



Ethiopian Food and Drug Authority

(EFDA)

Food and Health Products Regulatory Sector

Medium-Term Development and Investment

Plan

(FHRSDIP)

2016-2018 EFY

(2023/24-2025/26)

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List of Abbreviations and Acronyms

ADE	Adverse Drug Event
AEFI	Adverse Event Following Immunization
AIDS	Acquired Immuno Defficiency Syndrom
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
ART	Anti Retroviral Treatment/Therapy
BSC	Balanced Scored Card
CCTV	Closed Circuit Television
cGMP	Current Good Manufacturing Practice
COVID	Corona Virus Diseases
CRADAs	Cooperative Research and Development Agreements
CSA	Central Statistical Agency
EBD	Evidence Based Decision
EFDA	Ethiopian Food and Drug Authority
EFMHACA	Ethiopian Food Medicine and Health care administration and Control Authority
EFY	Ethiopian Fyscal Year
EPHI	Ethiopian Public Health Institute
eRIS	Electronic Regulatory Information System
ETB	Ethiopian Birr
ETS	Ethiopian Traceability System
EU	European Union
FAO	Food and Agricultural Organization
FCTC	Framework Conversion on Tobacco Control
FHRSDIP	Food and Health products Regulatory sector Development and Investment Plan
FHRSTP	Food and Health Products Regulatory Sector Transformation Plan
FMOH	Federal ministry of Health

FSCA	Field Safety Corrective Actions
GC	Gregorian Calendar
GCP	Good Catering Practices
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practice
GPS	Global Positioning System
GSP	Good Storage Practices
HPLC	High Pressure liquid Chromatography
HRSTP	Health Regulatory Sector Transformation Plan
HTM	Healthcare technology life cycle management
ICT	Information Communication Technology
IEC	Information Education Communication
IFMIS	Integrated Financial Management Information System
IGAD	Intergovernmental authority on Development
IMDRF	International Medical Device Regulators Forum
IQMS	Internal Quality Management System
ISO	International Standard Organization
LMIS	Laboratory Management Information System
M&E	Monitoring and Evaluation
MAH	Market Authorization Holders
MDGs	Millenium Development Goals
MDRs	Medical Device Reports
MDR-TB	Multi Drug Resistance Tuberculosis
MOU	Memorandum of understanding
MRIS	Medicine Registration Information System
NEPAD	New Partnership for Africa's Development
NGOs	Non Government Organizations
NPC	National Product Catalogue
NRAs	National regulatory Authorities

NSPA	National Strategy and Plan of Action for pharmaceutical manufacturing development
OTC	Over the Counter
PCB	Polychlorinated Biphenyls
PMS	Post marketing Surveillance
PoE	Port of Entry
PPEs	Personal Protective equipments
QC	Quality Control
QMS	Quality Management System
RCORE	Regulatory-sector Center of Excellence
RRBs	Regional Regulatory Bodies
SAEs	Serious Adverse Events
SDG	Sustainable Development Goals
SF	Substandard and Falsified
SOPs	Standard Operating Procedures
SPM	Strategic Planning Management
SRA	Stringent Regulatory Authorities
SWOT	Strength, Weakness, opportunities and threats
TB	Tuberculosis
TWG	Technical Working Groups
USFDA	United states Food and Drug Administration
WHO	World Health Organization
WorHOs	Woreda Health Offices
ZHDs	Zonal Health Departments

Foreword by the Minister of Health

Since the last two decades plus, Ethiopia is striving for rapid and comprehensive development schemes for transition from poverty to sustainable and reliable growth and prosperity. As societal health is a core vehicle for wealth, the government has forwarded significant investment in health system strengthening guided by its pro-poor policies and strategies, resulting in significant gains in improving the health status of the Ethiopian population. Although remarkable progresses and gains have been observed following the earlier HSDP and Health Sector Transformation Plans (HSTP), the country is still facing a triple burden of diseases consisting of communicable diseases, non-communicable diseases and injuries. This was further aggravated by the COVID 19 pandemic and the conflicts in some areas of the country, mainly in the northern Ethiopia as well as the drought encountered in some parts of the country. On the other hand, as middle class is growing, leading to an increase in non-infectious diseases such as cancer, diabetes, heart diseases, high blood pressure, mental health and eye problems. All these brought additional to the multiple challenges in infrastructure, human resources, supplies, consumables etc. that is further exasperated by our dependency on foreign suppliers for pharmaceuticals and medical supplies.

Visualizing the major challenges not only indicates the ruggedness of the path ahead of us but also helps to guide our focus areas for the three years investment plan at the federal and regional state levels with the overall vision: *”to see healthy, productive and prosperous Ethiopians”*. The MOH, its agencies and Authorities are recently implementing the structural reform and are considering the aforementioned major points vis-à-vis their respective mandates. In this connection, the plan of Ethiopian Food and Drug Authority will focus in areas that basically contribute to the vision and mission of the regulatory sector through increased regulatory oversight, promoting and protecting public health by ensuring the safety and quality of health products that ultimately contribute to see healthy, productive and prosperous Ethiopians.

Finally, I urge all concerned to play their part and assure you that our ministry is committed to make close follow up and provision of necessary support for effective implementation of the plan and advance the health of our people some steps ahead.

Lia Tadesse (Dr.)

Minister, Ministry of Health

Foreword by Director General

Safe, effective, and quality assured health products are backbone to the health care delivery system. Ensuring the safety and efficacy of medicines and medical products are maintained from the site of manufacturing, across the entire supply chain, until dispensed to the patient or disposed. Safe and wholesome food on the other hand reduces the impact of food-borne diseases, and reduces many illnesses and deaths which are also detrimental to economic consequences. Therefore, the Food and medicine regulatory system strengthening is very critical at all levels supported with implementation or enforcing legislation, regulations, guidelines, and operational procedures.

Though there were challenging conditions the effort exerted in previous years were appreciable, this momentum was maintained in the last few years in which EFDA was able not only to maintain the ISO accreditations but also attained additional certifications and scope expansions of the existing ones. Furthermore, from the effort exerted in the last couple of years the authority was able to be assessed by WHO assessors recently for securing Maturity Level 3 status.

Strengthening the regulatory sector was done in different capacity building activities including but not limited to equipping the federal and regions with materials and vehicles. At the EFDA level, the new structure has been approved and deployment of staff in these positions is finalized, this could have a positive influence in the regional levels too. To keep the list of successes short, the digitizing of major regulatory activities (importation, licensing and registration) using the online systems (e-RIS) was another remarkable accomplishment, coupled the center of excellence, the achievements in safety monitoring of medicines including vaccines, Risk-Based Post-Marketing Quality Surveillance and all activities performed in the quality assurance sphere. Yet, there are still many things to be done and various gaps to overcome to fully attain the targets in the planned activities, the list included in the body of the document.

Under the umbrella of our vision: “*to be a center of excellence in food and health products regulation in Africa*” much is expected from all of us to exercise on the strategic directions identified that pave the way to our ultimate target. It is anticipated that there will be challenges, but will make all possible efforts and use *living for our values* as a springboard for protecting citizens from dangers of unsafe, poor-quality products and services.

In this connection, I call up on all civil servants in the regulatory sector, our people, health professionals, civil societies, development partners and all stakeholders to put a coordinated effort to realize the targets stipulated in this strategic plan. I have no doubt that with the unwavering political commitment of our government, engagement and ownership of health programs by the steadfast commitment of our health workers and the support of our development partners, we will successfully accomplish the goals and will approach to our vision.

Heran Gerba

Director General, Ethiopian Food and drug Authority

Executive Summary

This is the Food and Health products Regulatory Sector Development and Investment Plan (FHRSDIP) covering the period between July 2023 and June 2026. It has been developed as part of a ten-year food and health products regulatory plan. It is prepared based on an in-depth situational analysis and performance evaluation of FHRSTP-II first three years and takes into consideration the country`s development and investment plan and the health sector long term priorities and strategies in consideration.

During FHRSTP-II first 3 years significant achievements were made despite on-going challenges such as Complexity of Illegal food, medicine and medical equipment trade; Fast going of food industry and production technology which results complex regulated products; and Inconsistent capacity with the global, national development and technological change including COVID-19 pandemic.

The FHRSTP-II first 3 years period was marked by encouraging achievements including efforts made to achieve Maturity level 3, improvements in Sustaining medicine lab accreditation and efforts to get WHO prequalification, strengthening of eRIS (e-registration, e-licensing, e-ADE reporting, electronic service in port of entry), Increasing & sustaining food and medicines and condom lab tests for both consignments and post marketing and Starting of enforcement IQMS (Internal Quality Management System) implementation at food and medicines facilities. Moreover, ratification of regulation based on proclamation number 1112/2019, which enabled the reform of health regulatory sector to product based (food and drug) regulation; and implementing new organizational structure to expedite the achievement of the designed goals.

This FHRSDIP is developed based on the recent reform taken place in the food and health products regulatory sector to protect the public from health risks due to substandard and poor-quality food, medicine, medical devices, cosmetics, tobacco and alcohol by building up on the successes of the last 3 years achievements of FHRSTP-II, and taking into its stride the lessons from its implementation.

An inclusive and active participatory process was adopted for the development of the plan. This included iterative process (as it was developed part of 10 years development and investment plan) whereby different versions of the Plan were shared with a wide-range of stakeholders including line

ministries and agencies, regional regulatory bodies, academia, professional association, private sector and development partners for comments and inputs.

The objectives of FHRSDIP are: Protect the public from unsafe and poor-quality food Safeguard the public from falsified, substandard and/or ineffective health products; Protect the public from tobacco and alcohol related health risks, and misuse of NPS; Attain public confidence on food and health product regulation. Targets have been set to measure its objectives and performance. The list of all indicators with the corresponding targets is presented in the document.

To achieve the targets, a list of 15 strategic directions is identified and each is described along with strategic initiatives and their respective core activities:

- Strengthen food safety regulation.
- Strengthen detection, prevention and response to food adulteration and illegal trade
- Improve regulation of safety, efficacy, quality and proper use of medicines
- Strengthen safety, quality and performance regulation of medical devices
- Improve regulation of safety of cosmetic products
- Strengthen tobacco, alcohol and misuse of NPS control system
- Enhance public ownership
- Improve efficiency and effectiveness
- Enhance partnership and collaboration
- Enhance good governance
- Improve human resource development and management
- Improve evidence-based decision making
- Strengthen regulatory infrastructures and digitization
- Improve quality management system
- Improve formulation and implementation of legal frameworks

The plan has identified four -priority issues as the “transformation agenda”. These priority issues will be implemented to transform the food and health product regulatory system. The transformation agenda are: Information revolution, quality infrastructure, alignment and Harmonization, leadership and regulatory workforce.

The overall costing for FHRSTP-II implementation is computed. Accordingly, 11.8 billion ETB is required for 3 years to be covered in the plan. It will be also cascaded to all levels of the food and health product regulatory sector and will be translated into annual operational plans. Its implementation will be regularly monitored using the agreed monitoring framework in a coordinated manner.

Chapter One: Introduction

The government of Ethiopia has been developing and implementing consecutive growth and development/transformational plans which have been implemented in alignment with the global targets in reduction of poverty. As part of the country priority, the health sector has achieved extraordinary results including the achievement of global targets prior to the designated time.

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 first 3 years performance of Food and Health Products Regulatory Sector Transformation Plan (FHRSTP-II) was thoroughly evaluated through assessments and surveys, quarterly, biannually and annual reviews with relevant stakeholders and regional regulatory bodies. The evaluations conveyed that most of the envisioned targets were achieved, and remarkable changes and improvements have brought in the regulatory sector. These achievements were brought due to the different high initiatives and strategies implemented through flagship programs, multi-sector collaboration, and community mobilization. Similarly, the key challenges and bottlenecks were identified through periodical and planned evaluations.

Even if there are two fiscal years remaining to finalize the implementation of FHRSTP-II period, it was important to align the national development and investment plan and the health sector medium term plan which are developed in alignment with program budgeting. The revision of the FHRSTP-II was essential because of the internal and global issues have highly affected the regulatory sector. For instance, the internal conflict, internal displacements and COVID-19 have challenged the implementation of FHRSTP-II. Hence, this medium-term development and investment plan has been planned in such a way that can address the above-mentioned problems.

This plan is developed on the basis of FHRSTP-II priorities which were reviewed in accordance that enable the regulatory sector to protect the public from health risks due to substandard and poor-quality food and health products.

This medium development and investment plan is the next three-year national food and health products sector strategic plan, which covers the period between 2023/24-2025/26 (2016-2018 EFY). During this strategic period, the sector envisions a leading and excelled food and health products regulatory system. It has made in-depth situational analysis of the last 3 years performance of HRSTP-II. This development and investment plan has taken the country`s development plan and the health sector long term priorities and strategies in consideration while designing its own objectives and strategies. An active participatory process was organized by EFDA from all functions and departments of food and health products regulatory sector.

The document is organized into seven chapters: Chapter 1 is introduction; Chapter 2 covers the country context; Chapter 3 describes the situation analysis; Chapter 4 the objectives, targets and strategic directions; Chapter 5 costing; Chapter 6describes the implementation arrangement; and Chapter 7 covers the monitoring and evaluation plan.

Chapter Two: Country Context

Geography

Ethiopia is located in the North Eastern part of Africa, also known as the Horn of Africa. It is bordered by Sudan and South Sudan on the west, Eritrea and Djibouti on the northeast, Somalia on the East and Southeast, and Kenya on the south. Ethiopia lies between the Equator and Tropic of Cancer, between the 30^oN and 150^oN Latitude and 330^o E and 480^o E Longitude. The country occupies an area of 1.1 million sq. kms and the water bodies occupy 7,444 sq. km. Ethiopia is a country with rich geographical diversity. It consists of rugged mountains, flat-topped plateaus, deep gorges and river valleys. Over the ages, erosions, volcanic eruptions and tectonic movements have contributed to the nation's diverse topography. More than half of the geographic area of the country lies 1,500 m above sea level. The highest altitude is at Ras Dashen (4,620 meters above sea level) and the lowest altitude is at Danakil (Dallol) Depression (148 m below sea level).

Demographic Profile

With a population of about 101 million in 2020, Ethiopia is the second most populous country of Africa and ranks 12th in the world. Ethiopia is the home to various ethnicities, with more than 80 different spoken languages. The population is characterized by rapid population growth (2.6%), young age structure and a high dependency ratio with a high rural-urban differential. Ethiopia has a high total fertility rate of 4.6 births per woman (2.3 in urban areas and 5.2 in rural areas) and a corresponding crude birth rate of 32 per 1000 in 2016. The average household size is 4.6. By 2024, the population is projected to reach 109.5 million (Ref. CSA projection) and will reach 122.3 million by 2030 (See figure 1 below). Children under age 15 years and individuals in the age group of 15-65 years account for 47% and 49% of the population respectively. Only 4% of the population is above the age of 65 years. The sex ratio between males and females is almost equal, and women of reproductive age constitute about 23% of the population. Nearly 80% lives in rural areas, mainly depend on subsistence agriculture (Ref. EDHS 2016 and CSA).

Socio-economic situation

It has long been communicated through different media that Ethiopia has registered commendable achievement on Millennium Development Goals (MDGs) mainly in reducing poverty head count, achieving universal primary education, narrowing gender disparities in primary education, reducing child and neonatal mortality, combating HIV/AIDS, TB and malaria. The government has put at most effort to implement various proactive macroeconomic policies including a market based and agriculture led industrialization that means transforming the economy from an agricultural to industrial lead economy. Despite the World Bank classification stating the country as a low-income country with gross domestic product (GDP) per capital (current US\$ OF US\$700 in 2016(update with latest data) up from about US\$ 340 in 2010, the country is one of the fastest growing economies in Africa experiencing rapid economic growth with an average of about 10% annual growth rate between 2004 and 2014, with the mainly contributors to the growth is the GDP include agriculture and, industry and service sector.

Health sector place in the country context

The success of the health sector depends on the overall level of development of the country that means the economic policy and the health policy and their successful implementation would guarantee the physical and mental wellbeing of the population. The contribution of the health sector towards socioeconomic development of the country is critical as equitable human development rely on health status and wellbeing of the society. Hence investing in the current and future generation towards sustainable development is critical. Otherwise, economic growth without equitable social development may not be sustainable.

Food and Health Products Regulatory sector

As the right to health for every Ethiopian has been guaranteed by the 1995 Constitution of the Federal Democratic Republic of Ethiopia, which stipulates the obligation of the state to issue a policy, a more demanding society has emerged, putting more pressure on the need for quality health care. The need for quality health care on its turn called for the need for intensified regulatory science implementation. Regulatory science is an emerging area within pharmaceutical medicine, including the shaping and implementation of legislation and guidelines, developing new tools, standards and approaches to evaluate the efficacy, safety, quality of medicine and performance of medical products in order to assess benefit and risk, and to facilitate sound and transparent regulatory decision-making. Food and Health products Regulatory sector has been recognized as having a significant impact on the industry's ability to bring new medicines and medical devices to patients in need. It

creates a platform for launching new ideas – not only by the pharmaceutical industry and regulatory authorities, but also by, for example, academia, which wants to contribute to a better use of its research activities within medical aspects.

Today, there is increasing innovation in the world and Ethiopian Food and Health products regulatory authority has been experiencing increasing imports of these technologies (food, new medicines, devices, diagnostic equipment and knowledge). The development of the Ethiopian local pharmaceutical manufacturing sub-sector has been very much limited in terms of production capacity, technology acquisition, creation of employment opportunity and investment. This shows that technology transfer and scientific development in Ethiopia with regard to pharmaceutical manufacturing and regulation is not (yet) consistent with the internationally required standards. Moreover, regulatory work is becoming increasingly complex, with new medicines coming to the market, such as biologicals, biosimilars and monoclonal antibodies. The old paradigm that each country should control all medicines in its territory by its own is being superseded by a recognition that RAs need to work closely together in their region, continent and even globally. Information exchange is vital, and requires harmonization of standards and information exchange. As the government, has been working to increase access to quality health services by developing health care infrastructure and increasing the number of health work force, strengthening the regulatory sector is one that has been given top priority.

Chapter Three: The mid-term (3 years) Performance of the Food and Health Products Regulatory Sector Transformation Plan II (FHRSTP I) – Situational Assessment

The HRSTP-II has depicted what the regulatory sector was intended to achieve by the year 2024/25. As the mid-term execution period has ended, the performance review and the identifying the achievements, failures and lessons learned throughout the implementation periods was vital and has paramount importance to indicate strengths and weaknesses, and to put as a basis for the next medium term (3years) food and health products regulatory sector development and investment plan. The flow of the situational analysis report is organized as per the HRSTP-II plan organization; this plan organization has fifteen strategic directions. Each strategic direction was evaluated in detail by the established team in collaboration with implementing functions and the management committee.

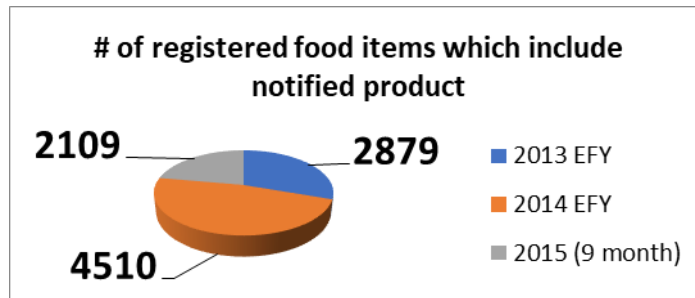
3.1. Improve quality and safety regulation of food

3.1.1. Food registration and market Authorization

Food registration and market authorization is one of the strategies to ensure food safety. Expedite the access of safe and quality food in the market was one of the transformation agendas in HRSTP-II. In addition, boost food market authorization was among the 14 initiatives identified and implemented by the year 2022/23.

To boost the registration, furthermore, model food registration and notification guideline for regions was developed and is under dissemination. The promotion of food registration via different mechanisms has also contributed to increase the number of registered foods.

During the last two years and 9 months a total of 9498 food items were registered which was 1998 in the baseline that includes: infant formula, dietary supplements, water treatment tabs & equipment and other selected food items based on their risks as shown in the graph below. A consultative workshop was conducted with the manufacturer and importer on the process of food registration using e-RIS system. The food registration system includes both notified and registered food. High risk products like baby food and food supplements passed through registration and low risk products like, food raw materials, vinegar and alcohol drinks with above 10% alcohol content passed with notification process.



(Source: EFDA annual and monthly report (2020/21, 2021/22 and 2022/23 (9month))

Figure 1: Number of registered food items (2020/21, 2021/22 and 2022/23

When we compared the performance of food registration against the plan, we have achieved more than the targets set, which exceeded the plan by 9%, 20% and 9.8%, in 2020/21, 2021/22 and 2022/23, respectively.

During the registration process some the challenges which sustained for the previous years are: low willingness to register food both by importers and local manufacturers, presence of foods that do not have national standard and also inadequate enforcing the existing standards, e-commerce (digital market) for selling of infant formulas and supplements, weak coordination and collaboration between directorates in EFDA and regional regulatory bodies. To overcome the challenge of food registration specifically in the regions a model registration directive was developed and ready for dissemination.

The national food alert system is one of the great achievements accomplished in the last two years. It is launched officially at national level, creates awareness to stakeholders and enrich with their comment. This national alert system should be expanding to the regions through health regulatory bodies and also will be link with the international food alert system (INFOSAN).

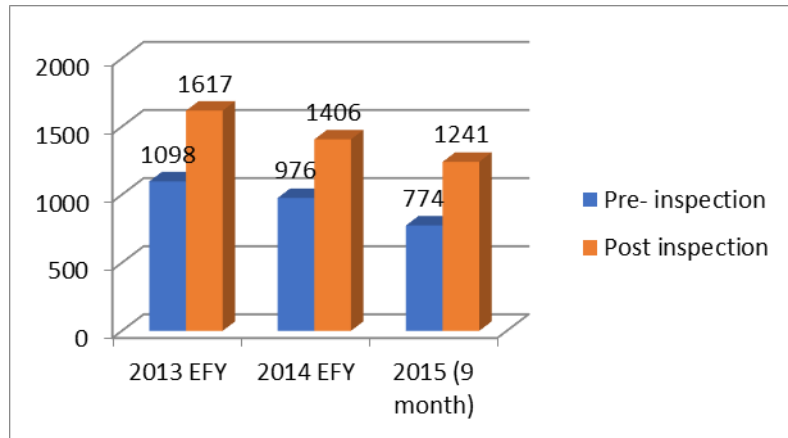
3.1.2. Food inspection and enforcement

3.1.2.1. Food facilities inspection and internal quality management system

EFDA is mandated for the inspection of food manufacturers’, importers, exporters and wholesaler for the ensuring of food safety and quality. EFDA has provided certificate of competence for about 2848 food facilities from 2020/21-2022/23 by conducting pre inspections. The pre-inspection coverage is depending on the number of new applicant for certificate of competence and the achievement compared to the expectation number (set target) was lower, which might be due to other root causes, such as the government policies availability of foreign currency for importing foods (which needs further assessment). On the other hand, the auditing inspection coverage was

87.5%. some of the challenges regarding post inspection were: some the food facilities returned their COC due to their own reasons, many facilities took the COC for one time import and became difficult to get them in their registered address, and inadequate resources to cover all facilities.

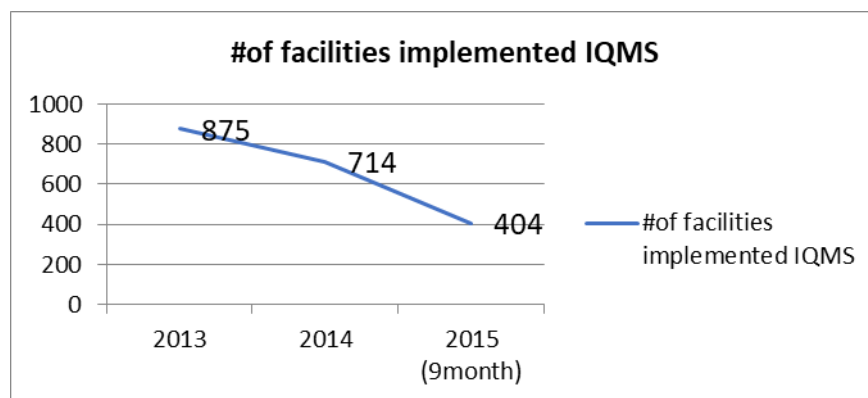
Pre and post inspection Achievements



(Source: EFDA annual and monthly report (2020/21, 2021/22 and 2022/23 (9month))

Figure 2: Pre and Post inspections of food facilities (2020/21, 2021/22 and 2022/23

Internal quality management system is one of the requirements for the better implementation of food safety which is expected to be implemented by the food facilities. Currently the implementation of IQMS is one of the requirements to renew the COC. In the last 2 years and 9 month performance the IQMS result shows decreasing trend. Hence, EFDA is currently conducting assessment to identify the challenges and the level of achievements regarding IQMS.



(Source: EFDA annual and monthly report (2020/21, 2021/22 and 2022/23 (9month))

Figure 3: Number of food facilities that implemented IQMS

By taking the existing challenges of pre-inspection into consideration, the existing pre licensing directive is being revised. On the other hand, to reach and address local and foreign food manufacturers, the GMP guideline in under development and will be implemented in 2023/24, will provide additional support to conduct the scientific implementation of inspection.

A monthly based market assessment has been conducted in the last two years (2013 and 2014EFY) as planned in the HRSTP II. As a results of the market assessments, administrative actions were taken and, the community awareness regarding the detained food items was conducted through different electronic and printing media channels and other social media platforms.

Concerning adulteration control practices survey was conducted on selected product butter, honey, pepper and other food products. Based on the findings operations were conducted, administrative measures were taken, risk communication has been done through social and mainstream Medias, and products were also recalled and local industries were made to take corrective and preventive action.

Major challenges faced during inspection are: the inspection not support by rapid test kit and other inspection tools, lack of on job training for the inspectors in relation to new technology, gaps to conduct science based or knowledge based inspection, specially to conduct pre-inspection lack of awareness and poor commitment in the implementation of food safety and quality management system and in adequate support by EFDA to facilities, absence of updated national central data based system for food institution based on their capacity and product nature, poor coordination and collaboration in the sector and overlap of mandate between sector ministries/institutions, and also ISO 17020 not implement by the inspection section.

3.1.2.2. Food product and raw material inspection at port of entry

Inspection of food products and raw material at ports of entries for imported food products and raw material is one of the major activities in the food regulation and enforcement. In this regard, EFDA has been working to improve the stakeholder coordination at ports of entries and it has shown a significant improvements.

In the last two years (2013 and 2014) and 9 month of 2015 EFY a total of 12, 414, 891.73 tons food items and raw materials inspected and clearance was given to enter to the country. On the other hand, 14,144.51 ton food products that didn't meet the required regulatory requirements was disposed/returned to country of origin.

Some of the challenges arise at port of entry are: - lack of rapid test kits (onsite verification kits), some skill and experience gaps on food quality and safety regulation (e.g. not familiar with new

technology and products produced with this new technology that are coming to our country, and inadequate infrastructures such as office and vehicles for their day to day regulatory activities.

