FHRSTP-II Performance Indicator Reference Sheet (PIRS)

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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 second Food and Health products regulatory sector transformation plan (FHRSTP-II) which covers the period between 2013-2017 Ethiopian fiscal years (July 2020 – June 2025) 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 88 indicators are selected to monitor and evaluate the FHRSTP II. 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 I 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 5 years. Some indicators are analyzed on a monthly basis, others on a quarterly, annual, 2-3 years and 5 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 indicatorsexplicitly and unambiguouslyso 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. **PreciseDefinition**: 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.

Objective 1: Protect the people from unsafe 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	The purpose of the measurement is to know the status of unsafe food available in the market. 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. 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.
Formula (numerator/denominator)	Numerator: Number of foods identified as unsafe during the survey period. Denominator: Total number of collected tracer food products for testing Prevalence of unsafe food available in the market can be calculated as: Prevalence = (number of foods identified as unsafe)/ (total number of collected tracer food products for testing) X100.
Unit of Measure	Percentage

Disaggregation	Product Category, product type, Region, food business operator type, ownership (public/private), country of origin, compliance status.
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 Four year
Baseline Value and targets	**NA** (Baseline) 25 (Target)
Point of clarity	● 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 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 ● 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), open markets (exhibitions/expo/street markets) and Internet if any.

Indicator name	Prevalence of illegal food products in the market
Indicator code	GO1- 02
Indicator type	Outcome
Precise definition	It is the prevalence of illegal food products found in the market during assessment/survey period.
purpose/Interpretation	The purpose of the these indicator is, to measure the prevalence of illegal food products in the market and to publicise the findings to the public and other relevant stakeholders, to bring back illegally manufacturing, marketing or importing facilities to legal track, to traceback the source, origin and other relevant informations, to establish track and tracing system, to effectively utilize alerting system, to create strong integration and collaboration among national and international organizations. High prevalence of illegal food products in the market indicates that the public is at high health risks raised from different food safety hazards due to the illegal operations without regulatory oversight or control on food business operators and weak control system at port of entry and informal markets, weak integration and collaboration among relevant stakeholders.
Formula (numerator/denominator)	Numerator 1: Number of food samples identified as illegal during the market survey period. Denominator 1: Total number of tracer food products' samples assessed Prevalence of illegal food available in the market can be calculated as: Percentage of illegal food = Number of food samples identified as illegal during the market survey period/Total number of tracer food products' samples assessed*100

Unit of Measure	Percentage
Disaggregation	Product category, product type, region, food business operator type, ownership (public/private), registration status (product, facility), country of origin, compliance status
Data source	Market survey report
Data collection method	Market survey Samples are verified through physical checking in the facility where product stored and samples will not be collected. Note: Detailed protocol should be prepared and conduct the survey based on the protocol.
Data Quality (verification)	Supervision
Frequency	Every 2 ½ years
Baseline Value and targets	**50** (Baseline) 40 (after 2.5 years), 30 (at the end of five years)
Point of clarity	● Illegal food products are food products that do not meet regulatory and statutory requirements set or accepted by the Authority which are found on the market(locally produced or imported through illegal route),products that are distributed in the market by non authorized facilities from non approved sources and legal products handled by unauthorized facilities. ● Survey protocol should be prepared for selection of survey sites, representative food establishments at different levels of supply chain (importer, wholesaler, distributor and retailer), inclusion of open markets (exhibitions/expo/street markets), types of tracer food products and how to conduct (eg intelligence led surveillance) the assessment.

Indicator name	Prevalence of food adulteration
Indicator code	GO1- 03
Indicator type	Outcome
Precise definition	It is the prevalence of adulterated food products in the market during the survey period as confirmed by testing of food samples.
purpose/Interpretation	The purpose of this indicator is to determine the level of prevalence of adulterated food products in the market and identify potential adulterants and their health risks High prevalence of adulterated food products in the market indicates that the public is at high health risks from adulterants. Hence, the finding should be communicated to the public and other relevant stakeholders, and take appropriate measures by collaborating with other stakeholders in preventing, detecting and responding to the challenges of adulteration.
Formula (numerator/denominator)	Numerator: Number of food samples confirmed as adulterated through laboratory testing during the survey period. Denominator: Total number of food samples tested during the survey period Prevalence of adulterated food available in the market can be calculated as: Prevalence = (number of food samples confirmed as adulterated)/ (total number of samples tested during the survey period) X1
Unit of Measure	Percentage
Disaggregation	Product category, region, food business operator type,
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. parallel testing will be done on 2% samples or confirmatory tests on doubtful samples by different laboratories. For details, please follow the protocol.
Frequency	Every three years
Baseline Value and targets	**NA** (Baseline) 30 (30, Target)
Point of clarity	● Food adulteration is the act of intentionally reducing the quality of food offered for sale either by the mixture or substitution of interior 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. 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. ● 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 analyzed 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). ● 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.

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

Indicator name	Prevalence of Substandard and/or Falsified (SF) medicines.
Indicator code	GO2 – 1
Indicator type	Outcome
Precise definition	The percentage of substandard and/or falsified medicines (as per WHO definition) detected in a territory of Ethiopia at a given time. It measures the degree of substandard and/or falsified medicines available in the market.
Purpose/Interpretation	This indicator is used to assess outcomes of the regulatory functions such as registration, inspection and laboratory testing; and the degree of problem of unsafe, poor quality, ineffective and falsified medicines available in the market so as to take appropriate regulatory interventions for public protection. Increase in the prevalence of substandard or falsified medicines is an indication of a weak regulatory system and the public is at risk.
Formula (Numerator/Denominator)	Numerator: Number of medicines identified as SF during the survey period. Denominator: Total number of surveyed tracer medicines. Prevalence of SF medicine can be calculated as: Prevalence = (number of samples identified as SF)/(total number of samples collected)X100.

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, type of defect (substandard, falsified,..
Data source	The source of the data will be a survey of medicines from healthcare facilities (e.g. hospitals, Health centers, clinics), manufacturers, importers, distributors, drug retail outlets (e.g. pharmacies, drug shops, RDVs), street markets and Internet (if any).
Data collection method	The data collection method will be by conducting a laboratory testing based survey on tracer medicines. A protocol needs to be developed for identifying tracer medicines and representative samples will be collected from randomly selected sites and outlets as per the protocol. 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 the collected samples at least 5% of the sample size. If the analysis result becomes suspicious, a confirmatory test will be done.
Frequency	Every Five years
Baseline Value and Targets	8.6% (Baseline) 5% (6.5% in the year of 2022/23 and 5% in the year of 2024/25, Target).

Point of clarity	**Substandard** also called "out of specification" are authorized medicines that fail to meet either their quality standards or specifications, or both. **Unregistered/unlicensed** medicines are products that have not undergone evaluation and/or approval or permitted for special conditions by the authority to be marketed/distributed or used in Ethiopia. **Falsified** medical products are medicines that are deliberately/fraudulently misrepresent their identity, composition or source. Protocol containing detail procedures for tracer medicine selection, site selection, number of units to be sampled, sample testing etc should be prepared for conducting the survey
Indicator name	Prevalence of Substandard and/or Falsified medical devices.
Indicator code	GO2 – 02
Indicator type	Outcome
Precise definition	The percentage of substandard and/or falsified medical devices detected in a territory of Ethiopia at a given time. It measures the degree of substandard and/or falsified 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; and the degree of problem of poor quality, ineffective and falsified medical devices available in the market and take appropriate regulatory interventions for public protection. Increase in the prevalence of substandard and/or falsified medical devices is an indication of a weak regulatory system and the public is at risk.

Formula (numerator/denominator)	Numerator: Number of tracer medical devices identified as SF during the survey period. Denominator: Total number of surveyed tracer medical devices Prevalence of substandard and/or falsified medical devices can be calculated as: Prevalence = (number of medical devices samples identified as SF)/(total number of tracer medical devices samples included in the survey) X 100.
Unit of Measure	Percentage
Disaggregation	Devices Category, Region, facility type, ownership (public/private), registration status, country of origin. Type of defect (substandard, falsified).
Data source	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). Note: Protocol should be prepared and conduct the survey based on the protocol.
Data collection method	The data collection method will be by conducting a survey on selected tracer medical devices. Tracer medical devices will be identified and representative samples will be reviewed onsite or samples will collected 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..

