



**FHRSDIP Performance Indicator Reference
Sheet (PIRS)**

January 2024

Addis Ababa

1. Introduction

The government of Ethiopia has undertaken a number of political and socio-economic reform measures on the healthcare sector. Issuance of the national health and medicine policies, different health sector strategic plans and programs are the strategic milestones that have revealed the commitment of the government to provide quality health services to the Ethiopian people.

Since the re-engineering held at the health sector to result in to three wings, purchaser, service provider and regulatory, successive reforms have been taken place to ensure the effectiveness and efficiency of the health sector. Re-organization and arrangement of the health regulatory sector was one of the re-designing priorities while implementing the changes made in the health sector in 2008. However, the mandate load vested upon it made lose its focus on mote important regulatory products and processes and loose its sphere of control because of limited human and financial resources. Assessment has been carried out and thereby the food and medicine product regulation were decided to be re-organized. Accordingly, it led to ratification of proclamation number 1112/2019, which enabled the reform of health regulatory sector to product based (food and drug) regulation.

The medium term Food and Health Products Regulatory Sector development and investment plan which covers the period between 2016-2018 Ethiopian fiscal years (July 2023 – June 2026) has been developed. During this strategic period, the sector envisions a leading and excelled food and health products regulatory system. Even though, the regulatory sector is operating with strategic plan, it lacks appropriate national measurable indicators that help to measure the achievement of the sector. Recognizing this and the importance of measuring the performance of the sector for improvement, this document was developed.

Where performance is measured, performance improves. Where performance is measured and reported, the rate of improvement accelerates. To know the performance of Food and Health products regulatory sector, developing indicators is very important. Indicators are signals that reveal progress towards objectives; means of measuring what actually happens against what has been planned in terms of quantity, quality and timeliness. Indicators in health regulatory are variables or summaries of variables that show or indicate how a regulatory system is functioning. They are essential components of the monitoring and evaluation (M&E) systems in which they played roles in program implementation, management, monitoring and evaluation.

A total of 107 indicators are selected to monitor and evaluate the FHRSDIP. Outcome, output and input indicators are selected in a balanced way. Input indicators will help ensure that resources are properly mobilized, equitably distributed and efficiently utilized for ensuring quality and addressing inequalities. Output indicators will be used to measure utilization and coverage, and assess whether the services are provided to the intended target groups. Outcome and impact indicators have the advantage of being “integrative” (i.e., many different factors are “integrated” into the outcome/impact), reflecting the end result of interventions within and outside the regulatory sector.

Some of the indicators are those that have been used during HRSTP II and accepted as it was, some are modified and new indicators are also included. The indicators are selected based on national and international priority regulatory interventions and requirements. Most of the indicators measure an individual event while there are some indicators that are designed as composite. The period for data collection and analysis varies for each indicator, ranging from a monthly basis up to 3 years. Some indicators are analyzed on a monthly basis, others on a quarterly, annual, 2-3 years time period.

2. General and Specific Objectives

2.1. General objective

- The general objective of this document is to define the meaning and basic characteristics performance indicators and to enable regularly and systematically track progress of implementation of strategic and annual work plans of the regulatory sector.

2.2. Specific objectives

The Specific objectives are:-

- To make clarity what is being measured; how to collect the necessary raw data; and how to process the raw data to derive the indicator’s value.
- To ensure Consistency in data collection
- To ensure indicator data quality

2 . Performance Indicators Reference Sheet

Performance Indicator Reference Sheet (PIRS) is a working monitoring and evaluation document in a standard format that defines performance indicators explicitly and unambiguously so that the reader thoroughly understands what is being measured; knows exactly how to collect the necessary raw data; and knows precisely how to process the raw data to derive the indicator’s value. It also ensures data quality

and consistency. A PIRS is required for all indicators. The development of PIRS considers international and national documents to identify the regulatory sector specific demands and keep standard for comparability at national and international levels. The elements of PIRS include name of the indicator, precise definition, and unit of measure, disaggregated by rationale for the indicator, data source, and method of data collection, reporting frequency, baseline and target, DQA, and points for clarification. It is critical to understand the terms used to define the elements of PIRS:

1. **Indicator name:** A brief heading that captures the focus of the indicator. The full and complete name of the indicator must be specified.
2. **Indicator code:** the code given to the specific indicator. It is designed by combining the sequence number of the strategic direction and the indicator itself.
3. **Precise Definition:** A clear and concise description of the indicator.
4. **Interpretation:** Gives brief explanation /underlying principle(s) about the indicator, the purpose or rationale for the indicator to be included and its usefulness. Recommendations on how best to evaluate and apply the findings; e.g. outlining what it means if the indicator shows an increase or a decrease in a particular measure. Strengths and weaknesses. A brief summary of what the indicator does well and not so well. Challenges- Potential obstacles or problems that may have an impact on the use of an indicator or on the accuracy/validity of its findings as the case may be.
5. **Formula:** The logical and specific sequence of operations used to measure the indicator. This includes:
 - a. Numerator: The top number of a common fraction, which indicates the number of parts from the whole that are included in the calculation.
 - b. Denominator: The bottom number of a common fraction, which indicates the number of parts in the whole.
6. **Unit of measure:** Unit of measure (e.g., number, percent) must be indicated.
7. **Disaggregation:** The relevant subgroups that the collected data can be separated in order to understand and analyze the findings more precisely. Common subgroups include category of product, region, sex, age and risk population. Data source: records, annual reports, databases, surveys, registers, logbooks extra used to collect data.
8. **Data source:** It includes the originator of the indicator data; indicate the leading data source, as applicable.
9. **Data collection method:** The general approaches (e.g. surveys, records, models, estimates) used to collect data.
10. **Frequency collection and reporting:** The intervals at which data are collected that is consistent with the data collection methodology; e.g. quarterly, annually, bi-annually. The frequency of reporting is associated with communicating the data to external organizations and agencies, particularly the house of people's representatives and collaborating partners by the owner of the data.

General Objective 1: Protect the public from unsafe and poor-quality food

Indicator name	Prevalence of unsafe food available in the market
Indicator code	GO1- 01
Indicator type	Outcome
Precise definition	It is the proportion of unsafe food available in the market which is determined by collecting and testing food samples locally manufactured and/or imported by authorized food business operators via survey.
purpose/Interpretation	<p>The purpose of the measurement is to know the status of unsafe food available in the market and to take evidence based decision for the protection of public health. It also provides adequate scientific evidence on the status of food safety to the regulatory sector so as to strengthen mechanisms for preventing, detecting and responding to food safety hazards in timely and harmonized manner, to point out immediate actions /short term/, medium- and long-term interventions and to take appropriate measures along the food supply chain (farm to fork) together with other relevant stakeholders.</p> <p>High prevalence of unsafe food available in the market indicates that the public is at high burdens of foodborne diseases due to acute, sub-acute and chronic health risks raised from different food safety hazards, economic lose to the country due to disposal/rejection/refusal of contaminated foods, social dissatisfaction and may cause political instability.</p>
Formula (numerator/denominator)	<p>Numerator: Number of foods identified as unsafe during the survey period.</p> <p>Denominator: Total number of collected food products for testing</p> <p>Prevalence of unsafe food available in the market can be calculated as:</p>

	$Prevalence = \frac{\text{Number of foods identified as unsafe during the survey period}}{\text{Total number of collected food products for testing}} \times 100$
Unit of Measure	Percentage
Disaggregation	Product Category, product type, Region, food business operator type, ownership (public/private), country of origin (locally produced/imported).
Data source	Survey report
Data collection method	Survey Note: Detailed protocol should be prepared and conduct the survey based on the protocol.
Data Quality (verification)	Supervision, random checks of the collected samples at least 5% of the sample size. Confirmatory tests will be done. For details, please follow the protocol.
Frequency	Every three year
Baseline Value and targets	NA (Baseline) 15 (Target) [(2016 (25%), 2017 (20%), 2018 (15%)]
Point of clarity	<ul style="list-style-type: none"> ● Safe foods are food products which are fit for human consumption and don't contain any substance which are not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. ● For this survey food contaminants (physical, chemical and microbiological) like mycotoxin (aflatoxin), pesticide residues, antibiotic residues, pathogenic microorganisms as appropriate additional parameters will be considered to assess the prevalence of unsafe foods in the market

	<ul style="list-style-type: none"> • A protocol will be developed to decide on the survey sites, number of categories of products, representative samples, appropriate sampling techniques, types of tests carried out by QC laboratory, selection of food establishments (manufacturer, importer, wholesaler, distributor and retailer),
	<ul style="list-style-type: none"> •

General Objective 2: Safeguard the public from falsified, substandard and ineffective health related products

Indicator name	Percentage of substandard medicine in the market
Indicator code	GO2-1
Indicator type	Outcome
Precise definition	The percentage of substandard medicines detected in a territory of Ethiopia at a given time. It measures the degree of substandard medicines available in the market.
Purpose/Interpretation	The indicator shows the increase or decrease in the prevalence of substandard medicines. This indicates the status of the regulatory system. It is used to assess the outcomes of the regulatory functions, and the degree of availability of unsafe, poor quality, ineffective medicines in the market
Formula (Numerator/Denominator)	<p>Numerator: Number of medicines identified as substandard during the survey period. Denominator: Total number of surveyed tracer medicines.</p> <p>Prevalence of SF medicine can be calculated as:</p> <p>Prevalence = (number of samples identified as substandard)/(total number of samples collected)X100.</p>

Unit of Measure	Percentage
Disaggregation	Therapeutic Category, Region, facility type (manufacturer, importer, distributor and retail outlets), ownership (public/private), medicine type (brand vs generic), registration/authorization status (registered/authorized Vs unregistered/unauthorized), country of origin, dosage form
Data source	Survey
Data collection method	The data collection method will be by conducting a laboratory testing based survey of tracer medicines. A protocol needs to be developed for identifying tracer medicines and representative samples will be collected from randomly selected sites and outlets. Samples will be visually inspected and their registration status will be verified, and/or tested by QC laboratory.
Data Quality (Verification)	Supervision, random checks of collected samples at least 5% of the sample size. If there is doubt on the analysis result, a confirmatory test will be done.
Frequency	Every three years
Baseline Value and Targets	6.9% (Baseline) 5% (x% in the year of 2022/23 and 5% in the year of 2024/25, Target).
Point of clarity	Protocol containing detail procedures for tracer medicines selection, site selection, number of units to be sampled, sample testing, etc. should be prepared for conducting the survey.

Indicator name	Percentage of falsified medicine in the market
Indicator code	GO2 -2
Indicator type	Outcome
Precise definition	The percentage of falsified medicines detected in a territory of Ethiopia at a given time. It measures the degree of falsified medicines available in the market.
Purpose/Interpretation	This indicator is used to know the availability of falsified medicines in the market so as to take appropriate regulatory interventions for public protection. The increase in the prevalence of falsified medicines is an indication of a weak regulatory system and the public is at risk.
Formula (Numerator/Denominator)	<p>Numerator: Number of medicines identified as falsified during the survey period.</p> <p>Denominator: Total number of surveyed tracer medicines.</p> <p>Prevalence of falsified medicine can be calculated as:</p> <p>Prevalence = (number of samples identified as falsified)/(total number of samples collected)X100.</p>
Unit of Measure	Percentage
Disaggregation	Therapeutic Category, Region, facility type (manufacturer, importer, distributor and retail outlets), ownership (public/private), medicine type (brand, generic), registration/authorization status (registered/authorized, unregistered/unauthorized), country of origin, dosage form

Data source	Survey
Data collection method	The data collection method will be by conducting a laboratory testing based survey of tracer medicines. A protocol needs to be developed for identifying tracer medicines and representative samples will be collected from randomly selected sites and outlets. Samples will be visually inspected and their registration status will be verified, and/or tested by QC laboratory.
Data Quality (Verification)	Supervision, random checks of collected samples at least 5% of the sample size. If there is doubt on the analysis result, a confirmatory test will be done.
Frequency	Every Five years
Baseline Value and Targets	NA (Baseline) 5% (x% in the year of 2022/23 and 5% in the year of 2024/25, Target).
Point of clarity	Protocol containing detail procedures for tracer medicines selection, site selection, number of units to be sampled, sample testing, etc. should be prepared for conducting the survey
Indicator name	Prevalence of Substandard medical devices in the market
Indicator code	GO2 – 03
Indicator type	Outcome

Precise definition	The prevalence of substandard medical devices detected in a territory of Ethiopia at a given time. It measures the degree of problem of substandard medical devices available in the market.
purpose/Interpretation	This indicator is used to assess outcomes of the regulatory functions such as registration, inspection and laboratory testing; as well as the degree of problem of poor quality and ineffective medical devices available in the market. It enables the authority to take appropriate regulatory interventions for public protection. Increase in the prevalence of substandard medical devices is an indication of a weak regulatory system and the public is at risk.
Formula (numerator/denominator)	<p>Numerator: Number of tracer medical devices identified as Substandard during the survey period.</p> <p>Denominator: Total number of surveyed tracer medical devices</p> <p>Prevalence of substandard medical devices can be calculated as:</p> <p>Prevalence = (number of medical devices samples identified as substandard)/(total number of tracer medical devices samples included in the survey) X 100.</p>
Unit of Measure	Percentage
Disaggregation	Devices Category, Region, facility type, ownership (public/private), registration status, country of origin.
Data source	<p>The source of the data will be healthcare facilities (e.g. hospitals, Health centres, clinics), manufacturers, importers, distributors, drug retail outlets (e.g. pharmacies, drug shops, RDVs)</p> <p>Note: Protocol should be prepared and the survey should be conducted based on the protocol.</p>
Data collection method	The data collection method will be by conducting survey on selected tracer medical devices. Tracer medical devices will be identified and representative samples will be reviewed onsite or samples will

	<p>collect from randomly selected sites as per the protocol. Samples will be visually inspected and their registration status will be verified, and/or tested by QC laboratory. Please refer to the prepared protocol for sample collection.</p>
<p>Data Quality (verification)</p>	<p>Supervision, random checks of the collected samples at least 5% of the sample size. For tested devices, If the analysis result becomes suspicious, a confirmatory test will be done. For details, please follow the protocol.</p>
<p>Frequency</p>	<p>Every 3 years</p>
<p>Baseline Value and targets</p>	<p>Baseline : NA Target: 10</p>
<p>Point of clarity</p>	<p>Substandard medical devices (also called “out of specification”) are authorized medical devices that fail to meet either their quality standards or specification, or both. Whereas, falsified medical devices are that deliberately or fraudulently misrepresent their identity, composition or source. SF includes medical devices that are not registered or authorized for use by the Authority. The protocol should include how to select tracer medical devices, onsite information review, sample collection sites, outlets and representative samples of each.</p>

Indicator name	Percentage of falsified Medical Devices in the market
Indicator code	GO2-04
Indicator type	Outcome
Precise definition	The percentage of falsified medical devices detected in a territory of Ethiopia at a given time. It measures the degree of problem associated with the availability of falsified medical devices in the market.
purpose/Interpretation	This indicator is used to assess outcomes of the regulatory functions such as registration, inspections and port control. Availability of falsified medical devices in the market initiates the authority to take appropriate regulatory interventions for public protection. Increase in the prevalence of falsified medical devices is an indication of a weak regulatory system, especial port control.
Formula (numerator/denominator)	<p>Numerator: Number of tracer medical devices identified as Falsified during the survey period.</p> <p>Denominator: Total number of surveyed tracer medical devices</p> <p>Prevalence of falsified medical devices can be calculated as:</p> <p>Prevalence = (number of medical devices samples identified as falsified)/(total number of tracer medical devices samples included in the survey) X 100.</p>
Unit of Measure	Percentage
Disaggregation	Devices Category, Region, facility type, ownership (public/private), registration status,

	country of origin.
Data source	<p>The source of the data will be healthcare facilities (e.g. hospitals, Health centres, clinics), manufacturers, importers, distributors, drug retail outlets (e.g. pharmacies, drug shops, RDVs), street markets and Internet (if any).</p> <p>Note: Protocol should be prepared and conduct the survey based on the protocol.</p>
Data collection method	<p>The data collection method will be by conducting a survey on selected tracer medical devices by using mystery shoppers. Tracer medical devices will be identified and representative samples will be reviewed onsite or samples will collect from randomly selected sites as per the protocol. Samples will be visually inspected and their registration status and sameness of labeling information will be verified against the one provided at the time of marketing authorization.</p>
Data Quality (verification)	Supervision, random checks of the collected samples at least 5% of the sample size.
Frequency	Every three years
Baseline Value and targets	<p>Baseline :NA</p> <p>Target : 5%</p>
Point of clarity	<p>Falsified medical devices those that are deliberately or fraudulently misrepresent their identity, composition or source. Survey protocol that guides how to select tracer medical devices, onsite information review, sample collection sites, outlets and representative samples of each etc, should be developed.</p>

Indicator name	Percentage of retail outlets dispensing of prescription only medicines (POM) without prescription
Indicator code	GO2- 5
Indicator type	Outcome
Precise definition	It is the ratio of medicines retail outlets which are found dispensing POMs against the total medicine retail outlets surveyed.
Purpose / Interpretation	<p>This indicator assesses implementation of good dispensing practices by the medicine retail outlets and contribute to the rational use of medicine at a point of medicine dispensing. The presence of irrational medicines dispensing practices is not only breach of law but also affects public health and integrity of pharmacy practices. The higher the percentage of medicines retail outlets dispensing POM without prescription indicates irrational use of medicines and enhances risk of medication error and antimicrobial resistance (AMR).</p> <p>The ideal preferable state is zero, which is a bit difficult to attain now, require hard work as we are a bit far from that.</p>
Formula (numerator/denominator)	<p>Numerator: Number of medicines retail outlets found dispensing POM without prescription during survey period.</p> <p>Denominator: Total number of surveyed medicines retail outlets</p> <p>Percentage of medicines retail outlets dispensing POM without prescription can be calculated as:</p> $percentage = \frac{\# \text{ of medicine retail outlets dispensing POM without prescription}}{\text{Total number of medicine retail outlets included in the survey}} \times 100$
Unit of Measure	Percentage

Disaggregation	Medicines retail outlets Category (Pharmacy, drug shop, health facility pharmacy, rural drug vendor), Region, ownership (public/private)
Data source	<p>Data regarding the status of medicine retail outlets with respect to the Good Dispensing Practice will be collected by conducting surveys. Disguised verbal request of selected POMs, Observation of actual practice during the survey, retained prescription papers, dispensed medicines record log books (if any) and/or electronic databases of the randomly selected medicines retail outlets found in all regions and city administrations and other relevant information and practices will be used as source of data and reviewed.</p> <p>Note: Protocol for selection of specific area in a region, number and types of retail outlets, and tracer medicines should be developed & accompanied by a checklist for collecting information. The survey should be conducted in accordance with the protocol.</p>
Data collection method	<p>The data collection method will be by conducting a survey. Representative samples of medicines retail outlets operating in all regions and city administrations will be selected using random sampling technique. The dispensing practices of the selected medicine retail outlets included in the sample will be assessed using a validated/pretested data collection tool.</p> <p>The collected, filled tool will be reviewed for completeness and information from each site is thematized and evaluated as per the procedures of the protocol. Please refer to the prepared protocol for assessment of medicine retail outlets good dispensing practices.</p>
Data Quality (verification)	Supervision, random checks of the collected samples at least 5% of the sample size. Comparing the survey finding with other relevant national studies, rational use of medicines etc and compiled data obtained from the regular bi-annual and annual reports of inspection findings by regional regulatory bodies can be used to triangulate with the survey finding. For details, please follow the protocol.
Frequency	Every 3 years
Baseline Value and targets	51.6% (Baseline) Target: 10%.

Point of clarity	Medicine retail outlets include public and private pharmacy, drug shop, and health facility pharmacy. Better to exclude medicines for chronic illness as a reference because they usually ordered as refill.
-------------------------	---

General Objective 3: Protect the public from tobacco and alcohol related health risks

Indicator name	Prevalence of tobacco use
Indicator code	GO3- 1
Indicator type	Outcome
Precise definition	It is the percentage of tobacco use including the use of tobacco smoke products or use of smokeless tobacco products among the population within the study period.
purpose/Interpretation	The purpose of this indicator is to determine the prevalence of tobacco use by individuals to serve as input for determining the potential health risks due to tobacco smoking, second hand smokers and use of smokeless tobacco products in the country.
Formula (numerator/denominator)	<p>Numerator: Number: The number of individuals who smokes tobacco products or use smokeless tobacco products at least once in one year period. This includes passive smokers.</p> <p>Denominator: Total number population as per the study protocol and the survey period</p> <p>Prevalence of tobacco use can be calculated as: Prevalence = (The number of individuals who smokes tobacco products or use smokeless tobacco products at least once in one year period / (Total number population as per the study protocol and the survey period) X100</p>

Unit of Measure	Percentage
Disaggregation	Sex, age, region, marital status, religion, groups, type of products, urban/rural, smokers/passive smokers
Data source	Survey report
Data collection method	Review of survey report Note: Detailed protocol should be prepared during the survey period and conduct the survey according to the protocol.
Data Quality (verification)	Supervision during data collection, triangulate with previous published research data
Frequency	Every five years(GATS) and every 2 years(GYTS)
Baseline Value and targets	5% (base line) 3% (Target)
Point of clarity	
Indicator name	Prevalence of alcohol use
Indicator code	GO3- 2
Indicator type	Outcome
Precise definition	It is the percentage of alcohol use among the population within the study period.
purpose/Interpretation	The purpose of this indicator is to determine the prevalence of alcohol use by individuals to serve as input for determining the potential health risks due to alcohol in the country.