3.1.2.3. Administrative measures taken on food facilities

In the last two years (2013, 2014) and 9 month of 2015 EFY the HRSTP II plan after food facility inspection, conducting market survey and post market surveillance, based on the customer compliance and in accordance with the intelligence/survey findings which violates the regulatory and statutory requirements the following administrative measures were taken;

Table 1: Administrative measures taken on food facilities

No	Types of administrative measures	Local manufacturer	Importer and wholesaler	Retailer
1.	Warning letter	4	2	-
2.	Suspension for restricted time	107	100	-
3.	Partial detention from practice	4	1	-
4.	Revocation/ cancellation	12	569	-
5.	Recall their product	3	1	-

In the above-mentioned budget year which was planned in HRESTP II the following products indicated in the table 2 were deposed after-market assessment, and inspection conducted on **(manufacture, importer, wholesaler, and retailer)**. The administrative measures were taken due to that the products were not safe, substandard, expired, mislabeled, damaged, adulterated and illegal;

Table 2: List and amount of products disposed

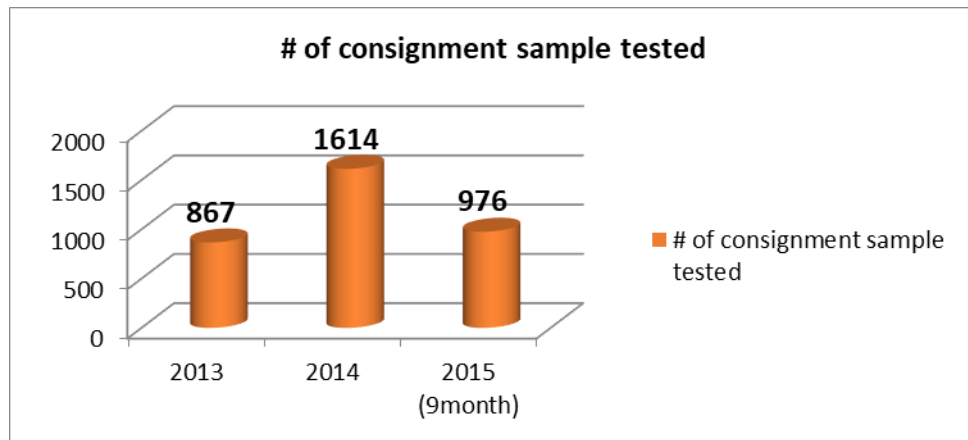
S.N.	List of food items	Amount	
1.	Edible salt	123.82 ton	
2.	Peanut butter	1426 Carton	
3.	Juice	86115 pieces	
4.	Crude oil	19.86 ton	
5.	Edible oil	132.67 ton	

6.	Biscuit	87 cartons	
7.	Dates	1024.2 ton and 63 cartons	
8.	Rice	145.88 ton	
9.	Lentil	99 ton	
10.	Wheat flour	62.02 ton	
11.	Sugar	990.3 ton	
12.	Honey	210 kg	
13.	Pepper	8700 kg	
14.	Vegetable ghee	111 cartons	
15.	Chicken	227 cartons	
16.	Cheese	2100 carton	
17.	Candy	290 kg and 206 cartons	
18.	Butter	68 kg	
19.	Acheto	72 litter	
20.	Coca-Cola	5472 pieces	
21.	Alcohol drinks	1742 pieces	
22.	Chocolate	408 cartons	
23.	Coffee mate	16 cartons	
24.	Jam	1000 carton	
25.	Milk powder	16.92 ton	
26.	Other food items which costs	6,754,703.5 Birr	

3.1.3. Food laboratory testing

Laboratory testing is one of the food safety and quality control techniques for the ensuring of food that the food is free of physical, chemical, and biological hazards and also determines the safety of

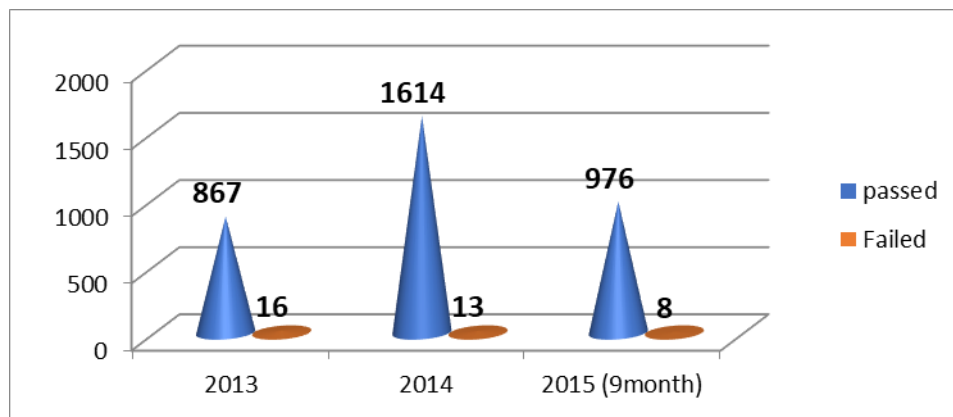
the food for use. Food consignment and post marketing surveillance are the two major strategic initiatives which are used to assure the quality and safety of food products for imported and locally manufactured product. Food items covered under both initiatives are selected based on their food safety risk considering the nature, perishability, mass consumption, end user of the product and others criteria. 38, 43 and 48 food items are planned for the HRSTP II which their performance is 38, 40 and 40 in 2013, 2014 and 2015 (9month) respectively. The number of tested products for consignment test indicated in below graph.



Source: EFDA annual and monthly report (2020,21, 2021/22, 2022/23(9month))

Figure 4: Number of food consignment samples tested (2020,21, 2021/22, 2022/23)

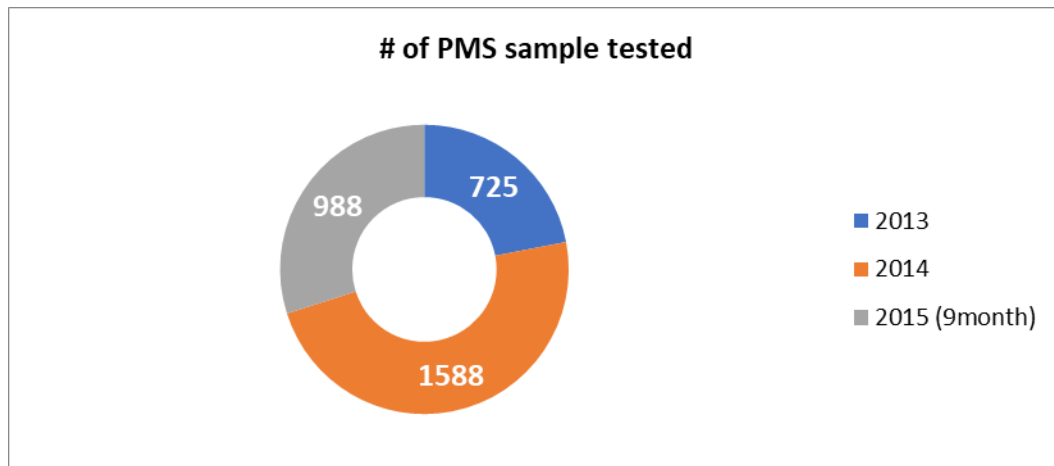
The test result of the above mentioned consignment food samples also indicated in the below graph. The entire product which failed its laboratory test result shall disposed or return back to the country of origin. The disposal process had been conducted in collaboration with other sector organizations.



Source: EFDA annual and monthly report (2020/21, 2021/22, 2022/23(9month))

Figure 5: # of consignment food samples tested with their result

Concerning PMS the following food items (iodized salt, edible oil, pasteurized milk, cheese and yogurt, packed juice, milk powder, baby foods, peanut butter, wheat flour, pip water, bottled water, candy,...) were tested in the past 2013,2014 and 2015 (9 months) of the EFY. The performance of the test result shows in the below graph.

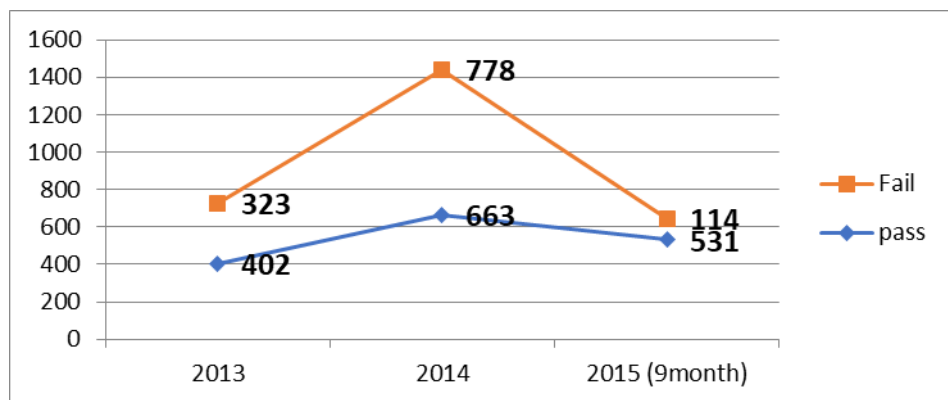


Source: EFDA annual and monthly report (2020/21, 2021/22, 2022/23(9month))

Figure 6: Number of Food PMS tested (2020/21, 2021/22, 2022/23)

Based on the laboratory result administrative measures (warning letter, suspension, cancellation and recall of the product) were taken on the facilities. All products which were expected public health hazard will recall, disposed and also announced to the public through different public media about its health effect.

List of PMS sample tested and results



NB: There are few PMS samples not yet tested which are collected in 3rd quarter of 2015 EFY

Figure 7: Lists of Food PMS tested with results

The increasing trend of PMS testing has reduced the failure rate of food products. This is because of the increment of EFDA's capacity to conduct post market surveys and the expanding of lab testing capacity with state of the art lab equipment and skilled man power. The reduction of failure of rate of food products in turn revealed that many lives were saved due to the availability of these poor quality and unsafe products in the market.

In addition, a laboratory testing also conducted on suspected food product to confirm the product safety and quality which found during inspection and market survey. The following table shows list of suspected food items tested by the authority and their results.

Table 3: Suspected food products laboratory test results

Year	Suspected food items	Complies to the standard	Doesn't comply to the standard	Remark
2013	3	1	2	
2014	116	51	65	
2015 (9 month)	65	35	26	4 sample are on the process of testing

Source: EFDA annual and monthly report (2020/21, 2021/22, 2022/23(9month))

Currently adulteration is one of the challenge in the ensuring of food safety available in the market. Most of the adulteration is suspected on (honey, butter, teff flour, pepper, ...). The test result of adulteration food products shown in the below table

Table 4: adulterated food products laboratory test results

Year	Amount tested	Remark
------	---------------	--------

	Passed	Failed	
2013	37	80	
2014	78	158	
2015 (9mth)	27	35	

Source: EFDA annual and monthly report (2020/21, 2021/22, 2022/23(9month))

One of the good successes of the food safety and quality control directorate in the previous two years was the accreditation of the food laboratory by Ethiopian Accreditation Service (EAS) in 11 parameters which are very essential for the ensuring of food safety. The expansion of testing parameters and maintain the current accredited parameters are very crucial in future plan.

Despite all the achievements major challenges in the area of food quality control are: lack of well-trained expertise, Challenges related the procurement process that affected that continuous supply of laboratory supplies and maintenance of laboratory equipments, limitation in testing of food safety chemical hazards like pesticide and veterinary drug residue, lack of food contact material testing are main challenges for the sector.

3.2. Strengthen detection, prevention and response to food adulteration and illegal trade

We aim to overcome on fraud, food adulteration and illegal food trade through detection, prevention and response at national level. Effective fraud prevention, detection and response mechanisms play a key role in safeguarding of the public from consumption of the public unsafe and poor quality food which causes morbidity and mortality. To conduct an advance detection of unsafe foods and prevention of illegal food trade and adulteration a Market survey conducted in 30 rounds in the last two and half budget year in different 49 cities and exhibition centers and also in a holyday event on different food products (peanut butter, salt, candy edible oil, honey baby food and milk ...). Administrative measure was taken on unsafe and poor food products. Laboratory testing was conducted on suspected and adulterated 18 honeys, 35 butter, 17 flour and 19 pepper product. The laboratory test result indicated in the QC section

3.3. Improve Regulation of safety, efficacy, quality and efficacy and proper use of medicines

3.3.1. Medicine registration and market authorization

To improve availability of safe, effective and quality assured medicines in Ethiopia, EFDA has been working to strengthen the registration system in the country. There have been substantial improvements in the medicine registration system since the last decades although there are areas to improve. The Authority has adapted and implemented medicine marketing authorization strategies and aligned its medicine registration requirements with the international practices. The Authority has implemented fast-track registration approach for critical public health concerns (e.g., anti-malarias, antiretroviral, anti-tuberculosis medicines, and maternal and child health); Stringent Regulatory Authorities (SRAs) procedures for dossier assessment; collaborative approach with WHO, outsourcing of dossiers evaluation, and use of external pool of assessors. In addition, the Authority has implemented the electronic regulatory information system (e-RIS). These resulted in reducing backlogs, reducing lead-time for registration and significantly increase registered medicines in the country.

In 2019/2020, the numbers of registered medicines in the country were only 3981 and the Authority planned to register 4,085 medicines in the year 2020/2021-2022/2023. At the end of the third year, 3,046 (74.6%) new medicines were registered and total registered medicines increased to 7027 (Figure 6). Compared to 2019/20; significant achievements have been gained in registration of medicines.

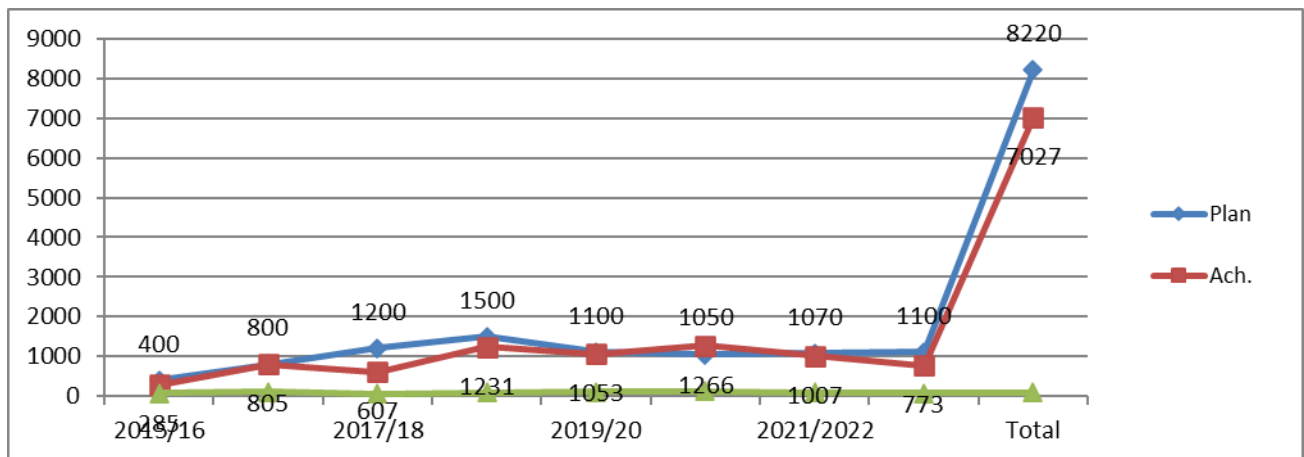


Figure 8: Number of registered medicines in Ethiopia, 2015/16-2022/2023

However, as compared to the demand, disease burden and large market coverage of the country, the number of registered medicines is still too low to ensure quality assured essential medicine access to citizens as compared to small countries in the region (figure 7). Based on supply base analysis done by EPSS in collaboration with development partners in 2021, 79% of the commodities were found to have inadequate supplier base of four and less. Furthermore, 27% of the commodities didn't have even a single registered supplier/s registered through EFDA².

Limited capacity, number and mix of human resource, proper utilization of the existing human resource, lack of efficiency and effectiveness, not properly implementing the market authorization strategy like outreach program to motivate industries to apply for registration. Moreover applicants are not aware of the change of agency restriction from 3 to none, and there are different conflict interests where some importers want to monopolize the market, delay to further information request responses and delay in clearing of backlog of dossier applications were the main challenges that hinder the performance of medicine registration. Moreover, relatively decreasing application flow, market withdrawal of significant number of registered international manufacturers and products (figure 8), long registration lead time of essential medicines and other external market related factors are newly emerging core challenges of the authority hindering to register more medical product options as required. There were also technical capacity gaps in evaluation of biologics, biosimilars, nanomedicines (products incorporating nanoparticle drug delivery systems) and traditional medicines.

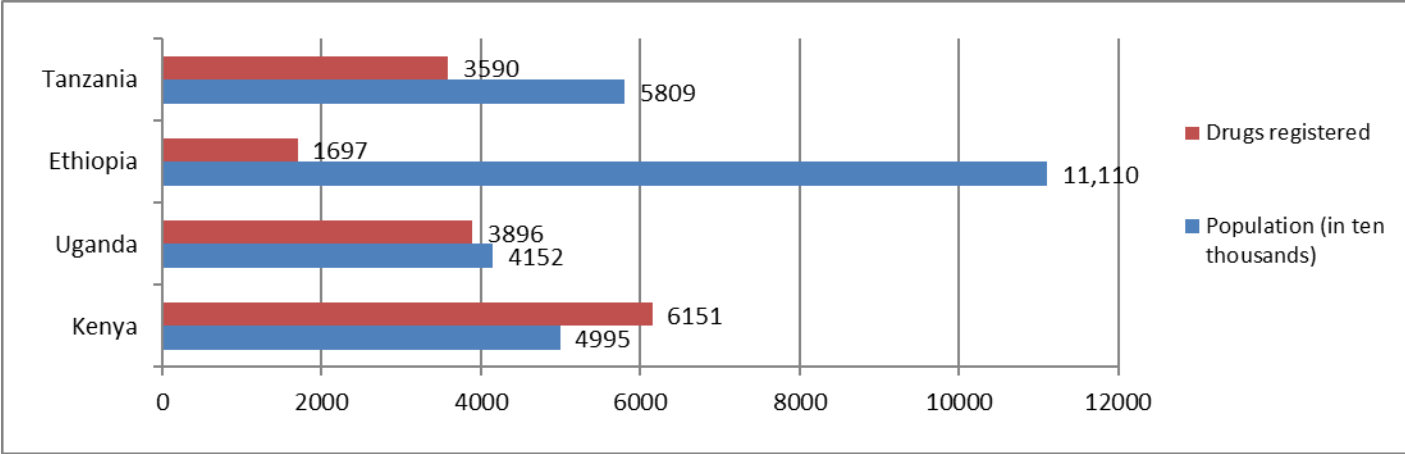


Figure 9: The national drug registers: Kenya, Uganda, Ethiopia and United Republic of Tanzania in 2017/2018 accessed on 26th February 2018¹.

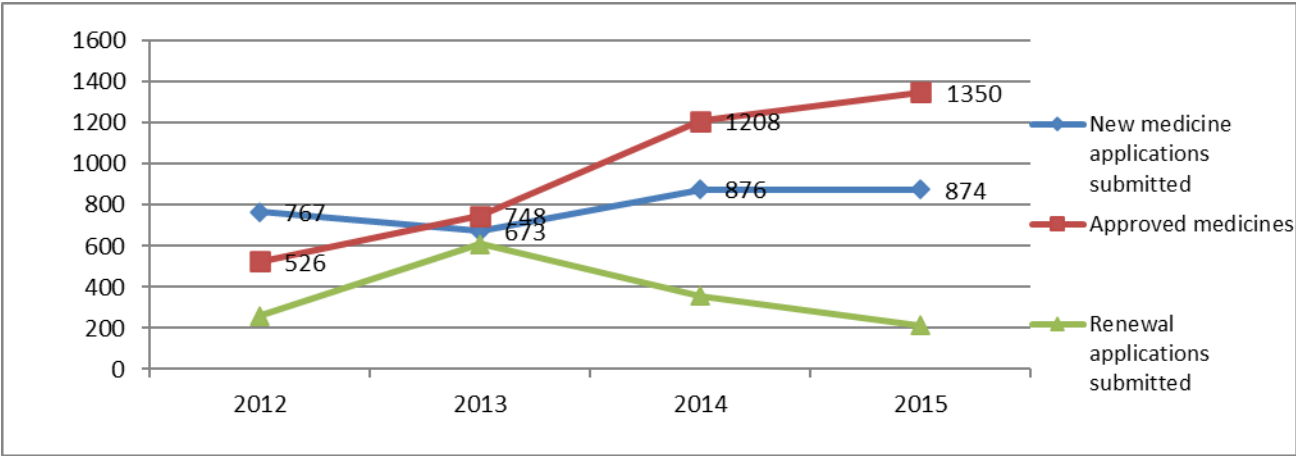


Figure 10: Registration application flow and approval pattern of EFDA, 2012-2015 E.C

Strengthening the capacity of the regulatory sector to further expedite marketing authorization process and reduce registration lead time within the registration system and different levels and scope of reliance, implementing API data base, conduct dossier assessments before GMP inspections, work sharing and cooperation schemes with other competent equivalent agencies, less regulated border sharing neighboring countries and ongoing harmonization initiatives need to be implemented.

3.3.2. Health Products Inspection and Enforcement

Comprehensive system of quality assurance must be founded on a reliable system of controlling the quality, safety and effectiveness of finished health products in the market. The level of quality of medicines should be maintained throughout the pharmaceutical supply system or distribution network.

As a results of non harmonized regulatory tools especially in the regions, non harmonized organizational structure for the regions, weak coordination between different actors(Customs commission, regional regulatory authorities, Ministry of Justice, Federal and regional police etc.) and weak enforcement, inefficient supply chain management, there are still poor quality of drugs in the market. As of 2019/2020, the number of licensed manufacturers, importers, wholesales, pharmacies, drug shops and rural drug vendors are 11, 883, 691, 1078, 4056 and 618 respectively. In 2019/20, 100% of importers & wholesale and 75% of medicine retail outlets were inspected for the purpose of licensing and compliance check against the set requirements (**Figure 11**). In the last two years, risk-based inspection approaches, auditing inspection and internal quality management system have been implemented at all levels in the distribution channel. 85% of medicine facilities have taken the initiative voluntarily and started implementation of internal quality management system (**Figure 12**). But there are gaps in understanding and implementing of the principle of internal quality management system at facility level. The achievements of product-based auditing inspection and internal quality assurance systems helped to reduce the circulation of substandard products in the market which in turn saved the life of the people (the prevalence of substandard medicines reduced from 8.6% to 6.9%).

In addition, the quality of drug manufacturers is generally inadequate. In 2020, only 33.3% of drug manufacturers were certified for current Good Manufacturing Practices. Reliance on local production was not properly demonstrated and there was no strong cross sector commitment in gaining successful results.

To cope with the current substandard and falsified medicines circulating in the region and Ethiopia, and the infiltration of illegal medicines through porous borders the medicine inspection system needs to be strengthened in terms of automatic identification systems, human capital and quality management systems. Moreover, intelligence led operation has to be strengthened.

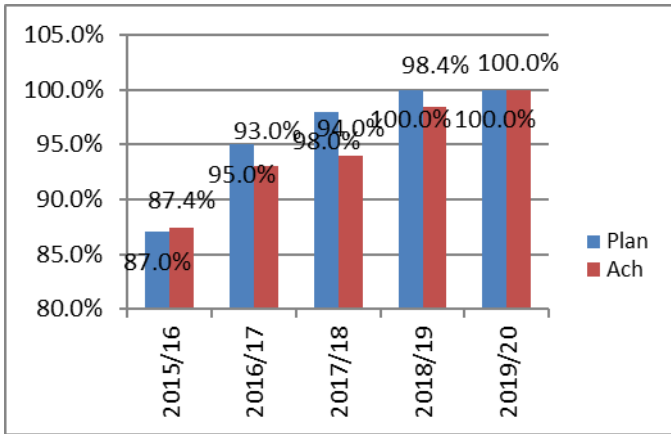


Figure 11: Inspection coverage of medical products manufacturers, importers and wholesaler, 2015/16-2019/20

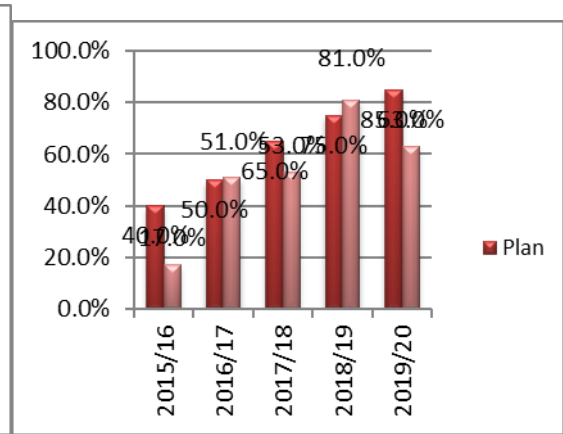


Figure 12: Number of medical products manufacturers, Importers and suppliers that implement quality assurance, 2015/16-2019/20

We have changed strategy of market surveillance from retailers and then with the information of distribution the inspection is done on importers and wholesalers. The EFDA East and South Ethiopia have been implementing this strategy and have been a good source of enforcement on the wholesalers that are operating in Addis and are licensed by the inspection department at the main office.

The regulation was not based on risks classification associated to the products. Post marketing regulatory practices were not sufficient and were not supported by self-regulation. A drug recall, voluntary action taken by a company or mandatory decision made by the Authority, is the most effective way to protect the public from defective or potentially harmful products. There were inappropriate collaboration among regional regulators, poor information exchange, poor commitment of the responsible distributors and manufacturers to recall defective medical products identified through PMS testing and market surveillances. These products were partially collected from the market due to inefficiency of recall system. Hence, all stakeholders shall be engaged in modernizing and systematizing the recall process, accountability and transparency.

According to World Health Organization (WHO), anywhere between 20 and 30 percent of the medicines entering in developing countries is either counterfeit or illegally imported. The latter are unregistered medicines imported into the countries by unregistered firms and individuals such as briefcase traders. The reason for high prevalence of unregistered products in Ethiopia is

especially due to the imbalance between supply and demand and the lead time for registering products and the foreign currency shortage which also affects local production as well as importation.

Most of the time, the illegal trading was spotted at entry points such as Moyale, Addis Ababa International Airport and Togochole. Besides this; there were also illegal trade on the internet. Collaborative operations and surveillances conducted with regional regulatory bodies showed that illegal trading is still a problem and needs attention at all levels.

3.3.3. Medicine Quality Control Testing

To ensure quality of medicines and meet the acceptable standards of quality, the Authority has established one national and five branch quality control laboratories. The national laboratory is accredited by ISO 17025:2017 and is under the process of WHO pre-qualification. Currently physicochemical and microbiological quality control tests are conducted for medicines and sterility test for sterile medical devices and laboratory reagents. The quality control laboratory had been engaged in testing of selected medical products for premarket approval, samples from consignments during importation and post marketing surveillance (PMS), and any suspected products(**Figure 13**).

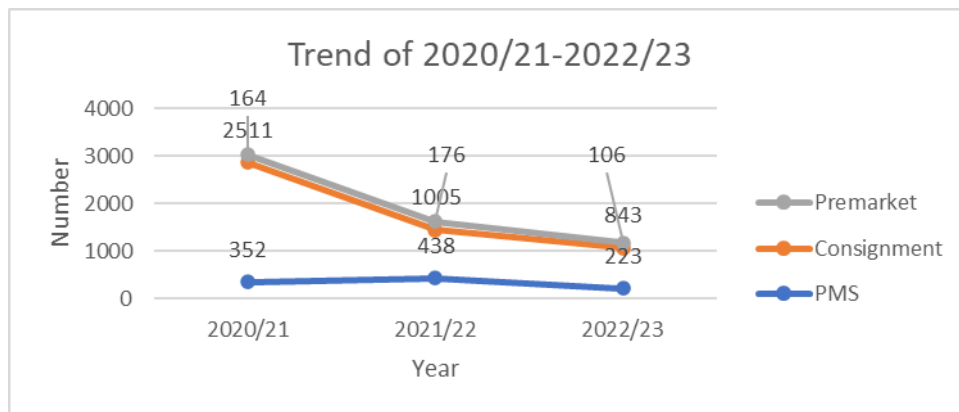


Figure 13: Number of samples tested (2020/21 - 2022/23) by physicochemical and microbiology units

At the beginning of the HRSTP-II (2020/21 - 2024/25 the consignment coverage was 19.3% and 48.6% for PMS of health products. (Figure 11). Even if it was challenging due to the absence of database the imported products by type and calculating the percentage, EFDA has increased the number of medicines types tested for consignment and PMS, which were 79 and 52, respectively.

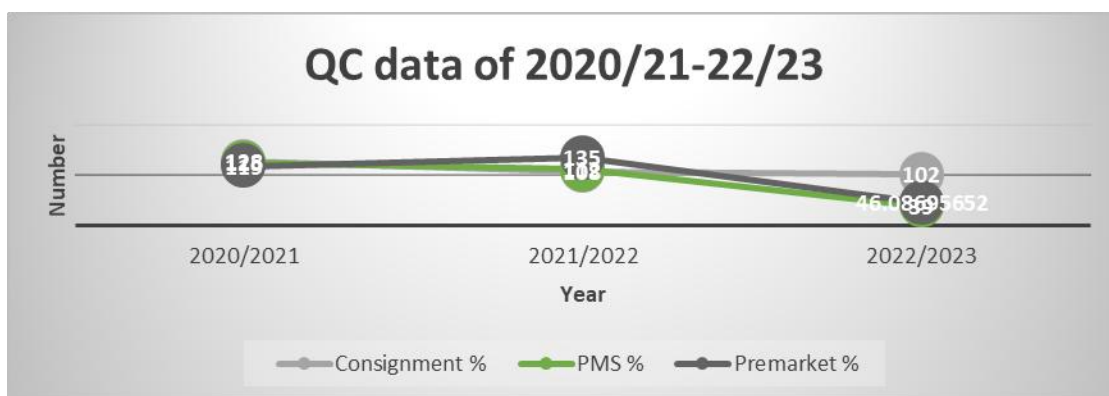


Figure 14: Comparison of the plan and achievement for Consignment and PMS sample testing (2020/21 - 2022/23).