Data Quality (verification)	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.
Frequency	Every five years
Baseline Value and targets	Not known (Baseline) 10% (12% in the year of 2022/23 and 10% in the year of 2024/25, Target).
Point of clarity	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.
Indicator name	Percentage of medicine retail outlets implementing Good Dispensing Practice (GDsP)
Indicator code	GO2- 3
Indicator type	Outcome
Precise definition	It is the ratio of medicines retail outlets (i.e. pharmacies, drug shops,health facility pharmacy, rural drug vendors) implementing good dispensing practice as compared to the total medicine retail outlets available in the country.
Purpose/Interpretation	The higher the percentage of medicines retail outlets implementing good dispensing

	practices indicates proper use of medicines and minimizes risk of medication error and antimicrobial resistance (AMR). 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 such as dispensing of prescription-only-medicines at partial doses and/or without prescription, poor labelling of the dispensed items, inadequate time for patient counselling, incomplete compiling and recording of prescriptions and dispensing of illegal medicines affects public health and integrity of pharmacy practices. On the base of the checklist of good dispensing practice percentage of score for each medicine outlets shall be determine and the passing score shall indicated in the protocol during the assessment period.
Formula (numerator/denominator)	**Numerator:** Number of medicines retail outlets implementing GDsP during survey period. **Denominator:** Total number of surveyed medicines retail outlets Percentage of medicines retail outlets that implement GDsP can be calculated as: $percentage = \frac{\#\ of\ medicine\ retail\ outlets\ that\ implment\ GDsP}{Total\ mumber\ of\ medicine\ retail\ outlets\ included\ in\ the\ survey}$ x 100
Unit of Measure	Percentage
Disaggregation	Medicines retail outlets Category (Pharmacy, drug shop, health facility pharmacy, rural drug vendor), Region, ownership (public/private), by GDsP parameters,
Data source	Data regarding the status of medicine retail outlets with respect to the Good Dispensing Practice will be collected by conducting surveys. Retained prescription papers (including NPS), 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. Other information such as actual dispensing, patient counselling and labelling of medicine envelopes and packs should be filled by observations made during the survey. In addition,

	questionnaires may be administered to responsible personnel in the survey retail outlets. **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.
Data collection method	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 standard and validated data collection tool that contains indicators and sub indicators (as necessary) for good dispensing practices. 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.
Data Quality (verification)	Supervision, random checks of the collected samples at least 5% of the sample size. Comparing the survey finding with WHO standard or other international and national relevant studies conducted in developing countries on dispensing practices, 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 5 years
Baseline Value and targets	50% (Baseline) 65% (60% in the year of 2021/22, 65% in the year of 2024/25: Target)
Point of clarity	Medicine retail outlets include pharmacy, drug shop, health facility pharmacy and rural drug shop.
Indicator name	Percentage of administrative measures taken against any regulatory non-compliance.

Indicator code	GO2 – 4
Indicator type	Output
Precise definition	The percentage of administrative measures taken in a year as compared to the total regulatory non-compliance reports received or obtained by the regulatory sector.
purpose/Interpretation	The increase in the percentage of administrative measures taken against any regulatory non-compliance is an indication of an enforcement capacity of the sector and good regulatory performance; and protecting the public from poor quality, unsafe and ineffective regulated products. This indicator is used to assess enforcement capacity of the regulatory sector (marketing authorization, inspection, laboratory testing, market surveillance and pharmacovigilance). Failure to take appropriate and consistent administrative measures by the regulatory sector may result in frustrations of both the regulatory work force and regulated facilities and possibly lead to good governance issues.
Formula (numerator/denominator)	Numerator: Number of administrative measures taken in the fiscal year. Denominator: Total number of regulatory non-compliance reported in the fiscal year Percentage of administrative measures taken against any regulatory non-compliance can be calculated as: Percentage = (number of administrative measures taken in the year)/(total number of regulatory non-compliance reported in the year) X100.

Unit of Measure	Percentage
Disaggregation	Product Category, product type, type of administrative measures (such as warning, suspension, cancelation, detain, disposal, recall, confiscation), Region, and facility type.
Data source	The source of data will be annual reports of regulatory non-compliance generated from Medicine registration, inspection, ADE reports, post marketing and laboratory analysis as well as the data of regulatory administrative measures (warning letters, suspension and revocation of licensure) taken by the inspectorates.
Data collection method	Review of the annual regulatory sector reports generated from medicine registration, inspection, pharmacovigilance (PV), post-marketing and laboratory analysis; and review of annual administrative measures taken by the Authority and regional regulatory bodies against the non-compliances.
Data Quality (verification)	Supervision, random checks of samples of non-compliance and administrative measures taken at least 5% of all non-compliance reports and administrative measures taken. If the result of the annual review becomes suspicious, triangulated against monthly, quarter and semi-annual reports, and integrated supportive supervision reports.
Frequency	Annual
Baseline Value and targets	95% (Baseline) 99% (96%, 96.5%, 97%, 98%, 99%: Target)
Point of clarity	Administrative measure is the range of actions taken against regulated persons (natural and juridical person) or products by the regulatory sector including warning letter, suspension, revocation/cancelation, detention, seizure, disposal of products; recall, confiscation and

	recommendation for prosecution.

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 prevalence of tobacco use including the use of tobacco smoke products or use of smokeless tobacco products among the population aged 15 years and over with in the study period.
purpose/Interpretation	The purpose of this indicator is to determine the prevalence of tobacco use by individuals aged 15 years and above to serve as input for determining the potential health risks due to tobacco smoking, passive smoker and use of smokeless tobacco products in the country.
Formula (numerator/denominator)	**Numerator: Number**: The number of individuals aged 15 years and above who smokes tobacco products or use smokeless tobacco products at least once in one year period. This includes passive smokers. **Denominator:** Total number population whose age 15 years and above during the survey period Prevalence of tobacco use can be calculated as: Prevalence = (Number of individual aged 15 years and above who smoke tobacco products or use smokeless tobacco products at least once in one year period)/ (Total number population whose age 15 years and above during the survey period) X100

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, and Ethiopian DHS
Frequency	Every five years
Baseline Value and targets	5% (base line) 3% (Target)
Point of clarity	

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

Indicator name	Percentage of community satisfaction on the regulated products
Indicator code	**GO4- 1**
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)	Numerator: Number satisfied Denominator: Total Respondents Level of community satisfaction on the regulatory sector calculated as: CSAT $= Satisfied \div Total\ included\ in\ the\ survey$ X 100% CSAT=$Total\ responses\ score\ given \div Total\ possible\ response\ scores$ X 100% Where CSAT - 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. Level of importance of each regulated product and difficulty of calculating the average to find the overall satisfaction. Cut off point = from literatures

Indicator name	Public trust score
Indicator code	GO4- 2
Indicator type	Outcome
Precise definition	It is a score to measure Public trust on the FHRS which is determined by conducting survey
purpose/Interpretation	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. Cutoff point 70% (above and 75% score indicates that the public has trust on the regulatory system) 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 = [(competence + integrity + 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	2.5 years
Baseline Value and targets	NA (Baseline) 4 (target)
Point of clarity	Trust is a person's belief that institutions will act consistently with their expectations of positive behavior.