Formula (numerator/denominator)	<p>Numerator: Number: The number of individuals who drinks alcohol at least once in one year period.</p> <p>Denominator: Total number population as per the study protocol and the survey period</p> <p>Prevalence of alcohol use can be calculated as: Prevalence = (The number of individuals who drinks alcohol at least once in one year period / (Total number population as per the study protocol and the survey period) X100</p>
Unit of Measure	Percentage
Disaggregation	Sex, age, region, marital status, religion, groups, type of products, urban/rural, smokers/passive smokers
Data source	Survey report
Data collection method	Review of survey report Note: Detailed protocol should be prepared during the survey period and conduct the survey according to the protocol.
Data Quality (verification)	Supervision during data collection, triangulate with previous published research data
Frequency	Every five years
Baseline Value and targets	41% (base line) 39% (Target)
Point of clarity	
Indicator title	Percentage of good dispensing practice of NPS
Indicator code	GO3-3

Indicator type	Outcome
Precise definition	It is the practice that ensure an effective form of the correct narcotic and psychotropic substance is delivered to the right patient, in the correct dosage and quantity, with the clear instruction and in the package that maintains the potency of narcotic and psychotropic substance,
Purpose/Interpretation	This indicator aims to measure the extent of implementation of the prescription paper of Narcotic and Psychotropic substance contains the name of the prescriber and the institution's stamp; the prescription is original, and the writing or print on the paper does not contain an error; narcotic and psychotropic medicine is prescribed using narcotic and psychotropic medicine prescription paper respectively; no more than one type of narcotic and psychotropic medicine is not prescribed using one prescription paper; the prescription paper contains readable series number; and the issue date is within the past fifteen days.
Unit of measurement	Count
Formula (numerator/denominator)	It is the count of the number of prescription paper that fulfils of good dispensing practice of NPS. This can also be converted into percentage by dividing the number of prescription paper that fulfils of good dispensing practice of NPS to the total number of prescribed and dispensed NPS prescription papers in the fiscal year multiplied by 100.
Disaggregation	Private Vrs Governmental Health facilities, Regions, Zones
Data source	Survey, Copy of NPS Prescription papers, report of EFDA and Regional Regulatory Bodies (RRBs)
Data collection method	
Data Quality (verification)	Data collector training, Random checks of the reports by checking samples of NPS prescription papers

Frequency	1 years
Baseline Value and targets	56.3% to 80%

General Objective 4: Attain public confidence on food and health product regulation

Indicator name	Percentage of community satisfaction on the regulated products
Indicator code	GO4- 01
Indicator Type	Outcome
Precise definition	It is a percentage that measures the perception of the community on the regulated products.
purpose/Interpretation	Increased in the Percentage of community satisfaction shows the strength and efficiency of the regulatory sector and the public is more protected. Conversely, a lower result is an indication that the community is at some level of risk or poor performance that requires appropriate intervention.
Formula (numerator/denominator)	<p>Numerator: Number satisfied</p> <p>Denominator: Total Respondents</p> <p>Level of community satisfaction on the regulatory sector calculated as:</p> $CSAT = Satisfied \div Total\ included\ in\ the\ survey \times 100\%$ $CSAT = Total\ responses\ score\ given \div Total\ possible\ response\ scores \times 100\%$

	Where CSA - community satisfaction Level.
Unit of Measure	Percentage
Disaggregation	Product type (food, medicine, med. Device, cosmetics...), Region, demography,
Data source	Survey Report
Data collection method	Survey. Representative samples will be randomly selected from statistically selected households. Details will be indicated in the protocol for the purpose.
Data Quality (verification)	Supervision, random checks of the interviewed households. For details, please follow the protocol.
Frequency	Every five years
Baseline Value and targets	Base line: NA Target: 75%
Point of clarity	How to consider neutral responses in the Likert Scale.

	<p>Level of importance of each regulated product and difficulty of calculating the average to find the overall satisfaction.</p> <p>Cut off point = from literatures</p>
--	--

Indicator name	Public trust score
Indicator code	GO4- 2
Indicator type	Outcome
Precise definition	It is a score to measure Public trust on the food and health products regulatory sector which is determined by conducting survey
purpose/Interpretation	<p>It helps to measure and understand how the public perceive the food and Health products regulatory sector. Having the public trust is considered as indication of fair and effective functioning of the regulatory system to determine its competitiveness, and to the quality of the relationship that it has with the citizens. It also helps to indicate whether the systems in the FHRS work together. It measures a continuous variable (ranging from 0 through 4). Trust score “0” represents a complete distrust and “4” represents a complete trust. The 3 dimensions that measure trust are competence, integrity and reliability/dependability. These dimensions will be measured independently based on standard measurements to bring up the trust score.</p> <p>Cutoff point 70% (above and 75% score indicates that the public has trust on the regulatory system)</p>

	Likert scale (1-5))
Formula (numerator/denominator)	The average of summation of the scores in the three dimensions, competence, integrity and reliability Public Trust Score = [(weightC*competence + WeightI*integrity + WeightR*reliability) / (3)]
Unit of Measure	Number/score
Disaggregation	Age, sex, Income, educational status, region, urban/rural, Religion, Marital status, Occupation, types of products
Data source	Survey Report Note: Protocol should be prepared and conduct the survey based on the protocol.
Data collection method	Data will be collected from the community by following scientific procedures based on the protocol developed for this survey.

Data Quality (verification)	Piloting, Training for data collectors and supervisors, Supervision, random checks of the samples selected at least 5% of the sample size. For details, please follow the protocol.
Frequency	3 years
Baseline Value and targets	NA (Baseline) 4.5 (target)
Point of clarity	Trust is a person's belief that institutions will act consistently with their expectations of positive behaviour.

Indicator name	Transparency score
Indicator code	GO4- 3
Indicator type	Outcome
Precise definition	It is a score that measures the level of transparency of the regulatory functions undertaken by the EFDA and Regional regulatory bodies.
purpose/Interpretation	Having a higher transparency score indicates a presence of publicly available and easily accessible documents and is considered a sign of transparency and thus the existence of such documents reduces the vulnerability to corruption. On the other hand, a lower transparency score shows absence of transparency and tells that there are gaps in the systems that need to be filled in order to make them

	<p>more resistant to corruption. The average scores in each function will be calculated, and the functions average result will give the total transparency score, and vulnerability to corruption of the sector. It measures a continuous variable (ranging from 1 through 10). Transparency score “1” represents no transparency/highly vulnerable to corruption and “10” represents transparency is ensured/no vulnerability to corruption.</p> <p>Therefore, the purpose of this indicator is to assess the availability and accessibility of the key documents and procedures necessary to manage food and health products regulatory systems. In other words, it aims to assess whether transparency is ensured in the food and health products regulatory sector. ≥ 67, 33-66, < 33 (High, moderate and low)</p>
Formula (numerator/denominator)	<p>Transparency Score = Total Average score of regulatory functions (Registration, inspection....)</p> <p>Refer WHO guideline for measurement this indicator</p>
Unit of Measure	Number
Disaggregation	Regulatory Functions,
Data source	<p>Survey report</p> <p>Note: Protocol should be prepared and conduct the survey based on the protocol.</p>
Data collection method	Data will be collected from the customers by following scientific procedures based on the protocol developed for this survey.

Data Quality (verification)	Piloting, Training for data collectors and supervisors, Supervision, random checks of the samples selected at least 5% of the sample size. For details, please follow the protocol.
Frequency	Every 3 years
Baseline Value and targets	NA (Baseline) 9 (8, 9 target)
Point of clarity	<p>Regional and branch offices will cascade the study to their context</p> <p>Transparency means clearness, honesty and openness. Transparency is the principle that those affected by administrative decisions should be informed, and the duty of civil servants, managers and trustees to act visibly, predictably and understandably. Transparency thus encompasses access, relevance, quality and reliability, and describes the increased flow of timely and reliable information. Transparency enables institutions and the public to make informed political decisions, it improves the accountability of governments, and reduces the scope for corruption.</p> <p>It is widely agreed that transparency reduces the scope for corruption. Thus, the basic assumption is that the more transparent any system is, the less vulnerable to corruption it will be.</p>

Strategic Direction 1: Strengthen food safety regulation.

Indicator name	Number of market authorized food products
Indicator code	SD1-01
Indicator Type	output
Precise definition	It is the count of registered food products for use by the public within the fiscal year.
purpose/Interpretation	<p>The purpose of this indicator is to measure the number of registered food products by assuring quality and safety and made available for public use.</p> <p>The increase in the number of registered (both locally produced and imported) food products indicates that the public has access to safe and quality food products and ultimately ensures public protection from food borne diseases and health risks.</p>
Unit of measure	Count
Formula (numerator/denominator)	<p>Numerator: NA</p> <p>Denominator: NA</p> <p>It is the count of all registered food products within the fiscal year</p>

Disaggregation	Product Category, product type, product risk, Registration Vs Notification, country of origin,
Data Source	Performance report
Data collection method	Performance report review
Data quality (Verification)	Cross check the reported data with the eRIS registered food products
Frequency	Monthly, Quarterly, Biannually and annually
Baseline value and targets	Baseline= 6488 Target = 11490 (2630, 2830,3030)
Point of Clarity	The count of the number of registered food products includes notifications and it does not include re-registered products.

Indicator name	Local food facilities audit inspection coverage
-----------------------	--

Indicator code	SD1 -02
Precise Definition	It is a percentage of audited local food facilities against the total number of local food facilities in the fiscal year
purpose/Interpretation	Increasing coverage audit inspection at food facilities (manufacture, distributors, importer, exporter and retail outlets) provides scientific evidence about the status of food facilities implementing Internal quality management systems that include identification of potential hazards and implementation of preventive control to minimize or prevent food safety hazards. Besides, it leads the facilities to comply with the regulatory and statutory requirements.
Unit of measure	Percentage

<p>Formula (numerator/denominator)</p>	<p>Numerator: Number of audited local food facilities</p> <p>Denominator: Total number of licensed local food facilities</p> <p>It is calculated as the number of audited local food facilities to the total number of licensed local food facilities and multiplied by 100.</p> <p>Percentage of audited local food facilities = (Total number of audited local food facilities)/ (Total number of licenced local food facilities)*100</p>
<p>Disaggregation</p>	<p>Product Category/product type, type of food facility (manufacturer with categorized production capacity, importer, distributor), region</p>
<p>Data Source</p>	<ul style="list-style-type: none"> · EFDA report · RHRBs annual report, eRIS
<p>Data collection method</p>	<p>Document review:</p>

Data quality (Verification)	Regular supervision, random check sample of food facilities (manufacturer, importer, wholesaler and retailer), internal audit, triangulation the report with the report generated by the system/eris/
Frequency	Monthly, Quarterly, Biannually and annually
Baseline value and targets	Baseline = 87.3% Target = 100 (90, 95,100%)
Point of Clarity	Local food facilities audit inspection coverage includes food facilities self-audit/check report

Indicator name	Number of foreign on-site inspection conducted on selected food product manufacturing facilities
Indicator code	SD1-3
Definition	It is the number of foreign food manufacturing on-site inspections against food quality and safety requirements (GMP/HACCP/FSMS/FSSC...)
purpose/Interpretation	Increasing coverage of foreign onsite inspection on selected food products indicates that manufacturing facilities ensure availability of safe imported food products in the market.
Unit of measure	Count
Formula (numerator/denominator)	Numerator: NA Denominator: NA It is the count of all onsite inspected foreign food product manufacturers with in the fiscal year

Disaggregation	Product Category/product type, Country
Data Source	GMP inspection report
Data collection method	Performance report/Document review
Data quality (Verification)	Supervision, critical review of audit reports, feedbacks from inspected food manufacturers
Frequency	Quarterly, Biannually and annually
Baseline value and targets	Baseline = 2 Target =65(15,25 ,25)

Point of Clarity	Foreign on-site inspection is conducted at manufacturing facilities on selected food products for ensuring that products are consistently produced and controlled according to the food safety and quality standards.
-------------------------	---

Indicator name	Coverage of food facilities implementing GMP/HACCP/FSMS requirements
Indicator code	SD1 -4
Definition	It is coverage of food facilities implementing GMP/HACCP/FSMS requirements against the total number of licensed food facilities.
purpose/Interpretation	Implementation of GMP/HACCP/FSMS requirements by food manufacturing facilities helps to minimize the risk of food safety hazards during processing, storage, transportation and distribution of safe food in the market, build confidence of consumers on food safety and also encourages the manufacturers, importers, wholesalers and retailers to be competent in the market.

Unit of measure	Percentage
Formula (numerator/denominator)	<p>Numerator: Number of food facilities which implemented GMP/HACCP/FSMS requirements</p> <p>Denominator: Number of licensed food facilities</p> <p>It is calculated as the number of food facilities who implement an GMP/HACCP/FSMS requirements Number of licensed food facilities and multiplied by 100.</p>
Disaggregation	Product Category/product type, type of food facility (manufacturer with categorized production capacity, importer, distributor and retailer), region
Data Source	Performance Report
Data collection method	Performance report review/Document review:

Data quality (Verification)	Regular supervision, random check samples of facilities implementing IQMS
Frequency	Quarterly, biannually and annually
Baseline value and targets	Baseline = 35 Targets = 70 (40, 45, 50,)
Point of Clarity	GMP/HACCP/FSMS requirements implemented by food facilities helps the food manufacturing facilities to meet the safety and quality requirements and improve its effectiveness and efficiency on a continuous basis.
Indicator name	Coverage of street vendor that implemented GHP
Indicator code	SD 1 -5

Indicator Type	output
Precise definition	It is the coverage of street food vendors implementing Good Hygiene Practice/GHP/ against available and registered food handlers in street food vending.
purpose/Interpretation	<p>This indicator is used to determine the coverage of street food handlers implementing Good Hygienic Practices by assessing and evaluating their status</p> <p>Implementation of Good Hygienic Practice by street food handlers has a direct impact on the food product safety and quality readily available for consumers. Therefore, assessing and evaluating the implementation of good hygienic practices by street food vendors ensures the food product quality and safety of the food marketed in the street.</p>
Unit of measure	Percentage

Formula (numerator/denominator)	<p>Numerator: Number of food handlers implemented GHP</p> <p>Denominator: Total number of food handlers available and registered street food vendors</p> <p>Coverage of Street food vendor's implemented GHP = (Total number of Street food vendors implemented GHP)/(Total number of food handlers available and registered *100)</p>
Disaggregation	<p>Product category/type, region, food business operator type</p>
Data Source	<p>RRBs report</p>
Data collection method	<p>RRBs report review</p>
Data quality (Verification)	<p>Review RRBs report, review complaint handling related to street food vending, random checks street food handlers' hygienic status and product safety and quality.</p>

Frequency	Quarterly, Biannually and annually
Baseline value and targets	Baseline = NA Targets = 50 (10,20, 20,)
Point of Clarity	Implementation of GHP by street food venders is that the food handlers have a working cloth with head cover and having a certificate for their health status that they are free from food related communicable diseases and also implementing a proper food preparation and service which protects food contamination.
Indicator name	Increase the coverage of mass catering service that implemented GHP & GCP
Indicator code	SD 1-6
Indicator Type	output

<p>Precise definition</p>	<p>It is the percentage of mass catering establishments (hotels, motels, restaurant, bakery and pastry and related food institutions) implementing Good Hygienic and good catering practices (GHP and GCP) against licensed mass catering service providers.</p>
<p>purpose/Interpretation</p>	<p>This indicator is used to measure the status of safety and quality of the product available in the mass catering establishments by conducting routine inspections to assure that the establishments comply with the set Good Hygienic Practices and Good Catering Practices set by the authority. Ensuring the implementation of GHP and GCP in mass-catering establishments guarantee the accessibility of safe food to the public.</p>
<p>Unit of measure</p>	<p>Percentage</p>
<p>Formula (numerator/denominator)</p>	<p>Numerator: Number of mass-catering establishments inspected and implemented GHP and GCP Denominator: Total number of licensed and registered mass-catering establishments</p> <p>Coverage of mass-catering establishments inspected and implemented GHP and GCP = (Total number of mass-catering establishments implemented GHP and GCP)/(Total number of mass-catering establishments licensed and registered)*100</p>

Disaggregation	Product category/ type, region, food business operator type
Data Source	RRBs report
Data collection method	RRBs report review
Data quality (Verification)	Supervision, review complaint handling related to mass-catering establishments, random checks mass-catering establishments and product safety and quality.
Frequency	Quarterly, Biannually and annually
Baseline value and targets	Baseline = NA Targets = 50 (10,20, 20)

Point of Clarity	Implementation of GHP and GCP by mass-catering establishments is that food handler with required personal hygiene and also the facilities fulfilling the standard of catering practices. This assists that establishments provide safe food to the consumers.
-------------------------	---

Indicator name	Number of food product types tested via PMS laboratory
Indicator code	SD1- 7
Indicator type	Output
Precise definition	It is the number of food product types tested via PMS to assure the quality and safety of food products which are manufactured, marketed or imported by authorized food business operators via planned post market surveillance.

<p>purpose/Interpretation</p>	<p>Increased number of food product post market assessment/survey followed by interventions shows the quality and safety status of PMS candidate food types in the market.</p> <p>Avail relevant information on the PMS shows how effective the overall regulatory activities are performed along the supply chain.</p> <p>As well the indicator provides important and tangible scientific data for the authority to undertake short-, medium- and long-term interventions which could be a recall as immediate action, consultative meeting among food business operators, stakeholders, policy makers as medium- and long-term interventions and for continual improvement of food business operators in meeting regulatory and statutory requirements.</p>
<p>Formula (numerator/denominator)</p>	<p>The summation of food product types tested via PMS with in the fiscal year</p>
<p>Unit of Measure</p>	<p>Count</p>
<p>Disaggregation</p>	<p>Product category, food safety parameters, region, food business operator type</p>

Data source	laboratory test result reports
Data collection method	PMS reports review. For details, please follow the protocol.
Data Quality (verification)	Supervision, exhibits (photo, video and others), random checks of the collected samples at least 5% of the sample size, Internal audit and review of laboratory analyst notebook and inspectors' notes. Confirmatory tests will be done. For details, please follow the protocol.
Frequency	Quarterly, biannually and annually
Baseline Value and targets	Baseline = 48 Target = 60 (52, 56, 60,)
Point of clarity	<ul style="list-style-type: none"> Food product types covered under post market surveillance are those which are produced, manufactured/imported and distributed in the market by authorized food business operators
Indicator name	Number of food product types for consignment laboratory tests

Indicator code	SD1- 8
Indicator type	Output
Precise definition	It is the number of food product types covered via planned consignment laboratory tests by taking food samples imported at port of entry on a regular basis.
purpose/Interpretation	<p>Increased number of imported food products covered under planned consignment laboratory analysis shows the quality and safety status of imported food products ensures availability of safe food in the market and builds consumer confidence.</p> <p>The indicator provides important and tangible scientific data for the regulatory sector to undertake short-, medium- and long-term interventions. Besides, conformance of imported food products against national and/or international standards shows reputation of suppliers, importers and regulatory functions.</p>
Formula (numerator/denominator)	The summation of food product types tested via planned consignment laboratory with in the fiscal year
Unit of Measure	Count

Disaggregation	Product category, food safety critical parameters, country of origins, manufacturers
Data source	laboratory test result reports
Data collection method	Food consignment test reports review.
Data Quality (verification)	Supervision (planned and sudden), conduct QC laboratories second party audit for outsourced samples, confirmatory tests. For details, please follow the protocol.
Frequency	Monthly, quarterly, biannually and annually
Baseline Value and targets	Baseline = 43 Target = 60 (50, 55, 60)
Point of clarity	Food product types covered under planned food consignment laboratory testing are those which are imported by authorized food business operators

Strategic direction: 2 Strengthen detection, prevention, and response to food adulteration and illegal food products

Indicator name	Prevalence of adulterated food available in the market
Indicator code	SD-2 - 1
Indicator type	Outcome
Precise definition	Is the assessment that takes place in food products that are mixed with different food grade products and foreign materials (like red soil, bricks,) that are not food grade.
purpose/Interpretation	The purpose of the assessment is to know the coverage of the adulterated foods, to differentiate most types of foods that are exposed for adulteration, to find spot areas in which this adulteration is abundant for each food product, to take short term and long-term measures/interventions based on the prevalence rate.

