks.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work process.

Organization and accountability

The Lead Executive Officer of Medical Device Inspection and Law Enforcement is answerable to the Deputy Director General of the Medical Device Regulatory Sector and holds three desks under his responsibility.

1. Medical Device Manufacturer Inspection and Law Enforcement Desk
2. Medical device safety and post-market surveillance desk
3. Medical Device Clinical Trial Desk

Duties and Responsibilities of Medical Device Manufacturer Inspection and Law Enforcement Desk

- Conduct inspection on the production capacity of the manufacturing company and submits the findings to the medical device licensing team to confirm the manufacturing capability before a providing a manufacturing license,
- Conduct renewal inspection of manufacturers who have been given production qualification certificate as necessary.

- Prepare, submit for approval, and implement the manuals and operational guidelines for the inspection of the medical device manufacturer based on the operating strategies for the inspection of the medical device manufacturer.
- Conduct physical inspection and verify the production processes follow the good manufacturing practices, and reports the findings to the relevant section before medical equipment manufacturers get market authorization for the medical equipment,
- Evaluate corrective and preventive actions for problems found during the inspection of medical device manufacturers, closely monitors the effectiveness, re-inspect the measures taken to correct them when necessary.
- While carrying out inspection activities, the desk works in collaboration with the Legal Affairs Executive, as necessary.
- In accordance with the law, take exhibits such as documents, invoices, electronic records, samples, photographs or videos, etc., organized and maintained, and given to the appropriate parties when deemed necessary.
- Understand the production process of medical devices in advance by taking current trainings and establish a system in which the necessary information such as quality, safety and effectiveness/competence information is provided in the appropriate manner.
- Solve challenges by implementing feasible innovative procedures obtained by searching various internet information/websites/ about the experience in other countries, blending it with the developments of science and technology and by providing various trainings and skills;
- Based on the findings of medical device safety monitoring and post-market assessment or surveillance reports, legal action will be taken against institutions and medical devices that need to be taken, and the performance will be reported to the relevant parties.
- Takes corrective measures based on problems/gaps found during Good Manufacturing Practice or Quality Management System Inspection.
- Take the necessary measure based on the findings of inspection or post-market assessment or surveillance or safety research on medical devices suspected of being counterfeit or substandard.
- Ensures that the advertisement and promotion of medical equipment is correct, non-fraudulent and as permitted by the guidelines.

- Investigates medical devices whose safety and quality have not been verified or whose source is unknown, and takes appropriate action, and if necessary, collects them from the market.
- Take administrative measures based on study reports conducted by the Inspection and Law Enforcement Desk, Post-Market Surveillance Desk or other departments, when necessary consult the legal affairs executive.
- Take necessary measures when receiving information about medical equipment that may cause serious damage to the health of the public is under manufacturing process or being transported to enter the country or may be put on the market or is on the market, before it causes damage, and inform same to relevant bodies.
- Evaluate the establishment proposal of new local medical device manufacturers along with various government offices about its feasibility, regularly monitors and coordinates their adherence to good manufacturing practices during construction.
- Ensure the correctness of the tasks performed by the desk;
- Design strategy to build the capacity of its staff; Make decisions on matters beyond the competence of experts; Implement decisions and directions of the lead executive;
- Develop system to ensure smooth communication and efficient and effective work in the desk.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Duties and Responsibilities of Medical device safety and post-market surveillance desk

- Prepare, submit for approval, and implement documents such as medical device post-market surveillance manuals and Standard Operating Procedures based on operational strategies that govern medical device post-market surveillance and control of clinical trial;
- Conduct market survey on any manufacturer, importer, distributor and health facilities.
- Performs medical device post-market surveillance activities at the national level.
- Coordinate with medical device manufacturers and importers to conduct post-market surveillance for medical equipment.
- Field safety corrective action is carried out and coordinated when there is a problem with the safety, quality and effectiveness of medical devices in use.