Strategic direction 1: Strengthen food safety regulation	
Indicator name	**Number of registered food products**
Indicator code	**SD 1- 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	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. 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 foodborne diseases and health risks.
Unit of measure	Count

Formula (numerator/denominator)	Numerator: NA Denominator: NA It is the count of all registered food products with in the fiscal year
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	2739 (Baseline) 12,213 (2520, 2550, 2400, 2350, 2393 each year Targets)
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**

Formula (numerator/denominator)	**Numerator:** Number of audited local food facilities **Denominator:** Total number of local food facilities It is calculated as the number of audited local food facilities to the total number of local food facilities and multiplied by 100. Percentage of audited local food facilities = (Total number of audited local food facilities)/(Total number of local food facilities)*100
Disaggregation	Product Category/product type, type of food facility (manufacturer with categorized production capacity, importer, distributor), region
Data Source	· EFDA report · RHRBs annual report, eRIS
Data collection method	**Document review:**

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	**76% (Baseline)** **100% (85%, 90%,95 %, 100%,Targets)**
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 03**
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 foriegn 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	**2** (Baseline) 110 (Target) [(2014 (20), 2015 (25), 2016 (30), 2017 (35)]

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 IQMS/ Regulatory requirements**
Indicator code	**SD1 04**
Definition	It is coverage of food facilities implementing internal quality management systems (IQMS) against the total number of licensed food facilities.
purpose/Interpretation	Implementation of internal quality management systems(IQMS) 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)	Numerator: Number of food facilities which implemented internal quality management system(IQMS) Denominator: Number of licensed food facilities It is calculated as the number of food facilities who implement an internal quality management system(IQMS)/ Number of licensed food facilities and multiplied by 100.
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	**35 (Baseline)** **70(Targets) (40, 45, 50, 60, 70)**
Point of Clarity	**Internal quality management system 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 food vendors implemented GHP**
Indicator code	**SD 1-05**
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	This indicator is used to determine the coverage of street food handlers implementing Good Hygienic Practices by assessing and evaluating their status 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.
Unit of measure	Percentage
Formula (numerator/denominator)	Numerator: Number of food handlers implemented GHP Denominator: Total number of food handlers available and registered street food vendors Coverage of Street food vendor's implemented GHP = (Total number of Street food venders implemented GHP)/(Total number of food handlers available and registered *100)

Disaggregation	Product category/type, region, food business operator type
Data Source	RRBs report
Data collection method	RRBs report review
Data quality (Verification)	Review RRBs report, review complaint handling related to street food vending, random checks street food handlers' hygienic status and product safety and quality.
Frequency	Quarterly, Biannually and annually
Baseline value and targets	0 (Baseline) 50 (Targets) (5,10,25, 35,50)

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	**Coverage of mass catering service implement GHP & GCP**
Indicator code	**SD 1-06**
Indicator Type	**output**
Precise definition	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.

purpose/Interpretation	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.
Unit of measure	Percentage
Formula (numerator/denominator)	**Numerator:** Number of mass-catering establishments inspected and implemented GHP and GCP **Denominator**: Total number of licensed and registered mass-catering establishments 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
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	TBD (Baseline) 50 (Targets) (5,10,25, 35,50)
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
Indicator code	SD1- 07
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.
purpose/Interpretation	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. Avail relevant information on the PMS shows how effective the overall regulatory activities are performed along the supply chain. 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.
Formula (numerator/denominator)	The summation of food product types tested via PMS with in the fiscal year
Unit of Measure	Count
Disaggregation	Product category, food safety parameters, region, food business operator type

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, bianually and annually
Baseline Value and targets	**28** (Baseline) 72 (Target) (33, 40, 50, 65, 72)
Point of clarity	• 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 covered via consignment laboratory tests
Indicator code	SD1- 08
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	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. 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.
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, bianually and annually
Baseline Value and targets	**28** (Baseline) 60 (38, 43, 48, 53,60 Target)
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 andillegal food products

Indicator name	**Number of operations conducted based on intelligence led surveillance**
Indicator code	**SD2-01**

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	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. 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.
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 10 (Targets) (2,2,2,2,2)
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 conducted**
Indicator code	**SD 2- 2**
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, 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 conductedwithin 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	12 (Baseline) 12 (Targets 12, 12, 12, 12,12)
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	Output
Precise definition	The count of medicines registered as new 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 marketing authorization process of the Authority.
Formula (numerator/denominator)	The total count of registered medicines per year.
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	Review of the eRIS database

Data Quality (verification)	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	**(4729)** (Baseline) Target - 9500 (1050, 1070, 1100, 1150,1170: Annual Target)
Point of clarity	The number of registered medicines will not include renewal and approved variations.

Indicator name	Number of registered traditional medicines
Indicator code	SD3-2
Indicator type	Output
Precise definition	The count of traditional medicines registered by the Authority in a year.
purpose/Interpretation	The increase in the number of registered traditional medicines is an indication of access to safe, and effective traditional medicines for the needs of the public as alternatives for treatment of different cases. 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. This indicator measures the efficiency of the traditional medicine marketing authorization process of the Authority. It will also promote integration and the transformation of traditional medicines to modern medicines
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	Review of registry logbook and other databases.
Data Quality (verification)	Supervision. Repeat counting of traditional medicines registered by assigning another expert. If the review result becomes suspicious, a confirmatory counting of traditional medicines registered will be done by repeating the counting of data registry logbooks and

	other databases using other experts.
Frequency	Quarterly
Baseline Value and targets	0 (Baseline) 10 (2, 2, 2, 2,2: Annual Target)
Point of clarity	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 numberof registered traditional medicines within a year.

Indicator name	Percentage of ADR reports received as per WHO standards
Indicator code	SD3-3
Indicator type	Output
Precise definition	The percentage of ADR reports received by EFDA in a year against the WHO standards.
purpose/Interpretation	Increase in the number of ADR reports received by EFDA is an indication of the improved post marketing safety monitoring of the marketed medicines and it enables the Authority to take appropriate interventions so as to improve patient safety. In addition, this indicator measures the effectiveness of the pharmacovigilance system of the country in monitoring the safety of medicines after being placed on the market.

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 reports registration log book and/or med-safe and other databases that received 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 targets	**Baseline** 1442 Target 10,000(4000, 7000, 8000, 9000, 10000: annual target)
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 shall contain information as per the content in the yellow card of EFDA and/or WHO standard.

Indicator name	Percentage of causality assessment performed on reportedserious adverse events
Indicator code	SD3 –4
Indicator type	Output
Precise definition	It is the proportion of causality assessment performed against the total number of serious adverse events reports received.
Purpose/Interpretation	The increase in the number of serious adverse events investigated and causality assessment performed as the basis to take immediate regulatory interventions on products with safety concerns and ensure better public health safety.
Formula (numerator/denominator)	Numerator: Number of causality assessments performed on serious adverse reaction in a year Denominator: Total number of serious adverse events received within a year Percentage of causality assessment = $\frac{\text{Number of causality assessments performed on reported SAEs in a year}}{Total\ number\ of\ serious\ adverse\ events\ received\ within\ a\ year}$x100
Unit of Measure	Percentage
Disaggregation	Product Category, product type,
Data source	performance reports
Data collection method	Review of quarterly A DE reports, WHOVIGI Flow & records of reporting center(if available)

Data Quality (verification)	Triangulate the data with, WHOVIGI Flow &/or records of reporting center(if available)
Frequency	Quarterly
Baseline Value and targets	12 (Baseline) 29 (16, 18, 21, 25, 29 -Annual Target)
Point of clarity	NA

Indicator name	Percentage of inspection coverage of medicine establishments
Indicator code	SD3- 6
Indicator type	Output
Precise definition	It is the percentage of inspected medicine establishments (i.e. importers, wholesalers and retail outlets) to the total number of licensed medicine importers, wholesalers and 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 importers, wholesalers and retail outlets in a given year from the total licensed medicine importers, wholesalers and retail outlets available in the country. The post license inspection is conducted for an establishment at least two rounds per annum for licenced establishments. 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 establishments 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 establishments **Denominator:** The total number of licensed medicine establishments Percentage of medicines inspection coverage can be calculated as**:** % of inspection coverage = (Number of inspected medicine establishments/Total number of licensed medicine establishments in the country) x100
Disaggregation	Region, type of medicine establishments, type of inspection
Data source	Performance Reports from EFDA, Regional Regulatory Bodies (RRBs)
Data collection method	Data will be collected by review of performance reports of EFDA and regional regulatory bodies.
Data Quality (verification)	Supervision and random checks of inspected importers, wholesalers and retail outlets. Reconcile the reports with data available in the electronic regulatory information system (eRIS).
Frequency	Quarterly
Baseline Value and targets	For medicine importers and wholesalers 100% (Baseline) 100% (Target) For medicine retail outlets 75% (Baseline) 90% (78,82,85,87,90Target)

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 medicine manufacturers inspected against the national GMP requirements
Indicator code	SD3 – 8
Indicator type	Output
Precise definition	It is the count of medicine manufacturers inspected per year against the national GMP requirements. This includes manufacturers granted with GMP inspection waiver certificate or these manufacturers inspected remotely.
Purpose/Interpretation	This indicator is used to count the number of medicines manufacturers inspected to evaluate their compliance level with the national GMP requirements. 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 count. 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.
Unit of measurement	Count (n)
Formula (numerator/denominator)	**Numerator:** NA **Denominator:** NA