Formula (numerator/denominator)	<p>Numerator: Number of food products that are tested in the laboratory</p> <p>Denominator: Total number of food products which are suspected to be adulterated during survey time.</p> <p>Prevalence of adulterated food available in the market</p> <p>Prevalence = (Number of food products that are tested in the laboratory)/ (Total number of food products suspected to be adulterated during survey time) * 100</p> <p>.</p>
Unit of Measure	<p>Percentage</p>
Disaggregation	<p>Product Category, product type, region, compliance status.</p>
Data source	<p>Survey and laboratory report</p>
Data collection method	<p>By doing Survey and test laboratory</p>
Data Quality (verification)	<p>Supervision, random checks of the collected samples Confirmatory tests will be done in the laboratory, implementing quality management parameters (intra laboratory comparison, quality control chart, CRM, equipment verification like balance and pH meter) and so on.</p>
Frequency	<p>Every three year</p>

Baseline Value and targets	NA (Baseline) 24 (Target)
-----------------------------------	------------------------------

<p>Point of clarity</p>	<ul style="list-style-type: none"> ● Food adulteration is the act of intentionally reducing the quality of food offered for sale either by the mixture or substitution of inferior substance or by the removal of some valuable ingredient. ● The survey for adulterated food will be conducted on food products already known to be adulterated and potential candidates for adulteration and the interpretation of the survey finding should not be confused with all food products available on the market. <p>The source of the data will be collected from selected food establishments (wholesaler, distributor and retailer), intelligence led surveillance and operation, open markets (exhibitions/expo/street markets), regional regulatory authorities, laboratory test result reports, federal & local ministry of trade and industry, task force report, i-alert, free call of 8482, social media, consumer response, literature.</p> <ul style="list-style-type: none"> ● Interview of food handlers and consumers based on the survey checklist. ● Conduct intelligence led surveillance and operation ● Market assessment base on the Disaggregation and the data will be analysed using scientific data analysis methods ● Representative samples will be selected using appropriate sampling techniques from selected food establishments (wholesaler, distributor and retailer), open markets (exhibitions/expo/street markets). <p>The samples will be tested by QC laboratory. Information on the overt versus covert nature of the sample collection would also need to be made available. Please refer to the prepared protocol for sample collection.</p> <ul style="list-style-type: none"> ● Samples that are suspected for adulteration and tested by the laboratory include flour and flour products, butter, pepper, honey and milk.

Indicator name	Number of illegal food products available in the market
Indicator code	SD-2 - 2
Indicator type	Outcome
Precise definition	Is the measurement that takes place in food products that are available in the market without registering and having market authorization
purpose/Interpretation	The purpose of the assessment is to know the coverage of illegal foods throughout the country, to know which type of products are found illegal at large portion, to intervene and to get the participants on illegal foods in line with the correct path that means to be registered and take market authorization.
Formula (numerator/denominator)	Count
Unit of Measure	Number
Disaggregation	Product Category, product type, region, country of origin, compliance status.
Data source	Survey and laboratory report

Data collection method	By doing Survey and test laboratory
Data Quality (verification)	Supervision, Market Assessment
Frequency	Every three year
Baseline Value and targets	91 Baseline 36 target
Point of clarity	<ul style="list-style-type: none"> ● Illegal foods are food products that are found in the market without permission or without getting market authorization from the regulatory authority. ● The survey will be conducted specially to differentiate prevalence of the illegal foods and differentiate areas which can we found the food products.

Indicator name	Number of risk-based intelligence led food surveillance operation conducted and take administrative and/or legal measure
Indicator code	SD2-3

Indicator Type	output
Precise definition	It is the number of operations conducted on risk-based food products through intelligence led surveillance. It needs to collect and evaluate information for the purpose of investigating and taking regulatory and legal action on illegal food business operators and products.
purpose/Interpretation	<p>The purpose of this indicator is to measure the intelligence led and risk-based operations as a proactive response on illegal food trade practices and products. It enables regulators to identify and understand criminal groups operating in their areas.</p> <p>Performing intelligence lead operations contribute to minimize the burden of adulterated, misbranded, and substandard food products distributed in the market and also to ensure enforcement conducted is evidence-based.</p>
Unit of measure	Count
Formula (numerator/denominator)	The summation of operations conducted on risk-based food products through intelligence led surveillance within the fiscal year.

Disaggregation	Product category, product risk, region, food business operator type
Data source	Performance report
Data collection method	Performance report review
Data quality (Verification)	validation of surveillance report and supervision
Frequency	Bi-annually and annually
Baseline value and targets	Baseline = 4 Targets = 10 (6,8,10)
Point of Clarity	An intelligence lead operation is conducted in collaboration with different stakeholders including but not limited to law enforcement bodies federal and/or regional police, RRBs and others to take administrative and legal action on illegal food business operators and products to minimize availability of adulterated, misbranded and substandard food products in the market.

Indicator name	Number of risk-based market assessments and take administrative and/or legal measure
Indicator code	SD 2- 4
Indicator Type	output
Precise definition	It is the number of risk-based market assessments conducted on selected products to assess legal status of food products.
purpose/Interpretation	This indicator is important to know the legal compliance status of food products in the market, traceability of the product, encourage legal food business operators, get awareness of the public about illegal food products, and build consumer confidence in total to minimize the burden of food borne diseases.
Unit of measure	Count

Formula (numerator/denominator)	The summation of risk-based market assessments conducted within the fiscal year.
Disaggregation	Product category, region, cities, food business operator types
Data Source	Performance report
Data collection method	Performance report review
Data quality (Verification)	Supervision, confirmatory test, critical review of whole assessment process
Frequency	monthly, quarterly, biannually and annually
Baseline value and targets	Baseline = 51 Targets = 72 (58, 65,72)

Point of Clarity

Risk based market assessment is conducted on the selected food products available in the market in which inspectors will assess the market once in a month and come up with scientific information, findings, defects, and non-compliance helpful to make appropriate interventions.

Strategic direction 3: Improve regulation of safety, efficacy, quality and proper use of medicines

Indicator name	Number of registered medicines
Indicator code	SD3-1
Indicator type	Outcome
Precise definition	The count of medicines registered by the Authority in a year. This will include medicines approved by emergency use authorization (EUA) and conditional approval.
purpose/Interpretation	The increase in the number of registered medicines is an indication of access to safe, effective and quality assured medicines for the needs. The Authority may use different approaches to marketing authorization of medicines including full assessment, fast track, SRA, low-risk, conditional approval, EUA, WHO collaborative procedure, and other approaches. Fewer number of registered medicines may result in shortage of medicines in the market and lead the public to seek for other sources such as illegal markets. This indicator measures the effectiveness of the medicine registration and marketing authorization process of the Authority.
Formula (numerator/denominator)	The total count of valid registered medicines.
Unit of Measure	count
Disaggregation	Therapeutic category (antimalaria, ant TB, antibiotics, ARV etc), product type (vaccine, new molecule, generic), application type (Full assessment, SRA, low risk, EUA, conditional approval etc.), country of origin.
Data source	eRIS database
Data collection method	Performance review

Data (verification)	Quality	Supervision. Repeat counting of medicines registered by assigning another expert. If the review result becomes suspicious, a confirmatory counting of medicines registered will be done by repeating the extraction of data from eRIS and other medicine registry logbooks using other experts.
Frequency		Quarterly
Baseline Value and targets		(3644) (Baseline) Target - 7444 (4844, 6144, 7444: Annual Target)
Point of clarity		The number of registered medicines will not include approved variations.

Indicator name	Approval of medicine with further request to MA in respective fiscal year
Indicator code	SD3-2
Indicator type	Output
Precise definition	The percentage of approved further requests from the total further requests generated in a year. This includes all further requests of all type of applications submitted to the authority.
purpose/Interpretation	The increase in the percentage of approval of further requests in a given budget year may increase the availability of medicines in the country. This indicator measures the effectiveness of the medicine marketing authorization process of the Authority.
Formula (numerator/denominator)	<p>Numerator: total number of approved further requests in year.</p> <p>Denominator: Total number of further requests generated in a year.</p> <p>Percentage approval of further requests released in a year can be calculated as:</p>

	Percentage = (total number of approved further requests in year/total number of furtherers generated in a year)X100
Unit of Measure	percentage
Disaggregation	Therapeutic category (antimalaria, ant TB, antibiotics, ARV etc), product type (vaccine, new molecule, generic), application type (Full assessment, SRA, low risk, EUA, conditional approval etc.), country of origin.
Data source	eRIS database
Data collection method	Performance review
Data Quality (verification)	Supervision. Repeat counting of approved further requests in a year. If the counting becomes suspicious, a confirmatory counting of approved furtherers and the total number of furtherers released will be done by repeating the extraction of data from eRIS and other registry logbooks available using other experts.
Frequency	Annually
Baseline Value and targets	(60%) (Baseline) Target – 60% (60%, 60%, 60%: Annual Target)
Point of clarity	The number of furtherers will include all type of applications including renewal and variations.

Indicator name	Percentage of public assessment reports of registered medicines
Indicator code	SD3-3
Indicator type	Output

Precise definition	It is the percentage of public assessment reports of registered medicines released from the total number of medicines registered in year.
purpose/Interpretation	This indicator measures the effectiveness of the authority on releasing public assessment. High number of public assessment report indicates better access to information on the decision of registered medicines.
Formula (numerator/denominator)	<p>Numerator: total number of public assessment report of registered medicines released in year.</p> <p>Denominator: total number of registered medicines in a year.</p> <p>Percentage public assessment report of registered medicines released in a year can be calculated as:</p> <p>Percentage = (total number of public assessment report release in year/total number of medicines registered in a year)X100</p>
Unit of Measure	count
Disaggregation	Therapeutic category (antimalaria, ant TB, antibiotics, ARV etc), product type (vaccine, new molecule, generic), application type (Full assessment, SRA, low risk, EUA, conditional approval etc.), country of origin.
Data source	eRIS database
Data collection method	Performance review
Data Quality (verification)	Repeat counting of registered medicines in a year from eRIS and other data available by assigning another expert.

Frequency	Annual
Baseline Value and targets	(80%) (Baseline) Target – 80% (80%, 80%, 80%: Annual Target)
Point of clarity	Public assessment reports of registered medicines will be for new applications

Indicator name	Number of registered traditional medicines
Indicator code	SD3-4
Indicator type	Output
Precise definition	It is the total count of traditional medicines registered by the Authority in a year.
purpose/Interpretation	This indicator measures the availability of registered traditional medicines in the market. It also measures the efficiency of traditional medicine marketing authorization process of the Authority. The increase in the number of registered traditional medicines is an indication of access to safe and effective traditional medicines to the public.
Formula (numerator/denominator)	The total count of registered traditional medicines per year.
Unit of Measure	count
Disaggregation	Product source (botanic/herbal, animal, minerals, mixture etc), therapeutic category, region (example Amhara, Tigrai, Oromia).
Data source	Traditional medicine registry logbooks and other databases.
Data collection method	Performance review
Data Quality (verification)	Repeat counting of traditional medicines registered by assigning another expert, If the result of the count becomes suspicious.
Frequency	Annual

Baseline Value and targets	0 (Baseline) 10 (3, 6, 10: Annual Target)
Point of clarity	<p>The registered traditional medicine will be collected quarterly. The number of traditional medicines registered will be counted in registry log books and other databases every quarter. The sum of quarter's performance of a year will be used for the total number of registered traditional medicines within a year.</p> <p>Despite the registration requirement may varies, Class II, Class III and class IV traditional medicines (based on WHO classification system) are subject to the Authority registration process.</p>

Indicator name	Percentage of medicines tested through PMS
Indicator code	SD3 - 5
Indicator type	Output
Precise definition	The percentage of medicines tested through PMS scheme from the total number of medicines available in the market. Samples of medicines should be collected from importers, wholesalers, pharmacies, drug shops, rural drug vendors, health facilities, and informal markets.
Purpose/Interpretation	<p>This indicator measures the compliance of manufacturers, importers, distributors, and drug retail outlets with the requirements of GMP, GSP and GDP as well as effectiveness of both premarket and post market regulatory activities.</p> <p>Increasing the percentage of PMS medicine samples tested improves public protection from poor</p>

	<p>quality, unsafe and ineffective medicines possibly resulting from deterioration of the product as a result of manufacturing defects or failure to implement GSP and GDP. It provides crucial information to the authority regarding the prompt actions (product recall and disposal) that needs to be taken to ensure public protection and to ensure that all manufacturers (domestic & overseas) take all the required corrective actions and notify the authority about the effectiveness of the actions taken before the next shipment or distribution of medicines for market (for domestic manufacturers) as long term intervention. In addition it may suggest the need to strengthen port control and coordination with other stakeholders to minimize availability of medicines in the informal market.</p>
<p>Formula (numerator/denominator)</p>	<p>Numerator: Number of medicines tested through PMS scheme with in the study time frame</p> <p>Denominator: Total number of medicines marketed in the country in the five years period.</p> <p>Percentage of medicines tested through PMS can be calculated as:</p> <p>Percentage = (number of medicines tested through PMS)/(total number of medicines in the market during the post market survey period) X 100</p>
<p>Unit of Measure</p>	<p>Percentage</p>
<p>Disaggregation</p>	<p>Product category, registration status, country of origin, region/sample selection site, test status (fail, pass),</p>
<p>Data source</p>	<p>Performance reports</p>
<p>Data collection method</p>	<p>Performance reports review.</p>

Data Quality (verification)	Supervision during sample collection, random checks on the number and types of samples collected from the market (trace back to the source). If the analysis result becomes doubtful, a confirmatory test will be done. For details, please follow the PMS protocol.
Frequency	Quarter
Baseline Value and targets	22 (Baseline) 55 (45,50,55: Target)
Point of clarity	The PMS scheme includes all medicines (both locally manufactured and imported) marketed in the country and candidate medicines should be identified and listed at the beginning of every new year for inclusion in the list of medicines for PMS testing. All medicines marketed in Ethiopia should be included in the PMS testing scheme at least once in five years (during its registration certificate or authorization validity period), The number of each product to be collected, dosage forms, strengths & related issues, sentinel sites & outlets selection, frequency of sampling and testing, sample size per product, and number of batches of a product to be tested in a year should be determined based on the procedures indicated in the protocol.
Indicator name	Inspection coverage of medicine importers and wholesalers
Indicator code	SD3-6
Indicator type	Output
Precise definition	It is the percentage of inspected medicine importers and wholesalers to the total number of licensed medicine importers and wholesalers in the country. The inspection included pre-licensing and post licensing inspections. The inspection include the remote inspection.

Purpose/Interpretation	This indicator is used to assess the inspection coverage of medicine importers and wholesalers in a given year from the total licensed medicine importers and wholesalers available in the country. The post license inspection is conducted on medicine importer and wholesaler at least two rounds per annum for licensed medicine importers and wholesalers. However, the time interval of inspection rounds may be decided based on the status of the institutions. The purpose is to ensure legality of importation, distribution, wholesaling and dispensing operations. The higher the percentage of medicine importers and wholesalers inspected, the better the regulatory performance and the more available safe, quality and efficacious medicines in the market.
Unit of measurement	Percent (%)
Formula (numerator/denominator)	<p>Numerator: The number of inspected medicine importers and wholesalers</p> <p>Denominator: The total number of licensed medicine importers and wholesalers</p> <p>Percentage of medicines inspection coverage can be calculated as: % of inspection coverage = (Number of inspected medicine importers and wholesalers /Total number of licensed medicine importers and wholesalers in the country) x100</p>
Disaggregation	Region, type of medicine importers and wholesalers, type of inspection
Data source	Performance Reports from EFDA and EFDA branch offices
Data collection method	Data will be collected by review of performance reports of EFDA and r EFDA branch offices.
Data Quality (verification)	Supervision and random checks of inspected importers and wholesalers. Reconcile the reports with data available in the electronic regulatory information system (eRIS).

Frequency	Yearly
Baseline Value and targets	52.6% (Baseline) 100% (Target)
Point of Clarity	The frequency of inspection for one facility should be set by the Authority and it will be considered in the measurement of this indicator. For example: if an importer is expected to be inspected twice a year and inspected once a year, half point (0.5) will be considered in the numerator for calculation of the percentage of inspection coverage.
Indicator name	Inspection coverage of medicine retail outlet
Indicator code	SD3- 7
Indicator type	Output
Precise definition	It is the percentage of inspected medicine retail outlets to the total number of licensed medicine retail outlets in the country. The inspection included pre-licensing and post licensing inspections.
Purpose/Interpretation	This indicator is used to assess the inspection coverage of medicine retail outlets in a given year from the total licensed medicine retail outlets available in the country. The post license inspection is conducted for an establishment at least two rounds per annum for licensed medicine retail outlets. However, the time interval of inspection rounds may be decided based on the status of the institutions. The purpose is to ensure legality of distribution and dispensing operations. The higher the percentage of medicine retail outlets inspected, the better the regulatory performance and the more available safe, quality and efficacious medicines in the market.
Unit of measurement	Percent (%)

Formula (numerator/denominator)	Numerator: The number of inspected medicine retail outlets Denominator: The total number of licensed medicine retail outlets Percentage of medicines inspection coverage can be calculated as: % of inspection coverage = (Number of inspected medicine retail outlets/Total number of licensed medicine retail outlets in the country) x100
Disaggregation	Region or city administrations, type of inspection
Data source	Performance Reports from Regional Regulatory Bodies (RRBs)
Data collection method	Data will be collected by review of performance reports of regional regulatory bodies.
Data Quality (verification)	Supervision and random checks of inspected. Reconcile the reports with data available in the electronic regulatory information system (eRIS).
Frequency	Yearly
Baseline Value and targets	84% (Baseline) 100% (100%, 100%, 100%)
Point of Clarity	The frequency of inspection for one facility should be set by the respective regional regulatory body of the region and it will be considered in the measurement of this indicator. For example: if an medicine retail outlet is expected to be inspected twice a year and inspected once a year, half point (0.5) will be considered in the numerator for calculation of the percentage of inspection coverage.
Indicator name	Percentage of medicine manufacturing facilities inspected against the applied for inspection per

	year
Indicator code	SD3-8
Indicator type	Output
Precise definition	It is the percentage of medicine manufacturers inspected per year against the applied manufacturers for GMP inspection. This includes manufacturers granted with GMP inspection waiver certificate or these manufacturers inspected remotely.
Purpose/Interpretation	This indicator is used to calculate the percentage of medicines manufacturers inspected to evaluate their compliance level with the national GMP requirements against the total numbers of applied manufacturing sites for inspection. The inspection of manufacturers includes both new applicants and manufacturers which were already granted GMP certificate but needs re-inspection due to the validity period of their GMP certificates. In addition, manufacturers granted GMP inspection waiver or remotely inspected manufacturers will be included in the calculation. This helps the authority to ensure that all new manufacturers intending to register their products in Ethiopian meet the minimum requirements of GMP and the previously authorized manufacturers have maintained or improved their GMP compliance with the national and/or international requirements. This also help the Authority to evaluate its responding capacity to the needs of manufacturers for GMP inspection.
Unit of measurement	Percentage (%)
Formula (numerator/denominator)	<p>Numerator: Total numbers of manufacturers inspected (i.e. physically and remotely) and issued waiver of GMP inspection per year</p> <p>Denominator: Total numbers of manufacturers applied for inspection inspected (i.e. physically and remotely) and waiver per year</p>

	<p>Percentage of Percentage of medicine manufacturing facilities inspected against the applied for inspection per year is calculated as:</p> $\% \text{ of medicine manufacturers inspected} = \frac{\text{Total numbers of manufacturers inspected (i.e. physically and remotely) and issued waiver of GMP inspection per year}}{\text{Total numbers of manufacturers applied for inspection inspected (i.e. physically and remotely) and waiver per year}} \times 100$
Disaggregation	Country of origin, compliance status, new vs renewal
Data source	Performance reports, data available in eRIS
Data collection method	Review of the performance report
Data Quality (verification)	Random checks of the reports of GMP inspections. Reconcile the MMIELEO reports with the data available in eRIS.
Frequency	Annual
Baseline Value and targets	46% (Baseline) 85% (55%, 65%, 85%)
Point of Clarity	
Indicator name	Types of medicines consignment tested
Indicator code	SD3 –9
Indicator type	Output

Precise definition	The types of medicines-tested by taking samples of imported medicines at the ports of entry or samples taken from locally manufactured medicines prior to distribution to the market.
purpose/Interpretation	The increase in the types of medicines tested before entering to the market ensures public protection from substandard medicines and provides precautionary information to the Authority to take immediate and appropriate measures (rejection of the shipment, disposal of the product, etc) and to ensure that all manufacturers (both domestic and overseas) take all the required corrective actions and notify the Authority about the effectiveness of the actions taken before the next shipment or distribution of medicines for market. Therefore, this indicator may be used to assess outcomes of the premarket regulatory activities (GMP inspection, and dossier evaluation & registration) and public protection capability against any substandard medicine.
Formula (numerator/denominator)	Types of medicines tested before distribution to the market
Unit of Measure	Count
Disaggregation	Product category, domestic vs overseas manufacturers, country of origin, compliance status (pass/fail)
Data source	Type of medicines made ready for distribution to the market by the local manufacturers can be found from Medicine Manufacturer Inspection and Enforcement Lead Executive Office and types of medicine consignments should be found from Entry and Exit Products Inspection Lead Executive Office records while the types of medicine tested should be obtained from Medicine Quality Control Lead Executive Office.
Data collection method	Data on the types of medicines to be locally manufactured, imported, tested prior to distribution to the market should be collected from the annual performance reports of the Medicine Manufacturer Inspection and Enforcement Lead Executive Office, Entry and Exit Products Inspection Lead

	Executive Office and Medicine Quality Control Lead Executive Office respectively. If there are any outsourced consignments testing, the data should consider the number of outsourced tests.
Data Quality (verification)	Annual performance audit and random checks of the types of medicine consignments inspected & released to the market, and number of types of local products distributed to the market. If the analysis result becomes doubtful, a confirmatory test will be done.
Frequency	Annually
Baseline Value and targets	79 (Baseline) 100 target (85,90,100)
Point of clarity	A medicine product means a product that is given a distinct MA or authorization to be marketed in Ethiopia and one shipment may include one or more medicine products ready for distribution to the market. A protocol should be developed to define the number of product type to be sampled from a given consignment, sample size per product, number of batches of a product and frequencies of sampling the same product in a year.