- The authority conducts post market surveillance every year on any manufacturer, importer, distributor and health facilities.
- Based on the findings of the medical device post-market surveillance, informs the concerned parties about the medical device that needs measures to be taken and monitors the performance.
- Conduct continuous awareness raising activities to protect the society and partners from health problems related to the safety and quality of medical device.
- Design strategies to build the capacity of its staff, when there are issues that are beyond the capacity of the desk, present it to the lead executive for decisions and execute same.
- Establish procedure to ensure smooth communication between the professionals in the desk and to do efficient and effective work.
- Provide professional support and information exchange for branches on medical device safety monitoring and post-market surveillance.
- Prepare necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.
- Investigate the risk of medical devices and report the findings to the relevant section and disseminate the measures and information to all relevant parties.
- Take the necessary measure by verifying the validity of the suggestions, reports and research findings from users or other parties.
- Perform and coordinate medical device safety monitoring activities at the national level.
- Management of Adverse Device Event, i.e. collection of adverse event, quality defect and medical device usage error reports, monitoring and analysis, data management, administrative measure to be taken based on the results and reports to relevant parties.
- Coordinate and monitor the establishment of medical device safety monitoring system in medical device manufacturers, importers and distributors.
- Inform concerned parties about the findings of the safety monitoring of medical device that measure to be taken and monitors the execution;
- Monitors the absence of counterfeit and substandard manufactured, misleading descriptive text and similar medical devices on the market, and when found, notifies the relevant parties and monitors the execution.

- Design system for conducting necessary measures when receiving information about medical device that may cause serious damage to the health of the public is under manufacturing process or being transported to enter the country or may be put on the market or is on the market, before it causes damage, and inform same to relevant bodies.
- Provide and coordinate the necessary awareness so that health professionals can timely report problems related to the safety and quality of medical equipment;
- Provide continuous awareness society and partners for prevention of health problems associated with the safety and quality of medical device to promote reporting.
- Carry out current medical device safety report monitoring, medical device safety risk monitoring, medical device safety risk communication
- Works in coordination with the bodies that work to ensure the proper use of medical device.
- Conduct study on whether the legal frameworks issued to ensure the appropriate use of medical device are being properly implemented at the national level, and based on the results of the study, informs the relevant parties so that the necessary action is taken.
- Conduct signal detection and casual assessment from the medical device adverse event reports obtained from different parties and active surveillance of.
- Monitoring, collecting and analyzing information on health problems and alerts related to the safety and quality of medical device at the international level, as well as products that are prohibited from use.

Duties and Responsibilities of Medical Device Clinical Trial Authorization Desk

- Prepare, submit for approval, and implement documents such as medical device clinical trial manuals and Standard Operating Procedures based on operational strategies that govern medical device post-market surveillance and control of clinical trial;
- Evaluate clinical trial applications and issue authorization in a way that is beneficial to society.
- Evaluate Clinical Evaluation, Clinical Investigation and clinical follow-up applications to be carried out in Ethiopia by a medical device manufacturer, representative or authorized person.
- After necessary evaluation authorize for use of upgraded medical devices from the one that is already on the market.

- Monitor and control the conduct of the clinical trial in accordance with good clinical trial practices, suspends or stops it when necessary;
- In order to make the society a user of technology, medical devices/diagnostic methods that have reduced their efficiency will be taken out of the market and provide directions for the introduction of modern diagnostic methods.
- Investigate and forward decisions on ethical and safety complaints raised by the subjects of the clinical trial.
- Designs strategies to build the capacity of the team, when there are issues that are beyond the capacity of the desk, present it to the lead executive for decision, and execute same.
- Develope system to ensure smooth communication between professionals in the desk and to do efficient and effective work.
- Medical device clinical trials are subject to scientific and ethical review by a committee set up in accordance with the Guidelines for Clinical Trials of Medical Devices.
- Outlines the clinical evaluation of medical devices to ensure overall safety and performance requirements, evaluation of unwanted side effects and comparison of benefits and risks relative to the standard condition of the device.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Medical Device Quality Control Lead Executive

Brief Description

The main purpose of the Medical Device Quality Control Lead Executive is to carry out safety and laboratory quality testing of medical devices for registration, consignment, suspected, post-market surveillance and testing in local and imported products.