	The number of medicine manufacturers inspected can be counted by adding the number of medicine manufacturers inspected per year against GMP requirements.
Disaggregation	Country of origin, compliance status, new vs renewal, local vs overseas
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 MFID reports with the data available in eRIS.
Frequency	Annual
Baseline Value and targets	120 (Baseline) 300 (150, 180, 220, 260, 300 annual target)
Point of Clarity	

Indicator name	Percentage of medicines tested prior to distribution to the market
Indicator code	SD3 –9
Indicator type	Output
Precise definition	The percentage 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 percentage 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)	Numerator: Number of medicine products tested before distribution to the market Denominator: Total number of medicine products made ready for distribution to the market (all consignments of imported medicines and/or all medicines made ready for distribution by local manufacturers) Percentage of medicines tested before distribution can be calculated as: Percentage = (number of medicine products tested prior to distribution to the market)/(total number of medicine products made ready for distribution to the market in the reference period) X100.
Unit of Measure	Percentage
Disaggregation	Product category, domestic vs overseas manufacturers, country of origin, compliance status (pass/fail)
Data source	Number of medicine products made ready for distribution to the market by the local manufacturers can be found from the authority`s medicines facility inspection and number of for medicine

	consignments should be found from POE inspections records while the number of tested samples should be obtained from EFDA medicines quality control laboratory. Note: Protocol should be developed, reviewed and updated on regular basis or as necessary and conducting the medicines sampling and testing prior to distribution to the market should be performed in accordance with the procedures in the protocol.
Data collection method	Data on the number of medicines tested prior to distribution to the market should be collected from the quarterly reports of the central branch, inspection directorate & medicine QC laboratory. If there are any outsourced consignment testing, the data should consider the number of outsourced tests.
Data Quality (verification)	Regular (quarterly) performance audit and random checks of the number of consignments inspected & released to the market, and number of local products distributed to the market. If the analysis result becomes doubtful, a confirmatory test will be done. Details should be included in the protocol.
Frequency	Quarterly
Baseline Value and targets	21 (Baseline) 55 (25,30,35,50,55Target)
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.

Indicator name	Percentage of medicines tested through PMS

Indicator code	SD3 – 10
Indicator type	Output
Precise definition	The percentage of medicines tested through PMS schemes conducted by taking samples of medicines from medicines` importers and wholesalers, pharmacies, drug shops, rural drug vendors, health institution's drug outlets and informal markets.
Purpose/Interpretation	Increasing the percentage of PMS medicine samples testing improves public protection from poor 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. This indicator may be used to assess the compliance of manufacturers, importers, distributors, and different drug outlets with the requirements of GMP, GSP and GDP as well as effectiveness of both premarket and post market regulatory activities undertaken by the regulatory sector.
Formula (numerator/denominator)	Numerator: Number of medicines tested through PMS Scheme with in the study time frame Denominator: Total number of medicines marketed in the country in the five years period Percentage of medicines tested through PMS can be calculated as: Percentage = (number of medicines tested through PMS)/(total number of medicines in the market

	during the post market survey period) X 100
Unit of Measure	Percentage
Disaggregation	Product category, registration status, country of origin,region/sample selection site, test status (fail, pass),
Data source	PMS performance reports
Data collection method	Performance reports 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	22 (Baseline) 55 (25,30,35,50,55Target)
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	Number of Clinical Trial applications approved
Indicator code	SD3-11
Indicator type	Output
Precise definition	The number of clinical trial applications received, reviewed & approved by the Authority with in the reporting period
purpose/Interpretation	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. Since less number of clinical trial authorization may not necessarily be an indication of less number of clinical trials undertaken by researchers, increase in the number of clinical trial authorization ensures that all clinical trials conducted in the country are fully oversighted by the Authority. The increase in the number of clinical trials approved means that the increased efficiency of the authority in assessing the clinical trial applications and oversight of the clinical trials conducted in the country.
Formula (numerator/denominator)	Total number clinical trial authorization applications approved within a quarter
Unit of Measure	Number

Disaggregation	By clinical trial phase, product type, Status (authorized, rejected)
Data source	Approved Clinical trial authorization applications record from
Data collection method	The number of clinical trial applications approved by EFDA is collected from the quarterly performance reports of the concerned directorate.
Data Quality (verification)	Verify the data on the number of approved clinical trial authorization applications against of ethical clearances issued by institutions and national ethical committee; and GCP inspection reports
Frequency	Quarterly
Baseline Value and targets	Baseline: 13 Target(by 2024/25): 200(30,35,40,45,50)
Point of clarity	
Indicator name	Clinical trials inspection coverage
Indicator code	SD3-12
Indicator type	Output
Precise definition	It is the percentage of clinical trials inspection 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 isconducted 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 oversightto 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)	The percentage of GCP inspections conducted on clinical trials after being authorized by the Authority. **Numerator**: the number of clinical trial sites inspected **Denominator**: The total number of authorized clinical trial sites on going during the fiscal period **Percentage** = number of clinical trial sites inspected/total number of authorized clinical trial sites on going during the fiscal period x 100
Unit of Measure	Percent
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: 13 Target **(**by 2024/25): 100% (Number 30 35 40 45 50 annual target)
Point of clarity	The list of active and authorized clinical trial conducted in the country should be identified. The inspection coverage shall considered based on the active and authorized clinical trial

	conducted in the country.

Strategic direction 4: Strengthen Regulation of Safety, Quality and Performance of Medical Device

Indicator name	Number of registered medical devices
Indicator code	SD4-1
Indicator type	Output
Precise definition	The number of new medical devices registered and/or approved by the Authority using the existing application routs 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	Registration system is a system that 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. 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.

Formula (numerator/denominator)	The number of medical devices registered and issued marketing authorization certificate or notification letter for low-risk medical devices.
Unit of Measure	Number
Disaggregation	Product Category (IVD device, device other than IVD, low-risk medical device &accessories& spare parts), product type, application type (medical device other than IVD, IVD medical device, notification, accessories & Spare parts), country of origin,
Data source	eRIS databases
Data collection method	Review of annual report. The number of medical devices registered will be counted from eRIS database every quarter. The sum of quarters performance of a year will be used to determine annually registered medical devices.
Data Quality (verification)	Supervision. Repeat counting of medical devices registered by assigning another second expert. If the result review becomes suspicious, a confirmatory counting of medical devices registered will be done by repeated review eRIS database using other experts.
Frequency	Quarterly
Baseline Value and targets	4527 (Baseline) 10050(6000, 7000, 8000, 9000, 10050 Target)
Point of clarity	The scope of medical devices fall within definition in Proclamation 1112/2019. If the eRIS database become inapplicable for some reasons, quarter reports will be used to calculate the number of medicines registered.

	The number of medical device application approved will be counted and equant the medical devices.

Indicator name	Number of types of medical devices consignment tested
Indicator code	SD4-2
Indicator type	Output
Precise definition	The percentage of medical Devices consignment tested by taking samples of imported eligible medical devices at the ports of entry or locally manufactured medical devices prior to distribution to the market. The percentage is calculated against the planned number of types of medical devices for consignment test.
purpose/Interpretation	Increasing the percentage of 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)	Numerator: The number of medical device types that are being tested in a fiscal year. Denominator: 25 Percentage of medical devices consignment tested can be calculated as:

	Percentage= (The number of medical device types that are being tested in a fiscal year)/(25)X100%.
Unit of Measure	Percentage
Disaggregation	Product category, domestic vs overseas manufacturers
Data source	Number of consignments sampled can be found from EFDA Medical devices inspection (for local products), local medical devices manufacturers, importers & distributors and POE inspections records (for imported products) while tested consignment samples can be from EFDA Medical devices quality control laboratory(ies). Note: Protocol should be reviewed & updated on as necessary and conducting the consignment sampling & testing be performed in accordance with the procedures in the protocol.
Data collection method	Data on the number of consignments sampled & tested should be collected from the quarterly reports of the inspection directorates & QC laboratory. If there are any outsourced medical devices consignments testing, the data should consider the number of outsourced tests.
Data Quality (verification)	Supervision during sample collection, random checks on the number and types of samples collected from the port and local manufacturers (trace back to the source). If the analysis result becomes doubtful, a confirmatory test will be done.
Frequency	Annually
Baseline Value and targets	**1** (Baseline)