Number of ADR Reports received per year

Indicator name	Number of ADR reports received as per WHO standards
Indicator code	SD3-10
Indicator type	Output

Precise definition	The number of ADR reports received by EFDA in a year.
purpose/Interpretation	The purpose of this indicator to measure the strength/ effectiveness of medicines safety monitoring system. Increase in the number of ADR reports received by EFDA is a marker of improved post marketing safety monitoring that enables the Authority to take appropriate interventions and consequently improve patient safety.
Formula (numerator/denominator)	The count of ADR reports received by EFDA in a year.
Unit of Measure	Count
Disaggregation	Reporting health facility type, professional, serious (mild, moderate, senior, serious), region, product category.
Data source	Performance reports of ADR reports
Data collection method	The number of ADR reports received will be counted from the ADR reporting form (ICSR) and/or from the approved tools like <i>medsafety</i> and other tools that reached the PV center every quarter. The sum of quarters performance of a year will be used for the annual number of ADR reports received.
Data Quality (verification)	Repeat counting of ADR reports received by the Authority by assigning another second expert. If the count result becomes suspicious, a confirmatory counting will be done by repeated review of the ADR reports registration log book in comparison with the actual ADR reports exist in the unit
Frequency	Quarterly
Baseline Value and	Baseline 4354 Target 11,000 every year making total of 33,000 reports for the three years.

targets	
Point of clarity	All adverse drug events (ADEs) need to be reported. The ADR report received will be considered, if the information on ADR cases contain information as per the content in the yellow card of EFDA and/or WHO standard.

30. Number of AEFI reports received per year

Indicator name	Number of AEFI reports received in the year
Indicator code	SD3-11
Indicator type	Output
Precise definition	The number of AEFI reports received by EFDA in a year.
purpose/Interpretation	The purpose of this indicator to measure the strength/ effectiveness of vaccines safety monitoring system. Increase in the number of AEFI reports received by EFDA is a marker of improved vaccine pharmacovigilance that enables the Authority to take appropriate interventions and consequently contribute to improvement of immunization program.
Formula (numerator/denominator)	The count of AEFI reports received by EFDA in a year.

Unit of Measure	Count
Disaggregation	Reporting health facility type, vaccine type, professional, serious (mild, moderate, senior, serious), region.
Data source	Performance reports of AEFI reports
Data collection method	The number of AEFI reports received will be counted from the AEFI reporting form (ICSR), Line list, and/or from the approved tools like <i>medsafety</i> and other tools that reached the PV center every quarter. The sum of quarters performance of a year will be used for the annual number of AEFI reports received.
Data Quality (verification)	Counterchecking by randomly checking clients using second expert will help to avoid double counting of AEFI reports received. If the count result becomes suspicious, a confirmatory counting will be done by repeated review of the documents in comparison with the actual AEFI reports exist in the unit
Frequency	Quarterly
Baseline Value and targets	Baseline 9427 Target 11,000 every year making total of 33,000 reports for the three years.
Point of clarity	All AEFIs need to be reported. The AEFI report received will be considered, if the information on the report contains information as per the content in the yellow card of EFDA and/or Line list.

31. Number of serious adverse event investigated per year

Indicator name	31. Number of serious adverse event investigated per year
Indicator code	SD3-12
Indicator type	Output
Precise definition	The number of SAEs investigated implies that number of adverse events reports conforming the serious definition completed the remaining steps of the investigation process.
purpose/Interpretation	The purpose of this indicator is to check the maturity of medicines safety monitoring both at national and subnational/ regional level. Optimal increase in the number of investigated SAEs reports received by EFDA shows proper functional pharmacovigilance system both at national and subnational level. As the system improves, more ADRs and proportionally increased amount of SAEs reach the regulatory. Accordingly, these SAEs received require proper investigation and feedback by the investigating taskforce.
Formula (numerator/denominator)	The count of SAEs investigated by subnational and National investigation task force in the planning period.
Unit of Measure	Count
Disaggregation	Reporting health facility type, region, product type.
Data source	Performance reports of SAEs status

Data collection method	The number of SAEs investigated can be obtained from the records and reports of sub-national and/or national regulatory. The sum of quarters performance of a year will be used for the annual number of SAEs investigated.
Data Quality (verification)	To improve data quality checking the knowledge randomly selected cases from another member of the investigating task force. In case of doubt confirmatory counting each case can be done.
Frequency	Quarterly
Baseline Value and targets	Baseline 61 Target: 60, 70 and 80 respectively for the successive three years.
Point of clarity	All cases reported as SAEs need to undergo confirmation step. Cases could not be counted as investigated include, cases; <ul style="list-style-type: none"> • that do not qualify SAE • that didn't pass confirmation step • that qualify investigation but clients are not willing to provide information or cases with inadequate information.

(32. Number of serious adverse event causality assessment conducted)

Indicator name	Percentage of causality assessment performed on reported serious adverse events ⇔ (32. Number of serious adverse event causality assessment conducted)
Indicator code	SD3 –13
Indicator type	Output

Precise definition	It is the number of causality assessment performed on reported serious adverse events during the reporting period.
Purpose/ Interpretation	This indicator also help to measure the maturity of safety monitoring in the country. Increase in the number of serious adverse events investigated and performing causality assessment to justify association between the event and the medicines serves as the basis to take immediate regulatory interventions on products with safety concerns and ensure better public health safety. This in turn boost the confidence of the public on the regulatory.
Formula (numerator/denominator)	The sum of causality assessments performed on serious adverse reaction in a year
Unit of Measure	Count
Disaggregation	Product Category, product type, type of case, classification category of cases
Data source	performance reports, investigation reports.
Data collection method	Review of records and investigation reports.
Data Quality (verification)	Triangulate the data with, WHOVIGI Flow &/or records of reporting center (if available)
Frequency	Quarterly
Baseline Value and targets	40 (Baseline) 190(45, 50 and 55 respectively for the three years annual targets)

Point of clarity	A single investigated case that is reviewed more than one session will be counted as one.
-------------------------	---

33. Signal detection

Indicator name	33. Number of signal detection per year
Indicator code	SD3-14
Indicator type	Output
Precise definition	“ Signal ” means any reported information on a possible causal relationship between an adverse event and a medicine, the relationship being previously unknown or incompletely documented where it is necessary to have more than one report to generate a signal, depending on the seriousness of the event and the quality of the information.
purpose/ Interpretation	Signal detection is helpful as early warning for protecting the public from harm. Signals could be generated from collecting, analysing and evaluating quantitative or qualitative data. The more the number of signals detected in a proper way, the more strong the pharmacovigilance system,
Formula (numerator/ denominator)	The count of detected signals in the planning period.
Unit of Measure	Count

Disaggregation	Product type, Classification of ADR (Type A, B, C..), Level of seriousness.
Data source	Reported cases, Database
Data collection method	The number of signals detected can be obtained from the records and reports of database, safety advisory meeting minutes.
Data Quality (verification)	Review of records and documents for the reported signal, evaluation of all available scientific evidences.
Frequency	Annually
Baseline Value and targets	Baseline 1 Target: 3, 3 and 4 products respectively for the successive three years.
Point of clarity	NA

34. Number of pharmacovigilance inspection conducted

Indicator name	34. Number of pharmacovigilance inspection conducted
Indicator code	SD3 – 15
Indicator type	Output

Precise definition	It is the count of inspections conducted on PV per year, using the checklist developed for the purpose. This includes manufacturers, MAHs and/or representatives.
Purpose/Interpretation	<p>This indicator is used to count the number of inspections conducted to:</p> <ul style="list-style-type: none"> • To ensure compliance of the pharmacovigilance system with the legislation and guidelines provided by the EFDA. • To ensure that the MAH and local representative has personal, system and facilities in place to meet their pharmacovigilance obligations. • To identify, record and address non-compliance which may pose a risk to public health. • To use the inspection results as a basis for enforcement action, where considered necessary. <p>The type of inspection could be: routine, for cause, re-inspection/follow up or, system and/or product related inspection.</p> <p>Existence functioning inspection system with increased number of inspection shows the strength of the safety monitoring system.</p>
Unit of measurement	Count (n)
Formula (numerator/denominator)	<p>Numerator: NA</p> <p>Denominator: NA</p> <p>The sum of count of inspection at medicine manufacturers, MAHs and representatives inspected.</p>
Disaggregation	Country of origin, compliance status, type of inspection, local vs imported
Data source	Performance reports, filled inspection checklist
Data collection method	Review of the performance report and/ or filled checklist
Data Quality (verification)	Random checks of the inspection reports. Review of the checklist and recommendation.

Frequency	Annual
Baseline Value and targets	0 (Baseline) 5 (2, 3 and 5 inspections per year respectively for the successive three years)
Point of Clarity	Inspection conducted twice in a single firm will be considered as two

40. Number of clinical trial applications approved

Indicator name	40. Number of Clinical Trial applications approved
Indicator code	SD3-16
Indicator type	Output
Precise definition	The number of clinical trial applications received, reviewed & approved by the Authority within the reporting period
purpose/Interpretation	The number of clinical trials approved helps to measure the efficiency of the authority in assessing the clinical trial applications. Increase in the number of clinical trials authorized provides a good ground for registration of new medicines. Hence it will increase the number of marketing authorizations issued by the authority and ultimately contribute to accessibility of new medicines in the market.

Formula (numerator/ denominator)	Total number (count) of clinical trial applications that got approval within a quarter
Unit of Measure	count
Disaggregation	By clinical trial phase, product type.
Data source	Documentation/ record or Database.
Data collection method	The number of clinical trial applications that got approval by EFDA is collected from the quarterly performance reports and review of registry or database
Data Quality (verification)	Verify the data on the number of clinical trial authorization applications against of ethical clearances issued by institutions and national ethical committee. Counterchecking reports with reviewers' technical report and registry or database.
Frequency	Quarterly
Baseline Value and targets	Baseline: 8 Targets: 15 (12, 14 and 15 inspections per year respectively for the successive three years)
Point of clarity	

Clinical trials inspection coverage

Indicator name	Number of clinical trials inspected per fiscal year
Indicator code	SD3-17

Indicator type	Output
Precise definition	It is the percentage of clinical trials inspection conducted as compared to the approved clinical trials, based on the protocol, by the authority within the reporting period.
purpose/Interpretation	The purpose of the oversight of the clinical trial is to ensure the trial is conducted as per the terms and conditions during initial authorization and GCP implementation during the conduct of the trial. Increase in the number of clinical trials inspected by the authority is an indication of the oversight to ensure participants safety at the time of clinical trial. It will enable to authority to take timely intervention based on the inspection finding
Formula (numerator/denominator)	<p>The percentage of GCP inspections conducted on clinical trials after being authorized by the Authority.</p> <p>Numerator: the number of clinical trial sites inspected</p> <p>Denominator: The total number of authorized clinical trial sites on going during the fiscal period</p> $percentage = \frac{\text{number of clinical trial sites inspected}}{\text{total \# of authorized clinical trial sites on going during the fiscal period}} \times 100$
Unit of Measure	Count
Disaggregation	Clinical trial phase, by product type, compliance status (comply, not comply)
Data source	Performance report
Data collection method	Review of clinical trial inspection performance report
Data Quality (verification)	Verify the data on the number of approved clinical trial authorization applications against and GCP inspection reports.

Frequency	Quarterly
Baseline Value and targets	Baseline: 8 Targets: 15 (10, 12 and 15 inspections per year respectively for the successive three years)
Point of clarity	The list of active and authorized clinical trial conducted in the country should be identified. Targets for number of decisions made on clinical trials application and the number GCP inspections conducted may be similar, but this may be due addressing backlogs and postponing the new for the coming year. Counting GCP inspection conducted more than once at a single site will be counted as one

42. 17. Increase evaluation of safety report for clinical trials from 0 to 15 (3, 8, 15)

Indicator name	42. Number of evaluated safety report for clinical trials
Indicator code	SD3-18
Indicator type	Output
Precise definition	It is the number of evaluated safety report for clinical trials conducted in order to protect safety of patients from misinterpreted statistical data or biased evidences.
purpose/Interpretation	The purpose of the evaluation of safety report for clinical trials is to ensure the evidence from the trial is properly compiled, analysed and interpreted. Increase in the number of evaluations of safety report of clinical trials is an indication of the strength of the regulatory and so credulity. It will also enable the authority to take timely/ proactive decision based on the finding of the evaluation.

Formula (numerator/denominator)	The count of evaluation of safety report for clinical trials reports before finalization/dissemination. Numerator: NA Denominator: NA
Unit of Measure	Count
Disaggregation	Clinical trial phase, by product type, compliance status (comply, not comply)
Data source	Performance report
Data collection method	Review of documents of evaluation of safety report for clinical trials. Review of the recommendation and/or action taken based on the evidence.
Data Quality (verification)	Verify the report submitted on the number of evaluations of safety report for clinical trials.
Frequency	Quarterly
Baseline Value and targets	Baseline: 0 Targets: Cumulative target 15 (3, 5 and 7 evaluation of safety report for clinical trials per year respectively for the successive three years)
Point of clarity	

Strategic Direction 4: Strengthen Regulation of Safety, Quality and Performance of Medical Devices

Indicator name	Number of registered medical devices (single and bundled)
Indicator code	SD4-1
Indicator type	Outcome
Precise definition	It measures the number of registered and/or approved medical devices with active marketing authorization. It includes medical devices approved by the Authority using the existing application routes including registration for IVD medical device and medical devices other than IVD, notification of low risk medical device and registration of accessories and spare parts.
purpose/Interpretation	<p>Medical devices registration system subjects all medical devices including in vitro diagnostic devices to the evaluation of safety, quality and performance before they are issued market authorization certificate; and this is among the critical responsibilities of EFDA. As evaluation requires time and sufficient qualified experts, the authority needs to cope up with the application dossiers submitted without compromising quality of the assessment output.</p> <p>Increase in the number of registered medical devices is an indication of increase in access to safe, quality and well performing medical devices for the needs of the public. This indicator measures the efficiency of medical device marketing authorization system implemented by the authority. Therefore, this indicator is developed to measure the efficiency of EFDA in approval and/or registration of medical devices submitted in need of marketing authorization. As the value increases, it indicates better efficiency of the Authority in this regulatory function.</p>

Formula (numerator/denominator)	The number of medical devices registered with active marketing authorization certificate or notification letter for low-risk medical devices.
Unit of Measure	Number/count
Disaggregation	By application type (medical device other than IVD, IVD medical device, notification, accessories & Spare parts),, product type country of origin,
Data source	Report from MDEMA lead executive office
Data collection method	Review of quarter, biannual and annual report.
Data Quality (verification)	Supervision. The number of medical devices registered with in the year and with active marketing authorization will be verified from the eRIS database every quarter.
Frequency	Quarterly
Baseline Value and targets	5420 (Baseline) Target 8500(6220, 7220, 8500,)
Point of clarity	The scopes of medical devices fall in Proclamation 1112/2019. The number of registered medical device with active MA includes new application approved and renewed MAs in the fiscal period, and all active MAs from previous years.

Indicator name	Types of medical devices sampled from consignment tested
Indicator code	SD4-2
Indicator type	Output
Precise definition	It is the number of types of medical Devices eligible for testing sampled from consignment and tested by taking samples of imported medical devices at the ports of entry or sampled from locally manufactured medical devices prior to distribution to the market.
purpose/Interpretation	Increasing the number of medical devices types consignment testing ensures improved public protection from unsafe and ineffective medical devices and provides precautionary information to the EFDA to take immediate and appropriate measures(rejection of the shipment, disposal of the product, etc) and to ensure that all manufacturers (domestic & overseas) take all the required corrective actions and notify the authority about the effectiveness of the actions taken before the next shipment or distribution of medical devices for market(for domestic manufacturers). Therefore, this indicator may be used to assess outcomes of the premarket regulatory activities (Gmp inspection & dossier evaluation & registration) and ensure public protection against any substandard, unsafe & ineffective medical devices.
Formula (numerator/denominator)	The cumulative number of medical device types that are tested in a fiscal year.
Unit of Measure	Number

Disaggregation	Product type, by manufacturers (including domestic vs overseas), country of manufacture , bundled versus single
Data source	Types of medical devices and number of consignments sampled can be found from EFDA Medical devices inspection and local medical devices manufacturers (for local products) , importers & distributors and POE inspections records (for imported products) while types and number of medical devices consignment samples tested can be from EFDA Medical devices quality control laboratory. <i>Note: Medical devices consignment testing protocol should be reviewed & updated on regular basis as necessary and conducting the consignment sampling & testing be performed in accordance with the procedures in the protocol.</i>
Data collection method	Data on the number of consignments sampled & tested should be collected from the quarterly reports of the Inspection and enforcement LEO & medical devices QC laboratory. If there are any outsourced medical devices consignments testing, the data should consider the types and number of medical devices outsourced for testing.
Data Quality (verification)	Supervision during sample collection, random checks on types of medical devices imported and on the number and types of medical devices samples collected from the port and local manufacturers (trace back to the source) and tested. If the laboratory test result becomes doubtful, a confirmatory test will be done.
Frequency	Annually
Baseline Value and targets	Baseline : 4 Target :10 (6,8,10)
Point of clarity	Consignment means all medical devices included in one shipment & ready for distribution by a local manufacturer or ready for inspection at the POE. This indicator is intended to quantify the number of consignment tested medical device by type. The sample size per product, no of batches of a product and

frequencies of sampling the same product in a year will be determined based on the procedures indicated in the protocol.

Indicator name	Types of medical devices subjected to Post Market Laboratory testing
Indicator code	SD4-3
Indicator type	Output
Precise definition	The percentage of medical device tested through Post market testing schemes conducted by taking samples of medical devices from medical device importers and wholesalers, pharmacies, drug shops, health institution's drug outlets and informal markets.
purpose/Interpretation	Increasing the percentage of Types of medical device subjected to post market sampling and testing ensures improved public protection from unsafe and ineffective medical devices and provides precautionary information to the EFDA to take immediate and appropriate measures(Product recall, disposal of the products, etc) and to ensure that all manufacturers (domestic & overseas) take all the required corrective actions and notify the authority about the effectiveness of the actions taken before the next shipment or distribution of medical devices for market(for domestic manufacturers). Therefore, this indicator may be used to assess outcomes of the premarket regulatory activities (GMP inspection,

	dossier evaluation & registration, port control, premarket QC testing and post license inspections) and public protection capability against any unsafe & ineffective medical devices.
Formula (numerator/denominator)	The number of medical device types that are sampled and tested in a given fiscal year.
Unit of Measure	Cumulative number
Disaggregation	Product type , domestic vs overseas manufacturers, country of origin
Data source	Types and number of medical devices marketed and eligible for sampling can be found from EFDA Medical devices inspection Enforcement LEO and local medical devices manufacturers (for local products), importers & distributors and POE inspections records(for imported products) while types and number of tested medical devices can be obtained from EFDA Medical devices quality control laboratory. <i>Note: Protocol should be reviewed & updated as necessary and conducting the post market sampling & testing should be performed in accordance with the procedures in the protocol.</i>
Data collection method	Data on the number of PMS sampled & tested should be collected from the quarterly/annual reports of the MD Inspection and enforcement LEO& MD QC laboratory. If there are any outsourced medical devices consignments testing, the data should consider the number of outsourced tests.
Data (verification)	Quality Supervision during sample collection, random checks on the number and types of medical devices marketed and samples collected from the market (trace back to the source). If the analysis result becomes doubtful, a confirmatory test will be done. For details, please follow the Post market testing protocol.

Frequency	Annually
Baseline Value and targets	Baseline: 4 Target: 10 (6, 8,10)
Point of clarity	A sample for Post market testing means all medical devices marketed in Ethiopia and eligible for sampling and testing. The number and types of products, sample size per product, no of batches of a product and frequencies of sampling the same product in a year will be determined based on the procedures indicated in the Post market testing protocol.