In addition, about 0.3% of PMS samples, 0.6% of consignment samples, 0% of registration samples, and 17.8 % of suspected samples tested were failed to comply the regulatory standards during the period of 2020/21 -2022/23 which is much below when compared to the past five years.

The enabling factors for these achievements were availability of trained and qualified personnel; shifting from testing samples for registration to consignment and PMS samples testing, outsourcing of some testing activities, and testing in branch laboratories, maintaining and increasing the scope of ISO 17025:2017 accreditation; improved support and follow-up from management, and improved resource mobilizations. However, shortage of reagents, chemicals and reference standards due to challenges in procurement processes, the effect of COVID 19 in creating shortage of supplies, the lack of competency of procurement experts; on time and proper maintenance problems (especially HPLCs); shortage of purified/distilled water, power outage, shortage of trained personnel (for microbiology and branch laboratories); delay of test reports; shortage of personal protective equipment (PPEs) due to unavailability of standard PPEs in the local market, inconvenience of laboratory premises for testing and work load were some of the critical problems. Moreover not implemented three tier system for testing of products and also not utilizing cutting edge technologies that are already at hand by the medicine inspection, port inspectors and Medicine quality control laboratory has affected the coverage of samples tested, if these were solved, it would have covered more samples .

Hence, expanding scope (test parameters) of QC testing and starting new testing parameters including testing for impurities (related substances), API, Reagent PMS, Microbiology (endotoxin and MLT), biological products, traditional medicine and cosmetic products need improvements. The main reason is due to chemical and reference standard shortage.

3.3.4. Medicine Safety Monitoring/Pharmacovigilance

To strengthen monitoring of safety and quality of medicines after they are placed in the market awareness creation and training conducted for more than 6000 healthcare professionals, necessary tools such as ADE reporting forms, AEFI reporting forms, allergy card, IEC materials have been revisited and distributed, inclusion of pharmacovigilance (PV) in pre-service curriculum, establishment of six PV centers at selected university hospitals, development and implementation of

roadmap and SOPs, development of electronic reporting and mobile application, carry out investigations on serious adverse drug events, performing of causality assessment, active surveillance on Covid-19 vaccines and ART medicines, safety monitoring of MDR-TB medicines conducted report produced, Supportive supervision conducted in the TICs (Treatment Initiation Centers for MDR-TB) and action plan developed based on the recommendations from the supportive supervision report during this period. Besides this, training, assessment and supportive supervision to strengthen Adverse Event Following Immunization (AEFI) have been performed.

Despite the significant increase in the number of ADE reports received from 706 in 2017/18 to 8004 in 2022/23, it is still very low as compared to the planned target which is 11,000 reports per year (Figure 15). The Authority took regulatory measures on 34 of medicines of which recall on 33 medicines was conducted. Furthermore, withdrawal of market authorization and closure of the manufacturing facilities was done and the measures taken were communicated to stakeholders. The safety information received were also shared with WHO database vigi-flow.

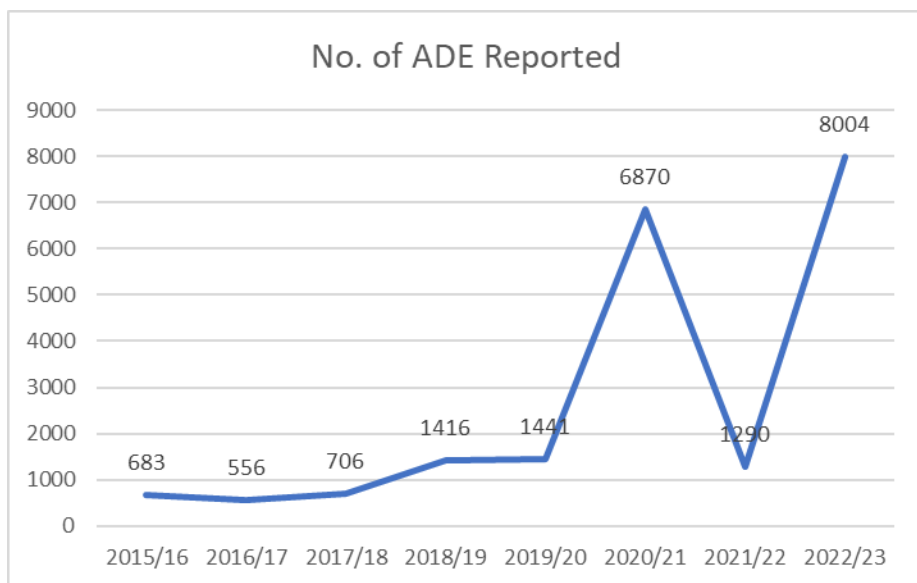


Figure 15: Number of adverse drug events (ADE) received, 2015/16 -2022/23.

The challenges could be categorized under: (1) Awareness and communication related– awareness and attitude gap by community in informing the ADE to health workers and lack of options for patient (self) reporting system, delay in detection, notification and reporting of adverse event, delay in investigation and Causality Assessment, and weak risk/feedback communication system (2) System and structure - Gap in structural arrangement for reporting route and communication, weak

functionality of regional task force, budget and M&E system, inadequate logistics/vehicle/ transportation and reporting tools/guides, inadequate collaboration at different levels (3) Technical issues like detection, quality/completeness of ADE reports, concern for accountability of the ADE by the professionals, inadequate knowledge/ training and supportive supervision.

3.3.5. Clinical trial authorization and monitoring

Authorization of clinical trials after a thorough review of clinical trial protocols and inspection of the clinical trial sites were performed. The number of clinical trials approved and Good Clinical Practice (GCP) inspection conducted are described in Figure 16. In addition, legal frameworks revision and guidelines and directive for authorization of clinical trials in the country and Good Clinical Practice (GCP) inspection were prepared and implemented.

Inadequate human resources (in terms of qualification mix up, experience and number), lack of national clinical trial advisory group, lack of appropriated structure, lack of **database** to register authorized clinical trials, and lack of appropriate collaboration and communication among the regulatory Authority, Research organizations and clinical trial sponsors were some of the main challenges.

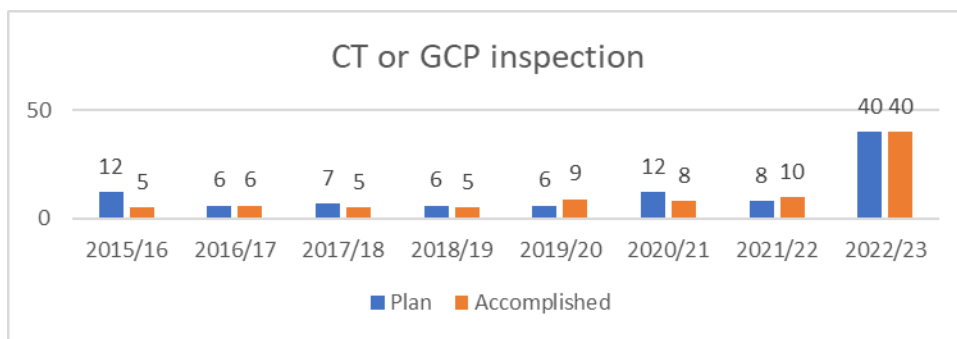
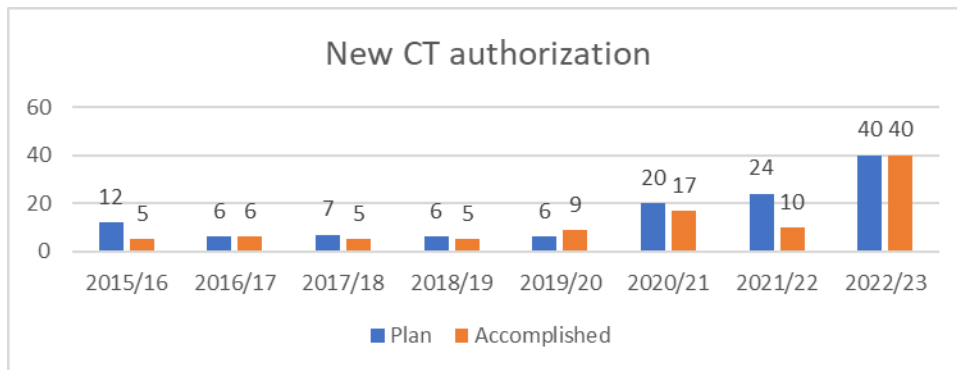


Figure 16: Performance of clinical trial authorization and GCP inspection

3.4. Strengthen regulation of safety, quality and performance of medical devices

3.4.1. Medical device registration and market authorization

To improve availability of safe, effective, and quality medical device in Ethiopia, the Authority has been working to strengthen the registration system. In its most recent efforts, the Authority developed the marketing authorization strategy that is mainly intended to increase the access to safe and effective medical devices. In addition, following the gap analysis report of the directorate in respect to the product’s registration system, the Authority developed and has been implementing different technical guidelines that detail the registration requirements of the two medical device types (In Vitro Diagnostic and Non- In Vitro Diagnostic Medical devices), devices grouping options and methods, devices risk classification systems and regulatory pathways for different types of devices or items related to medical devices (such as Software as Medical device, Spare parts and accessories, low risks medical devices). Therefore, it is fair to say that the Authority is striving to align its registration system with other Stringent and Competent National Regulatory Authorities. The Authority has also been using fast-track registration approach for medical devices used in critical public health concerns such as condoms, HIV RDT’s, malaria RDT’s, COVID-19 and etc. In order to increase access to safe and effective medical devices, the Authority also uses other approaches such as- reliance of the regulatory approval from Stringent Regulatory Authorities (prelisted by the Authority) and collaborative registration procedure with WHO for In Vitro Diagnostic Medical devices Prequalified the Organization. These different approaches of registration system are managed using electronic Registration Information System (e-RIS). These resulted in reducing lead-time for registration and reducing availability of poor quality and unsafe medical devices from the market. By implementing the aforementioned regulatory documents, strategies and approaches, the Authority registered a total of 5419 .

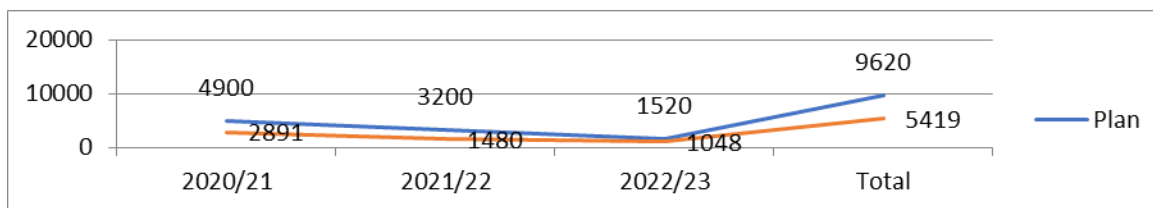


Figure 17: Number of registered medical devices in Ethiopia, 2020/21-2022/23

In Ethiopia, there are inadequate regulatory system and poor management of medical devices. There are huge complaints on availability of locally manufactured and imported defective medical devices including false positive and false negative results generated from Diagnostic Devices; this might cause wrong prescription, wrong treatment and might ends up with additional health crisis or mortality to the worst. There were personal protective devices that were easily breakable which might expose the health care professionals and patients to the risk of infection. In addition, there are also medical devices that got corroded and broken in a shorter period than recommended in the specification. In addition, not knowing exactly the manufacturer was among the challenges faced so far.

3.4.2. Medical device Import/Export control

Article 25 sub-article 2 of proclamation 1112/2019 restricts the importation of medical devices through a port of entry unless authorization is granted by the Authority while article 63 sub-article 4 gives power to the Authority to inspect the devices and their raw materials at port of entry, to ensure sameness of the imported product with the one registered or given permission by the Authority to be imported by reviewing the accompanying labeling and other relevant documents and inspecting the packaging, product and storage conditions. In addition, Article 19 sub-article 1 indicates that the rigor of regulatory assessment of medical device including the products' assessment at port of entry to be commensurate with the product's type, nature, and potential risk to human health.

To implement these legal requirements outlined in the proclamation, the Authority has developed and is using technical regulatory documents including- Risk-based management of incoming medical devices including risk-based planning for inspection, conducting of inspection, sampling, and issuance of port-clearance of imported medical devices.

For the last three years, medical devices estimated to worth 12.05 billion birr were inspected and cleared/approved to enter into the county's market. Though the plan of the conducted medical device inspection at port of entry was made based on the amount of money they are worth, the next remaining two years (i.e. 2023/2024 and 2024/2025) are re-planned as- the amount of medical device shipments cleared at the port of entry (with the number of generic types of medical devices in each shipment).

Despite the above achievements, lack of adequate competency in inspection of medical devices at port of entries and also inadequacy of tools has been identifying as the main challenges for regulation of medical devices at ports of entries.

3.4.3. Health Products Inspection and Enforcement

Comprehensive system of quality assurance must be founded on a reliable system of controlling the quality, safety and effectiveness of finished health products in the market. The level of quality of medicines should be maintained throughout the pharmaceutical supply system or distribution network. Due to inefficient supply chain management, there is still poor quality of drugs in the market. As of 2019/2020, the number of licensed manufacturers, importers, wholesales, pharmacies, drug shops and rural drug vendors are 11, 883, 691, 1078, 4056 and 618 respectively. In 2019/20, 100% of importers & wholesale and 75% of medicine retail outlets were inspected for the purpose of licensing and compliance check against the set requirements (**Figure 18**). In the last two years, risk-based inspection approaches, auditing inspection and internal quality management system have been implemented at all levels in the distribution channel. 85% of medicine facilities have taken the initiative voluntarily and started implementation of internal quality management system (**Figure19**). But there are gaps in understanding and implementing of the principle of internal quality management system at facility level. The achievements of product-based auditing inspection and internal quality assurance systems helped to reduce the circulation of substandard products in the market which in turn saved the life of the people.

In addition, the quality of drug manufacturers is generally inadequate. In 2020, only 33.3% of drug manufacturers were certified for current Good Manufacturing Practices. Reliance on local production was not properly demonstrated and there was no strong cross sector commitment in gaining successful results.

To cope with the current substandard and falsified medicines circulating in the region and Ethiopia, and the infiltration of illegal medicines through porous borders the medicine inspection system needs to be strengthened in terms of automatic identification systems, human capital and quality management systems. Moreover, intelligence led operation has to be strengthened.

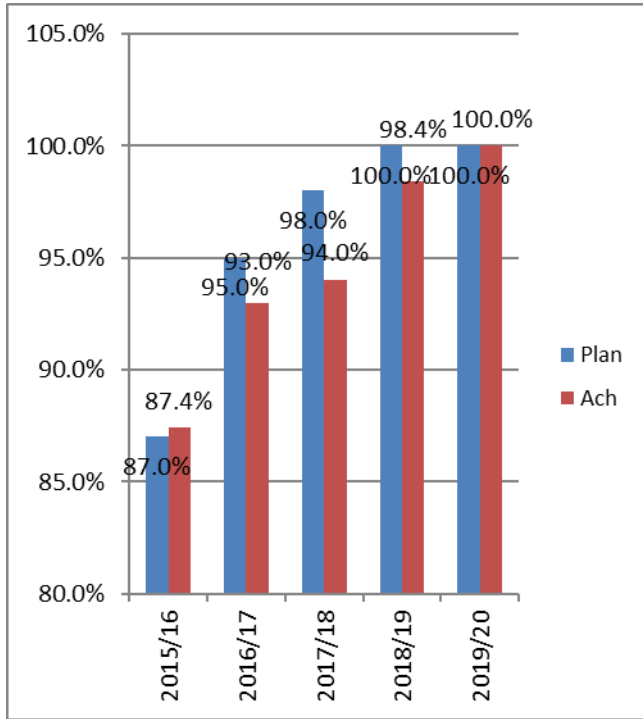


Figure 18: Inspection coverage of medical products manufacturers, importers and wholesaler, 2015/16-2019/20

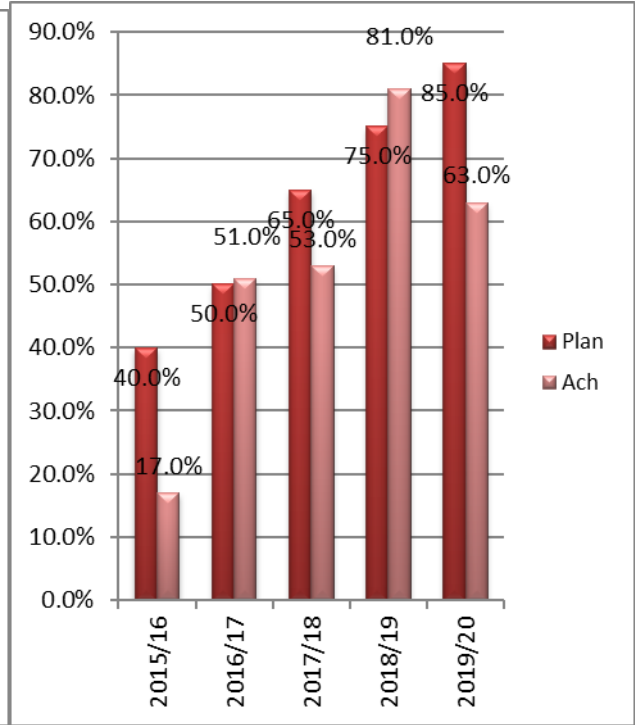


Figure 19: Number of medical products manufacturers, Importers and suppliers that implement quality assurance, 2015/16-2019/20

The regulation was not based on risks classification associated to the products. Post marketing regulatory practices were not sufficient and were not supported by self-regulation. A drug recall, voluntary action taken by a company or mandatory decision made by the Authority, is the most effective way to protect the public from defective or potentially harmful products. There were inappropriate collaboration among regional regulators, poor information exchange, poor commitment of the responsible distributors and manufacturers to recall defective medical products identified through PMS testing and market surveillances. These products were partially collected from the market due to inefficiency of recall system. Hence, all stakeholders shall be engaged in modernizing and systematizing the recall process, accountability and transparency.

According to World Health Organization (WHO), anywhere between 20 and 30 percent of the medicines entering in developing countries are either counterfeit or illegally imported. The latter are unregistered medicines imported into the countries by unregistered firms and individuals such as briefcase traders. Most of the time, the illegal trading was spotted at entry points such as Moyale, Addis Ababa International Airport and Togochale. Besides this, there were also illegal trades on the internet. Collaborative operations and surveillances conducted with regional regulatory bodies showed that illegal trading is still a problem and needs attention at all levels.

3.4.4. Medical device Inspection and Enforcement

The Regulatory Inspection is one of the functions that the Authority exercises to ensure the regulatory compliance of the medical devices and their associated facilities including the manufacturer, importer and distributor. The activities included in this regulatory function are- inspection and licensing of local establishments (such as manufacturers, importers and wholesalers), Auditing of licensed establishments, issuing corrective action reports and monitor actions taken, taking enforcement action and exact penalties (when required), investigating alleged counterfeit medical devices, conducting Good manufacturing practice inspection of local and foreign manufacturers, inspecting the appropriateness of disposal procedures for medical devices and other related activities.

The Authority has developed and is implementing relevant regulatory documents including technical guidelines for- Medical device Good Manufacturing Practice, guideline for Decommissioning and Disposal, Guideline for Importer, Exporter and Wholesaler establishment control and associated working Standard Operating Procedures. The Authority is also implementing separate approach for low risk medical device manufacturers control in its new

directive of “Low Risk Medical device Manufacturers Control” in which premises, professionals and other regulatory requirements are made easy when compared with other standard requirements to promote the local production of such devices. This increased the appetite of local manufacturers to develop and market the devices.

By implementing these regulatory documents and the mentioned approaches, the Authority is making efforts in increasing the number of licensed establishments, auditing of the establishments and GMP compliance inspection. Accordingly, in the past three years [2020/2021 (2013 E.F.Y) to 2022/2023 (2015 E.F.Y)], the Authority conducted the pre-licensing inspection of local manufacturers, pre-licensing inspection of importers and wholesalers, auditing of licensed importers and wholesalers. The details of the plan and performance is provided in the following table

Table 5: performance against planned inspections of medical device facilities

E.F.Y.	Local Man. Pre. Insp.		Importer, W/S Pre. Insp.		Importer, W/S Audit		GMP Inspection	
	Plan	Achiev.	Plan	Achiev.	Plan	Achiev.	Plan	Achiev.
2013	1	0	127	87	240	121	10	0
2014	2	1	109	159	205	408	10	0
2015	2	2	67	31	215	120	12	18

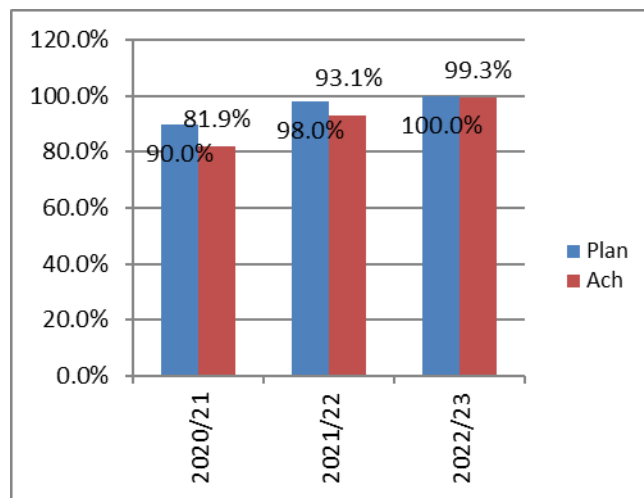


Figure 20: Inspection coverage of medical device manufacturers, importers and wholesaler, 2020/21-2022/23

There were some identified challenges during these three years performance. As the local establishments including manufacturers, importers and wholesalers inspection is conducted physically. In addition, the number of available inspectors were also not enough when compared with the high number of applications made for new importation and local distribution (wholesale) requests. The Authority has started virtual pre-inspection and reorganized the medical device sector separately to solve the existing challenges. To ensure the appropriateness of the information provided by the applicant, the Authority conducts post-licensing audits for all importers and wholesalers that have been licensed with virtual/online inspection.

3.4.5. Medical devices Quality Control Testing

To ensure quality of products and meet the acceptable standards of quality, the Authority has established one national and five branch quality control laboratories. The national laboratory is accredited by ISO 17025:2017. Currently physical and microbiological quality control tests are conducted for condoms, medical gloves and some Rapid test kits. The quality control laboratory had been engaged in testing of selected medical products for premarket approval, samples from consignments during importation and post marketing surveillance (PMS), and any suspected products(**Figure 21**).

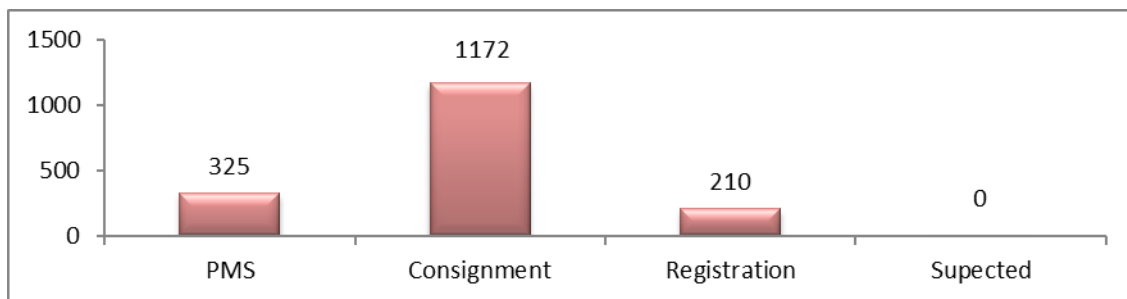


Figure 21: Number of samples tested (2020/21 - 2022/23) by medical device laboratory other than HIV RDTs.

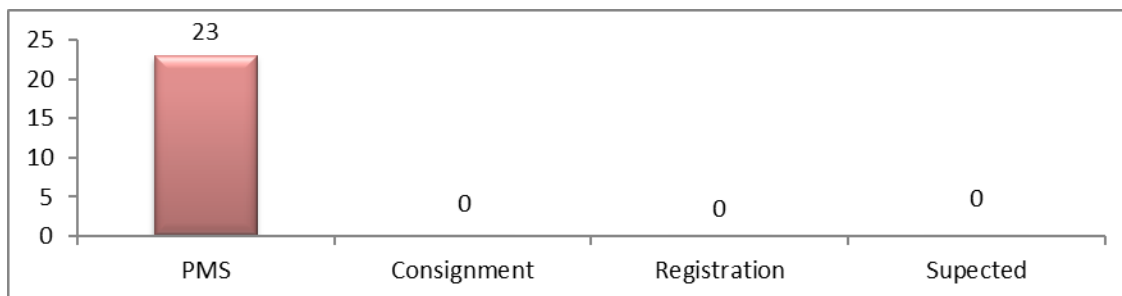


Figure 22: Number of HIV RDTs tested (2020/21 - 2022/23).

According to the HRSTP I (2020/21 - 2022/23), the Authority has planned to test 56.67% of medical devices arriving at the port of entry (consignment samples) and 26.23 % of medical devices (by type) from the market (PMS samples). At the end of the third year, 121% consignments samples were tested (more than 100% of the plan) and 18.95% of medical device samples of PMS were tested (72.54% of the plan). Consignment and PMS testing coverage at the beginning of the HRSTP-II were 131.57% and 67.38% respectively (Figure 23).

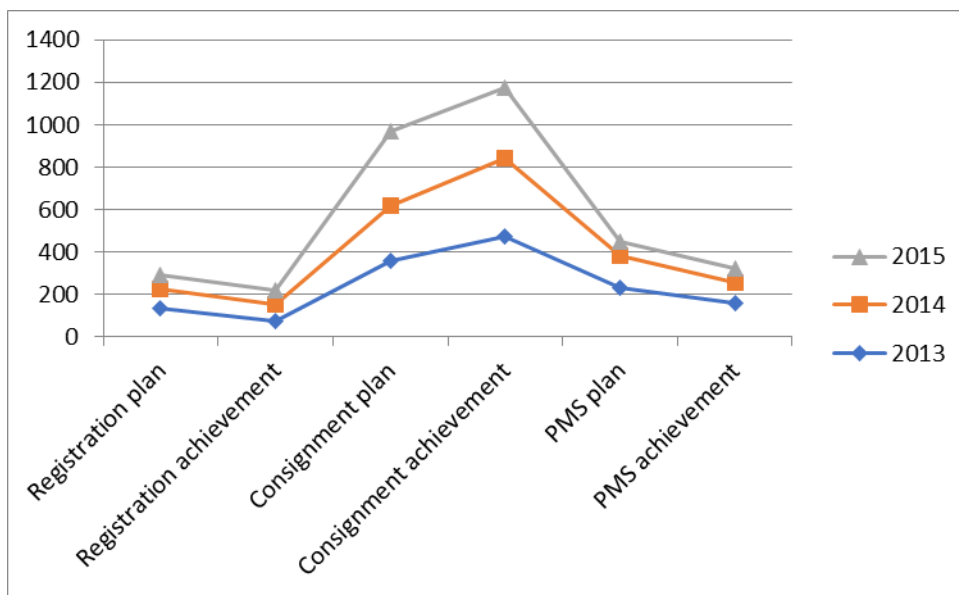


Figure 23: Comparison of the plan and achievement for Registration, Consignment and PMS sample testing (2020/21 - 2022/23).

In addition, about 27.45 % of PMS samples, 0 % of consignment samples, 25.34 % of registration samples, and 33.8 % of suspected samples tested were failed to comply the regulatory standards during the period of (2020/21 – 2023).

The enabling factors for these achievements were availability of trained and qualified personnel; shifting from testing samples for registration to consignment and PMS samples testing; increment of incoming samples (consignment glove) and increasing the scope of ISO 17025:2017 accreditation; improved support and follow-up from management, and support from partners.

However, shortage of purified/distilled water, power outage, shortage of trained personnel (for microbiology, and for medical device testing); delay of test reports; lack of trained personnel to do maintenance and verification for instruments for condom testing; test methods selection and method validation for medical devices testing; shortage of personal protective equipment (PPEs), lack of training on standards for the analysts (on syringe testing machine), insufficient incoming samples (new IVD kits), increment of incoming samples (for PMS glove samples), sample shortage (for registration of condom and glove samples), prevalence of COVID19 pandemic, rareness of laboratory reagents and supplies, insufficient number of personnel laboratory premises inconvenience for testing and work load were some of the critical problems.

In contrary, expanding scope (new test parameters) of glove testing and starting new testing parameters including testing for impurities (related substances), starting new RDT kit tests, conducting HIV RDT kit tests; expanding testing of medical device have shown considerable achievements.