	25 (4,10,15,20,25Target)
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 types and calculate the percentage of achievement by comparing with the target number, 25, in the transformation plan. 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	Number of types of medical devices PMS tested
Indicator code	SD4-3
Indicator type	Output
Precise definition	The percentage of medical device tested through PMS schemes conducted by taking samples of medical devices from medical device importers and wholesalers, pharmacies, drug shops, rural drug vendors, health institution's drug outlets and informal markets.
purpose/Interpretation	Increasing the percentage of PMS medical device samples 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

	public protection capability against any unsafe & ineffective medical devices.
Formula (numerator/denominator)	Numerator: The number of medical device types that are sampled and tested in a given fiscal year. Denominator: 25 Percentage of medical devices PMS tested can be calculated as: Percentage = (The number of medical device types that are sampled and tested in a given fiscal year)/(25)X100%.
Unit of Measure	Percentage
Disaggregation	Product category, domestic vs overseas manufacturers, country of origin
Data source	Number of PMS sampled can be found from EFDA Medical devices inspection (for local products), local medical devices manufacturers, importers & distributors and POE inspections records(for imported products) while tested PMS samples can be from EFDA Medical devices quality control laboratory(ies). Note: Protocol should be reviewed & updated on as necessary and conducting the PMS sampling & testing be performed in accordance with the procedures in the protocol.
Data collection method	Data on the number of PMS sampled & tested should be collected from the quarterly/annual reports of the inspection directorates & QC laboratory. If there are any outsourced medical devices consignments testing, the data should consider the number of outsourced tests.

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	Annually
Baseline Value and targets	**1** (Baseline) 25 (4,10,15,20,25Target)
Point of clarity	A sample for PMS means all medical devices eligible for laboratory testing included in one shipment & ready for distribution by a local manufacturer or ready for inspection at the POE. The number of product types, 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	Percentage of inspection coverage of medical devices establishment (local manufacturers, importers, wholesalers)
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 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 and the more availability of safe, quality and effective medical devices in the market.
Unit of measurement	Percent (%)
Formula (numerator/denominator)	**Numerator:** The number of inspected medical device importers, wholesalers and local manufacturers who are issued license or CoC by the Authority. **Denominator:** The total number of medical device importers, wholesalers and local manufacturers with valid license or CoC.

	Percentage of medical devices inspection coverage can be calculated as**:** % of inspection coverage = (Number of post-license inspected establishments/ Total number of establishments with valid license in the country in a fiscal year) x100%
Disaggregation	Region, type of medical device establishments (manufacturers, importers, wholesalers), new vs renewal inspection.
Data source	Performance reports and eRIS database.
Data collection method	Review of performance report.
Data Quality (verification)	Repeated counting of the conducted inspections of the licensed local medical device establishments from eRIS.
Frequency	Quarterly
Baseline Value and targets	For medical device importers and wholesalers 40% - (Baseline) 100% (Target)

Indicator name	Number of medical device types inspected against the national Medical device GMP requirements.
Indicator code	SD4 – 5
Indicator type	Output
Precise definition	It is the count of medical device types (identified with their generic names) that are subjected to and inspected for the compliance of the mandatory GMP principles by their manufacturers required by the Authority in a fiscal year.
Purpose/Interpretation	This helps the authority to ensure that high risk medical device 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. This indicator is used to ensure the compliance of medical device manufacturers with the national GMP/QMS requirements. The higher the number of the value of the indicator shows that the GMP compliance of high number of manufacturers are assessed and the appropriate regulatory decisions are made on the marketing authorization of the subject devices in the country.
Unit of measurement	Count (n)
Formula (numerator/denominator)	**Numerator:** Number of Medical device types whose manufacturers are inspected for the compliance of the regulatory GMP/QMS requirements. **Denominator:** 1

Disaggregation	Country of origin, product type,
Data source	Performance reports from the relevant directorate or team.
Data collection method	Collection and counting of medical device types from the GMP Inspection report by reviewing the performance reports of the EFDA.
Data Quality (verification)	Independent counting of the reports of GMP/QMS inspections by more than two persons.
Frequency	Annually
Baseline Value and targets	6 (Baseline) 65 (8,10,12,15,20Target)
Point of Clarity	medical device manufacturers granted with GMP inspection waiver certificates or letter will not be included in the calculation of the number of medical device manufactures inspected against the GMP requirements. 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.

Indicator name	**Number of adverse events reports received by EFDA**
Indicator code	SD4-6
Indicator type	Output
Precise definition	The numbers of adverse event reports on medical devices received by pharmacovigilance (PV) centre of EFDA.
purpose/Interpretation	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. 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 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	Vigiflow data base and/or received files (hard copy or soft copy) of the adverse event report received.
Data collection method	Review of annual data. The number of adverse event reports received will be counted from the vigiflow 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 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 existing in the unit.
Frequency	Annually
Baseline Value and targets	0 (Baseline) Target 430 (30, 100, 100, 1000, 100)
Point of clarity	All adverse events including: adverse effect, medical error and product quality defect on medical devices reported to EFDA will be considered in counting of adverse event reports.

Indicator name	**Number of Clinical Investigation applications approved.**
Indicator code	SD4-7
Indicator type	Output
Precise definition	The number of medical devices clinical investigationauthorized by the authority with in 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	reviewed clinical investigation authorization applications record from medical devices clinical trial authorization department/ unit of EFDA

Data collection method	The number of clinical investigation applications reviewed by EFDA is collected from the monthly reports & quarter reports **of** medical devices clinical investigation authorization department/ unit of EFDA
Data Quality (verification)	Verify the data on the number of reviewed clinical trial authorization applications against 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 (by 2024/25): 80(5,10,15,20,30)
Point of clarity	

Indicator name	**Percentage of ineffective medical devices in the market**
Indicator code	SD4-9
Indicator type	Outcome

Precise definition	The percentage of **ineffective medical devices determined by** taking samples of tracer medical devices in use in different health institutions
purpose/Interpretation	Decrease in the percentage of **ineffective medical devices** ensures the accurate diagnosis by diagnostic centers and health institutions and ultimately 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(maintenance requalification, calibration or disposal of the devices, etc) and to ensure that all manufacturers (domestic & overseas) and/or end users take all 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)	Numerator: Number of ineffective medical devices found on the ,market (end users facilities) Denominator: Total number of tracer medical devices surveyed Percentage of ineffective, defective or malfunctioning medical devices can be calculated as: percentage=(Number of ineffective medical devices found on the market)/(Total number of tracer medical devices surveyed)X100.
Unit of Measure	Percentage
Disaggregation	Product category, end users type, country of origin
Data source	Types of tracer medical devices for survey can be found from EFDA Medical devices

	inspection (for local products), local medical devices manufacturers, importers & distributors and POE inspections records(for imported products) while the actual medical devices to be surveyed will be found in the end users facilities Note: Protocol should be developed to determine
Data collection method	Data regarding the types and number of medical devices to be included in the survey should be collected from the central branch POE products release record and the number of ineffective, defective and/or malfunctioning medical devices should be collected from end users facilities.
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 effectiveness of medical devices and out of order medical devices etc.
Frequency	2-3 years
Baseline Value and targets	NA (Baseline) 30 (Target)
Point of clarity	**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.**

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 ingredients). The more the number of issued notification notes the better access to safe cosmetics in the market.
Formula (numerator/denominator)	**Numerator:** NA **Denominator:** NA The summation of the number of cosmetics products approved through notification in the fiscal period.
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	Quarterly
Baseline Value and targets	0 (Baseline) **3000** (500,500,500,500,1000Target)
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 cosmetics to be imported and marketed in the Ethiopian market.

Indicator name	Percentage of suspected cosmetic products tested for safety
Indicator code	SD5-2
Indicator type	Output
Precise definition	Percentage of suspected cosmetics tested measures the number of samples of suspected cosmetics 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 cosmetics 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 cases of 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
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	Every quarter
Baseline Value and targets	**0** (Baseline) 100 (Target)
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 authorities 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 institution which are licensed 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 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) **Denominator:** The total number of licensed cosmetics manufacturers, importers, wholesalers and retail outlets Percentage of cosmetics inspection coverage can be calculated as**:** % of inspection coverage = (Number of inspected cosmetics MIWR/Total number of licensed cosmetics MIWR in the country)x100
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, 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% (40,45,50,55,60Target)

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.