Indicator name	Auditing inspection coverage of licensed medical devices facilities (local manufacturers; importer and wholesaler)
Indicator code	SD4- 4
Indicator type	Output
Precise definition	It is the proportion of inspected local medical device establishments against the total number of licensed medical device establishments in the country.
Purpose/Interpretation	This indicator is used to assess the inspection coverage of licensed medical device establishment in a given year from the total number of licensed medical device importers, wholesalers and local manufacturers available in the country. The purpose is to ensure legality of the operations of the local manufacturing, importation and wholesaling. The higher the percentage of inspection coverage, the better the regulatory performance compliance of the regulated firms and it ensures availability of safe, quality and effective

	medical devices in the market.
Unit of measurement	Percent (%)
Formula (numerator/denominator)	<p>Numerator: The number of inspected (at least once in a year) licensed medical device importers, wholesalers and local manufacturers granted CoC by the Authority.</p> <p>Denominator: The total number of medical device importers, wholesalers and local manufacturers with valid license or CoC.</p> <p>Percentage of medical devices inspection coverage can be calculated as:</p> <p>% of inspection coverage = (Number of post-license inspected establishments/ Total number of establishments with valid license in the country in six months) x100%</p>
Disaggregation	Region, type of medical device establishments (manufacturers, importers, wholesalers),
Data source	Performance reports from Medical device Inspection and Enforcement Leo and branch LEOs
Data collection method	Review of performance report.
Data Quality (verification)	Can be verified from records of inspected facilities and database of licensed local medical device establishments from eRIS.

Frequency	Biannual
Baseline Value and targets	Baseline: 99.3% Target: 100%
Point of Clarity	The inspection of medical device manufacturers will be based on risks, and frequency of inspecting a medical device establishment shall be based on the risk based plan but all establishments shall be inspected at least once in a year. Medical devices imported and distributed by medicine and medical devices importers will be addressed by medicine facility inspection and such data will not be included in this indicator.

Indicator name	Number of cGMP inspected overseas medical devices manufacturers
Indicator code	SD4 – 5
Indicator type	Output
Precise definition	It is the number of overseas medical devices manufacturers that are inspected by the Authority to ensure their compliance with the mandatory GMP principles
Purpose/Interpretation	This helps the authority to ensure that high risk medical device from new manufacturers intending to market their devices in Ethiopian meet the minimum requirements of GMP/QMS and the formerly authorized manufacturers have maintained or improved their GMP/QMS compliance with the national and/or international requirements.

	<p>This indicator is used to ensure the compliance of medical device manufacturers with the national GMP/QMS requirements. The higher the number of inspected manufacturers it shows that there will be more applicants for medical devices marketing authorization. This will result in improved access to medical devices with better quality and performances.</p>
Unit of measurement	Cumulative Count (n)
Formula (numerator/denominator)	The number of Medical device manufacturers for the compliance of the regulatory GMP/QMS requirements.
Disaggregation	Country of origin, product type,
Data source	Performance reports from Medical Device inspection and Enforcement LEO.
Data collection method	Review of Medical Device inspection and Enforcement LEO annual report
Data Quality (verification)	Counting, independently by at least two experts, the number of medical devices manufacturers application for high risk or suspected medical products eligible for GMP inspection and the number of reports of GMP/QMS inspections conducted by the authority..
Frequency	Annually
Baseline Value and targets	<p>Baseline: 18</p> <p>Target(cumulative): 100 (40, 65, 100)</p>

Point of Clarity	<p>This indicator does not include medical device manufacturers granted MA without onsite GMP inspection. GMP Waiver letter will not be included in the count of the number of medical device manufactures inspected against the GMP requirements.</p> <p>The inspection of medical device manufacturers, which will be based on risks, includes both new applicants and manufacturers which were already granted GMP certificate but needs re-inspection due to the validity period of their GMP certificates. Manufactures to be inspected are identified based on the list of products eligible for medical devices for GMP inspection which is reviewed and updated on annual basis.</p>
-------------------------	--

Indicator name	Number of adverse device events reports received per year
Indicator code	SD4-6
Indicator type	Output
Precise definition	The numbers of adverse device event reports on medical devices received in a year, by medical devices pharmacovigilance (PV) Desk of EFDA. The adverse event reports comprises of incident reports relating to the occurrence of adverse events in the post-marketing period and events and incidents occurring during the pre-market period (e.g. during clinical trials)
purpose/Interpretation	<p>Reporting, analysing and interpretation of adverse events and subsequent safety monitoring of medical devices after being placed on the market is very crucial to maintain the safety of medical devices; improve protection of the health and safety of patients, users and others by disseminating safety related information that may help to reduce the likelihood of adverse events; prevent repetition of incidents and promote the use of safe medical devices.</p> <p>Increase in the number of adverse event reports received by EFDA is an indication of the improved post marketing safety monitoring of medical devices available in the country for use. This indicator</p>

	measures the efficiency of the medical device post market vigilance and surveillance system of EFDA in monitoring the safety and quality of medical devices after being placed on the market. As the value increases, it indicates better effectiveness of the established medical device post market vigilance and surveillance within the Authority.
Formula (numerator/denominator)	Count
Unit of Measure	Number
Disaggregation	Medical devices category, type of adverse events, seriousness of the adverse event
Data source	Quarter, biannual and annual report of medical devices PV desk regarding received MD adverse event report.
Data collection method	Review of annual data. The number of adverse event reports received will be counted from the medical devices adverse events/incident reports data base and/or files (hard copy or soft copy) of the adverse event reports that received every quarter. The sum of quarters performance of a year will be used for the annual number of adverse event reports received.
Data Quality (verification)	Repeat counting of adverse event reports received by PV centre (from registry) by assigning another second expert. If the count result becomes suspicious, a confirmatory counting will be done by repeated review of the vigiflow data base in comparison with the actual ADR reports received by the unit in the year.
Frequency	Annually

Baseline Value and targets	(Baseline): 14 Target: 56 (25, 45, 56)
Point of clarity	Medical devices adverse events report includes deaths, serious injuries, and malfunctions reported to EFDA by manufacturers, healthcare service providers, patients and users.

Indicator name	Number of clinical trial/ investigation applications approved
Indicator code	SD4-7
Indicator type	Output
Precise definition	The number of medical devices clinical investigation authorized by the authority within the reporting period
purpose/Interpretation	Increase in the number of clinical trials authorized; promotes clinical trials within the country, provides a good ground for registration of new technologies/medical devices. Hence, it will contribute to an increased number of MAs and ultimately contribute to accessibility of new medical devices in the health institutions.
Formula (numerator/denominator)	Total number of medical devices clinical investigation applications authorized within a year
Unit of Measure	Number/Count
Disaggregation	Clinical investigation phase, by product type, application type (new application and

	amendments)
Data source	Clinical investigation authorization applications record from medical devices clinical trial authorization Desk of EFDA
Data collection method	Review of the number of clinical investigation applications approved by EFDA is collected from the monthly reports & quarter reports of medical devices clinical investigation authorization desk of EFDA
Data Quality (verification)	Verify the data on the number of reviewed clinical trial authorization applications against the number of ethical clearances issued by Ministry of innovation & technology, research and ethic committees of different research institutions & universities and GCP inspection reports
Frequency	Annually
Baseline Value and targets	Baseline: 3 Target(cumulative): 20 (7,13,20)
Point of clarity	

Indicator name	Number of medical device market surveillances
-----------------------	---

Indicator code	SD4-
Indicator type	output
Precise definition	It is the number of medical devices market surveillances undertaken to ensure safety, quality and performance of medical devices by taking samples of tracer medical devices in use in different health institutions in selected sentinel sites in the country
purpose/Interpretation	Conducting market surveillances on medical devices enables the authority to get rational information on the safety, quality and performance of medical devices that are in use by health institutions. Market surveillance is also applicable for medical devices those can be sampled and tested once it is put in use. The survey aims at identifying availability of SF medical devices; well functioning and non-functional medical devices so as to ensure that accurate diagnosis are undertaken by diagnostic centers and health institutions. This will ultimately ensure proper medication and improved public protection from unsafe and ineffective medical devices. It provides information to the regulatory sector regarding the safety and performance of medical devices to take immediate and appropriate measures by users (maintenance requalification, calibration or disposal of the devices, etc) and to ensure that all manufacturers and/or end users take the required corrective actions and notify the relevant regulatory bodies about the effectiveness of the actions taken before using the medical devices for diagnosis purposes. Therefore, this indicator may be used to assess outcomes of the premarket regulatory activities and public protection capability against any unsafe & ineffective medical devices.
Formula (numerator/denominator)	The number of surveys conducted
Unit of Measure	number (count)
Disaggregation	Product Type, end users type, country of origin

Data source	From randomly chosen health institutions in the selected sentinel sites <i>Note: Protocol should be developed to determine the tracer medical devices, sentinel site selection criteria, assessment questionnaire, etc</i>
Data collection method	Data on the tracer medical devices will be collected from randomly chosen health institutions (end users) in the selected sentinel sites.
Data Quality (verification)	Supervision during data collection, random checks on the filled checklist for evaluating effectiveness of medical devices and data analysis and interpretation. Triangulate the findings with others relevant reports on the safety and effectiveness of medical devices and out of order medical devices etc.
Frequency	3 years
Baseline Value and targets	Baseline : NA Target: 1
Point of clarity	It should be noted that, as per WHO definition, substandard medical devices are those which are authorised but fail to meet their quality standards or specifications and falsified medical devices are those that deliberately/fraudulently misrepresent their identity, composition or source. The later includes substitutions and reproduction and/or manufacturing of an unauthorised medical product. Ineffective medical devices include defective or malfunctioning medical devices, are medical devices found in the end users facilities which became out of order due to quality or safety related issues. Medical devices which became out of use because of old technology or long periods of use should not be counted. The number of product types, sample size per product, no institution to be surveyed directed by a protocol.

Indicator name	Number of clinical trial GCP inspection
-----------------------	---

Indicator code	SD4-8
Indicator type	Out put
Precise definition	The number of medical devices clinical investigation authorized by the authority within the reporting period
purpose/Interpretation	Increase in the number of clinical trials authorized: promote clinical trials within the country, provides a good ground for registration of new technologies/medical devices. Hence, it will contribute to an increased number of MAs and ultimately contribute to accessibility of new medical devices in the health institutions.
Formula (numerator/denominator)	Total number medical devices clinical investigation applications authorized within a year
Unit of Measure	Number
Disaggregation	Clinical investigation phase, by product type, application type (new application and amendments)
Data source	Clinical investigation authorization applications record from medical devices clinical trial authorization Desk of EFDA
Data collection method	Review of the number of clinical investigation applications approved by EFDA is collected from the monthly reports & quarter reports of medical devices clinical investigation authorization desk of EFDA
Data Quality (verification)	Verify the data on the number of reviewed clinical trial authorization applications against the number of ethical clearances issued by Ministry of innovation & technology, research and ethic committees of

	different research institutions & universities and GCP inspection reports
Frequency	Annually
Baseline Value and targets	Baseline: 0 Target: 20 (3,7,10)
Point of clarity	GCP inspections will be carried out based on risk and the frequency of GCP inspection on single site will be based the previous GCP inspection findings. The number of GCPs conducted includes GCP inspections carried out at different sites of the same clinical trial.

Indicator name	Types of medical devices checked for functionality at POE
Indicator code	SD4-9
Indicator type	Output
Precise definition	It measures the number of medical devices types that are checked for functionality at port of entry by using suitable measuring device or technologies. It is the number of types of medical devices tested for functionality by taking samples of imported eligible medical devices at the ports of entry

purpose/Interpretation	Under taking medical devices functionality test ensures end users protection from ineffective and unsafe devices. Increased number of medical devices types functionality checked at the ports of entry ensures improved public protection from unsafe and ineffective medical devices and provides precautionary information to the EFDA to take immediate and appropriate measures(rejection of the shipment, disposal of the product, etc) and to ensure that all manufacturers take all the required corrective actions and notify the authority about the effectiveness of the actions taken before the next shipment or distribution of medical devices for market
Formula (numerator/denominator)	Types of medical devices checked for functionality at the ports of entry
Unit of Measure	Count (n)
Disaggregation	By product type, country of origin
Data source	Report of central branch LEO
Data collection method	Review quarter, biannual and annual reports.
Data Quality (verification)	
Frequency	Annually

Baseline Value and targets	Base line: 0 Target: 3(0,1,2)
Point of clarity	

Indicator name	Number of FSCA Reports
Indicator code	SD4-10
Indicator type	In put
Precise definition	It is the number of medical devices field safety corrective actions reported by the manufacturers to the authority in a year.
purpose/Interpretation	<p>Medical device field safety correction is to address safety issues related to a medical device. When a safety issue is identified with a medical device, the manufacturer or distributor may issue a field safety correction to notify users and report for national regulatory authorities about the issue and provide instructions for addressing it.</p> <p>This may involve repairing, modifying, or replacing the device to ensure that it functions safely and effectively. The goal is to minimize the risk of harm to patients, healthcare providers, and others who may meet the device.</p>
Formula (numerator/denominator)	It is the number of field safety corrective action reports submitted to the authority.
Unit of Measure	Count (n)
Disaggregation	By type of medical device, by manufacturers and distributors

Data source	Report from medical devices from Medical Device Vigilance & Post Market Surveillance Desk
Data collection method	Review of quarter, biannual and annual report
Data Quality (verification)	
Frequency	Annually
Baseline Value and targets	Baseline: 0 Target: 50 (0,10,40)
Point for clarity	A field safety corrective action (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of medical device that is already placed on the market.

Strategic Direction 5: Improve regulation of safety of cosmetic products

Indicator name	Number of cosmetic products authorized through notification
Indicator code	SD5-1
Indicator type	Output
Precise definition	It is the number of cosmetic products authorized through notification by the Authority in the fiscal year.
purpose/Interpretation	The purpose of this indicator is to ensure safety of cosmetics for users by reviewing composition of cosmetics products (e.g. prohibited & restricted ingredients). The more the number of issued notification notes the better access to safe cosmetics in the market.
Formula (numerator/denominator)	<p>Numerator: NA</p> <p>Denominator: NA</p> <p>The summation of the number of cosmetics products approved through notification in the fiscal period.</p>
Unit of Measure	Count (n)
Disaggregation	Application type (new, variation, renewal), country of origin,
Data source	Performance reports, logbooks or registry

Data collection method	The number of cosmetic products approved through notification will be counted from registry log books or performance reports every quarter.
Data quality (verification)	Supervision. Double check by another expert of the counting of notification notes issued is important. Review all sources of documents including the registry logbooks and performances reports.
Frequency	Annually
Baseline Value and targets	1240 (Baseline) 2440 (300, 400,500)
Point of clarity	Notification note is an authorization letter or certificate issued by the Authority in reference to the notification application submitted by an applicant to get approval of cosmetic products to be imported and marketed in Ethiopia.

Indicator name	Percentage of suspected cosmetic products tested for safety
Indicator code	SD5-2
Indicator type	Output
Precise definition	Percentage of suspected cosmetic products tested measures the number of samples of suspected cosmetic products tested for safety out of all suspicious samples submitted to the laboratory for QC testing by inspectors.
purpose/Interpretation	Increase in the percentage of suspected cosmetic products samples tested indicates that the authority is capable of responding to public concerns on cosmetics safety. The laboratory test will enable the regulatory sector to take appropriate immediate actions (administrative measures such as product recall & disposal) and long term interventions (changing strategies for ensuring cosmetics safety). Increased number of cosmetic products failing to meet safety requirements might lead to other health hazards and may need medication which ultimately results in physical, psychological & economic impacts.
Formula (numerator/denominator)	Numerator: Number of suspicious cosmetics samples tested Denominator: Total number of suspicious cosmetic samples submitted to the laboratory for testing Percentage of suspected cosmetics tested for safety can be calculated as: Percentage=(Number of suspicious cosmetics samples tested)/(Total number of suspicious cosmetic samples submitted to the laboratory for testing)X100.
Unit of Measure	Percentage

Disaggregation	Product category, source of test request, regions, types of tests, status (comply vs non comply)
Data source	Performance report of Medicine Quality Control Lead Executive Office
Data collection method	Review of performance report
Data Quality (verification)	Data regarding the total number of suspicious cosmetics test requests shall be triangulated with the requests submitted by EFDA & regional regulatory agencies inspectors and other relevant organizations within the reporting period (in the quarter).
Frequency	Annually
Baseline Value and targets	N/A (Baseline) 100% Target (100%, 100%, 100%)
Point of clarity	The data for reporting percentage of suspicious cosmetics tested shall focus only on the tests carried out on suspicious cosmetics products to determine the cosmetics safety and it should not include test requests by cosmetics manufacturers or other dealers and tests carried out on normal cosmetic samples for other purposes. The suspected samples should be received only if submitted by EFDA or regional regulatory body's inspectors and or police departments. The data on the number of tested suspicious cosmetics products collected from EFDA laboratory should include safety tests carried out by using laboratory animals, microbiological tests & chemicals tests as well as outsourced tests(if any)

Indicator name	Percentage of inspection coverage of cosmetics manufacturers, importers, wholesalers and retail outlets.
Indicator code	SD5- 3
Indicator type	Output
Precise definition	It is the percentage of inspected cosmetics manufacturers, importers, wholesalers and retail outlets to the total number of licensed cosmetics manufacturers, importers, wholesalers and retail outlets in the country. This is meant only for these institutions which are licensed (and applied for licensing, in case of new) to produce cosmetics, import cosmetic, wholesale cosmetic and retail cosmetics only.
Purpose/Interpretation	This indicator is used to assess the inspection coverage of cosmetics manufacturers, importers, wholesalers and retail outlets in a given year from the total licensed (and applied for licensing) cosmetics manufacturers, importers, wholesalers and retail outlets available in the country. The inspection coverage includes both the pre-licensing inspection and post licensing inspections. The purpose is to ensure legality of manufacturing, importation, distribution, wholesaling and selling operations. The higher the percentage of cosmetic establishments inspected, the better the regulatory performance and the more available safe cosmetics in the market.
Unit of measurement	Percent (%)
Formula (numerator/denominator)	Numerator: The total number of inspected cosmetic manufacturers, importers, wholesalers and retail outlets (MIWR)

	<p>Denominator: The total number of licensed (and applied for licensing) cosmetics manufacturers, importers, wholesalers and retail outlets</p> <p>Percentage of cosmetics inspection coverage can be calculated as: % of inspection coverage = (Number of inspected cosmetics MIWR/Total number of licensed (and applied for licensing) cosmetics MIWR in the country)x100</p>
Disaggregation	Region, type of cosmetic establishments (manufacturers, importers, wholesalers, retail outlets), new vs renewal inspection, pre-licensing vs post licensing inspection.
Data source	Reports from EFDA (Medicine Registration and Market Authorization Lead Executive Office & Medicine & Medical Device Control Lead Executive Office) and Regional Regulatory Bodies (RRBs). Data on the number of cosmetics manufacturers, importers, wholesalers and retail outlets will be collected from the monthly, quarterly, bi-annually and annual reports. eRIS can also be the main source of data.
Data collection method	Review of performance report.
Data Quality (verification)	Supervision and random checks of the manufacturers, importers, wholesalers and retail outlets inspected.
Frequency	Quarterly
Baseline Value and targets	For cosmetics manufacturers, importers, wholesalers and retail outlets 30% (Baseline) 60% target (40%, 50%, 60%)
Point of Clarity	The frequency of inspection for one facility should be set by the Authority and it will be considered in the measurement of this indicator. For example: if an importer is expected to be inspected twice a year and inspected once a year, half point (0.5) will be considered in the numerator for calculation of the percentage of inspection coverage.

Indicator name	Number of cosmetics adverse events reports received per year
Indicator code	SD3-4
Indicator type	Output
Precise definition	The number of cosmetics adverse event reports received by EFDA in a fiscal year.
purpose/Interpretation	Increase in the number of cosmetics adverse event reports received by EFDA is an indication of the improved post marketing safety monitoring of the marketed cosmetic products and it enables the Authority to take appropriate interventions so as to improve public safety from unsafe cosmetics. In addition, this indicator measures the effectiveness of the pharmacovigilance system of the country in monitoring the safety of cosmetic products after being placed on the market.
Formula (numerator/denominator)	The count of cosmetics adverse events reports received by EFDA in a year.
Unit of Measure	Count
Disaggregation	Reporting by users, serious (mild, moderate, senior, serious), region, product category.
Data source	Performance reports of cosmetics Adverse event reports
Data collection method	The number of cosmetics Adverse event reports received will be counted from the ADR reports registration log book and/or med-safe and other databases that received every quarter of Cosmetic

	Safety and Post marketing Surveillance Desk. The sum of quarter's performance of a year will be used for the annual number of cosmetics Adverse event reports received.
Data Quality (verification)	Repeat counting of cosmetics Adverse event reports received by the Authority with assigning another second expert. If the count result becomes suspicious, a confirmatory counting will be done by repeated review of the cosmetics Adverse event reports registration log book in comparison with the actual cosmetics adverse event reports exist in the Cosmetic Safety and Post marketing Surveillance Desk.
Frequency	Quarterly
Baseline Value and targets	N/A (Baseline) Annual Target 1250 (1250, 1250, 1250)
Point of clarity	All cosmetic adverse events need to be reported.