In addition, about 5 % of PMS samples, 5.7% of consignment samples, 3.4% of registration samples, and 33.8 % of suspected samples tested were failed to comply the regulatory standards during the period of 2020/21 -2022/23.

The enabling factors for these achievements were availability of trained and qualified personnel; shifting from testing samples for registration to consignment and PMS samples testing; part-time testing on weekends and evenings at the national laboratory for PMS samples, outsourcing of some testing activities, and testing in branch laboratories, maintaining and increasing the scope of ISO 17025:2017 accreditation; improved support and follow-up from management, and support from partners. However, shortage of reagents, chemicals and reference standards; on time; shortage of purified/distilled water, power outage, shortage of trained personnel (for microbiology, branch laboratories and for medical device testing); delay of test reports; lack of trained personnel to do maintenance and verification for instruments for condom testing; test methods selection and method validation for medical devices testing; shortage of personal protective equipment (PPEs), laboratory premises inconvenience for testing and work load were some of the critical problems.

3.5. Improve regulation of safety of cosmetic products

The authority planned to assess safety and quality of 1500 cosmetic products and issue notification note in the year 2020/21-2022/23 and 316, 456 and 468 cosmetic products were evaluated and issued a notification notes to enter to the market in 2020/2021 - 2022/2023 respectively with total of 1240 (82.7%) cosmetic products notifies.

Cosmetic products are currently one of the most popular consumer products used by all people, of all ages. But there might be use of unsafe cosmetics that might cause adverse effects. In spite of the incidents available, cosmetic regulation in Ethiopia was not adequate and effective. It focused only on premarket control through licensing. The regulation was not based on risk classification associated with the products.

Furthermore, in the year 2020/21-2022/23 a total of xx manufacturers, xx importers, xx exporters and xx wholesalers were licensed to manufacture, import, export and wholesale cosmetic products in Ethiopia. Besides, routine inspections and intelligence led operations were conducted in the country.

3.6. Improve Tobacco Regulation

Tobacco regulation is a multi-sector issue, and EFDA has a role in coordination of different stakeholders through a National Tobacco Steering committee. The government of Ethiopia has been committed to protect public health by regulating tobacco products. Comprehensive system, and strong legal framework has been issued by the government. As part of the FHRSTP II, it was planned that tobacco smoke free public places would increase from 109,000 to 218,000 during the planning period. Despite encouraging performances have been made, the amount of tobacco smoke free public places in 2022/23 was 189,939 assuming that once a place is smoke free, it will continue as smoke free.

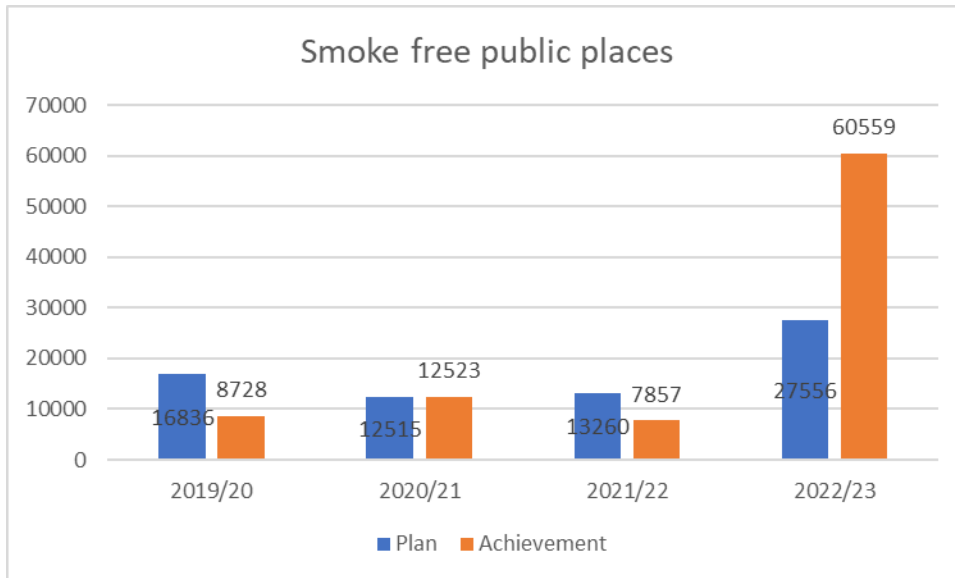


Figure 24: Tobacco smoke free public places in Ethiopia

The main challenges while enforcing the regulation include; poor inter-sector collaboration, public awareness regarding the dangers of tobacco smoke, inability to maintain the smoke free area, inadequate human resource and financial resources less priority in some regional states, and instability in some border areas hamper the control of illicit tobacco trade.

3.7. Improve Evidence Based Decision Making

Improving Evidence Based Decision Making was one of the strategic objectives it generates a quality evidence data and improves evidence-based decision making in the food and health product regulatory sector. It aims at improving evidence generation and use from electronic regulatory information systems, IFMIS, surveys, surveillance, researches, monitoring and evaluation systems and, census, etc.

Sound decisions and effective action rely on having the right knowledge in the right place at the right time. Therefore, the other component of this strategic direction is knowledge management, which is an integrated approach of creating, storing, sharing, and applying knowledge to improve evidence-based decision making and enhance the regulatory sector performance.

Available information needs to be disseminated in a timely manner and used for strategic decision making at all levels of the regulatory sector. The main focus was given on the

improvement of the quality and availability of data, knowledge management and capacity to use information for action at all levels.

One of the performance measures for this strategic objective was Increase the percentage of expected reports received from reporting units on time to 82% and the performance was found to be 79.6%.

The other performance measure for this strategic objective was to Increase percentage of expected complete reports received from reporting units to 68%, and the performance showed that 79.4 % reports received from reporting units are complete. Some of the achievements were implementation of one plan and one report approach at all levels of the regulatory system. Authority plan was prepared and sent to the concerned body on time. The health regulatory sector plan prepared together with regional health regulatory bodies and also evaluation of performance report done by joint stream committee and executive committee. Capital projects performance reports are sent to development partners in a timely manner. The authority's plan implementation report was prepared and sent to the concerned body at the time, and also program budget report was prepared and sent to the concerned body at the time.

The other performance measure for this strategic objective was conduct surveys to Measure the achievements of our objectives from this 29 survey was planned and 5 Survey (customer satisfactions, SF Medicine, NPS, illicit tobacco, the change in tobacco consumption caused by the increase in tobacco tax) was implemented and their performance is 17.2%

Challenges; a problem of cascading according to FHRSTP (Indicator, target, activity, time schedule), weather the performance reports are sent on time they have a problem of quality (Indicator, format, activity, target), the monitoring system is not automated, the attitude towards reporting is not weak, weak monitoring and evaluation framework.

3.8. Improving human resource development and management

In terms of human resource development and improving management, one of the key tasks that will be given special attention is the strategic plan. From this point of view, when we seem at the work done in the three years, a new structure was formed based on the authority's proclamation 1112/2011 and is approved by the civil service mission and the employee's deployment is finalized. In this way, the authority is organized into three sectors at the main office, namely, the food sector, medicine sector, medical equipment sector, quality management and surveillance,

and illegal trade prevention; it is also organized to have administrative departments. Moreover, it has 11 branch offices and 15 entrances and exits port. For this, necessary positions have been approved and put into practice.

In terms of capacitating the employee skill, knowledge, and altitude, the Authority has been provided with local and abroad training to build the capabilities of leaders and employees. Human forecasting, recruitment, selection, transfer, and performance carry out as per the proclamation and guidelines of the civil service commission. As an organization, the employee turnover rate is low and encouraging. Efforts are made to make work environments comfortable for employees and resources needed for work. The establishment of an integrated human resource management information system (IHRMIS) to update the human resources information system, and the implementation of several activities to perform gender-oriented activities, is the work of bringing women into leadership, and in this regard, only the leadership positions we currently have only occupied by women 33 % and 67% occupied by men. And also the gender audit of the organization's system to be studied by external bodies. Various initiatives have been designed and implemented to improve the organizational culture of the Authority, such as motivation, skill development, role clarity, and employee ownership.

They were expected on human resource development and management strategy direction in three years but some major activities weren't performed as:-

Regard to training: - there were gaps in identifying the need for training from employees' job description and performance, focusing on the authority's strategy plan, and department plan achievement. Limitations in building leadership capacity in a different way. The effectiveness of given training is not being measured, and there are limitations in terms of archiving the given training data. From the point of view of developing the culture of the organization, it did not implement as initiatives that were designed.

The performance appraisal evaluation system helped to identify those who work and those who don't, encourages hard workers, asks those who have problems, and identifies their gaps and fills our gaps. When we see the challenges in terms of fully implementing the strategic direction, the new structure of the organization took a long time to be approved and implemented, the inability to hire and transfer staff, and the non-implementation of the road map of the public service sector prepared as a country could be mentioned as an example.

In general, although they have gone a long way in terms of implementing the above plans to improve human resource development and management, they still need to improve leadership capacity and prepare a succession strategy, encourage and facilitate a learning culture, knowledge management, and organizational culture.

3.9. Enhance good governance

One of the strategic measures taken by the authority in the 5-year strategic plan is to enhance good governance. From this point of view, it was planned to enhance good governance in our regulatory work by focusing on transparency and accountability based decision-making system, fairness, free service delivery from discrimination, corruption and theft, rule of law, and participation, which were held as key the strategic period. In order to achieve this, when we overview at the key tasks identified in the strategy period, to ensure the implementation of good governance principles and tasks, to conduct evaluations using World Health Organization criteria on the vulnerability of corruption in key regulatory activities. Developing a code of conduct based on regulatory conditions, designing and implementing an anti-corruption strategy, strictly controlling corruption in the sector using various strategies, identifying and managing basic risks in the regulatory sector (risk management), improving the complaint handling system, to meet the needs of citizens and their expectations from the sector. In terms of ensuring the implementation of good governance principles and activities, the organization has been implementing an independent good governance plan every year by identifying problems arising from the society, customers and internal employees. Another key regulatory task is to conduct evaluations using World Health Organization criteria to identify activities that are vulnerable to corruption and to complete the preparation of documents to design an anti-corruption strategy. The draft document has been sent to Ethics and anticorruption commission for their comments and inputs. Also, it was possible to prepare a code of conduct and conflict of interest resolution guidelines as an institution in terms of developing a code of conduct based on regulatory conditions, and it is being implemented. Another and the main thing that is important for the development and confirmation of the principle of good governance is that our service provision is based on the citizens charter. In addition to this, we have automated our service that is e-RIS and also it is integrated to electronic single window system.

Moreover to create transparency we have very informative website and other communication platforms. In this regard, the work of preparing service delivery standards is being done and will be completed soon.

The activities we have done above and the ones we have tried to a certain extent have brought results in terms of the enhancement of good governance. 70% increase in customer satisfaction level in food and health product control, 95% increase in quality control services provided, 93% reduction in service delivery complaints, a prepared anti-corruption strategy was presented as a complement and their performance, t level of customer satisfaction has been 89% in 2023. It shows 100% performance in terms of reducing service delivery complaints. The anti-corruption strategy committee formation document has been prepared and the works have been completed to be reviewed and sent to the management.

In general, the assessment shows that we should prepare for better results by combining the principles we identified above and those set as benchmarks in order to enhance good governance by the authority.

3.10. Improve community ownership

In this strategic direction, the main focus is to increase the public's awareness for food and health product regulations. The main works done in the last 3 years are presented in detail as follows:- 291 radio and television live discussions on regulated products were planned and 319(>100%) were conducted. Live broadcasting on various topics on radio and television around food safety, medical devices, in relation to imported corona virus prevention products, in relation to proper use of medicine, in relation to illegal food trade, in relation to tobacco control, in relation to traditional medicine, in relation to drug trade and transfer, regarding the prohibition of smoking tobacco in public gatherings, They were broadcasted live on the control of importers and distributors of food manufacturers, measures to be taken around bottled water, mixing food with foreign matter, drug registration and licensing through the i-verifay application. In the same way, it has been possible to disseminate information using print media to make the above-mentioned topics accessible to different sections of the society.

305 television and 410 radio news coverage to make timely and quality information about food, medicine and other issues accessible to the public; 499(>100%) and 496(>100%) were planned

to prepare short messages and programs respectively. As the community is the owner of the regulation, we are doing a lot of work by giving tipoff and comments on the issues that need to be addressed. Therefore, in these 3 years, 68072 tipoff and comments were planned to be received and 50734(74.53%) were received. Among the suggestions and comments that came, by giving appropriate feedback at the time, the percentage of those who gave suggestions and comments increased to 70% because they needed to be responded to.

Table 6: Performance against media usage to ensure public ownership

Public Ownership	2013		2014		2015		Total		% total
	Plan	Report	Plan	Report	Plan	Report	Plan	Report	
radio and television live discussions	108	148	103	96	80	75	291	319	109.6220
radio news coverage	189	237	131	141	90	118	410	496	120.9756
television news coverage	109	166	114	254	82	79	305	499	163.6066
tipoff and comments	19308	14961	20456	16681	28308	19092	68072	50734	74.5299

Among the challenges in reaching the public is lack of innovative ways of creating community ownership.

3.11. Enhance partnership and collaboration

Food and medical products regulation without partnership and collaboration with private sector; international, local organizations, community and other key stakeholders could not be effective and sustainable. This strategic direction was formulated to enhance partnership and collaboration with key stakeholders to achieve the overall objective and improve the engagement of these stakeholders in planning, implementation, monitoring and evaluation of the regulatory activities. This creates awareness and ownership to advance the mission of the authority through building synergy.

In the year 2021/22 to 2023/24, it was planned to increase the percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities from 68 to 95. Most of the key stakeholders were participating in planning, implementation, monitoring and evaluation of the regulatory activities with 91% achievement.

In addition, it was planned to increase the number of joint activities conducted with different stakeholders to 27, and the performance was found to be 22 (81.5%). Furthermore, it was also planned to establish 5 strategic partnerships and collaborations with international, regional and national organizations, and the result was satisfactory. Strategic partnership and collaboration was created with INTERPOL, Customs, Federal Police, and regional regulatory bodies on conducting inspection, surveillance and operation. We are also working in collaboration with WHO and IGAD on pharmacovigilance and medical product registration, and with AVAREF on good clinical trial practice to create strategic partnership.

3.12. Strengthen regulatory infrastructures

As per the FHRSTP_II strategic plan, the authority planned to strengthen and capacitate its operations and regional regulatory bodies by digitizing its process and deploying and other infrastructures.

As part of and the key component of the FHRSTP-II plan, the health regulatory sector center of excellence was started to be built in collaboration with FMOH and World Bank. As of June 2023, the design works and some ground works were completed. The expansion of medical device laboratory (IVD lab) by doing renovation work on the basement of the main building, renovation of Hawassa branch, Bahirdar branch, renovation of medicine registration, renovation of food laboratory were done in the last 3 years.

On the other hand, about 61 vehicles were procured and one vehicle each was distributed to regions. The others are deployed to work at the main and branch offices.

The electronic Regulatory Information System (e-RIS)

Regarding the electronic Regulatory Information System (e-RIS), it has been in operation for the past three years and has had many expansions and additional modules added.

The complexity of EFDA's organization and its work, its size, the numbers and quantities of products, and the variety of tasks it is charged with (registration, quality testing, inspection, importation, post market surveillance, pharmacovigilance, etc.) require rigorous implementation of and adherence to laws, policies, and processes to ensure success in achieving its mission.

EFDA is building a technology infrastructure that links the various tasks it undertakes under one unbroken chain of information systems, from licensing and registration to import and quality assurance.

The Electronic Regulatory Information System (e-RIS) was designed and implemented to facilitate regulatory functions and processes. e-RIS is the umbrella system at EFDA and is comprised of sub-systems that work together:

e-RIS dramatically increases processing efficiency and transparency by enabling both EFDA and importers to manage the licensing, inspection, registration, and importation requests and approval processes fully online. With e-RIS, each step in the licensing, inspection, registration, and import application processes is now managed through a shared portal.

Adverse Events Following Immunization (AEFI)

As part of the COVID-19 vaccination campaign, an Android application was developed to be used by the public to capture adverse events following vaccination (AEFI). EFDA-AEFI is a reporting mobile app that will give the Ethiopian Food and Drug Authority (EFDA) real-time visibility to monitor the AEFI. This application is designed to be used at any point in the supply chain by health workers and other vaccinated clients to report adverse events following immunization.

Rapid alerting system

Based on the targets set by the authority in the past three years, the EFDA has developed the Ethiopian Food Safety Alert and Notification System (EFSANS), a web-based application that enables the public and organizations to report food safety incidents to ensure timely detection and response to incidents that result from contamination of food by food-borne hazards. This application has been launched to the public as a rapid alerting mechanism for food products. Following this, the EFDA has also been developing the rapid alerting system for the medical product, which will be available to the public.

Laboratory Information System (LMIS)

Although not according to the schedule and plan, developing systems for Laboratory Information System (LMIS) is started by breaking down the system development process into two phases. The first step will only focus on sample tracing and management and the second step will include the establishment and configuration of laboratory equipment automation and Quality Control

Electronic Records with the LIMS. Currently the requirement collection is started for the first phase of the LIMS development.

Establish traceability system in the pharmaceutical supply chain system, Performance Management System (PMS).

But Because of Budget unavailability, Lack of Skilled IT professionals, Government procurement bureaucracy and due to additional urgent tasks, the planned Software developments for planning and reporting automation (BSC), i-License for regional regulatory bodies, deploy traceability Implementation Systems, Software development for plan (BSC), Renovation of EFDA Data Centre, Establishing Excellency center Data center, Mobile application development for registered products, licensed facility, CCTV Camera at 20 points with complete system, Fleet management software procurement, Cascading the regulatory information system to region and woreda level, Hardware and software maintenance (license, server, network installation, networking equipment) For Head office, Excellency center, Branch office and Regional Regulatory Bureaus, Establish GPS system for vehicles and Establish risk analysis technology were not implemented as per the plan.

3.13. Legal framework development and implementation strategic plan

Following the adoption of the Food and Medicine Administration Proclamation No. 1112/2019, the mandate of the Authority limited to product regulation. As a federal agency, the Authority mandated with regulation of food, medicine, medical device, cosmetics, tobacco and other regulated products. It has developed the implementation regulation of the proclamation 1112/2019. Accordingly, it issues certificate of competency (COC), import permit, special regulatory license as appropriate for importer, exporter and manufacturer and wholesalers who distribute their products in more than one region. In addition to these products, the Authority regulate Bioequivalence Center and Quality control service provider. Contrary to the mandate of the Authority, regional regulators they regulate health facilities, health professionals, retail outlets and those which manufacture and distribute in one region only. However, the plan prepared taking into account product regulation at federal and regional level. Accordingly, in the HRSTP II, which lasts from 2020/21-2024/25, it is planned to adopt 95 legal instruments in addition to 106 already in effect. This includes preparation and adoption of proclamation, regulations, directives, guidelines, formulary, SOP, list, etc.

In addition to developing legal instruments, it was planned to increase follow-up and provide support to law enforcers; increase compliance through enforcements and voluntary compliance strategy; and increase the ability to win civil cases in court of law. The plan has been implemented for the last three years and the report prepared based on performance of three years and the remaining two years from the total HSTP II excluded from consideration.

Table 7: Plan to Improve Formulation and Implementation of Legal Framework Strategic Direction

Target area	Base line	Plan for 2020/21-2025	Plan for 2021	Plan for 2022	Plan for 2023	Plan for 2024	Plan for 2025	Remark
Develop legal instruments	106	95	20	20	40	10	5	overall 106+95=201
Increase follow-up, timely response and providing evidence to police and court for crime	NA* ¹	91.6%	90	90	92	92	94	To be evaluated through performance report
Increase regulatory legal framework compliance and enforcement	NA	100%			100		100	To be evaluated through survey
Increase percentage of voluntary compliance NI* ²	NA	92%	80	95	95	95	95	To be evaluated through survey
Increase rate of winning civil cases	NA	84%	75	80	85	90	90	To be evaluated through survey

Performance

The Authority and regional regulators have been implementing the strategic direction of improving the formulation and implementation of legal framework included under the HSTP II. Within the last three years of the implementation period for the HSTP II, the Authority has developed 49 legal instruments while regions developed 8. Among these, one regulation at federal (Ethiopian Food and Drug Authority Structure, Powers and Functions Regulation No. 531/2023) and two regulations at regional (Dire Dawa and Afar) were adopted. The Authority

¹*NA= Not available

²*NI= Not Included in the annual plan

adopted... directives while Oromia has adopted one directive. Guidelines and ...SOP. The Federal Food and Medicine Administration Regulation to implement proclamation No. 1112/2019 was drafted and reached at final stage while the first draft for Sidama, Harari, Amhara and SNNP regions were prepared. The only proclamation drafted in the last three years is a proclamation to regulate unhealthy diet. Directives such as tobacco control directive No. 771 and 334, Medicine Registration Directive No., Baby food directive, Alcohol advertisement control directive No. etc are directives adopted by the Authority while directives on blood and blood products, narcotic and psychotropic medicine, food, house hold water treatments etc. are on progress.

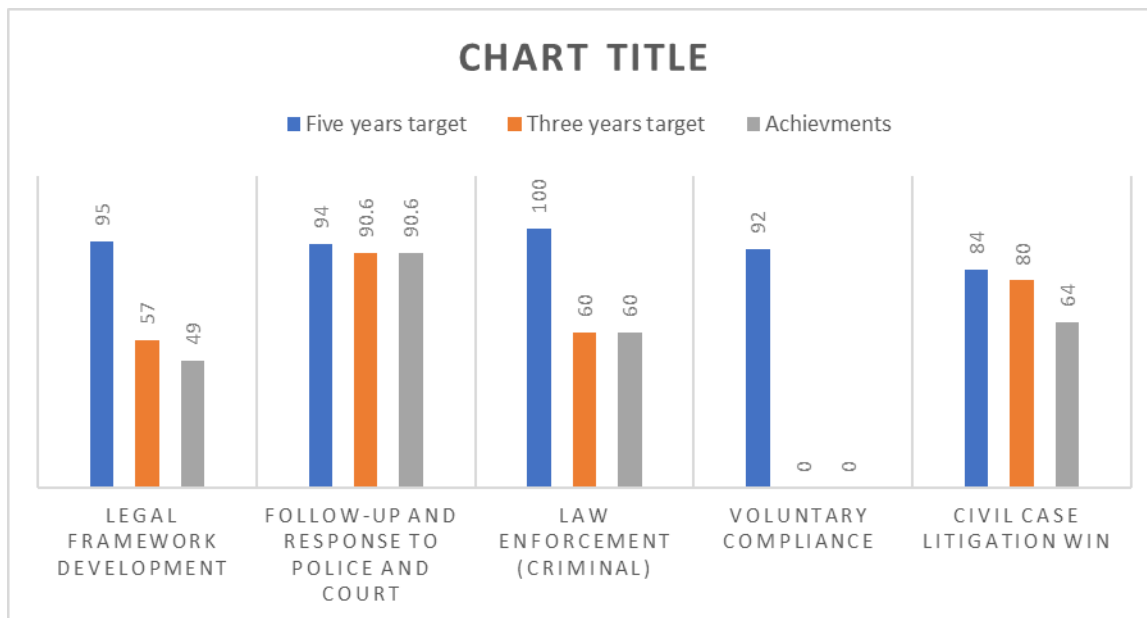
Concerning litigation, the Authority has conducted litigation of ...civil cases at federal courts. Among these cases, the Authority has won... cases while it lost 1. It has instituted...administrative cases at federal civil servant cases and sued by –employees. Final decision was given on these cases and the Authority has won ---while one case decided against it. Further, it has made adequate follow-up and provided relevant evidence to police to conduct criminal investigation and prosecute. Accordingly, criminal investigation opened on 37 cases while prosecution has been made against 4 cases.

The Authority has gone through different challenges in implementing the plan. Among others, limited human resource and budget, and delayed response from stakeholders affected speedy development and adoption of regulations and directives. Busy schedule of police officers hindered timely evidence collection and case load in courts affected rendering decision in short period. Lack of awareness and knowledge gap caused difficulties in evidence gathering and information leakage from team tasked with operation affected success of the case. Weak data handling/documentation also challenges to produce effective analysis on the implementation. The Authority has made efforts to mitigate these challenges through discussion with higher officials of relevant agencies, training and awareness creation activities, prioritizing and making extra efforts.

Table 8: Legal framework developed and implementation strategic direction progress

Target		2021/22	2022/23	2023/24	Remark
Developed legal framework	Proclamation			1	Unhealthy dietprocl , it is at draft stage
	Regulation	1	2	2	Two at draft stage and three adopted regulations

	Directive	7 (4/3)	19 (10/9)	23 (13/10)	Revised/new
	Guideline				
	SOP				
Increase follow-up,,responseand providing evidence to police and court		100%	100%	100%	
Increase regulatory legal framework compliance and enforcement		1			Investigation has begun on all identified cases and administrative measures excluded from here and treated under each strategic direction
Increase percentage of voluntary compliance		NA	NA	NA	This is not included in any of the annual plan
Increase rate of winning civil cases					



**The measurement for legal framework development was number (95, 57 &49) while the rest is provided in percentage.

Figure 25: Plan and progress for legal framework development and implementation

3.14. Improve efficiency & effectiveness

EFDA has been working to improve budget utilization, improve an efficient resource monitoring and control system, and allocate resources properly to streamline operations. Hence, IT-

supported effective procurement and financial management systems have been implemented to facilitate operations. The main works done in the last 3 years are presented in detail as follows: -

Medicine registration leads time (in days) has been 100 percent accomplished. The budget utilization for EFDA plan, the federal health regulatory body, increased from 276 million in 2020/21 to 316.25million birr in 2021/22 and 329 million birr in 2022/23. The total amount of budget utilization in the last 3 years 921 million birr.

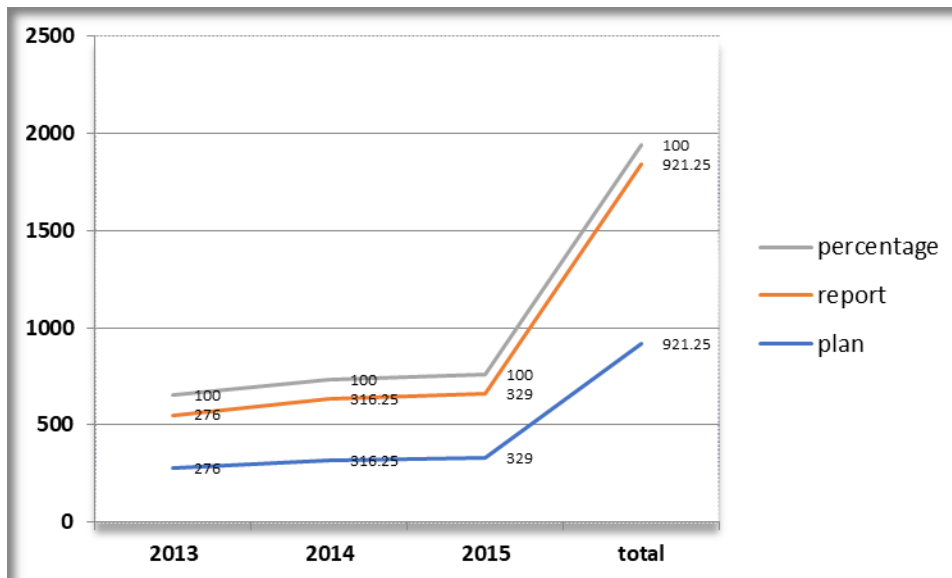


Figure 26: Resource planned vs. utilization report (from gov`t, revenue and donor)

Budget mobilize sufficient resources both from development partners and from the revenue in addition to the allocated budget from treasury. As depicted below in the figure..., the resource mobilization to implement the health regulatory sector plan was 832 million birr for three years. The allocated budget for EFDA, the federal health regulatory body, increased from 120 million in 2020/21 to 419million birr in 2021/22 and 939 million birr in 2022/23.

It was difficult to analyze the total budget mobilization by the sector due to the budget allocation to the regions is so heterogeneous and were not independently reported, as most of them are in the department levels within the regional health bureaus. As a result, the evaluation of the resource mobilization lied only at the federal level.