Strategic direction 6: People protected from risks related to tobacco and alcohol

Indicator title	Number of tobacco smoke free public places.
Indicator code	SD6 – 1
Indicator type	Output
Precise definition	It is the number of 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. 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 passive smoking.
Unit of measurement	Count
Formula (numerator/denominator)	It is the count of the number of public places that have been designated 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 designated 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, 218,000)
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	Prevalence **of Illicit Tobacco products on the market**
Indicator code	SD6 – 2
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)	**Numerator:** number of illicit tobacco products found on the market at time of survey **Denominator:** Total number of tobacco products sampled during the survey. 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
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 Reduction** in tobacco Advertisement, Sponsorship or Promotion (ASP)
Indicator code	SD6 – 3
Indicator type	Outcome
Precise definition	This indicator measures the percentage reduction in direct tobacco advertisement
Purpose/Interpretation	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. 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.

Unit of measurement	Percentage
Formula (numerator/denominator)	**Numerator:** number of advertising sites that have advertised tobacco in a specified period **Denominator:** Total number of advertising sites monitored during the survey period. The percentage of advertisement on tobacco product is = (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	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. The promotion on tobacco ASP on unregulated media shall not be considered in generating the number of tobacco ASP. Tobacco advertisement include sponsorship and promotion conducted on tobacco products. 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

Indicator title	Percentage of Advertisement, Sponsorship, and Promotion (ASP) of alcohol
Indicator code	SD6 – 4
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)	**Numerator:** number of advertisement, Sponsorship, and/or Promotion (ASP) of alcohol made in unlawful ways (those prohibited by proclamation 1112/2019) **Denominator:** Total number of advertisement, Sponsorship, and/or Promotion (ASP) of alcohol made in a given period of time Percentage of Advertisement, Sponsorship, and/or Promotion (ASP) of alcohol can be calculated as**:** % ASP= (number of unlawful ASPs /Total number of ASPs in a defined period of time) x100
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 (Target)
Point of Clarity	NA
Indicator title	Percentage of alcohol sale in prohibited public areas
Indicator code	SD6 -5
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)	**Numerator:** number of prohibited public areas that sell alcohol at the time of the survey

	Denominator: total number of prohibited public areas to sell alcohol according to national and regional laws **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.
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% (Target)
Point of Clarity	
Indicator title	Percentage of alcohol sale in prohibited areas
Indicator code	SD6 -5
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 of 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)	**Numerator:** number of prohibited areas that sell alcohol at the time of survey **Denominator:** total number of selected prohibited areas for the survey Percentage of alcohol sale in prohibited areas = The number of prohibited places that sell alcohol/the total number of selected prohibited areas during the survey multiplied by 100.
Disaggregation	Region, type of the prohibited area,
Data source	The source of the data will be collected from selected prohibited areas. Protocols should be prepared and conduct the survey based on the protocol. But, this can also be obtained from the routing performance report of EFDA and RRBs
Data collection method	Survey. Representative samples will be selected randomly from selected prohibited places. Please refer to the prepared protocol for sample collection.
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% (Target)
Point of Clarity	NA

Strategic direction 7: Improve Quality Management System

Indicator name	No of EFDA Inspection directorates (HQ and branches/ ISO 1720/ 2012 accredited
Indicator code	**SD7- 1**
Indicator type	**Output**
Precise definition	It is the number of inspection directorates of EFDA that are accredited with ISO 1720/2012
purpose/Interpretation	This indicator helps to measure the inspection services in both head quarter and branch offices whether their services and procedures fulfil the global standards. It also helps the regulatory body to assess the level of its services compliance with the global standards. Accreditation of the inspection services as per the ISO standard indicates that EFDA`s inspection result will be accepted at global level**;i.e** all regulated products meant for export and inspected by the authority will be acceptable at

	global level and all products rejected by the authority will be recognized by other parties.
Formula (numerator/denominator)	**The summation of t**he number of inspection directorates of EFDA that are accredited with ISO 17020
Unit of Measure	**Count**
Disaggregation	**Directorates, product types**
Data source	**Performance reports**
Data collection method	**Review performance reports**
Data Quality (verification)	**NA**
Frequency	**Every year**
Baseline Value and targets	**0 (Baseline)** **8 (1,1,4,2 targets)**
Point of clarity	**The indicator considers only the federal food and health products regulatory inspection directorates (head quarter and branch offices`directorates) that get accreditation for at least one type of product inspection.**

Indicator name	ISO 9001 certified EFDA
Indicator code	**SD7- 2**
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 it 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	**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 9001 doesn't include the branch offices**

Indicator name	Number of EFDA's laboratories that are ISO/IEC 17025 accredited
Indicator code	**SD7- 3**
Indicator type	**Output**
Precise definition	It is the count of EFDA's laboratories that are ISO/IEC 17025 accredited.
purpose/Interpretation	**A**s the number of ISO/IEC accredited laboratories increases it ensures that all tests carried out at different laboratories generate similar and accredited test results that will be acceptable at global level.

Formula (numerator/denominator)	**T**he summation of the of EFDA's laboratories that are accredited by ISO 17025/2017
Unit of Measure	**Count**
Disaggregation	**Product type**
Data source	**Performance report**
Data collection method	**Review performance report**
Data Quality (verification)	**Physical supervision**
Frequency	**Every year**
Baseline Value and targets	**2 (Baseline)** **5 (target)**
Point of clarity	**The laboratories are food, medicines and medical devices labs at the head office, branch laboratories**

Indicator name	EFDA Maturity level 3 recognition
Indicator code	**SO 7- 4**

Indicator Type	**Output/ Outcome**
Precise definition	Maturity level is a certification status issued by WHO. EFDAhas designed and implementing Institutional Development Plan (IDP) followed by assessment 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 regulatory system. Attaining level-3 is interpreted as a stable, well-functioning and integrated regulatory system respectively.
Formula	As per GBT tool standard
Unit of Measure	Count
Disaggregation	NA
Data source	Document review, self-assessment and external reviewers 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-1 Target: ML-3
Point of clarity	Clear understanding the GBT and the indicators

Indicator title	Number of WHO prequalified laboratories
Indicator code	SD7 -5
Indicator type	Output
Precise definition	This indicator measures the number of EFDA`s medicine quality control laboratories operating in compliance with the requirements of "WHO good practices for pharmaceutical quality control laboratories"
Purpose/Interpretation	This indicator serves to determine the number of EFDA`s laboratories operating at WHO prequalified laboratories international standards and hence generate globally acceptable test results. The authority`s medicine quality control laboratory prequalification is one of the major regulatory functions that would contribute to increase the overall maturity level of the authority.
Unit of measurement	Number
Formula (numerator/denominator)	**NA**
Disaggregation	NA
Data source	Medicine quality control laboratory, list of prequalified laboratories (WHO website)
Data collection method	Annual report

Data Quality (verification)	Check inclusion of the laboratory in the list of WHO prequalified laboratories
Frequency	Annual
Baseline Value and targets	0 (Baseline) 1 (Target)
Point of Clarity	NA

Strategic direction 8: Enhance partnership and collaboration

Indicator name	Percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities
Indicator code	**SD8-1**
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	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. 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.
Unit of measure	Percentage
Formula (numerator/denominator)	Numerator: Number of key stakeholders that participated either in the planning or performance review meeting of the regulatory activities during the physical period. Denominator: Total number of key stakeholders Percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities can be calculated as: % 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.
Disaggregation	By region

Baseline/Target	Baseline: 68% Target : 100 (80,85,90,95,100)
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 strategic partnership and collaboration established with international, federal, and local organizations
Indicator code	**SD8-2**
Definition	It is the summation of established strategic partnership and collaboration with international, federal, and local organizations with in the physical period.
Purpose/Interpretation	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. 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. The important determinants of strategic partnership and collaboration are:- the degree 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:- ● 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	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. Number of strategic partnership and collaboration established with international, federal, and local organizations can be calculated as:- # 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.
Disaggregation	by regulatory functions
Baseline/Target	Baseline: NA Target 10 (5, 5)
Data Source	Performance report
Data collection method	**Document review:** Performance report

Frequency	Annually
Point of Clarity	Partnership and collaboration refers to a group of organizations with a common interest who agree to work together toward a common goal. Partnership agreements should be put in writing, and reviewed annually. Collaborative relationships are the building blocks for the vast majority of partnerships. 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. A partnership and collaboration is strategic when it provides your organization with the means and methods for advancing your mission. 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 understanding, and collective focus to make lasting progress.