Point of clarity	Notification note is an authorization letter or certificate issued by the Authority in reference to the notification application submitted by an applicant to get approval of cosmetic products to be imported and marketed in Ethiopia.
-------------------------	--

Strategic Direction 6: Strengthen tobacco, alcohol and misuse of NPS control system

Indicator name	Evidence generated by GATS (the number of GATS conducted)
Indicator code	SD 6- 1
Indicator type	Output
Precise definition	The Global Adult Tobacco Survey (GATS) is a nationally representative household survey that enables countries to collect data on adult tobacco use and key tobacco control measures.
purpose/Interpretation	The purpose of this indicator is to support the collection, analysis, and dissemination of country-level risk factor information to inform and improve public health policy. Results from the GATS assist countries in the formulation, tracking and implementation of effective tobacco control interventions, and countries are able to compare results of their survey with results from other countries. The GATS is an important tool to assist countries in supporting WHO MPOWER, a package of six evidence-based demand reduction measures contained in the WHO Framework Convention on Tobacco Control (FCTC).
Unit of Measure	Count
Disaggregation	Prevalence of tobacco use, exposure to tobacco smoke, cessation, economic Impact and KAP of tobacco use
Data source	Survey report
Data collection method	Review of survey report Note: Detailed protocol should be prepared during the survey period and conduct the survey according to the protocol.

Data Quality (verification)	Supervision during data collection, triangulate with previous published research data, and Ethiopian DHS
Frequency	Every five years
Baseline Value and targets	1 (1 st round) 2 (2 nd round)
Point of clarity	
Indicator name	Evidence generated by GYTS (the number of GYTS conducted)
Indicator code	SD 6- 2
Indicator type	Output
Precise definition	The Global Youth Tobacco Survey (GYTS) is a self-administered, school-based survey of students in grades associated with 13 to 15 years of age. The GYTS uses a standard methodology for constructing the sampling frame, selecting schools and classes, preparing questionnaires, following consistent field procedures, and using consistent data management procedures for data processing and analysis.
purpose/Interpretation	The purpose of this indicator is to support the collection, analysis, and dissemination of country-level risk factor information to inform and improve public health policy. GYTS designed to enhance the capacity of countries to monitor tobacco use among youth and to guide the implementation and evaluation of tobacco prevention and control programmes. The GYTS is an important tool to assist countries in supporting WHO MPOWER, a package of six evidence-based demand reduction measures contained in the WHO Framework Convention on Tobacco Control (FCTC). The results from the GYTS assist countries in enhancing their capacity to design, implement, and evaluate tobacco control interventions.

Unit of Measure	Count
Disaggregation	Region, schools, age, grade
Data source	Survey report
Data collection method	Review of survey report Note: Detailed protocol should be prepared during the survey period and conduct the survey according to the protocol.
Data Quality (verification)	Supervision during data collection, triangulate with previous published research data,
Frequency	Every 2 years
Baseline Value and targets	1 (1 st round) 2 (2 nd round) 3 (3 rd round)
Point of clarity	
Indicator title	Number of tobacco smoke free public places.
Indicator code	SD6 – 3
Indicator type	Output
Precise definition	It is the number of all public places, that have been made tobacco smoke free in the country in fiscal year.

Purpose/Interpretation	This indicator aims to measure the extent of implementation of tobacco smoke free public places/areas by displaying of no smoking sticker, non appearance of cigarette butts, non appearance of ashtrays, absence of active smoking, absence of residual smoke and absence of designated smoking area. The higher the result, the better the implementation of the law and minimizes the number of smokers and hence, ensures public protection from health risk arising from tobacco smoking including second hand smoking.
Unit of measurement	Count
Formula (numerator/denominator)	It is the count of the number of public places that have been made as tobacco smoke free place in the country in the given fiscal year. However, this can also be converted into percentage by dividing the number of public places that have been made as tobacco smoke free against the total number of public places in the country in the fiscal year multiplied by 100
Disaggregation	Region, type of the public places
Data source	Performance report of EFDA and Regional Regulatory Bodies (RRBs)
Data collection method	Review of performance reports of EFDA and RRBs
Data Quality (verification)	Random checks of the reports by checking samples of public places supposed to be smoke free.
Frequency	Quarterly
Baseline Value and targets	109,000 (Baseline) 218,000 Target (130,800, 152,600, 174,400, 196,200)
Point of Clarity	Public places include all indoor workplaces, all indoor public places, all means of public transport, and all common areas within condominium housings that are designated smoke free public place. Moreover, additional smoke free public places might be identified by all regulatory bodies on

	regular basis.
Indicator title	Percentage of tobacco product packets with the required 70% of pictorial health warning on legal tobacco products
Indicator code	SD6 – 4
Indicator type	Output
Precise definition	It is the number of tobacco product packets manufactured, imported, wholesale, or distributed by legally licensed organization from the executive organ (EFDA and RRB) with the required 70% of rotating pictorial health warning.
Purpose/Interpretation	This indicator aims to measure the extent of implementation of the packaging of any tobacco product shall contain rotating health warnings and messages that are comprised of combined images and full-color pictures displayed on no less than 70% of the front and back side of each principal display area of its packaging and labeling, absence of any misleading statement with the likely effect to create an erroneous impression about the product's characteristics, health effects, hazards or emissions, or any expression or presentation purporting to signify one tobacco product has lesser harm compared to other tobacco product and absence of any term, descriptor, trademark, figurative, color, or other sign of any kind that directly or indirectly creates or is likely to create the false impression that a particular tobacco product is less harmful than others, including the terms "low tar", "light", "ultra light", or "mild", "extra", and "ultra" and similar terms or expressions. The higher the result, the better the implementation of the law and minimizes the number of smokers and hence, ensures public protection from health risk arising from tobacco smoking.
Unit of measurement	Count
Formula	It is the count of the number packet of tobacco products containing pictorial health warning

(numerator/denominator)	displayed on no less than 70% of the front and back side of each principal display area of its packaging and labelling. likewise, this can also be converted into percentage by dividing the number of packet of tobacco products containing pictorial health warning displayed on no less than 70% to the total number of tobacco product packets manufactured, imported, wholesale, or distributed by legally licensed organization from the executive organ (EFDA and RRB) in the country in the fiscal year multiplied by 100.
Disaggregation	Region, Manufacture, Importer and Distributor
Data source	Performance report of EFDA and Regional Regulatory Bodies (RRBs)
Data collection method	Review of performance reports of EFDA and RRBs
Data Quality (verification)	Random checks of the reports by checking samples of tobacco product packets manufactured, imported, or distributed by legally licensed organization.
Frequency	2 years
Baseline Value and targets	100% and Maintaining 100%
Point of Clarity	The packaging of any tobacco product which does not contain 70% rotating pictorial health warnings and messages are considered as illegal. The 100% of complying 70% rotating pictorial health warnings of tobacco product packet is expected from legally licensed organization of tobacco product manufacturer, importers and wholsalers.
Indicator title	Prevalence of Illicit Tobacco products on the market
Indicator code	SD6 – 5
Indicator type	Outcome

Precise definition	It is the percentage of illicit tobacco products available in the market during the survey period.
Purpose/Interpretation	This indicator is used to measure the prevalence of illicit tobacco products available for public use in the market. Increase in the prevalence of the illicit tobacco products leads to an increase in the number of smokers due to availability of alternative tobacco products that would negatively impact supply reduction efforts. The more the illicit tobacco products available in the market, the more the public health is at risk.
Unit of measurement	Percentage
Formula (numerator/denominator)	<p>Numerator: number of illicit tobacco products found on the market at time of survey</p> <p>Denominator: Total number of tobacco products sampled during the survey.</p> <p>Percentage of illicit tobacco products available in the market can be calculated as: % of illicit tobacco product = (number of illicit tobacco products found on the market/Total number of tobacco products surveyed) x100</p>
Disaggregation	By route of entry, region, product type, country of origin
Data source	Survey
Data collection method	Review of survey reports.
Data Quality (verification)	Supervision of the survey, comparing findings with other countries' similar studies.
Frequency	5 years
Baseline Value and targets	NA (Baseline) 15 (Target)
Point of Clarity	A survey protocol will be developed during the survey period to identify survey areas, number of

	tobacco products to be sampled and clarify how to identify types of tobacco products that are manufactured in or imported into the country through legal routes and those imported illegally.
Indicator title	Percentage of Advertisement, Sponsorship, and Promotion (ASP) of alcohol
Indicator code	SD6 – 6
Indicator type	Output
Precise definition	This indicator measures the percentage of Advertisement, Sponsorship, and/or Promotion (ASP) of alcohol products made in unethical or unlawful way to promote alcohol trade and consumption
Purpose/Interpretation	Increase in the percentage of Advertisement, Sponsorship, and/or Promotion (ASP) of alcohol is an indication for higher risk of public alcohol consumption. It will enable the authority, regional regulatory bodies and other relevant government agencies to take appropriate intervention to minimize risk of alcohol consumption, especially for the higher risk groups (under 21 years) .
Unit of measurement	Percentage
Formula (numerator/denominator)	<p>Numerator: number of advertisement, Sponsorship, and/or Promotion (ASP) of alcohol made in unlawful ways (those prohibited by proclamation 1112/2019)</p> <p>Denominator: Total number of advertisement, Sponsorship, and/or Promotion (ASP) of alcohol made in a given period of time</p> <p>Percentage of Advertisement, Sponsorship, and/or Promotion (ASP) of alcohol can be calculated as:</p> <p>% ASP= (number of unlawful ASPs /Total number of ASPs in a defined period of time) x100</p>

Disaggregation	Means of advertisement, types of events sponsored, by regions
Data source	Records/reports of unlawful ASP obtained from the regular federal & regional routine inspection & media monitoring on advertisements in prohibited areas, sponsoring of prohibited events & promotions on events and mass media, etc.
Data collection method	Reports on al ASPs & unlawful ASPs should be collected from regional and federal inspection sections and media monitoring units on regular basis (quarterly)
Data Quality (verification)	Random checks of the reports by checking samples of public places distinguished as smoke free public places.
Frequency	Quarterly
Baseline Value and targets	NA (Baseline) 25 (15,20,25 Target)
Point of Clarity	NA
Indicator title	Percentage of alcohol sale in prohibited public areas
Indicator code	SD6 -7
Indicator type	Output
Precise definition	This indicator measures the percentage of alcohol sale in prohibited areas proportional to the total public places where alcohol is not allowed to sell. Places prohibited to sell alcohol should be

	distinguished as per the national laws.
Purpose/Interpretation	This indicator is used to measure the percentage of alcohol sales in prohibited areas. This aims to measure the extent of implementation alcohol sale in prohibited places/areas. The lower the percentage of alcohol sale in prohibited areas the better the implementation of the regulatory enforcements and hence ensure the safety of the public.
Unit of measurement	Percent (%)
Formula (numerator/denominator)	<p>Numerator: number of prohibited public areas that sell alcohol at the time of the survey</p> <p>Denominator: total number of prohibited public areas to sell alcohol according to national and regional laws</p> <p>Percentage of alcohol sale in prohibited public places = (The number of prohibited public places that sell alcohol/the total number of prohibited public places by law) x100.</p>
Disaggregation	Region, type of prohibited public places, type of alcohols
Data source	Survey
Data collection method	Review of survey report.
Data Quality (verification)	Random checks of the reports by checking samples of public places distinguished as prohibited places to sell alcohol.
Frequency	Every three years
Baseline Value and targets	NA (Baseline) 50% (40,45,50 Target)
Point of Clarity	

Indicator title	Percentage Reduction in tobacco Advertisement, Sponsorship or Promotion (ASP)
Indicator code	SD6 – 8
Indicator type	Outcome
Precise definition	This indicator measures the percentage reduction in direct and indirect tobacco advertisement
Purpose/Interpretation	<p>This indicator is used to measure the impact of comprehensive efforts of EFDA and RRBs to minimize/eliminate tobacco advertising, sponsorship and promotion in a prohibited means so as to reduce tobacco consumption and therefore prevent tobacco-related health risks and deaths.</p> <p>This indicator, therefore, measures the outcome of regulatory intervention in reduction of tobacco advertisements, sponsorship or promotion by the tobacco industries. Increase in tobacco advertisement, sponsorship or promotion in a prohibited means is an indication for increased tobacco consumption which means the public is at risk of tobacco related health risks and death.</p>
Unit of measurement	Percentage
Formula (numerator/denominator)	<p>Numerator: number of advertising sites that have advertised tobacco in a specified period</p> <p>Denominator: Total number of advertising sites monitored during the survey period.</p> <p>The percentage of advertisement on tobacco product is</p>

	= (the number of advertising sites that have advertised tobacco in a specified period/ total number of advertising sites monitored during the survey period)
Disaggregation	By region, type (advertisement, sponsorship or promotion), media type
Data source	Survey report
Data collection method	Survey
Data Quality (verification)	Random checks of the reports.
Frequency	Five year
Baseline Value and targets	42 (Baseline) 15 (Target)

Point of Clarity	<p>If the survey is not conducted, the sum of five year performance reports of responsible directorate of EFDA on tobacco advertisement, sponsorship and promotion will be used to generate tobacco ASP data.</p> <p>The promotion on tobacco ASP on unregulated media shall not be considered in generating the number of tobacco ASP.</p> <p>Tobacco advertisement include sponsorship and promotion conducted on tobacco products.</p> <p>Data on the numbers of advertisements, sponsorship and promotion on tobacco products will be generated through surveys on tobacco industries and licensed media. The sum of numbers of advertisements, sponsorships and promotions are considered for the total number of tobacco ASP</p>
-------------------------	--

Strategic Direction 7: Enhance good-governance

Indicator name	Food and health products regulatory sector customer satisfaction level
Indicator type	Outcome
Indicator code	SD7-01
Definition	Customer satisfaction level is a measure of how products and services supplied by a provider meet or surpass customer expectation. The authority provides only the service on the registration, inspection, licensing and laboratory testing. Through implementation of transparent, efficient and effective service system in the authority the customer will satisfy by the service.
Interpretation	Customer Satisfaction Score (CSAT score) CSAT measures the level of satisfaction or dissatisfaction with your product or service. Usually, customers rate their satisfaction on a scale of 1-3, 1-5, or 1-7. CSAT score is the percentage number of satisfied customers who enjoy using your products and services. <i>Customer Satisfaction Score (CSAT) is the most commonly used measurement for customer satisfaction</i>

Formula (numerator/denominator)	Numerator: Results provided by respondents for overall satisfaction Denominator: total number of respondents in the study Percentage customer satisfaction level can be calculated as: $\% \text{ Satisfaction} = (\text{Results provided by respondents for overall satisfaction} / \text{total number of respondents in the study})$ Overall satisfaction=mean of satisfaction
Unit of Measure	Percentage
Disaggregation	Business type (manufacturers, importer, wholesalers, exporter), sex, age,
Data source	Survey Report
Data collection method	Survey. Representative samples will be randomly selected from statistically selected business type. Details will be indicated in the protocol for the purpose.
Data Quality (verification)	Supervision, random checks of the interview. For details, please follow the protocol.
Frequency	Annually
Baseline Value and targets	Base line: 89 Target: 100 (92, 95, 100)
Indicator name	Percentage of reduced service delivery complaints from 90% to 100%
Indicator type	Output
Indicator code	SD7-02
Definition	The definition of service delivery complaints refers to grievances or dissatisfaction expressed by customers or clients regarding the quality, timeliness, or effectiveness of the services provided by an

	organization.
Interpretation	The purpose/ interpretation of this indicator is a way for customers to express their dissatisfaction with long wait times, poor customer service, delays in delivery, incorrect billing, failure to meet agreed-upon standards, lack of communication of the services they have received. These complaints can provide valuable feedback to the service provider, highlighting areas for improvement and helping to identify any systemic issues that may be affecting multiple customers. By addressing and resolving service delivery complaints, organizations can improve their overall customer satisfaction and loyalty. Additionally, service delivery complaints can also serve as a warning sign for potential problems within the organization that need to be addressed in order to maintain a high standard of service. Resolving service delivery complaints is important for maintaining customer satisfaction and loyalty.
Formula (numerator/denominator)	Numerator: total number of relevant complaints during the previous fiscal year- complaints during the current fiscal year Denominator: total number of complaints in the previous fiscal year *100
Unit of Measure	Present
Disaggregation	Departments, branches
Data source	Performance report
Data collection method	Document review: report
Frequency	Annually
Baseline Value and targets	Base line: 95 Target: 100% (95, 100, 100)
Point of clarity	

Indicator name	Percentage of regulatory services provided as per the standard
Indicator code	SD7- 3
Indicator type	Output
Precise definition	The Percentage of regulatory services provided as per the standard In food and health products regulatory sector. It is the measurement of services or activities that are delivered as per the standard.
purpose/Interpretation	The indicator measures how many services provided as per the standard in the regulatory functions. This indicator is useful to identify Service standards that can be applied on the organization and also to monitor job performance while they are doing it. Measuring and improving service delivery effectiveness can bring many benefits to an organization and customers, such as increased customer satisfaction and loyalty, enhanced reputation and credibility, reduced costs and risks, improved efficiency and productivity, higher innovation and competitiveness
Formula (numerator/denominator)	Numerator: Number of activities provided as per the standard Denominator: Total number of regulatory activities % of performance= (Number of activities provided as per the standard / Total number of regulatory activities) *100

Unit of Measure	Percentage
Disaggregation	Departments, functions, Branch offices, port of entries, regions
Data source	Performance reports
Data collection method	Document review/ Physical supervision
Data Quality (verification)	Physical supervision
Frequency	Every year
Baseline Value and targets	(Baseline) 84 Targets: 100 (90, 95, 100)
Point of clarity	

Indicator name	Accountability scale on organizational gender mainstreaming
Indicator code	
Indicator Type	output
Precise definition	<p>It is a scale that describes the organization's overall vision of gender equality and makes a clear commitment to gender mainstreaming.</p> <p>A scale that identifies the extent of the gender mainstreaming efforts of organization.</p>
purpose/Interpretation	<p>The purpose of this indicator is to measure whether all staff members integrating gender equality in to their respective field of responsibility relying on not only staff's personal understanding, but also on strong institutional mechanism of accountability.</p> <p>This indicator aims to assess whether accountability on gender mainstreaming is ensured in the food and health products regulatory sector.</p>
Unit of measure	percentage

<p>Formula (numerator/denominator)</p>	<p>Organization's accountability scale on gender mainstreaming = (The sum of the score of responses of employees for the questions developed for all dimensions /the sum of possible maximum scores for all questions) x100%</p>
<p>Disaggregation</p>	<p>By level of positions at head office , all branch offices, exist and entry ports and regions, male and female</p>
<p>Data Source</p>	<p>Survey report</p> <p>Note: Protocol should be prepared and conduct the survey based on the protocol.</p>
<p>Data collection method</p>	<p>Primary and secondary data collection.</p>

Data quality (Verification)	It evaluates the ratio of accountability on organization’s gender mainstreaming status. Having a higher transparency scale indicates a presence of accountability on organizations gender mainstreaming on the respective field of responsibility. On the other hand, a lower accountability score shows absence of accountability on the organization in gender mainstreaming on respective field of responsibility The average scores in each leadership hierarchy will be calculated, and the functions average result will give the total accountability scale. It measures a continuous variable (ranging from 1- 5). Transparency score “1” represents no accountability on gender mainstreaming and “5” represents accountability is ensured on organizations gender mainstreaming.
Frequency	Every two years.
Baseline value and targets	(Baseline) 2.5 percent 2.7 percent on (2024/25)
Point of Clarity	The base line is taken from EFDA’S gender audit report of 2022.
Indicator name	Implemented civil service commission change tools (Kaison, Citizen charter, BSC, Alliance for Service Improvements (ASI)

Indicator code	SD7-
Indicator type	Output
Precise definition	It is the percentage that measures the level at which EFDA is implementing the national change tools developed by the Federal Civil Service Commission.
purpose/Interpretation	Having 100% performance for this indicator reveals that EFDA has implemented all the tools such as BSC, Kaizon, ASI, and citizen charter which are developed by the Federal Civil Service Commission at all levels. On the other hand, when the performance decreases from 100%, it shows that there are tools EFDA failed to implement partially or fully. If EFDA implements the 3 tools among 4 developed tools by the Federal Civil Service Commission, it indicates that EFDA has 75% performance. Hence, the purpose of this indicator is to measure the status of the implementation of Federal Civil Service Commission tools that are developed to be implemented in all public service organizations.
Formula (numerator/denominator)	Denominator = total number of tools developed by the Federal Civil Service Commission Numerator = Number of tools implemented by EFDA Performance: Number of tools implemented/Total number of tools developed by Federal Civil Service Commission
Unit of Measure	Percentage
Disaggregation	Types of tools, Branch offices
Data source	Quarterly Report

Data collection method	Document/Report review
Data Quality (verification)	Supervision, and checking sample departments and branches
Frequency	Every quarter
Baseline Value and targets	78 (Baseline) 100 (85, 90,100 target)
Point of clarity	The number of tools developed by the Federal Civil Service Commission may vary based on the new policies and related reasons. Hence, the measurement of this indicator should be based on the number of tools available during the reporting period.