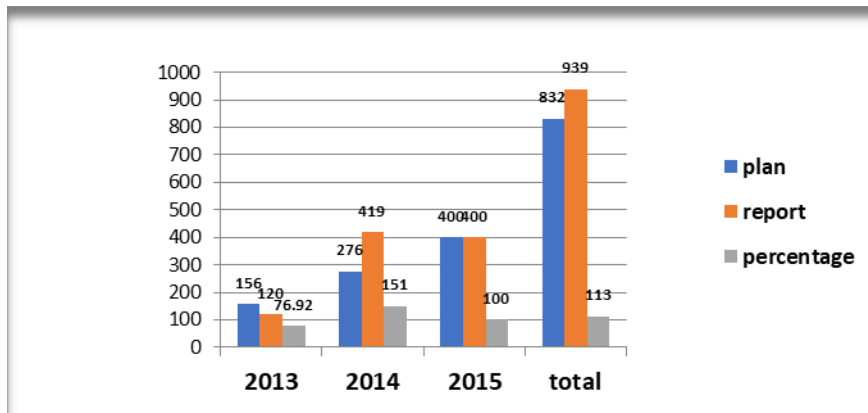


Figure 27: Resource planned vs. government allocation (revenue and donor)

The achievement trends by the last three years conveyed that the capacity of mobilizing resources has been improved as the high-level communications held between the Authority and partners has shown improvements. In addition, the revision of service fee regulation led a significant increment in the amount of revenue collected so far. Since the sector is very sensitive to the health of the community, the numbers of developmental partners and stakeholders who showed interest to invest their technical and financial efforts to work together has also increased. Even if the improvements in the amounts of resources mobilized were seen, the federal and Regional governments were not allocating sufficient budget to the regulatory bodies. The budget From developmental partners were also not flexible and were ear marked and limited to specific Areas. The health regulatory sector should have developed resource mobilization strategy to Systematically strengthen the capacity of the sector.

IFMIS has been improved by monitoring, monitoring and interim evaluation of the financial management systems and the development of new financial management systems. Support management system EFDA has been implemented, especially in cooperation with the branch offices, the monitoring of the budget paid to the regions has been verified by the budget and it has been possible to achieve the desired results. The resources allocated to the programs are rationalized and shared between departments. It is focused on the main activities that have a direct impact on public health. Improvements in resource absorptive capacity have significantly reduced resource wastage.

3.15. Improve Quality Management System

Ensuring quality management system of the regulatory system helps to the services and products to meet the statutory and international standards as well as customers expectations. Bearing in

consideration of its significant role, it has been designed as a key strategic direction in the second food and health products regulatory sector transformation plan (FHRSTP-II).

According to the FHRSTP-II plan, it was planned to get ISO 17020 accreditation for 2 inspection directorates. Hence, the medicine facilities inspection has been accredited ISO 17020 for 4 scopes, which is 50% of the plan. In addition, the food inspection is preparing itself for this accreditation by doing self-assessment by using the standard tools.

On the other hand, EFDA has been doing a great effort to achieve **maturity level 3 for the last two years**. It has achieved almost all requirements based on the auditing tools (indicators and sub-indicators). It has passed the first WHO official bench marking and has got important comments for areas of improvements. In addition, medicine and condom lab have sustained accreditation, and new accreditation for medicine and food lab was achieved.

As part of its quality management initiative, EFDA has participated in Ethiopian quality award competition, which is prepared by the Ethiopian quality award institute, and has achieved an encouraging result, 81%.

Despite the above achievements, there were some challenges that affected the implementation of quality management system. For instance, the limited budget resource, absence of well-trained human resource in the area, and lack of awareness in RRBs were the main challenges identified that hindered the implementation of QMS.

SWOT Analysis

The SWOT analysis is carried out to identify the enabling factors and pains. This helps the health regulatory sector to evaluate its environment and to make arrangements for the implementation of HRSTP-II. These are broadly divided into internal factors (Strengths & Weaknesses) and external factors (Opportunities & Threats). Based on the assessment of the existing HRSTP I performance, the following Table shows the result of the SWOT analysis.

Table 9: Strength, Weakness, Opportunities and Threats of the Regulatory Sector

	ENABLERS STRENGTHS	PAINS WEAKNESSES
INTERNAL	<ul style="list-style-type: none"> ● Development and facilitating the adoption of the Food and Medicine Proclamation No. 1112/2011, which contains strong tobacco and alcohol control articles. ● Sustaining accreditation and efforts to get WHO Maturity Level 3 ● Accreditation of medicine inspection with ISO 17020, accreditation of food laboratory with ISO 17025 ● Equipped QA laboratories with high tech laboratory instruments. ● Deployment of e-RIS (e-registration, e-licensing, e-ADE reporting, electronic service in port of entry) ● Availability of regulatory legal framework. ● Start-up audit and Risk based inspection. ● Conducting food product market survey ● Starting of enforcement of IQMS (Internal Quality Management System) implementation at food and medicines facilities. ● Increasing & sustaining foods and medicines lab tests for both consignments and post marketing. ● Achievements of most of the HRSTP- I targets. ● Steady increase in key intervention coverage such as registration of medicines. ● Deployment of new structure of EFDA. ● Working with regional and international regulatory bodies. ● Development of communication strategy and IT Policy. ● Strong collaboration with stakeholders such as Police & customs. ● Increasing & sustaining foods and medicines lab tests for both consignments (external labs) and post marketing. ● Adoption of the EFDA structure, powers and functions regulation No. 531/2023 ● Progressed integration and collaboration with key stakeholders ● New Market authorization strategy. ● Initiatives in the Organizational Style and culture. ● Infrastructure Renovation:- Hawassa branch Bahirdar branch, food lab, medicine registration office, meeting halls renovation at main office ● Contract agreement signed and construction of Center of Excellence started ● IVD laboratory establishment ● Strengthening of pharmacovigilance system which has also enabled to reach to Maturity Level 3. ● Increase in resource mobilization capacity ● Establishing food safety alert system at national level. 	<ul style="list-style-type: none"> ● Fragmented national regulatory structure ● Integration, coordination and execution of the regulatory laws. ● Insufficient support from regional governments to strengthen the regulatory system especially at zonal and woreda level. ● Shortage / absence of budget allocation, vehicles to the sector and inadequate capacity to mobilize resources for RRBs. ● Limited/ Inadequate engagement of stakeholders and communities at large in health regulation activities. ● Inadequate/absence of skilled personnel both in quantity and composition especially down to regional, zonal and woreda level. ● Lack of accessibility and affordability and also proper usage of the existing technologies to identify adulterated food, substandard and falsified health products. ● Weak boarder control of illegal food and medicines products. ● Weakness in Gathering of proper evidence to take the right enforcement measure Weak communication and international relations. ● presence of high employees attrition rate at regional & woreda level. ● Inadequate food quality and safety laboratory and capable of performing all requirements listed on the mandatory food standards. ● Weak and manual based Planning, monitoring & evaluation system in the regulatory sector ● Absence of research and development in the regulatory system. ● Lack of organized documentation system ● Lack of tracking and tracing capacity in the regulatory system. ● Absence of rapid test kits at port of entry, exit and inspection. ● Absence of testing of health products like cosmetics, and traditional medicines. ● Fragmented food safety regulation. ● Lack of standards for regulated products and problem enforcement of the existing standards ● Inadequate cosmetics, traditional medicines and medical device regulation. ● Inadequate implementation of preventive, risk and trust based regulation ● Inadequate control of intentional food adulteration.
	OPPORTUNITIES	THREATS

	ENABLERS	PAINS
EXTERNAL	<ul style="list-style-type: none"> ● Availability of International food safety management schemes. ● The economic growth of the country ● The revision of the health policy which includes which has ensuring food safety as one of the strategic directions ● Harmonization of medicine regulation and the establishment of AMA ● Endorsement of food and nutrition policy. ● Commitment of the government to bring change in the organization. ● Increased awareness among law enforcement bodies and courts ● Willingness of the existing partners to continue and strengthen their support. ● Increasing trend of community participation and availability of public wing and health extension programs. ● Industrialization (increase in local production of drugs and equipment, local manufacturers of food, etc.) ● Increased number of radio /TV and social media platforms with capacity to accommodate multiple languages with a positive sense of social responsibility. ● Improved access to education. ● Technology advancement and Globalization. ● Emerging Food safety issues as global agenda. ● Inter-sectoral and regional collaboration. ● Existence of third party Conformity Assessment Bodies (CAB) 	<ul style="list-style-type: none"> ● Fast going of food industry and production technology which results in complex regulated products. ● Existence of porous borders in the country. ● Losing experienced and skilled professionals. ● Conflict of interest between regulatory and other sectors. ● Inconsistent capacity with the global, national development and technological change. ● Complexity of Illegal food, medicine and medical equipment trade. ● Technology and globalization in contributing SFP\. ● Political instability of national and neighboring countries. ● Climate change. ● Industry interferences ● Increase issues of intentional food adulteration. ● Inadequate number of well capacitated public and private laboratories. ● Inconsistency and delay on law enforcement by the legal bodies. ● Chemicals and technologies used for the increment of productivity which affect the product safety.

Stakeholder Analysis

Continuous effort and participation of stakeholders is important for the accomplishment of the mission and vision of the sector. Stakeholders are individuals, organizations and institutes that could bring or receive positive or adverse influence on materializing the vision and mission designed by the sector. Consequently, stakeholders were identified and their stance, behavior, interest as well as their extent of influence and our response is analyzed. Furthermore, extent of their influence is assigned based on their political strength, level of participation in the sector and the service they obtain from the regulatory body. Considering the point mentioned above the stakeholders’ analysis is presented below:

Table 10: stakeholder analysis

Stakeholder	Their interest	Behaviors we desire	Resistance issues	Response of the FMRS
Community	Quality assured food and medical products in the market, Up-to-date and Reliable information and timely response; and empowerment	Active participation and ownership	Loss of credibility, dissatisfaction, collaborate with illegal practice	Community participation and mass mobilization; provision of adequate response for public queries, ensure the availability of quality and safety assured food and medical products in the market
Parliaments, Prime Minister's Office, Council of Ministers, Regional Governments	Initiating regulatory legal frameworks and implementing when approved; effectively executing functions and responsibilities entrusted to the authority and timely submission of plan and performance report, and implementation of feedbacks	Policies and legal framework that strengthens and support the sector, ratifications of legal frameworks, leadership support	Accountability, and it affects budget allocation	Strong monitoring and evaluation of plan and performance, proper execution of authority and responsibility, Corrective actions based on feedback obtained
Ministry of Finance	Submission of Program budget request, and performance reports on time, Effective and efficient financial utilization	Approval of requested budget and technical support	Affects budget allocation, and utilization	Strong monitoring and evaluation system, Effective and proper budget utilization, correction actions based on feedback
Federal Ministry of Health and Regional Health Bureaus	Effective execution of regulatory mandate and implementing regulatory frameworks; technical support; timely Plan and performance report,	Integration, collaboration, and leadership support	Accountability, lack of leadership support and loss of trust	Strong monitoring and evaluation system, MoU

Line ministries and agencies (Ministry of Trade and Regional Integration, Ministry of Revenue, Ministry of Agriculture, Customs Commission, Agriculture Authority, EPSS, etc.)	Multi-sector collaboration and engagement, exchange up-to-date information and resource sharing , technical support	Collaboration, transparency, technical support	Fragmentation, Dissatisfaction and considering food and health products safety and quality assurance a low priority and mandate overlap	Collaboration, engagement, transparency and advocacy, and MoU
Ethiopian Broadcast Authority, and media	Collaboration, up-to-date information, engagement, and empowerment	Collaboration, pro-active involvement, information dissemination, and media regulation	Give low priority for the sector, disseminate outdated and unreliable information to the public,	Advocacy, transparency, mass mobilization, and collaboration
Federal and regional courts, Ministry of justice, Regional Justice Bureau, federal and regional police commissions	Collaboration, evidence provisions and technical support, awareness on regulatory frameworks	Enforcing the laws, Technical support, Collaboration	Low priority to regulatory, Dissatisfaction, loss of trust	Collaboration, technical support, transparency and advocacy, MoU
Customers (Food Medical products manufacturers, Importers, wholesalers, exporters and retailers, and others)	Collaboration, Awareness, implementation in compliance with citizens charter and complaint handling system, efficient issuance of certificate of competence, market authorization and port clearance permit, Fast response, Technical advice and support	Comply with the rules and regulations, collaboration, and to act legally	Involvement in illegal trade, breaking rules and regulations	Ensuring good governance, Continuous provision of awareness on legal frameworks, Proper complaint handling system, Transparency and accountability, develop citizens charter, collaboration, advocacy

Academia, Associations of food professionals ,Health Professionals and Traditional and alternative medicines ,food manufacturers association	Collaboration, engagement, good governance, technical support	Collaboration, engagement, technical support and advocacy	Dissatisfaction unethical practices	Advocacy, awareness, MoU, good governance and collaboration and engagement
Civil societies, Consumers Associations	Empowerment, collaboration, up to date information	Ownership, information and tips off to regulatory bodies, engagement in combating illegal food and medical products	Loss of trust	Mobilization, advocacy, up to date information, empowerment, transparency
Nongovernmental organizations and Development Partners	Rational fund utilization, Up to date and reliable report, engagement in planning and performance review	Collaboration, Financial and technical support aligned with strategic objectives of the sector	weak M&E system	Comply with terms of the organizations, Establish strong M&E system, timely reports, collaboration, and Advocacy

CHAPTER IV: Food and Health Products regulatory Sector

Development and Investment Plan

4.1. Vision

To be a center of excellence in food and health products regulation in Africa

4.2. Mission

To protect and promote public health by ensuring the safety, effectiveness, quality and proper use of regulated products through licensing, inspection, registration, laboratory testing, post-marketing surveillance, community participation, and provision of up-to-date regulatory information.

4.3. Values

- **Public First:** all possible efforts are to ensure the best interest of the public at large not for satisfying the interest of some groups or segments of the public and get contribution from the public in the notion of ensuring the health of the public is ensuring my health.
- **Integrity and respect:** being ethical, professional, objective, honesty and adhering to moral values.
- **Continuous improvement:** be able to be responsive and adapt policies, systems and processes.
- **Accountability:** taking full responsibility for our actions and outcomes.
- **Quality:** strive to deliver the best services to the customers with utmost professionalism and with no compromise on safety and quality of products.
- **Commitment:** uphold highest standards of conduct and commitments while acting in the best interest of the public.
- **Transparency:** operate in a fully transparent manner and communicate openly and timely with the public and relevant stakeholders.
- **Excellence:** demonstrate the highest standards of performance consistent with international standards and best practices; and achieve excellence in regulatory operations and public services through promoting research, innovation, continual learning and openness to change.

- **Teamwork:** having a united sense of purpose that all members believe to achieve the mission, support one another, work cooperatively and respect one another’s views

4.4. General Objectives (Goals)

General objectives are operationally defined as high level result statements, equivalent to goal, that leads to the achievement of the vision of the sector. They are not expected to be SMART; they will be measured through targets stated under the “targets Section”. The overarching objective of this medium-term food and health products sector investment and development is to protect and promote public health through realization of the following objectives:

1. Protect the public from unsafe and poor-quality food
2. Safeguard the public from falsified, substandard and/or ineffective health products
3. Protect the public from tobacco and alcohol related health risks, and misuse of NPS
4. Attain public confidence on food and health product regulation

1. Protect the public from unsafe and poor-quality food

Description

Food safety is an important public health issue in the world as well as in Ethiopia, as food-borne disease disrupts the lives of consumers due to high rates of adulteration and unhygienic food handling practices across the food value chain. An effective food safety system is vital to safeguard the public from unsafe and poor-quality food and its associated detrimental health consequences, including food-borne disease. With the 2018 Food and Nutrition Policy (FNP), Ethiopia identified food safety and nutrition as a governmental responsibility at the federal level. The country’s constitution recognizes the importance of food safety, clearly placing the responsibility of maintaining the safety of food on the state as well as considering it as a fundamental human right. However, responsibility for food safety regulations, compliance, and inspection in Ethiopia is fragmented and disjointed across different ministries and executive governing bodies. Food safety authorities are distributed between several Ministries – most notably, the Ethiopian Food and Drug Authority within the Ministry of Health, the Ministry of Trade and Regional Integration, and Ethiopian Agriculture Authority under the Ministry of Agriculture– as well as their respective regional offices, and local authorities. At present, no integrated coordination mechanism exists to clarify

overlaps or gaps in food safety regulations. The fragmentation of regulatory authorities was also observed in compliance and inspection activities. In recent years, Ethiopia has made limited, but encouraging, regulatory efforts at the federal level to address food-borne illness and illegal food marketing practices (e.g., adulteration, counterfeiting, misbranding) that negatively impacts public health and the economy.

It is essential that food safety be addressed from production to consumption. This comprehensive & integrated approach ‘farm to fork’ value chain; it implies the responsibility of providing safe food to the consumer is shared by all stakeholders along the chain, also needs modern technologies, innovation labs, and scientific based interventions.

Different hazards can be introduced at different points of the ‘farm to fork’ value chain and regulation should take place at multiple areas as possible and rigorously evaluate where interventions are most effective. This objective focus on areas of food regulation that includes: food registration and market authorization, Inspection & enforcement, import control, food laboratory testing, delivering appropriate food regulatory information. Moreover, attention will be given in the prevention and controlling of food adulteration and illegal food products.

Ultimately the achievement of this objective will contribute to the success of sectoral and national plans with regard to increase the availability of safe and quality food in the market reducing food borne morbidity & mortality arising from unsafe food as well as contribute to economic development through export market.

Targets

- Decrease the prevalence of unsafe food available in the market from **NA** to 15%

2. Safeguard the public from falsified, substandard and/or ineffective health products

Description

This objective is defined based on the sector’s vision and Sustainable Development Goal Three (SDG-3) related to safety, quality and performance of health products. Safeguarding public health reflects the fundamental rights of the people to the enjoyment of the highest attainable standard of health with access to needed health products. Health products in this context include medicines, medical devices, blood and blood products, vaccines, cosmetics, antiseptics and

disinfectants; active and inactive pharmaceutical ingredients and traditional medicines. The need to resolve challenges posed by innovative new products and increased globalization require well-functioning pre-market and post-market regulatory systems that demonstrate to ensure the safety, quality and performance of the products, manage risks posed by those products, and optimizes regulatory systems and use of resources.

The objective will help to protect human health by conducting timely evaluation of safety, quality and performance of health products, inspection of manufacturers and distribution channels, authorization and oversight of clinical trials, post-market surveillance activities, control of promotion & advertisement, conducting market surveillance and ensuring proper use of health products. In addition, instituting effective regulation systems throughout the life-cycle of health products are critical to public health protection. Moreover, based on the philosophy of continuous improvements, the authority will enhance its efforts to prevent, detect and provide proper response to illegal health products, and take appropriate enforcement actions.

Targets

1. Decrease percentage of substandard medicine and medical devices in the market from 6.9% to 5% and from NA to 10% respectively.
2. Decrease percentage of falsified medicine and medical devices in the market from NA to 5, and from NA to 5%, respectively.
3. Decrease the percentage of dispensing of prescription only medicines without prescription from 51.6% to 10%

3. Protect the public from tobacco and alcohol related health risks, and misuse of NPS

Description

Misuse of NPS, and tobacco and alcohol use is a major barrier to sustainable development with perceived impacts on social, health, economy and environment. This objective is envisioned to reduce the health burden of the public by ceasing the risks which are emanated from tobacco and alcohol; and misuse of NPS. It is also intended to safeguard the vulnerable groups such as children, youth and women due to the excess use of tobacco and alcohol; and misuse of NPS. The objective also strives to mitigate the adverse outcomes of second-hand smoke exposure.

This objective will be achieved through implementing demand and supply reduction, and harm reduction. In addition, stakeholder coordination and collaboration with regional regulatory bodies will be used. The objective also focuses on raising the awareness of the public on the regulatory strategies and increasing the involvement and participation of the public on the regulatory activities.

Implementation of this objective will enable us to meet the WHO Framework Convention on Tobacco Control (WHO FCTC) and SDG 3. Executing this objective as per the international and national laws of tobacco, alcohol and rational use of NPS leads to reduction of mortality and morbidity.

Targets

1. Reduce the prevalence of tobacco use from 5% to 3%
2. Reduce the prevalence of alcohol use from 41% to 39%.
3. Increase the percentage good dispensing practice of NPS from 56.3% to 80%

4. Attain public confidence on food and health product regulation

Description

The main mission of the health regulatory sector is to protect public health from health risks associated with food, drugs, medical devices, and other health-related products.

To achieve this objective, increasing the capacity of the regulatory sector, digitizing and streamlining the process, ensuring coordination and partnership, developing regulatory legal frameworks, information communication from the current socio-economic and political development and dynamics, as well as health sector policy, strategic planning

Moreover, it focuses on improving the competence and skills, motivation, and commitment of the workforce in the regulatory sector, ensuring their satisfaction, and respect for customers, and being free from corruption and theft.

In addition to this, it focuses on regulatory infrastructure, integrated and efficient management systems, monitoring and evaluation, /supportive control, planning and reports, measuring results, resource mobilization, and community involvement in planning, lawmaking, and law enforcement.

The issues that need to be focused on to achieve the objective are the implementation of the communication strategy of the regulatory sector and work on strengthening the public relations

activities so that the public can receive current information and have a sufficient understanding of the regulatory work.

This objective is to establish a strong quality management system that is in line with regulatory policies and legal frameworks, and actively work to promote a risk-free and cost-effective management system with effective performance, transparency, and accountability.

In addition, the sector is focused on the ultimate goal of increasing participation in regulatory activities by creating awareness of the most commonly used health resources by performing regulatory activities efficiently in order to reach a higher level of excellence.

It aims to create an empowered society, to encourage the community to become more involved in proactively reporting the presence of illegal products and defective products in the market.

It strengthens the common understanding between the community and the regulatory sector as a whole, builds trust and ensures community ownership and sustains public trust.

Targets

1. Increase percentage of community satisfaction on the regulatory sector from NA to 75%
2. Increase public trust score from N/A to 4.5
3. Increase transparency score from N/A to 9

4.5. Strategic Directions

For this transformation plan, 15 strategic directions are formulated and described along with their major interventions. These interventions are either major strategic initiatives or key activities.

1. Strengthen food safety regulation.
2. Strengthen detection, prevention and response to food adulteration and illegal trade
3. Improve regulation of safety, efficacy, quality and proper use of medicines
4. Strengthen safety, quality and performance regulation of medical devices
5. Improve regulation of safety of cosmetic products
6. Strengthen tobacco, alcohol and misuse of NPS control system
7. Enhance public ownership
8. Improve efficiency and effectiveness
9. Enhance partnership and collaboration

10. Enhance good governance
11. Improve human resource development and management
12. Improve evidence-based decision making
13. Strengthen regulatory infrastructures and digitization
14. Improve quality management system
15. Improve formulation and implementation of legal frameworks

1. Strengthen food safety regulation

Description

Food safety regulation is a mandatory regulatory activity of enforcement by national and/or local authorities to provide consumer protection and ensure that all foods during manufacturing, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to national and/or international food safety and quality requirements. Food safety regulation systems should cover all food produced, processed and marketed within the country, including imported food. Such systems should have a statutory basis and be mandatory in nature. Currently the national food safety regulation and enforcement implemented through major three strategies which are, risk based, preventive based and trust based inspection system.

For effective food safety regulation implementation, a national food safety enforcement should be in place comprises of:

Food products registration and facilities licensing: Registration and market authorization of food products and facility licensing is one of the key components of the food safety regulatory system to ensure the safety of food. The food registration and notification database will be used as backing to know whether the food product complies with the existing national and/or international standards, for easy identification of food products in the market, for customer informed choices and to establish a track and trace system. The strategic directions which are going to be used are: identification and categorization of food for notification and registration based on the product characteristics and risk burden, developing and revising relevant directives, guidelines, and strategic roadmaps, implement fast tracking strategy for food products imported from countries which have stringent regulatory authority, conduct pre-license facility inspection and issue license, support the local and imported food registration process through GMP

inspection on selected food items, implement and expand food alert system at national level, enhance the capacity and capability of assessors on basic and advanced Food product dossier evaluation techniques, provide strong support and supervision for branch and regional food product assessors.

Inspection and enforcement: Due to the growing economy of the country a number of food business operators (focus on small, medium and large-scale food manufacturing facilities, importers, exporters, wholesalers, retailers, street vendors and mass-catering services) are available. The inspection and enforcement will cover all these food facilities at federal and regional level by categorizing the food items as animal origin, plant origin and other sources across the value chain. Moreover, inspection and enforcement will be highly supported with post licensing inspection, planned post market surveillance and intelligence- led market assessment strengthen and enforcement of agro-processing industries.

The role of inspection and enforcement services is to analyze scientific information as a basis to develop appropriate food safety standards (both processing and end product standards), verification or audit inspection to ensure that the control systems used by food operators are appropriate, validated, effective and operated in such a way that the standards are met, enforce implementation of internal quality management system, conduct post license risk based inspection, develop and implement food facilities grading system based on their status. In the event of non-compliance, regulatory bodies are responsible to ensure that appropriate corrective actions are taken and legal and administrative measures are applied.

The administration and implementation of food inspection and enforcement require qualified, trained, efficient and honest food inspectors. The food inspector is the key functionary who has day-to-day contact with the food industry, trade and often the public. The reputation and integrity of the food control system depends, to a very large extent, on their integrity and skill. Therefore, a lot of emphasis will be given for enhancing the capacity and capability of the inspectors and accredited the inspection service with ISO/IEC 17020 at federal and regional level.

Import control: Since the food supply chain is global, food safety controls must be placed on food entering the country. Import controls must be effective and consistent with national, regional and international standards. With this understanding, an import control is identified as a main component of a national food safety control enforcement implementation. The food import

control will be support with document evaluation, visual/organoleptic inspection pre-shipment inspection, consignment test and rapid test kit used at the port of entry. Selection of types of imported food products for consignment testing will be based on the product risk parameters and consumer complaints and foreign GMP/HACCP/FSMS audit inspection may also be conducted if necessary. Import standards for imported food that are consistent with standards for domestic foods; and clearly defined and transparent legislation implementation tool and operating procedures will be developed and implemented to ensure the protection of consumers. In the importing control the food control system applied by an exporting country's competent authority will be recognized and considered and uniform nationwide imported food control procedure will be implemented.

Assuring safety of food products through laboratory testing: Laboratory is an essential component of a food control system. The analytical results of a food control laboratory are often used as evidence for administrative measures and in a court of law to determine compliance with regulations or standards of the country.

The establishment of laboratories requires considerable capital investment and they are expensive to maintain and operate. Therefore, careful planning is necessary to achieve optimum results. In the next three years the food control laboratory will majorly focus on performing on products which are suspected their safety and quality, collected from post market surveillance and require market authorization and conduct advanced laboratory analysis like residue tests (veterinary, pesticide, hormones, and heavy metals), toxins (Alfa-toxin, acrylamide and others), environmental contaminants (PCB and dioxin), physicochemical, microbiological, adulteration, GMO's and food contact material test using validated and verified official laboratory test methods and state of the art laboratory technologies, facilities and infrastructures.

It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the method used, quality assurance programs and accreditation of the laboratory is crucial. To assure this the laboratory will perform a lot of works and maintain the accreditation of ES ISO17025 on selected parameters, provide strong support and supervision for branch and regional laboratories, enhance the capacity and capability of the laboratory personnel, expand scopes of testing, upgrading the laboratory with existing scientific laboratory technology, create a strong

partnership with local and international private and public food quality control laboratories and other relevant organizations.

Strategic Initiatives and Main Activities

- **Boost food registration / market authorization**

- Develop and implement strategy and road map for food registration and notification system
- Develop modern harmonized and risk based framework of food legislation and procedures (directive, guidelines, manuals, and SOP's) for product registration and facility licensing.
- Create awareness for food importers and manufacturers regarding food registration directive and requirements by conducting consultative workshop /meeting and accessible medias in sustainable manner through established platform.
- Dissimilation of model food registration directive and technical support for regions regarding local food product registration
- Supportive supervision for regional regulatory bodies regarding model food registration directive
- Conduct food product, registration/market authorization through document evaluation techniques and/or via notification for identified food products and supported with GMP/HACCP/FSMS inspection for local and selected imported food products.
- Develop and implement strategy for food products imported from countries which have stringent regulatory authority
- Develop and implement strategy for selected food products recommended for fast tracking process.
- Conduct capacity building of experts on different food products in dossier evaluation
- Conduct pre-licensing inspection and issue license and renewal for food facilities
- Strengthen enforcement of administrative measures on registered or notified food products based on the post licensing inspection, PMS and market assessment findings and advertisement evaluation
- Strengthen public awareness on food safety issues
- Harmonization of the pre- license guideline
- Enforce existing food advertisement directive

- Proper implementation and expansion of existing food safety alerting system
- Establish a strong network of food database systems at national level both federal and regional.
- To be accredited in pre license inspection service by accreditation bodies (ISO/IEC 17020)
- Develop strategy and implement printing of registration number on labeling of registered product.
- **Implement risk-based inspection**
 - Develop strategies, guideline and road map for risk identification and categorization.
 - Conduct risk-based food safety auditing inspection on food facilities and take appropriate administrative measure based on inspection findings.
 - Conduct foreign GMP inspection on selected food items
 - Perform scientific interventions based on over all food safety regulation findings
 - Develop and implement risk communication strategy.
 - Conduct assessment on un registered local and imported food products in different regions / largest markets and drive to registration
 - Strengthen the existing inspection and enforcement system through revised/develop revised and developed directives manuals, SOPs, rapid test kits and other inspection tools.
 - Encourage food safety regulatory agencies to participate in a national integrated food safety Strategy implementation.
 - Establishing integrated national communication channel among stakeholders.
 - Strengthen public information systems on inspection and enforcement.
 - To be accredited in inspection and enforcement service by international accreditation bodies (ISO/IEC 17020)
 - Develop and implement guideline to regulate the street food vendors.
 - Develop strategies and road map for strengthening national Food safety vigilance and PMS system
 - Establish interagency networks for information sharing.
 - Perform food safety risk Analysis (Assessment, Management and communication) across the value chain under the mandate of the health regulatory.