Strategic direction 9: Improve community ownership

Indicator title	**Percentage of populations who have awareness about food and health products regulation**
Indicator code	SD9-1
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	**Numerator:-** Number of peoples more than 18 yrs old who have awareness about food and health product regulations sampled **Denominator:-**Total no of peoples age more than 18yrs sampled This can be calculated as : percentage =No. of peoples more than 18 yrs old who have awareness about food and health product regulation sampled*100 Total no of peoples whose age are more than 18yrs sampled
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%(60, 70%, Target)

Indicator title	Percentage of addressed tip-offs, complaints and concerns that have been received from the public.
Indicator code	**SD9-2**
Precise definition	It is a proportion of the addressed tip-offs, complaints and concerns that have been received, investigated and addressed against the total number oftip-offs, complaints and concernsthat offered to the regulatory body.
Purpose /Interpretation/	Information generated from the collected tip-offs,complaints and concernsshould 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)	**Numerator:-** Number of addressed tip-offs, complaints and concerns that have been received from the public **Denominator:-** The total number oftip-offs, complaints and concernsthat offered to the regulatory body. *Percentage= Number of addressed tip-offs, complaints and concerns that have been received from the public *100* *The total number of tipoff, complaints and concerns that offered to the regulatory body.*
Disaggregation	Product type, regions,and branch offices
Data source	Reports from • EFDA &RRBs
Data collection methods	**Document review: records & reports from** HRIS, • EFDA • RRBs
Frequency	Monthly, Quarterly, bi-annually and annually
Baseline Value and targets	70(Baseline) 100% (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.

Strategic direction 10: Strengthen Formulation and implementation of legal frameworks

Indicator title	**Number of legal instruments developed**
Indicator type	**Output**
Indicator code	**SD10-1**
Precise definition	Number of legal instruments developed is the cumulative number of a proclamation, Regulation and Directives initiated and/or developed.
purpose/Interpretation	This indicator urges regulatory authorities to execute their responsibilities effectively, consistently and cope up with the changing environment. The more the amount developed in each year, the better the enforcement.
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 =Σ(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: 106 Target : 201 (20, 20, 40,10,5)

Indicator name	Rate of winning legal (Civil and criminal) cases
Indicator code	**SD10 – 5**

Definition	It is the ratio of winning legal cases and the number of resolved cases in the physical period.
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 FHRS proclamations, regulations, directives and guidelines. To win legal cases, there must be strong "Preponderance of evidence" or "Clear and convincing" standards. Therefore, the more Clear and convincing" standards available, the more the FHRS wins legal cases.
Unit of measure	**Percentage**
Formula (numerator/denominator)	Numerator: Number of winning legal cases during the physical period. Denominator: Total number of resolved cases Rate of winning legal cases can be calculated as: Rate of winning = (Number of winning civil cases)/ (Total number of resolved cases during the physical period) X100.
Disaggregation	**By region and type of product**
Data Source	**Performance report**
Data collection method	**Document review of performance report**
Frequency	**Annual**
Baseline/Target	**Baseline: NA** **Target 95 (75,80,85,90,95)**

Point of Clarity	

Strategic Direction 11: Enhance good-governance

Indicator title	**customer satisfaction level**
Indicator type	**Outcome**
Indicator code	**SD11-1**
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. ***Customer Satisfaction*** Score (CSAT) is the most commonly used ***measurement*** for ***customer satisfaction***

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: % Satisfaction=(Results provided by respondents for overall satisfaction/total number of respondents in the study) Overall satisfaction=mean of satisfaction
Unit of Measure	Number
Disaggregation	Satisfaction level, sex
Data source	Customers
Data collection method	Survey
Frequency	Annual
Baseline/Target	Baseline: 50.2 Target: 80 (60,65,70,75,80)

Indicator name	Transparency score
Indicator code	SD 11- 2
Indicator type	Outcome
Precise definition	It is a score that measures the level of transparency of the regulatory functions undertaken by the EFDA and RRBs.
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 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. 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)
Formula (numerator/denominator)	Transparency Score = Total Average score of regulatory functions (Registration, inspection….) Refer WHO guideline for measurement this indicator
Unit of Measure	Number
Disaggregation	Regulatory Functions,
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 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 2 and half years
Baseline Value and targets	NA (Baseline) 9 (7.5, 9 target)
Point of clarity	**Regional and branch offices will cascade the study to their context** 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. 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.

Indicator title	percentage of women in leadership positions

Indicator code	**SD11-3**
Precise definition	The percentage of women at higher decision making positions such as team leader, director, deputy and general positions.
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)	**Numerator: -** number of women in managerial positions **Denominator:-** the total number of decision makers at all managerial positions Percentage = number of women in managerial positions *100 / the total number of decision makers at all managerial positions
Disaggregation	By level of positions at all branch offices, exist and entry ports and head office
Data source	Record • Gender disaggregated data • Human resource directorate's report
Data collection methods	**Records & reports from** • EFDA
Baseline Value and targets	Baseline (36.7%) Targets (50%)
Frequency	Quarterly, bi-annual and Annually
Indicator title	Rate of gender mainstreaming in the authority
Indicator code	**SD11-4**
Precise definition	Gender mainstreaming is a strategy to ensure gender equality at anywhere and any level to integrate gender sensitivity in the programs, projects, standards, initiatives, legislations, monitoring and evaluation and activities at

	activities at all.
Purpose /Interpretation	Increased and practiced the rate of gender mainstreaming in the organization's activities, projects and programs which can measure the institutionalized gender mainstreaming.
Unit of measurement	Percentage
Formula numerator/denominator)	**Numerator: -** number of gender mainstreaming reports **Denominator:-** the total number of reports from all directorates and branch offices Percentage = number of gender mainstreaming reports *100 / the total number of reports from all directorates and branch offices
Disaggregation	
Data source	Record • Gender disaggregated data • report
Data collection methods	**Records & reports from** • EFDA
Baseline Value and targets	Baseline (1%) Targets (100%)
Frequency	Quarterly, bi-annual and Annually

Strategic Direction 12: Improve human resource development and management

Indicator name	Employees` satisfaction level
Indicator code	SD12- 1
Indicator type	Outcome
Precise definition	It is a percentage/proportion which measures the satisfaction level of the regulatory sector employees assessed through survey.
purpose/Interpretation	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.) It also helps to measure the proportion of employees whose desires are fulfilled/satisfied. 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.
Formula (numerator/denominator)	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%
Unit of Measure	Percentage

Disaggregation	Sex, Age, Educational status, Marital Status, position, Work experience, Regulatory Functions, Branch offices, regions,
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 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	38% (Baseline) 65% (45%, 50%, 55%, 60%, 65%, targets)
Point of clarity	**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

Indicator name	Attrition rate of employees
Indicator code	**SD12- 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)	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. **Yearly attrition rate** $=\left(\frac{\sum \ Total\ \#\ omployees\ left\ the\ organisation}{\sum \ (Biginning\ year+End\ of\ year)/2}\right) X100\%$**.**
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 ● 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: 3.4 Target: 2%
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 13: Improve efficiency and effectiveness

Indicator name	Medicine registration lead time (in days)
Indicator code	**SD13- 1**
Indicator Type	**Output**
Precise definition	Registration lead time is the average number of Authority days taken for different types of medicine registration 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 dossier evaluation submitted for registration. The lesser the days the better the efficiency and vice versa.
Formula (numerator/denominator)	Numerator: Summation of the Authority days taken to evaluate different medicine registration dossiers. $=\sum_{i=1}^{n} \quad AD1 + AD2 + AD3 \ldots\ldots + ADn$ Denominator: The total number of dossiers $=\sum_{i=1}^{n} \quad Xi$ Medicine registration lead time is calculated as: MRLT $=\sum_{i=1}^{n} \quad AD1 + AD2 + AD3 \ldots ADn \div \sum_{i=1}^{n} \quad Xi$ Where MRLT - Medicine registration lead time Di- Authority 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 n^{th} dossier
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 *e-RIS* values and MA certificates.
Frequency	Annually

Baseline Value and targets	Base line: 90 days Target: 60 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 prescreening and response days taken by the client for further request during evaluation.