Duties and Responsibilities of Medical Device Quality Control Lead Executive

- Prepare, approve, and implement documents such as operating strategies, manuals, Standard Operating Procedure, etc. to guide medical device quality testing.
- Develops a method of analysis and quality criteria for testing samples of medical devices that do not have a quality testing method.
- Compiles and implements international experiences in the field of medical device quality testing

- Works to establish effective and sustainable cooperation with international and national institutions regarding medical device quality testing representing the authority.
- Maintain and expand accreditations for quality control obtained by international accreditation organizations.
- Create income generation for the authority by providing quality testing services from other countries and institutions.
- Validation of existing and new quality testing methods work properly using various advanced medical testing methods (method validation).
- Testing the quality, effectiveness and compatibility of medical device produced locally and imported; inform the relevant parties about the results (Quality, performance and biocompatibility).
- Carry out quality and effectiveness tests on invitro diagnostic (IVD) medical devices, whether produced locally or imported from abroad, and inform the concerned parties of the results.
- Conduct quality, verification and validation work on medical devices and invitro diagnostic medical devices that are marketed and suspected of having quality and effectiveness problems and informs the relevant parties of the results.
- Conduct microbiological testing for medical devices that are manufactured locally or imported from abroad; inform the results to the relevant parties.
- Conduct post-market quality testing on medical devices manufactured locally and imported, and also perform the necessary quality testing on suspect samples; inform the the results to concerned parties.
- Premarket consignment test could be done for localally produced medical devices.
- Conduct necessary quality and effectiveness tests on medical equipment manufactured in foreign countries and imported into the country; inform the results to relevant parties.
- Prepare technical specifications for laboratory equipment and resources necessary for medical device quality testing; perform technical evaluation when they are purchased, ensure that they are properly maintained, and that they are in operation at all times.
- Receives laboratory samples ensuring they meet the required standards and handles them appropriately.
- Establishes procedures for the handling and use of retention samples, leftover samples and expired samples, and monitors the execution;

- Formulates strategies to build capacity; Make decisions on matters beyond the scope of the desks; work to implement the decisions and directions forwarded by the authority.
- Establish procedure to ensure smooth communication and efficient and effective work at the executive's desks.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the work process.

Structure and governance

The Lead Executive Officer of Medical Device Quality Control is answerable to the Medical Device Regulatory Sector Deputy Director General and have two desks under him. Namely,

1. Medical equipment quality and effectiveness control desk
2. Medical Device Microbiology Quality Control Desk

Duties and responsibilities of the medical device quality and effectiveness control desk

- Prepare, submit for approval and implement documents such as medical device quality and effectiveness testing manuals and standard operating procedures based on operational strategies for medical device quality and effectiveness testing.
- Develops a method of analysis and quality criteria for testing samples of medical devices that do not have quality and effectiveness testing methods.
- Validate that the existing and newly prepared quality inspection methods work properly using various advanced inspection methods (method validation).
- Conduct quality testing of medical device manufactured locally and imported from abroad; inform the results to relevant bodies.
- Conduct post-market quality testing on medical devices produced and marketed locally and abroad, and alsoperforms necessary quality testing on suspect samples, and informs the results to the relevant parties.
- Premarket consignment tests could be done for localally produced medical devices.
- Conduct quality control of medical devices manufactured abroad and imported into the country as necessary, and inform the results to relevant parties.
- Conduct pre-market quality testing for imported medical devices manufactured abroad when required; Inform the concerned parties about the results.

- Prepare the technical specifications of laboratory equipment and resources necessary for medical equipment quality and efficiency testing together with the relevant parties, performs technical evaluation when they are purchased and delivered, and ensures that the equipment in use is working properly.
- Designs strategies to build the capacity of the desk, when there are issues that are beyond the capacity of the desk, present it to the lead executive so that decisions can be forwarded to be implemented.
- Develop system that enables smooth communication between professionals in the desk and efficient and effective work.
- Dispose properly of biological and non-biological samples brought to the laboratory for testing according to appropriate guidelines.
- Prepares necessary guidelines, operating manuals and standard operating procedures (SOP) for the desk.