- Establishing informative, concert and inclusive data base system at national level and disseminate up to dated information on food safety regulation and enforcement
- Conduct scientific based post market surveillance
- Establish IEC system on findings of vigilance and PMS
- Conduct capacity building of experts on different food products inspection system
- **Strengthen compliance of national food standards**
 - Identify required standards ES, CES and international standard to be implemented by the manufacturer and importer
 - Strength the coordination and collaboration with IES on the area of standard development.
 - Develop strategy for imported products to level standard mark
 - Follow up of fully implantation of the mandatory fortification standards and fortification logo for flour and edible oil
 - Enforcing implementation of national mandatory/compulsory food standards
 - Conduct an assessment on the standard implementation and labeling standard mark by the food facilities.
 - Collect and distribute required food standards both to federal and regional inspectors for their reference.
 - Create awareness to food manufacturer and importers on required food standard and labeling of standard mark.
 - Promote voluntary standard implementation
 - Identify food products which do not have standards and support for their standard development
 - Strengthen regional/international relationships on the food standard area
 - Conduct awareness creation to the consumer about food leveling based on CES 73 (will be conduct in collaboration with PR)
 - Participate on national standard development process
- **Improve implementation of effective GMP/HACCP/FSMS by food facilities**
 - Create incentive mechanisms for food business actors implementing GMP/HACCP/FSMS
 - Reinforce food business actors' responsibility to produce and place safe food on the market
 - Enforce implementation of GMP/HACCP/FSMS in food facilities

- Develop relevant directives, guidelines, manuals and SOP's
- Conduct assessment on the status of implementation of GMP/HACCP/FSMS in relation to the mandate of the authority.
- Conduct intervention for the enforcement of implementation of GMP/HACCP/FSMS
- Capacity building for inspectors both federal and regional regulatory bodies.
- **Implement 3 tier food product testing system**
 - Develop strategy and road map for the implementation of 3 tier system product testing
 - Select product to be tested with 3 tier system
 - Identify and procure equipment used for 1st and 2nd tier testing
 - Develop SOPs, guidelines and manuals for testing procedure
 - Conduct training for the laboratory technicians and inspectors
 - Procure rapid/mobile test kit used for at port of entry and routine field inspection and conduct testing.
 - Establish and equip mobile laboratories at entry and exit port.
 - Establish electronic reporting system within 3 tier system
- **Establish and implement Track and trace**
 - Benchmarking collect reference on the track and trace implementation in food value chain
 - Develop process flow and guideline
 - Establish electronic track and trace system
 - Conduct training to inspectors
 - Create awareness to food manufacturer on the system
 - Establish the national integrated food safety regulation system covering the supply chain from farm-to-table.
 - Coordinate food safety regulatory agencies' oversight to ensure a unified approach along the food supply chain from farm-to-table.
- **Advance food laboratory testing**
 - Implement existing strategies and road map for strengthening head quarter and branch food quality and safety control laboratory
 - Provide theoretical and operational intensive training to laboratory personnel on state of art laboratory technologies both local and abroad

- Secure continues availability of important laboratory consumables, spare parts and upgrading existing technology
- Undertake planned equipment calibration, verification, preventive and breakdown maintenance
- Perform advanced laboratory analysis on consignment samples, PMS, suspected and for market authorization of food products.
- Conduct advanced tests on food adulteration
- Start new tests like residue, contaminant, fatty acid profile, food contact material, pathogenic microorganisms and others
- Design projects with other stakeholders like academia, research centers, partners and governmental organization to fully operate state of art technologies.
- Develop and implement phase approach laboratory information management system /LIMS/
- Maintain and expand ISO/IEC 17025:2017 accreditation of head quarter laboratory and prepare and implement branch laboratories for accreditation.
- Develop, validate and verify laboratory test methods using advanced analytical techniques
- Continuously conduct Quality control samples, proficiency testing and intra-laboratory comparison
- Implement Kaizen principles
- Provide continuous training on ISO/IEC 17025, method validation, uncertainty, internal audit etc for laboratory personnel.
- Implement and maintain a network among accredited laboratories.
- Fully utilize procured laboratory instruments at branch food safety and quality control laboratory and start new testing
- Provide basic and advanced training for branch food laboratory personnel
- Develop relevant manuals, guidelines and SOP's
- Continually support branch laboratories
- Procure important laboratory goods
- Participate on national laboratory test standard development process.
- **Enhance GHP, GDP and GSP implementation in the food retail outlet**
 - Conduct market assessment with regional regulatory bodies on GHP, GDP and GSP

- Develop model checklist, SOP's, guidelines and manuals.
- Conduct training on GHP, GDP and GSP for regional regulatory bodies.
- Conduct public mobilization on good storage and distribution practices of food products in different regions.
- Follow up on improvement of implementation and enforcement of GHP, GDP and GSP
- Enforce implementation of GHP, GDP and GSP on retail outlets
- Conduct intervention on implementation of GHP, GDP and GSP on retail outlets in relation to the mandate of the regional health regulator body
- Create strong linkage with trade offices and other concerned institutions.
- **Strengthen Import control**
 - Design an efficient and effective risk-based regulatory process for importing food.
 - Develop necessary directive, guidelines/manuals and SOPs for the effective implementation of import food product control;
 -
 - Ensure the safety of imported food products through risk-based food safety inspection system, conformation of registration certificate, food consignment testing and also using test kits at port of entry.
 - Adopt/adapt/develop regulations which provide incentive mechanisms for traders to move from the informal to the formal movement of goods.
 - Design an efficient and effective process for documentation requirements for imported foods.
 - Enhance the regulatory food import system to include preventive measures.
 - Improve partnering with local import control agencies and establish partnership and collaboration with foreign import control agencies.
 - Use rapid test kits for import control

Targets

1. Increase the number of market authorized food products from 6488 to 11,490
2. Increase the percentage local food facilities audit inspection coverage from 87.3% to 100%

3. Increase the number of foreign on-site inspection conducted on selected food products manufacturing facilities from 2 to 65
4. Increase the coverage of food facilities implementing GMP/HACCP/FSMS requirements from 35 % to 70 %
5. Increase the coverage of street vendor that implemented GHP from N/A to 50 %
6. Increase the coverage of mass catering service that implemented GHP & GCP from N/A to 50%
7. Increase the number of food product types tested via PMS laboratory from 48 to 60
8. Increase Number of food product types for consignment laboratory tests from 43 to 60
9. Increase Number of accredited food control laboratory from 1 to 4
10. Increase Number of national standard mark labeled product from 3 to 8
11. Increase Number of branch offices implement 3 tier system from 0 to 7
12. Increase Number of ISO 17020 certified directorate from 0 to 8

2. Strengthen prevention, detection and response to food adulteration and illegal food products.

Description

Currently food adulteration and illegal food products are major national and global health threat and practiced for financial gain and used even as a weapon (bio-terrorisms) which is practiced at different level both on locally manufactured and imported food products. By nature, the practice is complex to identify the source, raw material used, the manufacture, and other issues used to trace the product and safety of food products

Food fraud is the intentional adulteration which includes deliberate substitution, dilution, counterfeiting, or misrepresentation of food, ingredients or packaging; or even false or misleading statements made about a product. All these examples of fraud can have a negative impact on the quality and safety aspects of foods. They can also damage consumer confidence and harm food businesses.

Strengthen the mechanism of detection, prevention and response to food adulteration and illegal food product in our country is essential to addressing the safety, source, nature of food product from production to consumption.

To tackle both intentional food adulteration and illegal food product it is crucial to design and implement appropriate prevention, detection and response mechanisms.

Prevention of intentional food adulteration and illegal food should be focus on creating a strong multi-sector collaboration among stake holders like code enforcement, regional regulatory bodies, MOTRI, IES, EAA, police, attorney general and courts, associations, broadcast authority, trade and industry minister and others. In addition to this awareness creation for the public is vital tool.

Detection of intentional food adulteration and illegal food comprises of inspection and surveillance, market assessment, collection of public complaints and as well it should be supported with rapid test kits and advanced laboratory analysis.

Proactive and reactive response techniques should be developed and applied, like administrative and legal measure, information dissemination, panel discussion, celebrating food safety day, using social and main stream media on detected food adulterated and illegal food.

Strategic Initiatives and Main Activities

● Stop food Adulteration

- Expand and implement food safety alerting system
- Establish control system to address food safety in informal markets
- Strengthen strong multi-sector collaboration among stake holders
- Support development of standards with concerned agency for adulteration exposed foods (pepper, raw butter, ...)
- Conduct awareness creation and collaboration with the community.
- Strengthen effective and efficient surveillance and vigilance system.
- Conduct risk-based intelligence led food surveillance and operation
- Conduct capacity building for inspectors and stakeholders
- Conduct risk-based inspection and market assessment
- Conduct laboratory testing using advanced and/or rapid test kits

- Develop appropriate directives and technical guidelines on how inspection, surveillance and market assessment undertaken on adulterated and illegal food products.
- Take administrative and legal measure
- Implement Information, Education and Communication system (IEC)

Targets

1. Decrease the prevalence of adulterated food available in the market from N/A to 24%
2. Decrease the number of illegal food products available in the market from 91 to 36
3. Increase the number of risk-based intelligence led food surveillance operation conducted and take administrative and/or legal measure from 4 to 10
4. Increase the number of risk-based market assessments and take administrative and/or legal measure from 51 to 72

3. Improve regulation of safety, efficacy, quality and proper use of medicines

Description

This strategic direction aims at ensuring that all medicines accessible to the Ethiopian public are of acceptable safety, quality and efficacy thereby safeguarding the well-being of the society. In order to achieve this, EFDA will employ science based and practically tested regulatory tools and approaches. The Authority will implement risk and/ or trust and/or preventive-based regulation, exercise responsibility sharing within pharmaceutical establishments and adopt utilization of new technologies including the introduction of track and trace systems. The key regulatory functions covered in this strategic direction include registration and marketing authorization, quality control testing services, licensing and inspection, authorization and oversight of clinical trials, post-marketing surveillance, drug promotion and information contents and ensuring proper use of medicines.

During the period of FHRSTP II, emphasis will be given to upgrade the existing laboratory in terms of infrastructure, equipment, quality systems, human resources, testing capacity and scope of accreditation. In addition to expanding scope of ISO accreditation, the laboratory will work towards implementing at three tier system approaches (i.e. Visual & physical inspection, rapid analytical tests and Pharmacopeial or Manufacturer's Validated Tests). The main laboratory will

focus on advanced and confirmatory testing while the branch laboratories will be tasked with routine testing and post marketing quality surveillances.

To enhance the performance of medicine registration function, risk-based assessment, good reliance practices such as SRA procedures, mutual recognition, conditional approval procedures, collaborative approach with WHO, regional harmonization; and joint inspection and assessments will be implemented.

The Authority will also institute effective licensing, inspection and surveillance practices throughout the life cycle of medicines with proper implementation of audit inspection, intelligence operations, market surveillance which will be supported with rapid alert system and use of cutting-edge technologies.

On the other hand, pursuant to implementation of the National Strategy and Plan of Action for pharmaceutical manufacturing development (NSPA), the Authority will streamline its regulatory requirements and strengthen enforcement capacity to ensure safety, quality and efficacy of the locally produced medicines.

Systematic and holistic approach of medicine quality and safety monitoring will be strengthened. The Authority will strengthen its collaboration with regional health regulatory bodies to enforce appropriate prescribing, dispensing and use of medicines including the containment of AMR and control of promotion and advertisements.

Strategic Initiatives and Main Activities

● Boost medicine marketing authorization

- Conduct assessment of the implementation of medicine marketing Authorization and revise and implement medicine registration strategies based on reliance and risk-based classification schemes.
- Implement outreach program of foreign pharmaceutical manufacturers
- Establish database for API/DMF
- Optimize and standardize medicine registration processes and tools

- Strengthening the implementation of fast-track registration system, risk-based dossier assessments, conditional approval, SRA procedures, WHO collaboration scheme, joint assessments and regional (e.g. IGAD) harmonization.
- Create a platform for medicine shortage alleviation and monitoring at national level in collaboration with concerned stakeholders and partners.
- Assess market withdrawal rate and associated factors and design retention mechanism.
- Strengthen medicine advertisement and promotion material evaluation
- Establish and implement a system to improve the registration status of EPSS procurement list (50 in one initiative).
- **Establish and Implement 5+5 policy:**
 - The manufacturers will be pushed to produce locally on those products whose registration renewed twice.
 - Conduct assessment on feasibility of the 5+5 policy on certain category of products
 - Develop roadmap that facilitate the implementation of 5+5 policy
 - Promote local production
 - Develop a roadmap/strategy for local pharmaceutical manufacturers to comply with GMP and conduct BE study for those products required BE study report.
 - Strengthen regulatory, industry and academia linkage
 - Encourage other sectors such as construction industry to involve in pharmaceutical manufacturing
- **Implement good review practice and improve transparency in MA system**
 - Implement Good Review Practices for market authorization.
 - Institutionalize a robust system to ensure access to public dossier assessment reports (photograph of the product, labeling, package leaflet, SMPC and public dossier assessment summary report).
 - Update registered medicines lists, expired MA, canceled, rejected, suspended products and place them on public domain on a regular basis.
 - Strengthen use of national drug advisory committee for medicine marketing authorization.
- **Improve collaboration and partnership**
 - Increased use of collaborative and work sharing models facilitating reliance, joint assessment, mutual recognition and confidence building among regulatory authorities

- Leveraging on well-resourced regulatory agencies
- Establish regulatory; -university, professional associations, industry linkage.
- Improved recognition of EFDA by other regulatory agencies in neighboring countries to expand market coverage under EFDA approval.
- **Promote registration of traditional medicines**
 - Establish and implement registration systems of traditional medicines.
 - Support the development and registration of traditional medicines
 - Support the implementation of National traditional medicine strategy
 - Establish and strengthen use of national traditional drug advisory committee for medicine marketing authorization.
- **Stop substandard and falsified (SF) medicines**
 - Develop and implement SF detection, prevention and response guideline
 - Strengthen the Inter-Agency, Inter-Professional Collaboration and Community Efforts or Multi-stakeholder engagement
 - Conduct continuous Risk-Based Post-Marketing Surveillance
 - Improve ability to identify counterfeit medicines using Deployment of Cutting-Edge Monitoring Technologies
 - Conduct intelligence led operations on SF especially targeting Internet Sales.
 - Facilitation of implementation of i-Verify app at full scale
 - Reduce illegal internet sales of medicines
 - Strengthen use of ADE related data
 - Strengthen rapid alert system
- **Improving Risk-based Inspection Systems**
 - a) **Manufacturing Sites**
 - Conduct full regulatory oversight to the implementation of NSPA so as to ensure compliance to global and/or National cGMP requirements.
 - Strengthen systems for effective licensing and certification of local manufactures.
 - Provision of skilled regulatory oversight for the new industries inhabited in the newly built pharmaceutical industry parks and the existing industries.
 - Review and approve of conceptual designs for compliance to cGMP requirements as part of strengthening local production of medicines.

- Establish systems for inspection and licensing of traditional medicine manufacturing
- Develop and implement criteria for reliance and risk-based cGMP inspection
- Comply with international best practices in cGMP inspection and become a member of PIC/s

b) Import, Export, wholesalers and retail outlets

- Revise and implement Good Storage, Good Distribution, Good Transportation, Good Documentation and Good Dispensing Practices guidelines.
- Develop and implement medicine retail outlets standard
- Develop and implement criteria for risk-based inspection of importers, wholesalers and retailers
- Strengthen systems for effective licensing and certification of importers, exporters, wholesalers and retailers.
- Enforce track and trace systems across the supply chain.
- Build intelligence capability towards risk-based and intelligence-led enforcement with focus to public health impacts.
- Develop robust licensing and inspection platform that ensures uniformity of decisions among regions.
- Enhance medicines safety and patient outcomes by effective risk management and market surveillance.
- Establish mechanisms and promote voluntary compliance of importers, wholesaler and retailers;
- Establish mechanisms to encourage model medicine establishments that excel regulatory requirements.
- Strengthen licensing and control system of medicine promoters

c) Strengthen import and export control of medicines

- Implement stringent import/Export control system
- Implement risk based inspection at port of entry and exit
- Implement first and second tier testing of consignment at port of entry
- Collaborate with stakeholders to strengthen border control

- Create mechanism in networking and information exchange within regions and neighboring countries
- **Advance laboratory testing**
 - Increase testing capacity covering biological products, APIs, vaccines, cosmetics, traditional medicine and other regulated products.
 - Expand test parameters to address performance and safety concerns on risk-based approach.
 - Strengthen branch laboratories testing capacity.
 - Conduct quality assurance related research and trend analysis as an input for evidence-based policy making
 - Implement LIMS in the laboratory testing
 - Conduct validation and verification to confirm the suitability of analytical methods used.
 - Develop analytical methods as appropriate for new testing schemes.
 - Implement GLP on main and branch laboratories
 - Implement phased based Laboratory strategy
- **Implement three tier system in medicine quality testing**
 - Develop and implement guideline for three tier testing
 - Prepare and update library (data base) for selected medicines
 - Validate the three tier testing system
 - Create platform to exchange data with internal regulatory functions
- **Improve Clinical Trial Authorization and Oversight**
 - Develop a system for prioritization and expedition clinical trial authorization and inspection
 - Develop local capacity on inspection of clinical trials/bioequivalence study sites for GCP and GLP.
 - Implement traditional medicines clinical trial authorization and site inspection system
 - Establish national clinical trial registry and register all clinical trials in the registry
 - Re-vitalize clinical trial advisory committee
 - Strengthen the ethics committees supervisory body
- **Improve Post Market Quality Surveillance systems**
 - Implement three tier testing system

- Strengthen and implement risk-based post marketing surveillance.
- Ensure PMS results are used for decision making
- Disseminate PMS result and decisions taken to public and other stakeholders
- **Improve Pharmacovigilance Systems**
 - Maintain global standard for pharmacovigilance and become WHO collaborative center.
 - Enhance new methods for monitoring products and rapidly evaluating safety issues (e-reporting, risk-based prioritization, new molecules).
 - Strengthen a mechanism to disseminate the safety and quality information obtained from international organizations and national regulatory authorities.
 - Strengthen pharmacovigilance risk assessment committee
 - Establish a structural linkage and procedures for the detection, signal generation and risk management of medicines of public health importance and monitor their safety.
 - Strengthen the investigation and causality assessment of Serious Adverse Events (SAEs) including Adverse Event Following Immunization (AEFI)
 - Strengthen the monitoring of Marketing Authorization Holders (MAH) and ensure assignment of qualified pharmacovigilance personnel.
 - Create a system for receiving of periodic safety update report
 - Strengthen passive and active surveillance system
 - Establish pharmacovigilance inspection system
 - Establish patient reporting system for monitoring safety and quality of medicines
 - Enhance the implementation of traceability system to ensure the quality of medicines.
 - Establish and strengthen regional pharmacovigilance centers
 - ⊖ Co-organize world patient safety day regularly
 - Provide safety alerts to public on regular basis
 - Improve data compilation, analysis and utilization of safety monitoring
- **Improve Control of Narcotic drugs and Psychotropic substances**
 - Revise and implement national strategy on the NPS control system.
 - Collaborates with National Drug Law Enforcers to control diversion into illicit trade and abuse
 - Strengthen a system for import control of narcotic drugs, psychotropic substances and precursor chemicals.

- Strengthening national NPS reporting system on consumption data from health facilities.
- Strengthen the reporting system to the International Narcotic Control Board on consumption and demand of narcotic drugs, psychotropic substances and precursor chemicals.
- Enforce good prescribing and dispensing practice of NPS medicines.
- Revitalize NPS inter-ministerial coordination Committee
- Update and publish list of NPS medicines
- Provide awareness creation on NPS law enforcement
- Implement audit based NPS regulation at all levels of the supply chain.
- Establish NPS information exchange platform that accommodates health facilities, pharmaceutical companies, regional health regulatory bodies and other stakeholders
- Conduct forecasted, consumed and imported data analysis on NPS medicines and use for regulatory decisions
- **Strengthen enforcement in prevention and containment of Antimicrobial Resistance (AMR) and Proper Use of Medicines**
 - Enforce prevention and containment of Antimicrobial Resistance (AMR)
 - Conduct trend analysis of antimicrobial medicines consumption
 - Conduct review of degree of AMR and use for regulatory measure
 - Integrate prevention and containment of AMR with one health
 - Enforce proper use of medicines including good prescribing and dispensing practice
 - Implement a system of providing up-to-date regulatory information
 - Revise and implement National Medicines Formulary
 - Ensure safe disposal of expired or otherwise unwanted medicines.
 - Establish a system to prompt communication on emerging issues related to medicines to target audiences through different communication channels.
 - Improve advocacy and public awareness system on proper use of medicines
 - Ensure availability of public information on product safety, prescribing information and summary of product characteristics.
 - Regulate medicine promotion, promotional materials and promoters
 - Integrate regulatory information in HEP.
 - Enforce the implementation of essential medicines lists and categorized lists

Targets

1. Increase the number of registered medicines from 3644 to 7,444
2. Increase approval of medicine with further requests those granted MA in each fiscal year to 60%.
3. Increase the public assessment report from 80% to 80% of registered medicines
4. Increase the number of registered traditional medicines from 0 to 10
5. Increase the Percentage of medicines tested through PMS from NA to 55%
6. Increase the number of ADR Reports received per year from 4354 to 11,000
7. Increase number of AEFI reports received per year from 9,427 to 11,000
8. Increase the number of serious adverse event investigated per year from 61 to 80
9. Increase the number of serious adverse event causality assessment conducted from 40 to 190
10. Increase signal detection from 1 to 11
11. Increase number of pharmacovigilance inspection conducted 0 to 10
12. Percentage of inspection coverage of medicine importers and wholesalers from 52.6% to 100%; medicine retail outlet from 84% to 100%
13. Increase the types of medicines consignment tested (prior to distribution to the market) from 28% to 55%
14. Increase the percentage of medicine manufacturing facilities inspected against the applied for inspection per year from 46% to 85%
15. Increase the number of clinical trial applications that get final decision per fiscal year from 16 to 32
16. Increase the number of clinical trials centers inspected per fiscal year from 8 to 15
17. Increase evaluation of safety report for clinical trials from 0 to 15

4. Strengthen Regulation of Safety, Quality and Performance of Medical Devices

Description

This strategic direction aims to ensure the safety, quality and performance of medical devices marketed in the country throughout its life cycle i.e., from conception and development to use and disposal. This covers the pre-market, placing on the market and post market regulatory activities. Despite several efforts made by the authority to improve medical devices regulation,

there are a number of challenges that need to be addressed to strengthen nationwide regulation of medical devices. There are limited numbers of registered medical devices on the market and the status of risk of infiltration of illegal medical devices is unknown. Furthermore, the medical device quality control (QC) testing was focused on limited types of medical devices and Good Manufacturing Practice inspection is almost at an infant stage. Cognizant of this, in mid-2019, a well experienced and high caliber medical devices regulatory expert/consultant was deployed to carry out assessment on the overall status of medical devices regulation in the country with the objective of enhancing medical devices regulatory system across the product lifecycle and ultimately improve quality of health care. A road map to strengthen medical devices regulation was developed based on this analysis, and combined with benchmarking from other regulatory agencies best practices, which provides the foundation for prioritizing the execution of various initiatives by enhancing existing strengths and exploiting all opportunities while attempting the pain points is being implemented. The initiatives indicated in the road map, proposed to strengthen the medical device regulatory system in the country, needs to be fully implemented to bring the anticipated outcomes.

The Authority will also implement risk-based regulation, and it will share responsibility to medical device establishments, other stakeholders and adopt utilization of new technologies. The regulatory functions will be designed based on the device regulatory life cycle (i.e., pre-market, placing on the market and post market regulatory activities). Emphasis will be given to establishing well organized quality control access and laboratory testing; and establishing risk based GMP inspection systems for devices that require GMP inspection for all devices with a risk class of III/C and above. In addition, proper attention will be given to clinical trial authorization, oversight of field trials, vigilance, post-marketing surveillance and field safety corrective actions as well as decommissioning or disposal of medical devices.

Strategic Initiatives and Main Activities

- **Boost Medical Devices registration and Marketing Authorization**
 - Implement risk-based dossier assessments and notification scheme
 - Implementing a fast-track registration
 - Implement abbreviated review procedures through:

- Reliance approach for SRA approved and WHO prequalified medical devices
- WHO collaborative registration Procedure for IVDs
- Conditional approval approach
- Joint assessments and regional harmonization
- Implement 60 in 1 and 50 in 1 procedures
 - 50 in 1 is to grant market authorization for 50 percent of all products in the EPSS list of procurement which don't have any registered manufacturer or few manufacturers that do not meet EPSS need.
 - 60 in 1 is to push 60% of the applications on which further information requests sent to applicants to Market Authorization within a year.
- Engage other medical devices regulatory functions staff in dossiers assessment of marketing authorization applications (specification and method of analysis by laboratory experts)
- Identify market authorization induced shortage of Medical Devices and publicize the list on regular basis to attract more applicants
- Implementing Good Review Practices in market authorization process
- Finalize the Optimization of registration and marketing authorization processes and tools (Notification, fast track, SRA pathways, etc) and implement by integrate into the e-RIS.
- Developing and implementing additional guidelines (reliance, UDI, special access etc)
- Accelerate clinical investigation applications review process and approval
- Create database for clinical trial authorization and oversight activities
- Establish and engage clinical trial advisory committee
- Strengthen collaboration and coordination with relevant stakeholders (eg national ethics committee) for clinical trial
- Simplify and speed up the renewal procedures to maintain authorized medical devices of known safety, efficacy and Performance
- **Implement Risk based Medical Devices inspection**
 - Decide major categories and types of medical devices in each category as the basis for risk classification
 - Implement effective pre-licensing inspection of local manufactures, importers, and wholesalers

- Conduct post licensing audit to ensure that the applicable regulatory requirements (GXP) compliance is maintained throughout the supply chain and take appropriate enforcement actions
- Identify medical devices those can be subjected to functionality checks at the ports of entry
- Conduct quality management system audit/cGMP inspection on overseas high risk and selected medical devices manufacturers
- Provide skilled regulatory support for local medical devices manufacturers (industry parks and the existing industries) to implement QMS
- Ensure alignment of inspection and enforcement activities between EFDA and regional regulatory bodies
- Review comprehensive assessments conducted by other parties on potential risks associated with medical devices throughout its life cycle and take appropriate regulatory action
- Set criteria and establish mechanisms for encouraging model medical devices establishments
- Conduct GCP inspection on medical devices and take appropriate measures
- Ensure appropriateness of disposal and/or decommissioning of medical devices
- Implement guidelines for specific devices types such as donations, and devices for humanitarian aids, custom made devices, education, demonstration etc.
- **Stop Substandard and Falsified Medical Devices**
 - Conduct National Substandard and Falsified medical devices survey
 - Establish Alert System to monitor substandard and falsified medical devices
 - Strengthening port (Import/Export) control system of Medical Devices and tightening border control
 - Strengthen information exchange among EFDA, Regional regulatory bodies and health institutions
 - Establish system for random checks on flights and cargo for minimizing risk of products release without inspection
 - Establish track and trace systems/unique device identification in the supply chain.
- **Advance Medical Device QC Testing Capability**

- Strengthening the existing QC tests (registration, consignment and PMS samples)
 - Condoms, gloves and sterility for sterile medical devices
- Identify and risk categorize the types of devices that need QC testing (mechanical, physical, chemical microbiological) etc
- Expand scope of testing in terms of test parameters (eg Gloves QC test parameters)
- Expand scope of laboratory testing by medical devices type
 - Syringe, catheter, gauze, catgut suture test, suture needle test
 - IVD (HIV, HBV & HCV, Malaria, TB, Covid 19 kit, hCG),
- Improve laboratory equipment management system (equipment maintenance and calibration/ verification)
- Adopt/adapt ISO and other international standards for MDs testing
- Perform test methods verification and validation
- Establishing medical devices basic QC testing booth (functionality check point) at port of entry
- Develop and implement laboratory information management system (LIMS) and data base
- Ensure suitability of laboratory infrastructure including biosafety for IVDs and non IVDs products testing
- Ensure availability, proper management and utilization of chemicals, reference standards and reagents.
- Establish and implement general laboratory safety program
- **Strengthening Post-market surveillance and vigilance of Medical devices**
 - Conduct regular market surveillance and vigilance inspection.
 - Conduct regular risk-based post marketing quality monitoring.(Risk-based product selection, site identification, sample collection, and testing)
 - Establish and implement a system for medical devices adverse events and incidents reporting, and recall
 - Enforce field safety update reporting
 - Establish and implement a system for monitoring of reported recalls of medical devices by other agencies
 - Creating awareness on medical devices adverse effect/incidents reporting

- Establish a system for obtaining medical devices safety and quality information from international organizations and other national regulatory authorities and disseminating mechanisms.
- Enforce MAH to report on MD safety and Quality information
- Follow-up and report on compliance with after-sales services(regular maintenance, calibration, verification and or qualifications) and obligations
- **Establish medical device promotion and advertisement control system**
 - Developing and implementing directive and guideline for medical device promotion and advertisement control
 - Reviewing and approval of advertisement and/or promotional materials
 - Monitor medical devices promotion and advertisements practices at healthcare institutions
 - Support regional regulatory bodies to regulate promotion and advertisements of medical devices
 - Ensure that Medical representatives/promoters of Medical devices are licensed

Targets

1. Increase the number of registered medical devices (**single and bundled**) from 5420 to 8500
2. Increase the number of types of medical devices consignment tested from 4 to 10
3. Increase the number of types of medical devices subjected to PMQM from 4 to 10
4. Increase inspection coverage of licensed medical devices facilities (local manufacturers; importer and wholesaler) from 99.3 % to 100%
5. Increase the number of cGMP inspected overseas medical devices manufacturers per year from 18 to 35
6. Increase the number of adverse device events reports received per year from 14 to 56
7. Increase the number of clinical trial/investigation applications that get final decision from 3 to 20
8. Increase the number of clinical trials GCP inspection from 0 to 20
9. Increase the types of medical devices checked for functionality at POE from 0 to 3
10. Increase the number of field safety corrective action (FSCA) notifications from 3 to 50%

5. Improve regulation of safety of cosmetic products

Description

This strategic direction aims to ensure the safety of cosmetic products placed on the market. It will address concerns of consumers on the safety of cosmetic products, due to allergies and dermatitis caused by toxic and contaminated ingredients, over-exposure to preservatives, and false or incomplete label information.