Indicator title	**Amount of resource mobilization (in million birr)**
Indicator code	SD13-2
Indicator Type	Output
Definition	It is the amount of resources mobilized for the health regulatory sector in the budget year
Purpose/ Interpretation	This indicator shows the amount of resources mobilized in monetary value for the regulatory sector. When the amount of resource mobilized increased, the performance of the regulatory sector will be enhanced.
Unit of measure	Number
Formula:	The total sum of resources mobilized for the health regulatory sectorin the budget year
Disaggregation	sources of resources (Partners, loans, revenue and treasury)
Data Source:	EFDA, Partners,MoF, MoH, RRBs reports and records
Data Collection methods:	Document review
Frequency	Quarterly, bi-annually and yearly

Indicator title	Improved percentage of budget utilization

Baseline value and target	Baseline: 295.6 Target: 1,641.50 (at the end of 5th year)

Indicator code	SD13- 3
Indicator Type	Out put
Definition	It is the percentage of properly utilized budget against the total allocated budget within the budget year. Improved budget utilization includes both capital and recurrent budget within budget year.
Interpretation	It indicates efficiently and effectively of the authority to properly utilize the budget allocated in a fiscal year. Proper utilization means using the allocated budget for the intended purpose of health regulatory budget properly utilized to total budget allocated in the sector.
Formula	Percentage of health regulatory budget utilization can be calculated as the total budget properly utilized divided by the total budget allocated and multiplied by 100. Percentage of health regulatory budget to national health budget $=\left(\frac{\textbf{thetotalbudgetproperlyutilized}}{\textbf{thetotalbudgetallocated}}\right)\textbf{X100.}$
Unit of measure	Percentage
Disaggregation	By Head quarter (departments and branches), capital and recurrent budget.
Data Source	Financial performance report
Data collection methods	Financial performance report review
Frequency	Quarterly, bi-annually and yearly
Baseline value & target	Baseline: 85.33 Target: 95
Point of Clarity	It shows only federal level

Strategic Direction 14: Improve Evidence Based Decision Making

Indicator title	**Percentage of expected reports received from reporting units on time**
Indicator type	**output**
Indicator code	SD14-1
Precise 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.
purpose/Interpretation	Expect Reports received from the reporting units on time.
Formula (numerator/denominator)	Numerator: Number of reports summited or 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 summited or received on time / Total number of received reports)*100
Unit of Measure	percentage
Data source	Performance Report
Disaggregation	FDA and RRBs
Data collection method	review of performance report
Frequency	Quarterly
Baseline/Target	Baseline NA Target 95 (75, 80, 85, 90,95)

Indicator name	Percentage of expected reports received from reporting units complete
Indicator code	**SD14 -2**
Definition	It is the percentage of expected reports received complete from reporting units during the reporting period.
purpose/Interpretation	Completeness is one of the measurements for a reporting quality. A report is considered "complete" when every unit is reporting a full set of data and when it fulfills expectations of comprehensiveness. To ensure completeness, all data sets and data items must be recorded. The purpose of this indicator is to examines the extent to which: ▪ Data reported through the system are available and adequate for the intended purpose ▪ All units that are supposed to report are actually reporting ▪ Data elements in submitted reports are complete The more complete the received report, it will be more meaningful and helps for appropriate evidence based decision making.
Unit of measure	Percentage
Formula (numerator/denominator)	Numerator: Number of reports received complete during the reporting period. Denominator: Total number of total reports available or received percentage of expected reports received complete can be calculated as: Completeness of reports (%) = # reports that are complete (all data elements filled out)/ (# total reports available or received) X100.

Disaggregation	**NA**
Data Source	**Performance report**
Data collection method	**Document review of performance report**
Frequency	Quarterly, Bi-annually and annually
Baseline/target	Baseline NA Target 80 (60, 65, 70, 75,80)
Point of Clarity	

Indicator name	**Number of conducted surveys/assessments**
Indicator code	SD14-3
Indicator type	Output
Definition	Conducted surveys/assessment is a measure that describes or reflects how our customers/stakeholders feel, functions, or survives. Stakeholders reported outcomes (SRO) measures. Observer-reported outcome (ObsRO) measures and Performance outcome (PerfO) measures.
purpose/Interpretation	The assessment process guides the development of recommendations and action plans to support achievement of regulatory sector objectivesfor evidence based decision making

Unit of measure	Number
Formula (numerator/denominator)	Count the total number of surveys completed
Disaggregation	
Data Source	Final assessment/Survey report
Data collection method	Observation, expert or peer review, and interviews and focus groups discussion document review.
Frequency	**Quarterly?**
Baseline value and target	Baseline: NA Target: 56
Point of Clarity	

Strategic Direction 15: Strengthen food and health products Regulatory Infrastructures

Indicator name	**Constructed center of health regulatory excellence**
Indicator code	SD15-1
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: • EFDA • MoH
Frequency	Yearly
Baseline value and target	Baseline: 0 Target: 1
Point of Clarity	

Indicator name	Established and well-equipped mini- labs at entry/exit ports
Indicator code	**SD15- 3**
Indicator type	**Output**
Precise definition	The summation of the number of established and well-equipped mini labs at entry/exit ports in food and health products regulatory sector
purpose/Interpretation	The indicator measures how many well established and equipped mini-labs are established in the regulatory sector. This in turn measures the capacity of the regulatory sector to assure the quality of regulated products. Hence, this indicator helps to measure the quality assurance capacity of the sector to assure quality of regulated products by using mobile labs at ports of entries across the country.
Formula (numerator/denominator)	The summation of the number of established and well equipped mini-labs at ports of entries % of performance= (the number of established and well equipped mini-labs at ports of entries/ number established and well equipped mini-labs at ports of entries planned by the regulatory sector) *100
Unit of Measure	**Number**
Disaggregation	**Branch offices, regions**

Data source	**Performance reports,**
Data collection method	**Document review**
Data Quality (verification)	**Physical supervision**
Frequency	**Every year**
Baseline Value and targets	**0 (Baseline)** **22 (5,10,7 targets)**
Point of clarity	

Indicator name	Number of regional regulatory bodies that implemented i-license system
Indicator code	**SD15-5**
Indicator Type	**Output**
Precise definition	Regional regulatory bodies that implemented i-license system is the number regions adopting the software with appropriate HR to support the system

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.
Formula (numerator/denominator)	Count: Number of regulatory bodies implementing i-licensing system
Unit of Measure	Number
Disaggregation	Region
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
Point of clarity	Operationalization and the support system

Established national rapid alert system

Indicator name	Number of Established national rapid alert system (nRAS)
Indicator code	**SD15-4**
Indicator Type	**Outcome**
Precise definition	The Rapid Alert Systems are mechanisms for ensuring timely reporting on issues related to food and medical products for allowing speedy detection of problems to provide the proportionate, accurate and consistent response to health events in time so as to minimize the risk on consumers. EFDA will establish automated alert system for the regulated products, this planning period will consider food (EFSANS) and for medicines (EMSAS).
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: 0 Target: 2
Point of clarity	Checking functionality of web-based system is dependent up on different factors like power, internet connection etc.

Indicator name	Number of automated systems implemented
Indicator code	**SD15- 6**
Indicator type	**Output**
Precise definition	The number of electronically networked/automated systems implemented in food and health products regulatory sector
purpose/Interpretation	**The indicator measures how many automated and implemented 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.** **Hence, this indicator helps the regulatory sector to measure its progresses in changing the services to electronic system.**

Formula (numerator/denominator)	**Numerator: the summation of the number of automated and implemented systems** **% of performance= (the number of automated and implemented systems / the number of automated and implemented systems planned by the regulatory sector) *100**
Unit of Measure	**Numbers**
Disaggregation	**Departments, functions, Branch offices, port of entries, regions**
Data source	**Performance reports**
Data collection method	**Document review**
Data Quality (verification)	**Physical supervision**
Frequency	**Every year**
Baseline Value and targets	**NA (Baseline)** **4 (2,2 targets)**
Point of clarity	