Indicator title	Number of developed anti-corruption strategy
Indicator code	SD7
Indicator type	Output
Precise definition	Anti-corruption strategy is plan developed by the state to achieve specific goals related to preventing and fighting corruption on short, medium, and long terms.
Purpose /Interpretation	collective action is a form of collective action with the aim of combating corruption and bribery risks in public procurement
Unit of measurement	count
Formula numerator/denominator)	It is the count of developed anti-corruption strategy
Disaggregation	
Data source	Ethics Directorate(Performance report)
Data collection methods	Performance report review
Data Quality (verification	Standardize data formats and validation, cleanse and audit data regularly, integrate and transform data effectively, train employees on data quality, and documentation
Frequency	Annually
Point of clarity	Anti-corruption is intended or intending to prevent or reduce corruption (= illegal, bad, or dishonest behaviour, especially by people in positions of power):
Baseline Value and targets	Baseline (1) Targets 3 (1,1,1)
Indicator title	percentage of women in leadership positions
Indicator code	SD 7- 4

Indicator type	Output
Precise definition	The percentage of women hold leadership positions compared to men.
Purpose /Interpretation	Increased the percentage of women in managerial position is a key measurement to improve gender equality and women empowerment in the Authority.
Unit of measurement	Percentage
Formula numerator/denominator)	<p>Numerator: - number of women in managerial positions</p> <p>Denominator:- the total number of decision makers at all managerial positions</p> <p>Percentage = $\frac{\text{number of women in managerial positions}}{\text{the total number of decision makers at all managerial positions}} * 100$</p>
Disaggregation	By level of positions at all branch offices, exist and entry ports and head office
Data source	<p>Record</p> <ul style="list-style-type: none"> • Gender disaggregated data • Human resource directorate's report
Data collection methods	<p>Records & reports from</p> <ul style="list-style-type: none"> • EFDA
Data Quality (verification	Standardize data formats and validation, cleanse and audit data regularly, integrate and transform data effectively, and Train employees on data quality, and documentation
Frequency	Quarterly, bi-annual and Annually
Point of clarity	Leadership positions are higher decision making positions such as team leader, desks, and director, deputy and general positions.

Baseline Value and targets	<p>Baseline (25%)</p> <p>Targets 35% (28%, 31%, 35%)</p>
----------------------------	--

Strategic Direction 8: Improve human resource development and management

Indicator name	Employees` satisfaction level
Indicator code	SD8- 1
Indicator type	Outcome
Precise definition	It is a percentage/proportion which measures the satisfaction level of the regulatory sector employees assessed through survey.

<p>purpose/Interpretation</p>	<p>It is designed to measure the different dimensions of satisfaction separately and then to use these to explain a general satisfaction level. These dimensions are management satisfaction, satisfaction, Other Work Group/Groups Satisfaction, job satisfaction, physical environment satisfaction, salary and other material benefits satisfaction. Cut off point 75% (if the percent is above cutoff point employees satisfaction level is good and if it is below it needs serious actions/decisions to improve employees satisfaction.)</p> <p>It also helps to measure the proportion of employees whose desires are fulfilled/satisfied.</p> <p>The purpose of designing this indicator is to assess the employees` satisfaction level so that the food and health products regulatory sector will identify possible interventions to improve the satisfaction level which in turn will improve the organizations performances and relations.</p>
<p>Formula (numerator/denominator)</p>	<p>Employees` satisfaction level = (The sum of the score of responses of employees for the questions developed for all dimensions /the sum of possible maximum scores for all questions) x100%</p>
<p>Unit of Measure</p>	<p>Percentage</p>
<p>Disaggregation</p>	<p>Sex, Age, Educational status, Marital Status, position, Work experience, Regulatory Functions, Branch offices, regions,</p>

Data source	<p>Survey report</p> <p>Note: Protocol should be prepared and conduct the survey based on the protocol.</p>
Data collection method	Data will be collected from the employees by following scientific procedures based on the protocol developed for this survey.
Data Quality (verification)	Piloting, Training for data collectors and supervisors, Supervision, random checks of the samples selected at least 5% of the sample size. For details, please follow the protocol.
Frequency	Every year
Baseline Value and targets	<p>38% (Baseline)</p> <p>70% (50%, 60%, 70%, targets)</p>
Point of clarity	<p>The satisfaction level of employees is a concept reflecting the degree to which the individual's needs and desires are met. It is also perceived as the scope of the work and all the positive attitudes regarding the work environment and can only be attained if the parties regard one another as customers they have to satisfy</p>

Indicator name	Attrition rate of employees
Indicator code	SD8- 3
Indicator Type	Outcome
Precise definition	Attrition rate is the yearly percentage of employees who left the regulatory sector to the yearly average of employees.
purpose/Interpretation	This indicator shows the stability of the organization to serve the intended purpose or the strength of staff retention for accomplishing the mission in protecting the health of the public. The lower the percentage the better the performance.
Formula (numerator/denominator)	<p>The decrease in the attrition can be compared yearly after calculating the yearly attrition rate by dividing the employees left the organization to the yearly average number of employees, multiplied by 100.</p> $\text{Yearly attrition rate} = \left(\frac{\sum \text{Total \# employees left the organisation}}{\sum (\text{Beginning year} + \text{End of year})/2} \right) \times 100\%.$
Unit of Measure	Percentage
Disaggregation	By federal, regions, sex, Category (technical vs support process), year of services
Data source	Survey Report

Data collection method	Document Review <ul style="list-style-type: none"> • EFDA yearly report • RRBs yearly report
Data Quality (verification)	Random review of the record and countercheck with the data.
Frequency	Every years
Baseline Value and targets	Base line: 1.6 Target: 1 (1.4, 1.2, 1)
Point of clarity	The baseline and target is for the federal only, When making national, conditions at the regional states need to be considered. The Allowable Attrition Rate varies from area of work or sector and depends upon many socio economic and political factors. The HR manual is expected to indicate this rate for the federal, regional and the cumulative or national.

Strategic Direction 8: Improve human resource development and management								
77	Percentage of training effectiveness	outcome	71	85	75	80	85	
79	Organizational health status	outcome	NA	90	70	80	90	

Strategic direction 9: Enhance partnership and collaboration

Indicator name	Percentage of stakeholders that participated in the planning, monitoring and evaluation of the
----------------	--

	regulatory activities
Indicator code	SD9-1
Definition	It is the percentage of key stakeholders that participated in the planning or performance evaluation of the regulatory activities out of the total key stakeholders.
Interpretation	<p>Participation of stakeholders means sharing a common understanding and involvement in the decision-making process of the regulatory activities. Participation by stakeholders leads to empowerment and joint ownership of the regulatory activities, and ensures that the regulatory plans are a reflection of the real needs and priorities.</p> <p>The more you engage and involve stakeholders, the more you will reduce and uncover risks on the regulatory activities and improve efficiency of the regulatory system.</p>
Unit of measure	Percentage
Formula (numerator/denominator)	<p>Numerator: Number of key stakeholders that participated either in the planning or performance review meeting of the regulatory activities during the physical period.</p> <p>Denominator: Total number of key stakeholders</p> <p>Percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities can be calculated as:</p> <p>% of Stakeholders = (Number of key stakeholders that participated either in the planning or performance review meeting of the regulatory activities)/ (Total number of key stakeholders) X100.</p>
Disaggregation	By region
Baseline/Target	<p>Baseline: 91%</p> <p>Target : 100 (95,100, 100)</p>
Data Source	Performance report
Data collection method	Document review: Performance report
Frequency	Bi-annually and annually
Point of Clarity	Key stakeholders are stakeholders that have a moderate or high level of influence. Effective engagement of stakeholders in planning helps translate stakeholder needs into organizational goals and creates the basis of effective strategy development.

Indicator name	Number of joint activities of regulatory function conducted with different stakeholders
Indicator type	Outcome
Indicator code	SD9-02
Definition	This indicator refers to collaborative efforts between regulatory bodies and various stakeholders involved in a particular activity.
Interpretation	The purpose/ interpretation of this indicators is that regulatory bodies are collaborating with governmental and non-governmental institutions, woman and youth federations, private health associations and other relevant parties to develop and implement regulations. these joint activities serve to enhance the effectiveness of regulatory functions by leveraging the expertise and resources of multiple stakeholders to achieve common goals related to public health, safety, and other important regulatory objectives. This collaboration allows for a more comprehensive and balanced approach to regulation, taking into account the perspectives and expertise of all stakeholders involved. It also promotes transparency, accountability, and effectiveness in the regulatory process. Overall, the joint activities aim to ensure that regulations are fair, practical, and beneficial for all parties involved.
Formula (numerator/denominato	Numerator:- number of Stakeholders who perform joint regulatory functions

r)	Denominators:- total number of stakeholders $\frac{\text{number of Stakeholders who perform joint regulatory functions}}{\text{total number of stakeholders}} \times 100$
Unit of Measure	Number
Disaggregation	EFDA, RRBS,
Data source	Performance report
Data collection method	Review performance report
Frequency	Annually
Baseline Value and targets	Baseline: 22 Target: 49 (31, 40, 49)
Point of clarity	

--	--

Indicator name	Number of strategic partnership and collaboration established with international, federal, and local organizations
Indicator code	SD9-03
Definition	It is the summation of established strategic partnership and collaboration with international, federal, and local organizations with in the physical period.
Purpose/Interpretation	<p>The purpose of forming Partnership and collaboration is to bring about more effective and efficient delivery of programs and eliminate any unnecessary duplication of effort. Gathering all the organizations involved in a particular issue can result in a more cohesive and comprehensive intervention.</p> <p>Strategic partnership and collaboration between organizations can give benefits such as: saving costs through sharing administrative expenses; expanding value propositions; improving efficiency; strengthening programs; make use of compatible skills and abilities; and improve leadership skills.</p> <p>The important determinants of strategic partnership and collaboration are: - the degree</p>

	<p>to which partnership objectives have been realized; and the extent to which stakeholders are prepared to abide by collectively agreed actions. The weight of the determinants during performance evaluation will be as follows: -</p> <ul style="list-style-type: none"> ● Extent to which key objectives have been achieved (70) ● Extent to which stakeholders abide by or implement agreed actions (30)
Unit of measure	Number
Formula	<p>The established strategic partnership and collaboration will be calculated by using the determinants of strategic partnership and collaboration. Based on the weight given, each of the determinant result will be summed and if the result is greater than 75, we can say that, a strategic partnership and collaboration has been established.</p> <p>Number of strategic partnership and collaboration established with international, federal, and local organizations can be calculated as: -</p> <p># of strategic partnership and collaboration = the summation of the number of established partnership and collaboration with international, federal, and local organizations and that has a calculated weighted result more than 75 within the physical period.</p>
Disaggregation	by regulatory functions
Baseline/Target	Baseline: 2

	Target:6(4, 5, 6)
Data Source	Performance report
Data collection method	Document review: Performance report
Frequency	Annually
Point of Clarity	<p>Partnership and collaboration refer to a group of organizations with a common interest who agree to work together toward a common goal.</p> <p>Partnership agreements should be put in writing, and reviewed annually. Collaborative relationships are the building blocks for the vast majority of partnerships.</p> <p>Partnerships need to develop a long-term strategy if they are to work effectively and have a lasting effect. Also necessary are a shared commitment to implement the programme and arrangements for monitoring and reporting progress.</p> <p>A partnership and collaboration are strategic when it provides your organization with the means and methods for advancing your mission.</p> <p>Effective partnerships leverage the strengths of each partner and apply it strategically to the issue at hand. Strategic partnership and collaboration build the relationships, shared</p>

understanding, and collective focus to make lasting progress.

Strategic Direction 10: Improve efficiency and effectiveness

Indicator title	Amount of resource mobilized in million birr/year
Indicator code	SD10-1
Indicator Type	Output
Definition	It is the amount of resource mobilized in millions birr for the health regulatory sector in the respective budget years
Purpose/ Interpretation	This indicator shows the amount of resource/in monetary value mobilized in monetary value for the regulatory sector. When the amount of resource mobilized increases, the performance of the regulatory sector will be enhanced. The amount of resource mobilized increment shows that the regulatory sectors have great achievement in filling the budget scarcity across the regulatory sector from federal to regional regulatory bodies. On the other hand, when the amount of resources/in monetary value mobilized decreases, it shows that the regulatory body has weaker performance which in turn leads to an increased budget gap across the sector which significantly affects the performance of the food and health products objectives.
Unit of measure	Number
Formula:	Denominator = The target set to mobilize the resource in the respective fiscal year in millions of ETB Numerator = The total sum of resources mobilized in millions of ETB for the health regulatory sector in the

	<p>respective budget year</p> <p>Performance in %= (The total sum of resources mobilized in millions of ETB for the health regulatory sector in the respective budget year/ The target set to mobilize the resource in the respective fiscal year in millions of ETB) *100</p>
Disaggregation	sources of resources (Partners, loans, revenue, and treasury), Sectors (Food, Medicine, Medical device, etc.)
Data Source:	EFDA, Partners, MoF, MoH, RRBs reports and records
Data Collection methods:	Document review
Frequency	Quarterly, bi-annually and yearly
Baseline value and target	Baseline: 90 Target: 214 (at the end of 3 th year. (127,165,214)

Indicator name	Medicine registration lead time (in days)
Indicator code	SD10- 2
Indicator Type	Output
Precise definition	Registration lead time is the average number of authority days taken for different types of medicine application dossiers to evaluate and issue market authorization certificates in a specified period, in consideration with the lag time.
purpose/Interpretation	The indicator used to measure the efficiency of medicines application dossier evaluation submitted for registration. The lesser the days the better the efficiency and vice versa.
Formula (numerator/denominator)	<p>Numerator: Summation of the Authority days taken to evaluate different medicine Application dossiers.</p> $= \sum_{i=1}^n AD1 + AD2 + AD3 \dots + ADn$

	<p>Denominator: The total number of dossiers $= \sum_{i=1}^n Xi$</p> <p>Medicine registration lead time is calculated as:</p> $\text{MRLT} = \frac{\sum_{i=1}^n AD1 + AD2 + AD3 \dots ADn}{\sum_{i=1}^n Xi}$ <p>Where MRLT - Medicine registration lead time Di- working Days taken to evaluate and issue MA certificate for each dossiers in consideration with the lag time Xi- Number dossiers, eg. D1= the first Dossier while Dn the nth dossier</p>
Unit of Measure	Days
Disaggregation	Product category (therapeutic classification...), fast track versus normal.
Data source	e-RIS, Periodic reports
Data collection method	Document Review
Data Quality (verification)	Random checks the <i>e-RIS</i> values and MA certificates.
Frequency	Annually
Baseline Value and targets	Base line: XX Target: 270 days ()
Point of clarity	Defining Authority days, it is the total days from the date of submission of the dossier less the client days or lag time which is the days taken by the client on return to applicant during pre-screening and response days taken by the client for further request during evaluation.

	NB: The waiting time elapsed for payment of service fee, response time to EFDA further request, submission of laboratory samples (if applicable) are considered customer lag time and will not be considered as a medicine registration lead time.
Indicator name	Medicine consignment test lead time (in day)
Indicator code	SD10- 3
Indicator Type	Output
Precise definition	Medicine consignment test lead time is the average number of working days taken for medicine consignment testing and issue certificate of analysis in a specified period, in consideration with the lag time.
purpose/Interpretation	The indicator used to measure the efficiency of Medicine Quality Control Lead Executive Office in testing medicine consignment taken from port of entry. The lesser the days the better the efficiency and vice versa.
Formula (numerator/denominator)	<p>Numerator: Summation of the Authority days taken to test medicine consignment taken by Entry and Exit Products Inspection Lead Executive Office.</p> $= \sum_{i=1}^n TS1 + TS2 + TS3 \dots + TSn$ <p>Denominator: The total number of medicine consignment tested</p> $= \sum_{i=1}^n Xi$ <p>Medicine registration lead time is calculated as:</p> <p>The average lead time(in day) for medicine consignment testing in a year $= \frac{\sum_{i=1}^n TS1 + TS2 + TS3 \dots + TSn}{\sum_{i=1}^n Xi}$</p>

	Xi- Number medicine consignment tested per year, TS –test sample
Unit of Measure	Days
Disaggregation	Product category (therapeutic classification...), ports.
Data source	Laboratory database, Periodic reports and laboratory analysis report.
Data collection method	Review laboratory database, periodic report and laboratory analysis report.
Data Quality (verification)	Check Laboratory database and analysis report
Frequency	Annually
Baseline Value and targets	Base line: 44 days Target: 44 days ()
Point of clarity	Defining Authority days, it is the total days from the date of submission of the dossier less the client days or lag time which is the days taken by the client on return to applicant during pre-screening and response days taken by the client for further request during evaluation.

Strategic direction 11: Improve community ownership

Strategic direction 11: Improve community ownership

Indicator title	percentage of the population who are informed about regulatory measures, laws and activities
Indicator code	SD11 -1
Definition	It is the proportion of people whose age are more than 18 years that have awareness about the availed regulated food and health products against the total number of peoples more than 18 years old in the country.
Interpretation	It measures the awareness of the community on health regulatory measures, laws and services acquired by means of different media, like mass media, printing media, and community mobilization program and so on. A person, who is aware of food and health products regulatory laws & services, would likely be able to exercise his /her rights. ie, protect him/herself & the public from illegal, unsafe food and health products thereby give tip offs & comments to the regulatory body.
Unit of measurement	Percentage
Formula	<p>Numerator:- Number of peoples more than 18 yrs old who have awareness about food and health product regulations sampled</p> <p>Denominator:-Total no of peoples age more than 18yrs sampled</p> <p>This can be calculated as :</p> <p style="text-align: center;">percentage = $\frac{\text{No. of peoples more than 18 yrs old who have awareness about food and health product regulation sampled}}{\text{Total no of peoples whose age are more than 18yrs sampled}} * 100$</p>
Disaggregation	By product type, sex, age, education, occupation, type of media outlet, regions ,socioeconomic status, urban/rural, special needs
Data source	Survey report
Data collection methods	House hold survey
Data Quality (verification)	The detail of the Data Quality verification will be based on the study protocol

Frequency	Every 2 and 1/2 years
Baseline Value and targets	46% (Baseline) 70%(55, 60, 70%, Target)
Indicator title	Number of investigated tipoff, complaints and concerns from the public
Indicator code	SD11-2
Precise definition	It is a number of the addressed tip-offs, complaints and concerns that have been received, investigated and addressed against the total number of tip-offs, complaints and concerns that offered to the regulatory body.
Purpose /Interpretation/	Information generated from the collected tip-offs, complaints and concerns should be investigated and addressed in time. This will help the regulatory body to develop Increase in the proportion of addressed tip-offs, complaints and concerns create trust & sense of ownership in health regulatory system. If it doesn't get addressed in a timely manner it hurts business and customer relationships.
Unit of measurement	Percentage
Formula (Numerator/Denominator)	Count
Disaggregation	Product type, regions, and branch offices
Data source	Reports from <ul style="list-style-type: none"> • EFDA & RRBs
Data collection methods	Document review: records & reports from HRIS, <ul style="list-style-type: none"> • EFDA • RRBs
Frequency	Monthly, Quarterly, bi-annually and annually
Baseline Value	9806(Baseline)

and targets	21082 (10296, 10786, 11276 Target)
Data Quality (verification)	Data Audit
Point of clarity	Tip-offs and complaints are a piece of confidential, advance, or inside information that offered to the regulatory body in written or oral form.

92	Percentage of population whose age above 13-year-old, who got regulatory information through media outlet	output	54	75		75	Abera
----	---	--------	----	----	--	----	-------

Strategic Direction 12: Improve Evidence Based Decision Making

Indicator name	Percentage of expected reports received from reporting units on time
Indicator type	Output
Indicator code	SD12-1
definition	Report is an account given of a particular matter, especially in the form of an official document, after thorough investigation or consideration by an appointed person or body. The definition of this indicator refers to the anticipation or requirement for receiving specific reports from various reporting departments within an organization or system, and receiving them within the designated timeframe (schedule).
purpose/Interpretation	Expect Reports received from the reporting units on time.