Duties and responsibilities of the Medical Device Microbiology Quality Control Desk

- Prepare, submit for approval and implement documents such as medical device microbiology test manuals and standard operating procedures based on operational strategies that guide the microbiological testing of medical devices.
- Develop method of analysis and quality criteria for microbiological testing of medical devices that do not have a microbiological testing method.
- Validate that existing and new microbiology test methods work correctly using various advanced test methods (method validation).
- Develop list of necessary resources for conducting the microbiological examination of medical device manufactured locally or imported from abroad, confirm for conformance with what was requested, and make them available for the work, and inform the relevant parties of the results.
- Perform microbiological test on marketed medical devices suspected of having microbiological problems using necessary testing methods, and report the results to the concerned parties.
- Conduct microbiological testing based on post-market surveillance on medical devices manufactured locally or abroad, and conduct the necessary microbiological testing on suspect samples and informs the relevant parties of the results.

- Conduct consignment microbiological tests on medical devices manufactured abroad and imported into the country and inform the relevant parties of the results.
- Conduct microbiological tests of consignments of localally produced medical devices used in the market as necessary, and inform the results to the concerned parties.
- Conduct pre-market microbiological testing as necessary for imported medical equipment manufactured locally or abroad; Inform the concerned parties about the results.
- Issue micro-biological test results for out of specification medical devices along with the test confirmation document and will be notify to the relevant body on time.
- Maintain and expand international accreditation of the microbiological testing of medical devices.
- Validation and verification of microbiological testing methods required for the operation of existing and new diagnostic equipment to be put into operation.
- Prepare technical specifications for laboratory equipment and materials necessary for microbiological testing of medical devices; performs technical evaluation when they are purchased.
- Validate proper functioning of equipment used for microbiological testing of medical devices;
- Design strategies to build the capacity of the desk, when faced with issues that are beyond the scope of the desk, present it to the lead executive for decisions and executes same.
- Develop system that enables smooth communication between professionals in the desk and efficient and effective work.
- Develop necessary guidelines, procedures manuals and standard operating procedures (SOP) for the microbiology team.
- From the samples brought to the laboratory for testing, dispose appropriately the microbes used for microbiological testing effectively according to the established guidelines.

Branch Offices Coordination Lead Executive Officer

Brief Description

To properly control the products that are regulated at the national level according to Article 3 of Proclamation No. 1112/2011 and for proper executionof the responsibilities assigned to the authorityby the regulation No. 531/2015Branch Offices Coordination lead executive is organized. The main purpose of this coordination office is to support the branch offices to carry out their work

properly, to liaise the work relationship between the regions, the branch and the region and the regions with the head office efficient and effective, ultimately creating a convenient environment and strengthening regulation at the national food, medicine, and medical equipment. and other regulated products regulation,

Branch office coordination lead executive officer is answerable to the director general and will have the following **main functions**.

- Provide necessary administrative and technical support to the branch offices under the authority to properly carry out their regulatory activities.
- Monitor the problems encountered onduty and provide solutions and to formulateand put in place strategies to strengthen the branches in the future.
- Monitor and coordinate the work units in the offices to send current information and reports to the relevant sections in the head office.
- Facilitate timely acquisition of regulatory infrastructure, human resource and budget to enhance the performance capacity of the branches and ensure proper utilization of resources.
- Design and implement and monitor operational systems and strategies that allow the branches to carry out the regulatory process in a consistent manner.
- Compilation and organization of available information on the activities of the branches.
- Ensure that the resources needed by the branch offices to carry out their responsibilities properly,
- Monitoring the problems faced by the branch offices in the process of operation, forward direction for solutions, provisioncapacitycapacity building trainings to improve their implementation capacity.
- Attending the meetings of the management committee on behalf of the branch offices, proposing solutions to the bottleneck problems and making decisions to be made so that the management decisions will reach branches in a timely manner.

- Expanding the best practices between the branch offices and the regions and making them learn from each other.
- Providing the necessary monitoring and support to the regional regulatory bodies where the branch offices are located so that they work in coordination and cooperation as well as provision of appropriate support.
- Provide financial and technical support so that branch offices support the capacity of regional regulatory bodies.
- Support and monitor the implementation of plans and activities between regions and branch offices.
- Study the gaps in regulatory coordination between the region and the region, between the branch office and the region, and provide solutions to be corrected in time and ensure the execution.