The Authority will deploy risk-based approaches in its regulatory functions to ensure safe cosmetic products are placed on the market. The key regulatory functions covered in this direction include strengthening licensing and inspection, implementing strong market control and surveillance systems, introducing safety laboratory testing, implementing notification procedure, tightening port and border control, introducing cosmo-vigilance systems etc.

In collaboration with international and local stakeholders the Authority will control illegal trade and infiltration of poor-quality cosmetics to the supply chain. Improvement in regulation of safety of cosmetic products is expected to decrease adverse effects of cosmetics products and contribute to improvement of health status of the users.

Strategic Initiatives and Main Activities

- **Improving the notification system:**
 - Implement cosmetic notification system (software)
 - Establish and update notified cosmetic products central database.
 - Update registered cosmetic lists, expired notification note, canceled, rejected, suspended cosmetic products and place them on public domain on a regular basis.
 - Establish cosmetic notification system at EFDA branches and port of entry
- **Stop the availability of unsafe cosmetics on the market**
 - Strengthen licensing system of cosmetic facilities
 - Strengthen market control and surveillance
 - Strengthen regulation of cosmetics at port of entry
 - Implement risk-based inspection of the cosmetic supply chain.
 - Take measures on unsafe cosmetics found in the market and publicize the measures taken.
 - Strengthen cooperation EFDA with regional regulatory bodies
 - Conduct assessment on safety of the cosmetics on the market

- Create a system for the control of field safety study on cosmetic products
- **Strengthen laboratory testing for safety of cosmetics**
 - Conduct post market safety testing for cosmetic products.
 - Conduct laboratory safety testing for suspected cosmetic products.
- **Improve cosmo-vigilance system**
 - Establish a system for monitoring and evaluating safety issues including reporting mechanisms.
 - Establish a mechanism to disseminate the cosmetic safety information obtained from users, concerned individuals, international organizations and national regulatory authorities.
 - Establish consumers reporting system for monitoring safety
 - Promote public awareness of safety of cosmetics products
 - Cooperate with regional regulatory bodies on control of cosmetic product
 - Revised directive for control of cosmetic products

Targets

1. Increase the number of issuances of notifications from 1240 to 2440
2. Increase the percentage of suspected cosmetic products tested for safety from 0 to 100%
3. Increase the type of cosmetic products tested through PMS from 0 to 5
4. Increase the percentage of inspection coverage of cosmetic establishments from 30% to 60%
5. Increase the number of cosmetics adverse events reports received per year from 0 to 1250

6. Strengthen tobacco, alcohol and abuse NPS control system

Description

This strategic direction aims to improve the regulatory system that enables the demand and supply reduction of tobacco and tobacco products, and alcohol thereby protects and promotes the health of the public from harmful health risks of those products. It also aims to control the misuse of NPS. The strategic direction primarily complements the prevention and control interventions set out by the health sector that are targeted to the reduction of risk factors for the major non-communicable diseases and promotion of healthy lifestyle.

This will be able to institute effective coordination for the implementation of the World Health Organization Framework Convention on Tobacco Control (FCTC) and national laws at national level and execute comprehensive, integrated and sustained control measures that reduce the use of tobacco and tobacco products and exposure to cigarette smoking, alcohol use and promotion and mis-use of NPS. The main tobacco and tobacco products regulatory functions that will be employed comprises of licensing and inspection of manufacturers and distribution channels, enforcement of smoke-free environment, market surveillance activities, control of illicit tobacco and tobacco products circulation, control of promotion, sponsorship & advertising

Control of content disclosure and pictorial graphic health warning; and related aspects of tobacco products at regions.

Strategic Initiatives and Main Activities

● Improve and enforce tobacco control

- Generating evidence on policy implementation status monitoring
- Monitoring tobacco industry interference
- Enforce disclosing of ingredients of tobacco products
- Enforcing and implement smoke free environment laws
- Conduct regular inspection and enforce compliance to requirements by manufacturers, importers, wholesalers, and retailers.
- Supporting regional governments to customize national smoke free laws into their context
- Enforcing to sustain effective graphic health warning by adapting and generating local pictorial health warning
- Enforcing all forms of direct and indirect TAPS on tobacco marketing
- advocate to increasing and adjusting tax rates for tobacco products
- Curbing illicit trade in tobacco products
- Enforcing single stick sale prohibition
- Enforcing the ban on sale of tobacco to and by less than 21 years
- Develop and implement tobacco disposal guideline
- Develop and implement tobacco surveillance system
- Establishing and strengthening a national and regional coordination mechanism

- Mobilizing resources for tobacco control program implementation

- **Improve alcohol control**

- Enforce promotion and advertising directive of alcohol
- Enforcing the ban on sale of alcohol to and by less than 21 years

- **Improve the regulation of abuse of NPS**

- Enforce NPS abuse as per the directive
- Conduct NPS abuse indicative survey

Targets

1. Increase evidence generated by GATS on the prevalence, exposure to Tobacco smoke, cessation, economic impact and KAP of tobacco use from 1 to 2
2. Increase GYTS (13-15 years of age) and increasing the evidence generated by GYTS from 1 to 3
3. Increase number of Tobacco smoke free places from 109,000 to 174,400
4. Sustaining 100% of tobacco packs with the required 70% of pictorial health warning on legal tobacco products on 100
5. Reduce Prevalence of illicit trade of tobacco from NA to 15%
6. Reduce percentage advertisement, promotion and sponsorship of alcohol from NA to 25
7. Reduce the percentage of alcohol sale prohibited areas from NA to 50
8. Reduce the percentage abuse of NPS from NA to 5%

7. Enhance good governance

Description:

Governance deals with the structures and processes by which an organization is directed, controlled and held to account. Good governance provides the means to help an organization achieve its vision and objectives. Therefore, this strategic direction aims to improve good governance in the food and health product regulatory system which is critical for the implementation and achievement of the overall objective of the sector.

Good governance practices based on good governance principles are very important in food and health product regulatory sector. Basically, they provide transparency and clear decision-making processes, authority and responsible structures, measured performance and

accountability. Therefore, effective governance is characterized by robust investigation, which provides important pressures for improving the sector performance, gaining transparency and tackling corruption. The achievement of good governance in the food and health product regulatory sector can improve management, leading to more effective implementation of the chosen interventions, better service delivery and operation, and, ultimately, better outcomes.

The focus of this strategic objective will enable the regulatory system to operate effectively in accordance with the principles of effective governance, the application of good governance principles and the implementation of accountability.

Strategic Initiatives and Main Activities

- **Ensure gender mainstreaming and Women empowerment**

- Implement gender mainstreaming
- Strength disability inclusion & Child welfare in the health regulatory system
- Implement gender strategic action plan
- Enhance women empowerment
- Provide training on gender technical capacity
- Mainstream social welfare activities in the health regulatory system

- **Strengthen the prevention of corruption**

- Develop anti-corruption strategy
- Create awareness to prevent corruption
- Assess and identify the main source of corruptions and theft
- Take action based on the finding

- **Strengthen Good governance principles implementation**

- Create awareness on the good governance principles
- check and balance the principles appropriately implemented
- develop and implement compliant handling and Appeal directive
- Revise and implement citizen charter

Targets

1. Increase the food and health products regulatory sector customer satisfaction level from 89% to 100 %
2. Reduce the percentage of service delivery complaints from 90% to 100%
3. Increase the percentage of regulatory services provided as per the standard from 84 to 100
4. Increase the number of women in to leadership from 25% to 35%
5. Increase the organization's gender technical capacity scale from to 1.98 to 2.5

8. Improve human resource development and management

Description:

This strategic direction aims to improve the performance level both at individual and organizational levels, and to achieve the desired results through the implementation of a proper human resource management system and, bringing about food and health products regulatory workforce. This helps to develop sustainable capacity, promote professionalism, create a learning culture in the regulatory sector, and link knowledge, skills, and personal attributes to organizational performance. On the other hand, an appropriate human resource management system will strengthen the sector's planning, implementation, monitoring, and evaluation of policies and strategies. This will be realized by fostering effective leadership in diversity, knowledge, level, resource and information, management, and strengthening of communication, partnerships, and cooperation skills.

Hence, in this strategic direction, the focus areas will be developing a human resource development strategy, and improving the organizational culture of the Authority, such as motivation, skill development, role clarity and employee ownership, and organizational norms and values.

In addition, the recruitment plan will focus on the gap and priority area by diverse professions, especially, second degrees in different qualifications. Improve the training and development approach those are, the development will focus on upgrading the qualification according to the new organizational structure, and give emphasis on training need assessment, plan,

implementation, evaluation, and inventor and records of the training. In addition, focus on a performance appraisal evaluation system for entire the organization

Strategic Initiatives and Main Activities

- **Develop and implement Human resource management Automation and Analytics**
 - Tracking and Management of Employee Attendance with finger and photo print
 - Managing Leave Requests
 - develop Employee Performance Management system
 - Design the Recruitment Process
 - Establish Workflow Management system
 - develop Employee training Analysis tools
 - implement Integrate human resource management information system(IHMIS)
- **Implement Human resource management strategy**
 - Implementing a Knowledge Management Program.
 - Improve leadership capacity and develop succession strategy.
 - Implement modular strategies for capacity building training.
 - Identify Training needs, plan, implement and evaluate the outcome of the training.
 - Implement recruitment plan based on the new structure.
- **Develop and Implement Performance management and appraisal system**
 - Develop workflow chart of all department.
 - Link the job description with department plan of action.
 - Automate the Authority, each department and each employee function.
 - Evaluate the performance Appraisal by the system.
 - Provide recognition system for high performer department and employees.
- **Improve organizational culture in the Authority**
 - Engage employees on organization planning. Activities and decision making
 - Create and promote healthy work habits and conducive work environment.
 - Make sure employees have the right tools for their task.
 - Provide Recognition and reward system.
 - Initiate employee's motivation, role clarity, talent development and personal ownership.
 - Conduct employee satisfaction surveys.

Targets

1. Increase employee satisfaction level from 38% to 70%
2. Increase the percentage of training effectiveness from 71% to 85%
3. Decrease employee attrition rate from 1.6 % to 1%
4. Established organizational culture/organizational health status 42 % to 60%

9. Enhance partnership and collaboration

Description:

This strategic direction aims to enhance partnership and collaboration with the private sector; international, federal, and local organizations, and other stakeholders to achieve the overall objective and advance the mission of the authority through building synergy. This strategic direction also aims to improve the engagement of the key stakeholders in planning, implementation, monitoring and evaluation of the regulatory activities to create awareness and ownership.

Partnership and collaboration with the private sector; international, federal, and local organizations, and other stakeholders could strengthen the food and health products regulatory system in many ways: it could improve the awareness and ownership of the different stakeholders about the regulatory; it could also allow to build mutual reliance and leverage resources through joint work-planning, shared data, and targeted risk-informed joint core regulatory functions in order to improve efficiency of the regulatory system.

Partnership with EFDA can be formalized through multiple mechanisms including Cooperative Research and Development Agreements (CRADAs), memorandum of understanding (MOUs), contracts, cooperative agreements, or through other public-private partnership mechanisms.

Strategic Initiatives and Main Activities

- **Improving participation and engagement of stakeholder**
 - Conducting mapping of potential stakeholders
 - Engage stakeholders in the planning, implementation, monitoring and evaluation of the regulatory system
 - Inform and engage all stakeholders through effective internal and external communication

- Carry out joint activities of basic regulatory functions with key stakeholders
- **Strengthen strategic partnership**
 - Formulate and implement partnerships and collaborations strategy
 - Establish partner forum
 - Prepare and implement memorandum of understanding (MOU) for partnerships and collaborations with international, federal, and local organizations
 - Engages in partnerships with foreign governments, regulatory coalitions, development organizations, academic institutions, professional Associations and others.
 - Collaborate with federal and local offices to detect and respond on illegal food and drug trade
 - Establish harmonization with independent organizations like, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
 - Harmonize legal documents among regulatory bodies (EFDA, regional regulatory bodies, and city administration regulatory bodies).

Targets

1. Increase the percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities from 91% to 100%
2. Increase the number of joint activities of regulatory function conducted with different stakeholders from 22 to 49
3. Increase the number of strategic partnerships established with international, federal, and local organizations from 2 to 6

10. Improve efficiency & effectiveness

Description

It is known that Effectiveness refers to the process of producing a desired result, and it requires doing the right thing for accomplishment of mandate. On the other hand, efficiency refers to preventing or minimizing wastage of resources (materials, energy, effort, money or time) or doing things right. The mandate of protecting citizens from unsafe and poor-quality products and services demands mobilization of resources and utilizing them optimally. This strategy is designed to outline the interventions for enhancing systems and processes that are important for

improving efficiency and effectiveness in the regulatory sector. In other words, the focus areas could be thematized as managing resource, strengthening the M & E system, enhanced internal audit and proper compliance of regulatory function to the predefined standards of business activities. Managing resources could be further cascaded to mobilization and utilization financial resources as well as material and human resources. This will be complemented by auditing of processes and performance vis-à-vis the business standards/citizens charter defined by the authority and the overall performance shall be continuously monitored and periodically evaluated.

Strategic Initiatives and Main Activities

Strengthen Resource Mobilization and Optimum Utilization

- Develop and implement Resource Mobilization strategy.
- Conduct yearly resource gap analysis.
- Resource pooling from different sources for investing on priority activities.
- Develop project for resource mobilization
- Optimize utilization of material resources
- conduct fund liquidation
- Design system for improvement for optimum resource utilization
- **Strengthen Internal Audit system (Optimum Resource Utilization and compliance to standards)**
 - Conduct periodic financial and property audit with feedback
 - Conduct performance audit on regulatory functions
 - Conduct awareness training for staff.
 - conduct compliance Audit against standards
- **Improve Grant management system**
 - Record and monitor every grant with their grant agreement document
 - Identifying anticipated risks of different grants and manages accordingly
 - Develop detailed implementation plan for every grant agreement, monitor the grant specific deliverables and take corrective action for gaps identified at all level (Directorates and RHBs)

Targets

1. Increase the amount of resource mobilization (in million birr) per year from 90 to 214

2. Reduce cumulative wastage of resources (human, material, financial ...) from NA to 5%
3. Reduce Medicine registration lead-time from 83 to 60 days
4. Reduce Average medicine recall time from NA to 15 days
5. Reduce Medicine consignment test lead-time to 44 days

11. Improve community ownership

Description:

The community has a vital role in food and health product regulation. This direction focuses to ensure active participation and engagement of the community in food and health product regulation and protect them from unsafe and illegal product. It is also about enabling the public to increase control over their lives through creating food and health product regulation literacy and decision power. This needs further effort to enhance safe and quality health product seeking behavior of the public through information communication using different Medias.

Community ownership will be ensured through informing and mobilizing the public using different media channels about quality and safety of food and health products and legal frameworks, and strengthening the participation and engagement of organized community like Women and youth associations and community civic forums in the food and health product regulatory sector.

Internal communication is an entire process within the organization. It includes how information is shared up and down through emails, memorandums, letters, video conferencing, websites, circulars and conference calls in order to achieve the organization's goals.

External communication is a communication between the organization and community, government organizations(stakeholders), private organization, medias and others advertisements, press releases, service calls, company websites, social media posts.

public and community engagement is a way of bringing government organizations (stakeholders), different civic forums, customers, medias and others for increases the visibility and understanding of quality and safety of food, health products and legal frameworks that empowers communities to solve problems that affect people's lives.

Strategic Initiatives and Main Activities

● Strengthen internal and external communication

- Create awareness using broadcast, Online and print Medias to the public.
- Establish smooth internal information share within the EFDA through email, SMS/Messenger, Newsletters, Conferences, Webinars, Social media, Formal correspondences, and other internal to announcements and updates.
- produce and implement communication through events, visits, publications, media relations, videos / photos / podcasts, websites, social media, influencers / third party endorsement, advertising and integrated communication campaigns
- Boosting our social media (Facebook, Telegram and YouTube----) and increase our followers.
- Develop and review strategies and communication working documents.

● Strengthen community and stakeholders engagement

- Engage the public and stakeholders about the safety ,quality of food , health products and legal frameworks regulation throughout communication and relation
- Create awareness through Public mobilization, media campaign and seminars.
- Engage Stakeholders, youth, women, civic forums, educational institution and citizens with special needs

Targets

1. Increase the percentage of the population who are informed about regulatory measures, laws and activities from 46% to 70%.
2. Increase the number of investigated tipoffs, complaints and concerns from the public from 9806 to 21,082.
3. Increase the percentage of population whose age above 13-year-old, who got regulatory information through media outlet. From 54%. to 75%.
4. Increase Number of the population who reached and took action to inform the regulatory about unsafe and illegal food and health product as a result of engagement from 16,911 to 55,585.

12. Improve Evidence Based Decision Making

Description

This strategic direction focuses on the generation of quality evidence data and improves evidence-based decision making in the food and health product regulatory sector. It aims at improving evidence generation and use from electronic regulatory information systems, IFMIS, EGP, ICSMIS, surveys, surveillance, researches, monitoring and evaluation systems, Inspection result, supportive supervision, planning , reports ,Performance Audit, Asset registration, Dissemination of current information of the regulatory sector through mass media and census etc. Sound decisions and effective action rely on having the right knowledge in the right place at the right time. Therefore, the other component of this strategic direction is knowledge management, which is an integrated approach of creating, storing, sharing, and applying knowledge to improve evidence-based decision making and enhance the regulatory sector performance.

Available information need to be disseminated in a timely manner and used for strategic decision making at all levels of the regulatory sector. Therefore, focus will be given to the improvement of the quality and availability of data, knowledge management and capacity to use information for action at all levels.

Strategic Initiatives and Main Activities

- Improve Monitoring and Evaluation system
 - Implement M&E guideline and manual
 - Develop and Implement automated performance management system (PMS)
 - Strengthen Integrated Supported Supervision (ISS)
 - Strengthen the implementation of one plan and one report approach at all levels of the regulatory system.
 - Review plan with performance report validation of the regulatory activities.
- **Strengthen knowledge management**
 - Identify surveys that measure the level of achievement
 - Organize dissemination of survey result and easy to access
 - Organizing best practice of the Authority
 - Monitor to measure outcomes in addition to output
 - Generate evidence for continues improvement

- Analyzing & integrating the conducted surveillance data to usable information
- **Improve data analysis and uses**
 - Organizing and analyzing public suggestion and comments to get Rapid response
 - Analysis of electronic regulatory data and information
 - Organize and manage electronic regulatory information system
 - Organizing and analyzing media monitoring.

Targets

1. Increase the % of expected reports received from reporting units on time from 79.6 to 95%
2. Increase the % of expected reports received from reporting units complete from 79.4 to 90%
3. Increase the number of performance audit reports from 3 to 5
4. Increase the number of media monitoring and analysis per year from 1 to 12

13. Strengthen Food and health products Regulatory Infrastructures and Digitization

Description

This strategic direction aspires to establish well organized infrastructures in the food and health products regulatory system that can tackle the burden of illegal and substandard food and health products. It includes establishment of food and health products regulatory excellence center, with full laboratory premises, training center and utilities. It will support the local food & pharmaceuticals manufacturing industries and enable the country and regulatory authorities in the region to cope with the dramatic changes in pharmaceutical technologies and control of substandard and falsified food and health products. Expand and renovation of head quarter buildings and premise. It has also planned to strength branches and regional laboratories and mobile labs at entry/exit ports, equipping with state of art equipment, strengthening and escalating of the electronic food and health products regulatory system by deploying high tech ICT systems/infrastructures. It is also planned to improve the ergonomic system to improve workplace safety.

The issue of digitalize the regulatory sector is an issue of food safety, vaccine, cosmetics, medicines quality assurance and rational use of medicine and; all these are under the mandate of EFDA. Besides, it's a question of health and development demanding identical approach up to

Woreda level, digitalize the regulatory sector is an advanced fast activity of intervention this project is formulated to protect the health and wellbeing of Ethiopian society and beyond with modern digitalize health regulatory services

Strategic Initiatives and Main Activities

● Improve Construction, renovation of premises and other infrastructures

- Construct the center of excellence in Addis Ababa
- Establish and strengthen medical device and vaccine labs at the head laboratory
- Establish mobile quality assurance laboratories at entry/exit ports
- Renovate and expand head and branch office and laboratory premises.
- Furnish and equip the existing lab premises with the art of technologies
- Furnish the regulatory offices with ergonomic furniture
- Procurement of vehicles for the federal new branch, ports and regional regulatory bodies
- Procure motorcycles for regional regulatory bodies and entry/exit ports
- Rent branches office.

● Improve Digitization of the regulatory system

- Develop and implement LIMS, port clearance, cosmetics notification system, clinical trial database, and NPS database
- Integration of e-RIS with trade portal and e-Payment
- Implement Alert system to detect, prevent, and respond substandard and falsified medicines and Food products
- Develop pharmaceutical products traceability system
- Develop or customize Performance management Evaluation system
- Continue working on digitalization excellence center attainment
- Establish integration of pharmacovigilance (PV) with DHIS2
- Build Track and trace Demonstration lab
- Expand e-RIS /electronic Regulatory Information Service/ to regional regulatory bureaus
- EFDA human resource system development and implementation
- Software for handling & retrieval of Documentation system

● Strengthen regulatory security system

- Perform security and load testing /Audit and Validate the authority System/

- CCTV Camera at 20 points with complete system
- Rent alternative data center for 3 years
- Establish GPS system for vehicles
- Renovate main Data center
- Rent Disaster Recovery Site
- Renovate data center and expand the existing Branch office
- Fleet management software: procurement, maintenance and service

Targets

1. Increase the number of established, well equipped and furnished the center of excellence food and health products laboratory 0 to 1
2. Attained ISO/IEC 27001 accreditation of EFDA information security management system from 0 to 1
3. Increase well established national rapid alert system from 1 to 2
4. Increase the number of regional regulatory bodies that implemented retail out let system from 0 to 12
5. Increase the number of automated systems implemented from 6 to 19
6. Increase the frequency of Audit and Validate the authority System from 1 to 3
7. Increase the number of Integration of e-RIS with other system from 1 to 3

14. Improve Quality Management System

Description:

This strategic direction describes the quality management system (QMS) development and implementation of the regulatory sector. It focuses on ensuring that the products or services the Authority provides consistently meet statutory and regulatory standards and meet customers' expectations and enhance their satisfaction. A QMS provides opportunities to enhance customer satisfaction; address context-associated risks and opportunities for continued improvement; demonstrate conformity to specific QMS requirements; and assure the quality, safety and effectiveness of regulated products.

In this connection, EFDA has accredited some of its functions including medicine, food and medical device (condom tests) laboratory testing system to ISO/IEC 17025; medicine inspection

system to ISO/IEC 17020 and PIC/S membership. Furthermore, the authority has developed QMS Roadmap to establish and implement requirements of ISO 9001 throughout the organization; to maintain and continuous improvement of the already accredited functions; to expand the scope of accreditation; attain and maintain WHO maturity level 3 in medicine regulatory sector; and WHO prequalification at EFDA main medicine laboratory.

Furthermore, standardization of activities and processes are also critical to the EFDA branch offices and regional food, medicine and healthcare regulatory bodies. Hence, the regulatory sectors will continue working in the accreditation of the inspection system and branch laboratories for ISO/IEC 17020 and ISO/IEC 17025 respectively. In addition, certification to ISO 9001 is also part of this strategic plan.

There are complaints about the quality, safety and effectiveness of the regulated products. To resolve this, EFDA is committed to effectively implement ISO 9001 across all its departments, ISO 17020 on its inspection processes, expand and sustain the implementation of ISO 17025 on its laboratories, and implement other required quality tools.

Strategic Initiatives and Main Activities

● Strengthen quality management system throughout the organization

- Implement QMS roadmap.
- Certify and maintain EFDA organizational wide ISO 9001 quality management system.
- Attain and maintain EFDA medicine WHO maturity level 3
- Provide QMS and related training to EFDA and regional regulatory bodies' staff. section
- Monitoring and evaluation of the overall QMS.
- Transfer medicine laboratory ISO/IEC 17025 accreditation from ANAB to EAS.
- Maintain and expand the scope of ISO/IEC 17025 accreditation of main food and Medicine laboratory testing.
- Attain WHO prequalification for main medicine and IVD laboratory testing
- Attain ISO/IEC 17025 accreditation of Hawassa and Diredawa branch laboratories.
- Maintain ISO/IEC 17020 accreditation of medicine inspection processes.
- Attain ISO/IEC 17020 accreditation of food inspection of EFDA HQ, Hawassa and Diredawa branch offices of food and medicine inspection.

- Attain ISO/IEC 27001 accreditation of EFDA information security management system
- Conduct internal audit and management review.
- Implement quality risk management system within the Authority

Targets

1. Increase EFDA Maturity level as per GBT from 2 to 3
2. ISO 9001 certification of EFDA HQ attained
3. Increase the number of ISO/IEC 17025/2017 accredited EFDA's laboratories from 3 to 5
4. Increase scope of ISO/IEC 17025/2017 accreditation by types of test parameters and/or testing technology from 31 to 59 (food from 11 to 16, medicine from 11 to 16, medical device from 9 to 27)
5. Increase the number of accredited EFDA inspection directorates (HQ and branches) for ISO 17020/ 2012 from 1 to 4
6. Increase number of EFDA laboratories WHO prequalified from 0 to 1

15. Improve formulation and implementation of Legal Frameworks

Description

For the effective and efficient regulation of products like food, medicine, medical devices, cigarettes, etc., the law is a crucial and significant tool. It establishes rights and duties, requirements, legal measures, and procedures for the regulatory and parties engaged in the activities of regulated products while directing and obliging the federal and regional regulatory authorities to carry out their regulatory powers and responsibilities. The legislation should be correctly formulated and implemented because it serves as a tool to regulate the actions related to the production, importation, exportation, sale, distribution, and supply of regulated products, as well as the relationship between the regulator and the regulated party.