	The purpose of this indicator is to ensure timely and accurate information flow within an organization depending on the context and specific requirements. These reports are typically requested by strategic affairs executive office to monitor the progress, performance, and compliance of various departments. Overall, the purpose and interpretation of expected reports received on time revolve around maintaining organizational efficiency, effective communication, performance evaluation, and compliance monitoring.
Formula (numerator/denominator)	Numerator: Number of reports received on time Dominator: Total number of received reports Percentage of expected reports received from reporting units on time can be calculated as: % report= (Number of reports submitted or received on time / Total number of received reports) *100
Unit of Measure	Percentage
Data source	Performance Report
Disaggregation	EFDA and RRBs
Data collection method	review of performance report
Frequency	Quarterly
Baseline/Target	Baseline:79.6 Target: 95(85,90,95))
Indicator name	Number of performance audit reports
Indicator type	output
Indicator code	SD12-03
definition	A performance audit report is a document that presents a detailed and systematic examination of an organization, program, or activity to assess its effectiveness, efficiency, and economy in

	achieving its objectives.
purpose/Interpretation	<p>The purpose of a performance audit report is to provide an independent and objective assessment of the performance of an organization, program, or activity. The report aims to evaluate whether the entity is achieving its objectives efficiently, effectively, and in compliance with relevant laws and regulations. It also identifies areas for improvement and makes recommendations for corrective actions.</p> <p>The interpretation of a performance audit report involves analyzing the findings and conclusions presented in the report to understand the strengths and weaknesses of the audited entity's performance. This can help higher management body make informed decisions about resource allocation, program improvements, and accountability measures. The report can also serve as a tool for transparency and accountability by providing insight into how public resources are being used and whether they are being used effectively.</p>
Formula (numerator/denominator)	<p>Numerator: NA Denominator: NA To count number of performance audit report</p> <p style="text-align: center;">OR</p> <p>Numerator: number of findings, case in the report/documents Denominator: total number of audited report/documents</p> <p>(total number of findings in the report(documents) /total number of audited report/documents) *100</p>
Unit of Measure	Number
Data source	Performance audit report
Disaggregation	Product type, Departments, branches
Data collection method	Review performance audit reports

Frequency	Annually
Baseline/Target	Baseline: 9 Target:24(14, 19, 24)
Point of Clarity	

Indicator name	Percentage of expected reports received from reporting units complete
Indicator code	SD12 -2
Definition	<p>It is the percentage of expected reports received completes (a report that includes all the necessary information) from reporting units during the reporting period.</p> <p>It explains how the plan of work was carried out and what conclusions and recommendations can be drawn from the project or the planned activity.</p>
purpose/Interpretation	<p>Completeness is one of the measurements for a reporting quality. A report is considered “complete” when every reporting unit is reporting a full set of data and when it fulfils expectations of comprehensiveness. To ensure completeness, all data sets and data items must be recorded. Quality complete report should be clear, concise, accurate, reliable & well organized with clear section headings.</p> <p>The purpose of this indicator is to examines the extent to which:</p> <ul style="list-style-type: none"> ▪ Data reported through the system are available and adequate for the intended purpose ▪ All reporting units that are supposed to report are actually reporting ▪ Data elements in submitted reports are complete <p>The more complete the received report, it will be more meaningful and helps for appropriate evidence based decision making.</p>

Unit of measure	Percentage
Formula (numerator/denominator)	<p>Numerator: Number of reports received complete during the reporting period.</p> <p>Denominator: Total number of reports available or received</p> <p>percentage of expected reports received complete can be calculated as:</p> <p>percentage of complete reports = (Number of reports that are complete(all data elements filled out) / Total number of received reports) * 100</p>
Disaggregation	EFDA and RRBs
Data Source	Performance report
Data collection method	Document review of performance report
Frequency	Quarterly, Bi-annually and annually
Baseline/target	<p>Baseline 79.4</p> <p>Target 90 (83, 86, 90)</p>

Point of Clarity	A good complete report should be accurate(reveal the truth), use easy language (easy understandable words should be used), responsive format (appropriate format or style should be followed)
-------------------------	---

Strategic Direction 13: Strengthen food and health products Regulatory Infrastructures

Indicator name	Constructed center of health regulatory excellence
Indicator code	SD13-1
Indicator type	Output
Definition	The number of newly built, center of excellence for health regulatory services and activities,
Purpose / Interpretation	The newly built, center of excellence for health regulatory services and activities including medical device, food, medicine, and Vaccine quality control laboratories helps regulatory authorities to check their capacity in order to execute their responsibility of protecting the public from poor quality products.
Unit of measure	Number
Formula	Count the number of newly built center of health regulatory excellence
Disaggregation	
Data source	EFDA and MoH report (project performance report)
Data collection methods	Physical observation and Document Review: <ul style="list-style-type: none"> • EFDA • MoH
Frequency	Yearly
Baseline value and target	Baseline: 0 Target: 1

Indicator name	Increase well established National Rapid Alert System (nRAS)
Indicator code	SD13-2
Indicator Type	Outcome
Precise definition	<p>The Rapid Alert Systems is a procedure of timely, proportionate, accurate and consistent response to health events arising from SF medical products which represent a significant threat to the public health and used to minimize the risk on consumers.</p> <p>To protect public health, it may become necessary to implement urgent measures such as the recall of one or more defective batch (es) of medicinal products during its marketing period. To facilitate this, the Ethiopian Food and Drug Authority (EFDA) is required to develop and implement an effective technology to notify the public and relevant stakeholders. EFDA developed Medicine Rapid Alert System to enable the public to report medicinal product quality defects in the market.</p> <p>The aim of the Medicine Rapid Alert System (MRAS) is to transmit alerts whose urgency and seriousness cannot permit any delay in transmission, and create access to information on alerts related substandard and falsified medicines.</p>
purpose/ Interpretation	The indicator used to measure establishment of functional alert system that protect citizens from safety risks of regulated products by taking a timely, proportionate, accurate and consistent response.

Unit of Measure	Number
Formula	Count the number of established functional national rapid alert system
Disaggregation	Product category (Food, medicine, medical device), Region, source of information
Data source	Public, investigation reports, Regulatory bodies,
Data collection method	Database of the alert system
Data Quality (verification)	- Challenging the functionality of the database
Frequency	Annually
Baseline Value and targets	Base line: 1 Target: 2
Point of clarity	Checking functionality of web-based system is dependent up on different factors like power, internet connection etc.

Indicator name	Increase the number of regional regulatory bodies that implemented COC system for retail out let
-----------------------	--

Indicator code	SD13-3
Indicator Type	Outcome
Precise definition	i-License is an online application developed for the Ethiopian Food and Drug Authority (EFDA) that allows importers, exporters, wholesalers, and manufacturers to apply for a certificate of competency and for EFDA to approve these applications online. This application is designed to manage the licensing process for all entities that wish to manufacture, register, import, and distribute food and medical products in Ethiopia—from the start of a licensing application to approval. Further incorporating an additional module for licensing of Retail Outlet in the work of regional regulatory bodies so that it can be used by regional regulatory bodies
purpose/ Interpretation	The indicator used to measure the status of regional regulatory bodies equipped with proper electronic licensing system. The greater the number the better the performance of the regulatory sector.
Unit of Measure	Number
Formula	Count: Number of regulatory bodies implementing i-licensing system
Disaggregation	Regions
Data source	Performance report

Data collection method	Review of performance report
Data Quality (verification)	Challenging the system
Frequency	Annually
Baseline Value and targets	Base line: 0 Target: 12 (4, 4, 4)
Point of clarity	

Indicator name	Number of automated systems implemented from 6 to 19 (6,8,5)
Indicator code	SD13-4
Indicator type	Output

Precise definition	The number of electronically networked/automated systems implemented in food and health products regulatory sector
purpose/Interpretation	<p>The indicator measures how many automated and implemented systems in the regulatory sector. This indicator measures the achievements in changing all the food and health products regulatory services to electronic and online services. In the other words, this reveals how the regulatory services suits for the customers.</p> <p>Hence, this indicator helps the regulatory sector to measure its progresses in changing the services to electronic system.</p>
Formula (numerator/denominator)	<p>Numerator: the summation of the number of automated and implemented systems</p> <p>% of performance = (the number of automated and implemented systems / the number of automated and implemented systems planned by the regulatory sector) *100</p>
Unit of Measure	Numbers
Disaggregation	Departments, functions, Branch offices, port of entries, regional regulatories
Data source	Performance reports
Data collection method	Document review,
Data Quality (verification)	Physical supervision

Frequency	Every year
Baseline Value and targets	6 19 (6,8,5 targets)
Point of clarity	

Indicator name	Increase the number of renovate and equipped data center from 1 to 2
Indicator code	
Indicator Type	Outcome
Precise definition	Data center renovation is the process of updating the physical infrastructure of an existing data center to improve the efficiency and reliability of its operations. This may include replacing outdated hardware, upgrading power and cooling systems, adding new network and storage capabilities, and implementing new security measures. Additionally, data center renovation may include reconfiguring the physical layout of the data center, such as by relocating existing equipment or adding additional racks and floor space.
purpose/ Interpretation	The indicator measures how many automated, renovated and equipped data center in the regulatory. This indicator measures the achievements of equipped and renovated data centers in the regulatory.

Unit of Measure	number
Formula	Numerator: the summation of the number of automated, renovated and equipped data center % of performance = (automated, renovated and equipped data center / the number of automated and implemented systems planned by the regulatory sector) *100
Disaggregation	
Data source	Annual Performance Report
Data collection method	Document review
Data Quality (verification)	Physical review
Frequency	Annually
Baseline Value and targets	Base line: 1 Target: 2
Point of clarity	

Indicator name	Frequency of Audit and Validate the authority System
Indicator code	SD13-5
Indicator Type	Outcome
Precise definition	The audit of systems involves the review and evaluation of controls and computer systems, as well as their use, efficiency, and security in the company, which processes the information.
purpose/ Interpretation	The indicator measures how much time for the institution's systems performance audit has been done
Unit of Measure	Number
Formula	Count number of Audit report
Disaggregation	
Data source	Annual performance report
Data collection method	
Data Quality (verification)	-

Frequency	Annually
Baseline Value and targets	Base line: 1 Target: 3 (1, 2)
Point of clarity	

Indicator name	Increase the number of Integration of eRIS with other system
Indicator code	SD13-6
Indicator Type	Outcome
Precise definition	System integration is essential both for system to system or organization-to-organization communication and internal cooperation within an enterprise. The main reason for our organization to use system integration is to improve the productivity and the quality of the regulatory operations, and tasks with different organizations like Custom, Trade and industry. The goal is to get the organization's various IT systems to “talk to each other” through the integration, to speed up information flows and reduce operational costs for the organization.
purpose/ Interpretation	System integration is a complex process, but it can offer a wide range of benefits for organizations of all sizes. major benefits of system integration include: Productivity, Data Accuracy, Faster decision-making, Cost-effectiveness etc. The integration of eRIS with eTrade system of Ministry of Trade and Regional Integration will

	<p>allow the EFDA iLicense clients to apply through the eTrade system and get reviewed and approved through the iLicense system.</p> <p>Integration of eRIS with ESW system will allow importers to apply pre-import permit, pre-shipment, and port clearance requests on eSW system and get review and approval on eRIS</p>
Unit of Measure	Number
Formula	
Disaggregation	
Data source	eRIS
Data collection method	Annual performance report
Data Quality (verification)	-
Frequency	Annually
Baseline Value and targets	<p>Base line: 1</p> <p>Target: 3 (1, 1)</p>
Point of clarity	

Strategic direction 14: Improve Quality Management System

Indicator name	EFDA Maturity level 3 or WHO listed authorities certification attained
Indicator code	SD14- 1
Indicator Type	Output
Precise definition	Maturity level is a certification status issued by WHO. EFDA has designed and implementing Institutional Development Plan (IDP) followed by official bench marking assessment by WHO using WHO Global Benchmarking Tool (GBT) to attains Maturity level 3 recognition which means Stable, well-functioning and integrated regulatory system.
purpose/Interpretation	To promote the competency level of the national regulatory system. Attaining level-3 is interpreted as a stable, well-functioning and integrated regulatory system.
Formula	As per GBT tool standard
Unit of Measure	Count

Disaggregation	NA
Data source	Document review, self-assessment and WHO official benchmarking assessment report, certification paper
Data collection method	Document review
Data Quality (verification)	Physical check of the certification
Frequency	3 years
Baseline Value and targets	Base line: ML-2 Target: ML-3
Point of clarity	Clear understanding the GBT and the indicators
Indicator name	Attained ISO/IEC 27001 accreditation of EFDA information security management system
Indicator code	SD14-2
Indicator type	Output
Precise definition	It is certification status of EFDA by ISO/IEC 27001. ISO/IEC 27001 is the standard for Information Security Management System (ISMS). Conformity with ISO/IEC 27001 mean that EFDA has put in place a system to manage risks related to the security of data owned or handled by the Authority, and that this system respect all the best practices and principles enshrined in this international standard

purpose/Interpretation	Certification of EFDA for ISO/IEC 27001 by an accredited certification body indicates that it has established and implemented all requirements of the information security management system and the services it provides are in compliance with the requirements of this standard and hence will be recognized at global level.
Formula (numerator/denominator)	NA
Unit of Measure	Count
Disaggregation	NA
Data source	Performance report
Data collection method	Review performance report
Data Quality (verification)	Physical supervision
Frequency	Every year
Baseline Value and targets	0 (Baseline) 1 (target)
Point of clarity	The scope of Certification of EFDA for ISO/IEC 27001 doesn't include the information system

	of branch offices that are used locally (at the branch office only).
Indicator name	Number of ISO/IEC 17025/2017 accredited EFDA's laboratories
Indicator code	SD14-3
Indicator type	Output
Precise definition	It is the number of EFDA laboratories accredited for ISO/IEC 17025/2017.
Purpose/Interpretation	This indicator measures the level of compliance of the EFDA laboratories to ISO/IEC 17025/2017 requirements. High level of compliance to the standards indicates better assurance to the health of the people, and increase acceptance of decisions made by the authority.
Formula (numerator/denominator)	The count of EFDA laboratories accredited for ISO/IEC 17025/2017.
Unit of Measure	Count
Disaggregation	Geographical location (HQ, branch), test parameters, product types (food, medicine, or medical devices)
Data source	Performance reports
Data collection method	Performance review

Data Quality (verification)	Supervision during sample collection, random checks on the number and types of samples collected from the market (trace back to the source). If the analysis result becomes doubtful, a confirmatory test will be done. For details, please follow the PMS protocol.
Frequency	Quarter
Baseline Value and targets	3 (Baseline) 5 (1, 0, 1) Target
Point of clarity	The indicator include quality laboratories for food, medicine or medical devices

Indicator name	Number of EFDA laboratories WHO prequalified
Indicator code	SD14-4
Indicator type	Output
Precise definition	It is the number of EFDA laboratories that are WHO prequalified
Purpose/Interpretation	This indicator measures the level of compliance of the EFDA laboratories to the WHO prequalification requirements. High level of compliance to the standards indicates better assurance to the health of the people, and also increases acceptance of decisions made by the authority.

Formula (numerator/denominator)	The count of EFDA laboratories that are WHO prequalified
Unit of Measure	Count
Disaggregation	Test parameters
Data source	Performance reports
Data collection method	Performance review
Data Quality (verification)	
Frequency	Annual
Baseline Value and targets	0 (Baseline) 1 (0, 0, 1:Target)
Point of clarity	

108. ISO 9001 certification of EFDA HQ attained

Indicator name	ISO 9001 certified EFDA (108. ISO 9001 certification of EFDA HQ attained)
----------------	--

Indicator code	SD14-5
Indicator type	Output
Precise definition	It is certification status of EFDA by ISO 9001
purpose/Interpretation	Certification of EFDA for ISO 9001 by an accredited certification body indicates that the organization has established and implemented all requirements of the quality management system and the services it provides are in compliance with the requirements of this standard and hence will be recognized at global level.
Formula (numerator /denominator)	NA
Unit of Measure	Count
Disaggregation	NA
Data source	Preparatory documents, auditors' report, CAPA and the certificate.
Data collection method	Review performance report
Data Quality (verification)	Physical supervision

Frequency	Every year
Baseline Value and targets	0 (Baseline) 1 (target)
Point of clarity	The scope of Certification of EFDA for ISO 9001 doesn't include the branch offices

Indicator name	Scope of ISO/IEC 17025/2017 accredited test parameters of EFDA laboratories from 31 to 59 (food from 11 to 16, medicine from 11 to 16, medical device from 9 to 27)
Indicator code	SD-14 - 6
Indicator type	Output
Precise definition	ISO/IEC 17025/2017 accredited laboratory parameters are parameters which their quality is assured by the third party and certified by that body, to get additional parameters which are tested by the laboratory to be accredited it is called Scope expansion

<p>purpose/Interpretation</p>	<p>The purpose of the scope expansion is to get all the parameters done by the authorities laboratories to be accredited, to give confidence for those who want to get the service of the laboratories, to be competent from the laboratories found in the region.</p>
<p>Formula (numerator/denominator)</p>	<p>Numerator: total number of parameters accredited</p> <p>Denominator: Total number of test parameters conducted in the laboratory</p> <p>Scope of ISO/IEC 17025/2017 accredited test parameters of EFDA laboratories from 31 to 59 (food from 11 to 16, medicine from 11 to 16, medical device from 9 to 27)</p> <p>= (total number of parameters accredited)/ (Total number of test parameters conducted in the laboratory</p> <p>.</p>
<p>Unit of Measure</p>	<p>number</p>
<p>Disaggregation</p>	<p>No of total parameters in all the laboratories, number of accredited parameters</p>

Data source	Laboratory/EAS website
Data collection method	By looking laboratory reports
Data Quality (verification)	Supervision, Confirmatory tests will be done in the laboratory, implementing quality management parameters implementing ISO 17025/2017 requirements
Frequency	Every year
Baseline Value and targets	31 (Baseline) 59 (Target)
Point of clarity	The laboratories are food, medicines and medical devices labs at the head office, branch laboratories

Strategic direction 15: Strengthen Formulation and implementation of legal frameworks

Indicator title	Number of legislations on regulated products
Indicator type	Output
Indicator code	GO15-1
Precise definition	It is the cumulative number of a proclamation, Regulation, Directives and other legal documents initiated and/or developed in relation to regulated products and institutions.
purpose/Interpretation	The purpose of this indicator is to support the regulation system by law and urges regulatory authorities to execute their responsibilities and mandates effectively, consistently and cope up with the changing environment.
Formula (numerator/denominator)	The Number of legal instruments developed is the summation of developed legal instruments in the given period. Number of legal instruments developed = $\Sigma(\text{developed})$
Unit of Measure	Number
Disaggregation	By region, type of function
Data source	Report
Data collection method	review of performance report
Frequency	Quarterly
Baseline/target	Baseline=120 Target=170(10,20,20)
Point of clarity	

Indicator title	Number of criminal cases instituted and follow-up made until decision is rendered by the court
Indicator type	Output
Indicator code	GO15-2
Precise definition	It is the number of criminal cases that are instituted criminal liability on the persons who violate any laws in relation to regulated products and follow up until the court of law renders its decision.
purpose/Interpretation	The purpose of this indicator is to take legal measure and punishment on institutions or Any person who is in violation of the proclamations, regulations, directives and any other laws by instituting criminal liability and providing evidences for judicial bodies.
Formula (numerator/denominator)	Number of criminal cases instituted and follow-up made until decision is rendered by the court in the given period.
Unit of Measure	Number
Disaggregation	By region, type of function
Data source	Report
Data collection method	review of performance report
Frequency	Quarterly
Baseline/target	Baseline=48 Target= 195(60,65,70)

--	--

Indicator title	Percentage of civil cases decided in favor of the regulatory
Indicator type	Output
Indicator code	GO15-3
Precise definition	The percentage of winning civil cases and the number of resolved cases in the physical period.
purpose/Interpretation	The purpose of this indicator is to win civil claims instituted by the Authority or on the Authority in relation to civil laws. There must be strong “Preponderance of evidence” or “Clear and convincing” standards. Therefore, the more Clear and convincing” standards available, the more the decisions will be rendered in favor of the Authority.
Formula (numerator/denominator)	Numerator: Number of winning civil cases during the physical period. Denominator: Total number of resolved cases Rate of winning civil cases can be calculated as: Rate of winning = (Number of winning civil cases)/ (Total number of resolved cases during the physical period) X100.
Unit of Measure	Percentage
Disaggregation	By region, type of function
Data source	Report
Data collection method	review of performance report

Frequency	Annual
Baseline/target	Baseline =75 Target= 95(85, 90, 95)
Indicator title	Percentage of legal advices provided including to take administrative measures
Indicator type	Output
Indicator code	GO15-4
Precise definition	It is the ratio of provided legal advices before administrative measurements or decisions are rendered.
purpose/Interpretation	It helps to make any administrative measurements or decisions based on the legal scope of the regulatory in order to implement the law within the mandates and responsibilities as stated/provided in the law. And it also helps to avoid complaints on administrative measurements and decisions.
Formula (numerator/denominator)	Numerator: Percentage of legal advices provided including to take administrative measures. Denominator: Total number of administrative measures taken Rate of provided legal advices = (Number of provided legal advices)/ (Total number of administrative measures taken during the physical period) X100.
Unit of Measure	Percentage
Disaggregation	
Data source	Report
Data collection method	review of performance report
Frequency	Annual
Baseline/target	Baseline =95 Target= 99(99, 99, 99)

Indicator title	Percentage of Administrative measure taken against non-compliance
Indicator type	Output
Indicator code	GO15-5
Precise definition	It is the ratio of administrative measurements against regulated products and/or institutions those violate the regulatory requirements as provided in the law.
purpose/Interpretation	It helps to take administrative measurements on illegal actions.
Formula (numerator/denominator)	
Unit of Measure	Percentage
Disaggregation	
Data source	Report
Data collection method	review of performance report
Frequency	annual
Baseline/target	Baseline =95 Target= 99(99, 99, 99)