Proclamation, regulation and directive are the three types of legislation (legal instruments) that are recognized under the Ethiopian law-making system. At federal government level, the House of Peoples Representatives promulgates a proclamation whereas the Council of Minister enact a regulation and an Agency issue a directive when they are delegated by the parliament. Regional state follows the same approach in their respective jurisdiction and government branch. The

strategic direction of improving formulation and implementation of legal frameworks focus on improving the development and implementation of legal instruments both at federal and regional level.

The regulatory legislation has to be comprehensive and harmonized both at federal and regional level. The Food and Medicine Administration Proclamation No. 1112/2019 has set the framework and regulation and directives are expected at federal level while regions are expected to customize it in their respective framework. The development and adoption of regulatory laws must be done in a way that benefits the general public and encourages businesses to operate in the sector. Adopted laws must be put into effect and enforced against those non-compliant. This include implementing the law without disparity and taking administrative measures and criminal prosecution. This requires capacitating professionals of the regulatory and justice sector; support the justice sector through evidence generation and provision to facilitate investigation, prosecution and decision; and follow-up until final decision is given by the court. And also create awareness to the public, stakeholders and customer by different communication tools.

In addition to law enforcement, implementing a system that promotes industry self-regulation will significantly contribute to an effective and efficient regulatory system. In order to close regulatory gaps and strengthen the regulatory system, it is important to evaluate how the law has affected behavioral (compliance) changes and public health protection. Initiatives are formed according to their importance, and targets are established taking into account the performance report of the preceding strategic direction.

Strategic Initiatives and Main Activities

- **Enhance comprehensiveness of regulatory legislation**

- Conduct legal gap and need assessment
- Develop legislation

- **Strengthen law enforcement**

- Train law enforcement and regulatory sector professionals
- Collect evidence, take administrative measures and share evidence with law enforcement
- Provide legal advice on administrative measures and legal matters of the sector
- Undertake litigation
- Follow-up execution of decision given by courts

- **Improve the impact of regulatory legislation on public health protection and service accessibility**
 - Conduct impact assessment
 - Improve gaps in the legal instruments and ease procedures and requirements
 - Familiarize legislation to key stakeholders and parties engaged on regulated products
- **Establish voluntary compliance scheme**
 - Conduct assessment and develop guiding documents
 - Implement the scheme
 - Monitor and evaluate the implementation

Targets

1. Increase the number of legislations on regulated products from 120 to 170
2. Increase the number of criminal cases instituted and follow-up made until decision is rendered by the court and inform the public from 48 to 195
3. Increase the percentage of civil cases decided in favor of the regulatory from 75% to 95%
4. Increase the Percentage of Administrative measure taken against non-compliance from 95% to 99%.
5. Increase the impact of legislation on public health protection from NA to 70%

4.6. Transformational agendas

Introduction: Description of transformation Agenda

This transformation agenda refers to ensuring excellence in quality assurance of products and creating resilient regulatory systems which in turn creates access to safe and effective products. It is about ensuring availability and implementation of the best quality infrastructures at all levels of the regulatory systems. This will support organizational excellence and better performances.

The overall goal of the transformation agenda is establishing a well-functioning regulatory body and optimization of regulatory systems including the implementation of quality management system aligned with the regulatory policies and legal frameworks, and aspires to build a high performing regulatory system with consistent results at all times. Efforts initiated during HRSTP-I will be accelerated during this strategic period to ensure equal access to safe and effective products, and proactively intervene on substandard and falsified products, adulterations and other illegal practices.

1. Quality infrastructure

The Authority has been working to create robust and resilient regulatory systems supported with proper information technology infrastructures. Various quality assurance system initiatives with respect to quality of products and regulatory services has been implemented by the authority. In addition, different reforms and initiatives have been implemented.

However, realizing the desired effect in regulatory center of quality of products is far from being achieved at all levels of the regulatory sector. Erratic monitoring of quality of products, poorly structured quality assurance functions, inadequate implementation of the infrastructures for quality assurance and management of the initiatives and reforms contributed to failure of achieving the goal. Hence, uplifting the systems and functions of the to the highest level so as to build trust by the public as well as relevant stakeholders is important.

Cognizant of the fact that EFDA has launched three tier quality testing approach of medical products, establishment of food and medical products at national and branch office levels, Regional Centers of Regulatory Excellence (RCOREs) initiatives, center of excellence, introduce detectors and scanners to check quality of products; and sustaining, maintaining and expansion of quality management systems of the authority at all level of its regulatory functions. However,

the Authority lacks the availability of regulatory roadmap for quality management systems, protocol for CoREs, structure for center of excellence in quality, and guideline for three tier quality assurance system etc. As most of the initiatives remain unfinished, this transformation agenda will be critically designed and continue in the HRSTP-II plan period. The major interventions under this transformation agenda are:

- Set-up center of excellence for quality assurance and trainings
- Regional Centers of Regulatory Excellence (RCOREs) initiative on selected regulatory functions
- Establish and sustain quality management systems at institutional and technical functions level
- Institutionalize the practice of the three tiers of laboratory testing approaches and implement properly at all levels y preparing proper protocol or guidance documents.
- Establish and strengthen laboratory testing at all levels of the regulatory sector
- Establish mobile quality assurance laboratories at port of entry (POE)
- Introduce detectors and scanners to furnish the quality of products
- Establish different regulatory policy reform initiatives at all levels
- Strengthened follow-up of functionality of existing platforms and regular measurement of quality assurance tools coupled with accountability framework

2. Information Revolution

The information revolution refers to the advancement on the methods and practice of collecting, analyzing, presenting, using and disseminating information that can influence decisions. It requires a systematic information management approach supported by corresponding level of technology. Information revolution is about changing the techniques of data and information management; bringing fundamental cultural and attitudinal change regarding perceived value and practical use of information.

The overall goal of this transformation agenda is improving the capability of the regulatory system to generate and use high quality data for evidence-based decision-making and drive towards a better regulatory system so as to elevate the performance of health systems.

The complexity of the regulatory functions, the numbers and quantities of products, legality issues, and the variety of functions (registration, quality testing, licensing, inspection,

importation control, post-market surveillance, safety monitoring etc.) requires rigorous implementation of and adherence to laws, policies and processes, and proper data utilization for decision making. Information revolution supported with technology plays a pivotal role in facilitating and maintaining both implementation and adherence to laws by digitizing the Ethiopia's food and medical products regulatory system.

The Authority has been working to create proper information technology infrastructures and striving to become paperless organization that links the various tasks it undertakes under one unbroken chain of information from licensing and registration to import and quality assurance. Noting this, EFDA has launched electronic regulatory information system (e-RIS), track and trace system, drug safety reporting system and alert systems. Different regulatory functions have been digitized and deployed at national levels; and close follow-up has been put in place to ensure adequate implementation of the digitized functions. However, the Authority lacks the availability of regulatory information revolution roadmap, data sharing protocol, woreda network, and information use and data quality assurance guidelines which will improve the regulatory data quality and enhance the culture of data use at all level. As most of the initiatives remain unfinished, this transformation agenda will be critically designed and continue in the FHRSTP II plan period.

The major initiatives under the digitization of information revolution will include development and implementation of already started and newly initiated electronic applications. This includes optimization and expansion of e-RIS such as i-Register, i-Import, i-License, port clearance, Medsafe, Laboratory Information Management System (LIMS), Inspection Systems, i-Verify and other mobile technologies. In addition, the Ethiopian Traceability System (ETS), National Product Catalog (NPC), medical products Shortage Alert System (SAS), Substandard & Falsified Alert System (SFAS), Balanced Scored Card for plan (BSC), Human Resource Information System (HRIS), Fleet Management Software and Handling & Retrieval of Documentation System will also be the focus area of this transformation agenda. Appropriate design, interfacing within and outside systems, ensuring interoperability between systems will be emphasized. In addition, appropriate regulatory technologies such as RIFD, T&T scanners, GPS, port clearance scanners, CCTV Camera etc.

The major expected results of this agenda are improved culture of data demand and use of high-quality data for decision-making supported by technology to improve service quality, patient

safety, efficiency and effectiveness, transparency and accountability, end-to-end data visibility, and facile and robust reporting. The agenda will be regularly monitored using properly designed performance indicators.

3. Alignment and Harmonization

This transformation agenda refers to ensuring the proper harmonization of regulatory functions among national medicine regulatory agencies and alignment of activities among national relevant institutions and interdepartmental activities so as to create access to safe and effective products. It is about ensuring availability of agreed and legally framed harmonization of activities or regulatory services that avoids discrepancies in policies or to duplicate effort. Harmonization involves negotiation, legislation, compliance and enforcement, and is said to promote similarity of regulatory systems as a consequence of political recognition of interdependence and awareness of the costs of divergence on various regulatory functions; for example, medicines registration procedures, GMP inspection requirements and others.

It is accepted to be a largely state-centered, multilateral process involving negotiations among sovereign states, and that working regulatory requirements are agreed on and formulated at this multilateral level before domestic implementation and compliance. Harmonization of regulatory requirements and processes is a critical element of regulatory system strengthening. True harmonization goes far beyond development of common technical requirements. It requires effective communication and collaboration aimed at building capacity and trust (e.g., information sharing, reliance, recognition and joint activities).

Ethiopia through EFDA has been participating as an observer in the East African Community (EAC) and requesting for membership. Besides, Ethiopia has initiated the Intergovernmental Authorities on Development (IGAD) harmonization on medicine registration, GMP inspection and information sharing of substandard and falsified (SF) medicines. Currently, common requirements for medicine marketing authorization are developed and actual assessment activities of medicine dossiers have started. Different expert trainings, technical working group meetings, and annual head of National Regulatory Authorities (NRAs) consultative conferences have been performed.

The major initiatives under the harmonization of regulatory functions will include becoming member of EAC Medicines Registration Harmonization, strengthen and expand the IGAD medicine registration harmonization, facilitate mutual recognition activities with different regulatory bodies, strengthen WHO PQ collaborative assessment, and other joint assessments. In addition, creating and collaborating with NEPAD, FAO, IMDRF, Asian harmonization initiatives, codex and etc will be emphasized. The main expected result of this agenda is facilitating access to safe and quality products for all who needs them.

4. Leadership and regulatory workforce

This agenda refers to ensuring the availability of adequate number and mix of quality regulatory workforce at all levels that are Motivated, Competent and Compassionate to provide quality regulatory services. Creating motivated, competent and compassionate workforce depends on well-regulated and quality pre-service education, in-service training and continued professional development opportunities. Fair recruitment, selection, orientation and placement, and creating enabling work environment with clear roles and responsibilities, equitable remuneration packages, performance support through strong human resources management policy and practices are important milestones to create adequate number of well qualified professionals and managers.

In addition, enhancing the leadership and governance system at all levels of the regulatory system to drive attainment of the strategic objectives. Lack of clear accountability, transparency, shared vision, evidence-based decisions and coordination are some of the leadership and governance challenges. Leadership is a crucial pillar of a regulatory system that has a direct influence on the performance of the sector. Besides, creating leadership pools at all levels is important. Hence, redesigning and restructuring the regulatory system, institutionalize accountability and transparency mechanisms, ensuring regulatory system autonomy, strengthen stakeholders' engagement and partnership, and building leadership capacity at all levels are critical interventions to transform leadership at all levels of the regulatory sector.

Chapter V: Implementation Arrangement

The implementation arrangement aims at facilitating the implementation of the FHRSTP-II by all levels of the regulatory system and relevant stakeholders. The following main implementation arrangements are identified and described:

5.1. Integration and collaboration

Building on the experiences of the implementation of HRSTP-I, sets of initiatives and programs will be packaged and put into practice for the realization of the regulatory transformation agenda within FHRSTP-II. At national, region and woreda level, efforts will also be made to integrate sets of initiatives, programs or/and main activities within the perspective of collaboration. Collaboration and alignment of plan with global and regional such as IGAD initiatives are also to be given particular focus. The planned activities are designed in a way to incorporate dimensions of environment, equity across gender, socio-economic, and special vulnerability categories.

Inter-sectoral collaboration in regulatory activities is one of the essential principles which focus on broad multi-sectoral approach for the regulatory activities such as illegal trade, boarder control, intelligence led inspections, tobacco and alcohol control and others as appropriate. This requires efforts to engage and coordinate different stakeholders within the public sector, private sector, non-government agencies, civil services as well as community level organizations.

The mechanisms for the realization of integration and inter-sectoral collaboration include joint planning, implementation, and evaluation of strategic plan's initiatives, projects and programs.

5.2. Governance

Ensuring good governance is crucial in the realization of the vision and mission of the plan and in ensuring the outlined activities. The strategic plan is designed to be linked to the concerted efforts of development partners, the private sector, non-governmental organizations and the community at large. Therefore, its governance encompasses the different stakeholders involved in its operationalization. Citizens, non-government and community organizations, development partners, and civil society and professional associations will have role with different levels of

governance responsibilities in the implementation and evaluation of the HRSTP-II activities. Based on the above considerations, the overall governance the following frameworks

- MOH EC: the highest governance body which decides, guides, oversees and facilitates the implementation of the health sector plan. As part of this, EFDA top management is part the committee. The implementation and overall direction of FHRSTP-II will be reviewed and directions will be provided for its successful implementation.
- EFDA-RHRBs Joint Steering Committee – is a forum that brings together the EFDA and the Regional Health Regulatory Bodies (RHRB). The meeting is chaired by the EFDA DG, and the participants include the DDGs of EFDA, Regional Health Regulatory Body Heads, Directors of EFDA and EFDA Branch Office Heads. During the meeting guests from parliament, partners and stakeholders will participate. The Committee meets every six months to facilitate the effective and smooth implementation of the FHRSTP priority issues. Its meetings focus on issues that pertain to the implementation and progress of the plan as well as challenges faced during the course of its implementation. The Committee is also responsible for updating the plan as well as for introducing new initiatives, programs, creating systems and mechanisms for communication and experience sharing.
- EFDA Management Committee (MC) – The MC composed of the DG, DDG and directors of all directorates will meet regularly every month to guide and follow the implementation of the plan.
- EFDA Executive Committee: is a forum that brings together the Ethiopian Food and Drug Authority leaders together. The meeting is chaired by the EFDA sponsors, and the participants include the EFDA management members, branch directors and all case team coordinators. The Committee member meets every quarter. The meetings focus on issues that pertain to the implementation and progress of the plan as well as challenges faced during the course of its implementation.

Besides the above forums, forums at regional/zonal/woreda levels will be formed and monitor the implementation of FHRSTP-II in each level.

5.3. Planning and budgeting

FHRSTP-II follows the “one plan, one report and one budget” principles where “one plan” signifies that all the major activities happening at various levels of the regulatory sector are included in one joint plan in which all stakeholders agree to be part of. The overall planning framework consists of strategic and annual plans, and strategic plans such as FHRSTP-II are to be cascaded to annual operational plans for their actual implementation. Both strategic and annual plans are the results and consultations of top-down and bottom-up processes. The top-down process ensures alignment of national priorities and targets with that of the regions and woredas. The bottom-up process ensures that the priorities and targets of regions and woredas take local challenges and capacity into account. Annual plans describe the activities in the regulatory sector in the geographical areas, and starts with resource mapping that lists all the planned expenditure by government, donors, NGOs and other stakeholders.

The principles governing both strategic and annual plans are:

- Government ownership and leadership in all regulatory planning processes: It means that the EFDA, RRBs, and WoROs at all levels of the health system own the process, have the responsibility to organize and lead the planning sessions. It also ensures all relevant stakeholders (government, development partners, NGOs, private sector, the community etc) will have active roles in the consultation. The plan and budget should also be approved by the relevant local government authority through the formal approval process.
- Linkage to resource mapping from all stakeholders (government, development partners, NGOs, private sectors, etc.) which includes financial and non-financial resources in line with the “one budget” principle;
- Alignment to other plans vertically (strategic-annual) and geography (federal → regional → zonal → woreda) as well as horizontally (including activities of all stakeholders operating at that particular level). Annual plans represent the detailed operationalization of the five-year strategic plan reflecting the priorities as well as the stipulated targets in sufficient details within the specified period.
- Comprehensiveness in terms of; scope of covering all relevant activities (including those of stakeholders) in the regulatory sector; resource mapping with estimates of the total amount of resources available from all sources; implementation schedule (quarterly/monthly) with major activities and responsible bodies for implementing each activity; monitoring

framework with key performance indicators, baseline data, annual targets, sources and mechanisms of collecting data; as well as reporting and feedback mechanisms.

5.4. Optimizing monitoring and evaluation system

The critical issues in optimizing the monitoring and evaluation system are strengthening the electronic regulatory information systems and addressing the issues of completeness and timeliness of data. Evaluation of the performance of FHRSTP II will be conducted at midterm and final implementation periods.

5.5. Risks and Mitigation

During the implementation of the plan, the sector may encounter risks that may hamper the achievement of results. In order to mitigate the major risks that the regulatory sector may face, mitigation strategies are identified. The following table summarizes the major expected risks and its mitigation strategies.

Table 11: Risks and mitigation strategies

S.N	Risks	Mitigation Strategy
1	COVID-19 and its effect on the regulatory system	EFDA will implement strategies that ensures the availability of safe and quality health products for the prevention and treatment COVID-19.
2	Inadequacy of financial resource (reduction of sudden donor fund)	The regulatory sector will focus more on domestic financing to fill the financial gap required during the FHRSTP II period. The following efforts will be done: <ul style="list-style-type: none"> - Implementation of food and health product regulatory financial sustainability strategy to mobilize adequate finance domestically - Strengthen public-private partnership
3	Weak inter-sectoral collaboration	The EFDA will work closely with line Ministries and Agencies to collaborate in addressing the challenges of food and health product regulation.

4	Food safety risks (risks arise from microbial agents, significant residuals from pesticides, toxic chemicals and due to mislabeling of products containing allergens)	EFDA will act according to the guideline for managing crisis and emergencies management.
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Chapter VI: Costing and Financing

The costing of regulatory activities was computed both by one health tool and by developing appropriate format in microsoft excel version 19 that can accommodate possible cost items.

6.1. Cost Estimation for strategic Directions

There are about 15 strategic directions in the medium term plan and each of them were costed based on the key activities that were accompanied under them.

The total cost estimation for FHRSDIP is about ETB 11.8 billion for 3 years. The food and health products regulatory sector has three financial sources: treasury, revenue and external sources.

6.1.1. Financial estimation from treasury

This is the budget estimation from the government for food and health products regulatory sector. The last years` experience and trend showed that the government was increasing the budget allocation to the food and health products regulatory sector. The allocation to regional regulatory bodies has been heterogeneous and depends on the current structure they are working in. The government is promising to allocate tax of hazardous products, like tobacco and alcohol to strengthen the food and health products regulatory sector. This will potentially improve the government shares of the costs, both recurrent and capital. It is difficult to estimate the exact estimation of the government budget as the heterogeneous commitments of regional governments to the food and health products regulatory sector.

6.1.2. Financial estimation from revenue

The food and health products regulatory sector has planned to rely on its revenue after the establishment of center of excellence. Currently, about 150 million Birr is being collected from the revenue (at the federal level) and there is no exact figure at the regional regulatory bodies, and will be boosted by expansion of lab services, establishments of training center and revising the amount of service fee.

6.1.3. Financial estimation from external sources

The external sources, mostly from donation, have been contributing to the achievement of hood and health products regulatory programs, and will take significant share in costing.

Table 12: The **medium term development and investment plan cost estimation of strategic directions (in millions of ETB)**

	Strategic Directions	Estimated cost (in millions of ETB)			
		2023/24	2024/25	2025/26	Total 3years
1.	Food Regulation	1,211.39	1,212.34	1,212.39	3,636.12
2.	Medicines	328.58	321.65	338.48	988.71
3.	Medical Devices	42.49	38.24	42.63	123.36
4.	Cosmetics	8.28	7.92	8.28	24.48
5.	Tobacco Regulation	200.89	199.09	200.89	600.87
6.	Quality Management System	89.82	107.78	129.34	326.94
7.	Good Governance	3.12	3.28	3.2	9.60
8.	Human Resource Development and Management	1,150.20	1,343.19	1,513.39	4,006.78
9.	Public Ownership	34.5	34.5	40	109.00
10.	Partnership and Collaboration	20.38	20.38	20.38	61.14
11.	Evidence Based decision making	7.31	3.34	7.07	17.72
12.	Formulation and Implementation of legal frameworks	2.33	1.88	4.68	8.89
13.	Health regulatory Infrastructure	1,477.54	292.94	144.69	1,915.17
14.	Efficiency and Effectiveness	4.19	4.61	5.07	13.87
	Grand Total	4,581.02	3,591.14	3,670.49	11,842.65

Chapter VII: Monitoring and Evaluation Plan

7.1. Monitoring and Evaluation System

Monitoring and Evaluation (M&E) system is an integral part of the FHRSDIP plan. Informed decision making is seriously compromised when decisions are not based on Monitoring and Evaluation system. The monitoring and evaluation system includes techniques and processes that continuously collect, analyze and interpret data for knowing the appropriateness of the activities under process and provide up to date information for responsible body necessary for taking corrective actions that help to reach the planned outcomes and objectives.

Conducting periodic monitoring and evaluation is imperative to track that activities lead to accomplishment of objectives and strategic directions targeted for the coming 3 years' regulatory sector transformation plan. Recognizing the status of implementation of the planned activities and their achievements from continuous collection and analyses of data that also indicate the trend, timely reinforcing support or corrective measures will be taken.

7.2. Indicators

A total of -- indicators are selected to monitor and evaluate the FHRSDIP. Impact, 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 3 years. Some indicators are analyzed on a monthly basis, others on a quarterly, annual, and 2-3 years

7.3. Transforming data into information and information into action: the data cycle

FHRSTP identified evidence-based decision-making as one of the strategic directions to transform use of information in decision making in the sector, including the M&E system. The cycle includes how data is gathered, analyzed, interpreted, reported, shared and used in decision-making. This section will describe the components of a data cycle. It highlights the current situation and indicates improvements to be made in the coming years.

7.3.1. Data Sources

Multiple data sources will be used in the M&E of FHRSDIP. The common data sources used to measure and inform FHRSDIP include:

Routine Regulatory information sources

This is data collected routinely to mainly measure progress on input, process, output and outcome related indicators regularly. Some of the data sources include electronic regulatory information system(E-RIS), Human resource information system, integrated financial management information system and administrative reports.

Non-Routine Regulatory information sources

As a non-routine data source, population based and food and pharmaceutical facility-based assessments and surveys will be used to monitor and evaluate the performance of FHRSDIP. Some of the non-routine data sources include: Population and Housing Census, Community satisfaction Indicator Survey, customer satisfaction survey, food and pharmaceutical facility-based assessments and EDHS etc.

7.3.2. Data quality

Data quality improvement is an ongoing process and it is an integral part of the M&E system of the FHRSTP II plan. Improving the quality of data for meaningful decision-making process will be a focus in this FHRSDIP. Interventions will be designed and implemented in order to tackle technical, organizational and behavioral factors affecting the quality of data. Improving data quality requires the effort of every actor in the Regulatory sector primarily every worker as well as the comprehensive implementation of techniques for improving data quality.

Reporting quality as measured by completeness (both content and representative), timeliness, reliability and validity will be enhanced through the continuous application of techniques such as visual scanning, consistency check via Lot quality assurance sampling (LQAS) techniques and food and pharmaceutical facility verification. Regular report reviews and feedback, desk review of data quality status, routine data quality assessment (RDQA) and food and pharmaceutical facility verification will be conducted. Moreover, planning experts and directors will be trained on data quality monitoring and improvement activities. The undergoing electronic regulatory data collection tools and reporting mechanism will play massive role in the endeavor to improving quality of data.

7.3.3. Data reporting

Information flow of the existing regulatory information system follows the “one report” principle of “one plan-one budget-one report” harmonization, meaning that all institutions and stakeholders report according to the standard reporting format based on the common set of indicators and within the same reporting calendar.

7.3.4. Use of information for action

Available information needs to be disseminated in a timely manner and used for strategic decision-making at all levels of the food and health products regulatory sector. Focus will be given on strengthening information culture, knowledge management and capacity to use information for action at all levels.

Improving data demand, information culture, knowledge management, learning and capacity to change data in to meaningful information and use of it for action will be priority at all levels. Synthesizing research and study findings and making insight for policy and strategy revision/formulation in a coordinated manner will be conducted. To systematically undertake follow-up on the decisions/action items from performance review meetings, reports and studies, a decision tracking matrix will be used. The data analysis, summarization, visualization and progress tracking will be augmented through the development and use of electronic tools.

Data use will predominantly be led by the performance monitoring team which will additionally guide and oversee other data use platforms such as directorate level data reviews, quality improvement processes, and other data use forums etc. Food and health products regulatory sector planning and periodic review meetings will continue to serve as the main

data use forums for decision. The major principles in information use culture among others will be engaging every employee, shifting from emotional to evidence-based decision.

7.4. Performance review

Regular and participatory performance review meetings will be undertaken quarterly, biannual and annual at all levels. In these meetings, stakeholders are brought together with organizations' staff to review performance and to determine actions needed to ensure achievement of the annual plan. The food and health products regulatory sector officials involved represent the implementing organizations for each level: EFDA gathers RRB managers and Planning experts in the biannual and annual Review Meeting (JSC); RRBs meet ZRD and WorRO. During these meetings, strengths and challenges will be reviewed and future plans will be agreed upon.

EFDA will conduct inspections and supportive supervision to verify activities undertaken at grass roots level. In addition to food and pharmaceutical facility verification of data quality, need driven inspections will be employed to verify the routine reports as well as to promote accountability, ensuring compliance with agreed performance standards and targets.

7.5. Evaluation

Evaluation of the FHRSDIP will be undertaken at mid-term (2022/23) and end-term (2025) to assess attainment of set objectives and targets. The mid-term evaluation will assess progress towards achievement of results and generate lessons learned, while the end-term will inform development of the subsequent strategic plan.

7.6. Dissemination and communication

Available information needs to be disseminated in a timely manner and used for strategic decision making at all levels of the food and health products regulatory sector. M&E findings will be disseminated to stakeholders using different channels. Monthly, quarterly, and annual reports will be produced. Quarterly, bi-annual and annual performance reports will be submitted to the relevant government bodies. M&E digests, food and health products regulatory bulletins and fact sheets will be produced as per established schedules

FDA will strengthen electronic outlets, such as the web site and social media, for dissemination of results. Furthermore, documentation of best practices and dissemination of results will also be promoted at the national and international level through conferences and publication of peer reviewed journals.

7.7. Details of Indicators and Targets of FHRSDIP Monitoring

Table 13: Indicators and Targets

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
General Objective 1: Protect the public from unsafe and poor-quality food								
GO1-1	Prevalence of unsafe food available in the market	Outcome	NA	15	25		15	Food inspection
General Objective 2: Safeguard the public from falsified, substandard and ineffective health related products								
GO2-1	Percentage of substandard medicine in the market	Outcome	6.9	5			5	Med inspection
GO2-2	Percentage of falsified medicines in the market	Outcome	NA	5		5		Med inspection
GO2-3	Prevalence of substandard medical devices in the market	Outcome	NA	10			10	MD inspection
GO2-4	Percentage of falsified medical devices in the market		NA	5		5		MD Inspection
GO2-5	Percentage of dispensing of prescription only medicines without prescription	Outcome	51.6	10	25		10	PVCT LEO
General Objective 3: Protect the public from tobacco and alcohol related health risks, and misuse of NPS								
GO3-1	Prevalence of tobacco use	outcome	5	3			3	Med inspection

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
GO3-2	Prevalence of alcohol use	Outcome	41	39			39	Med inspection
GO3-3	Percentage of good dispensing practice of NPS	Outcome	56.3	80		80		Med inspection
General Objective 4: Attain public confidence on food and health product regulation								
GO4-1	Percentage of community satisfaction on the regulatory sector	outcome	N/A	75			75	Strateci Affairs
GO4-2	Public trust score	outcome	NA	4.5	4		4.5	Reform
GO4-3	Transparency score	outcome	NA	9	8		9	Reform
Strategic direction 1: Strengthen food safety regulation								
SD1-1	Number of market authorized food products	output	6488	11,490	2630	2830	3030	Food regis
SD1-2	percentage local food facilities audit inspection coverage	output	87.3	100	90	95	100	Food inspection
SD1-3	Number of foreign on-site inspection conducted on selected food products manufacturing facilities	output	2	65	15	25	25	Food inspec
SD1-4	Coverage of food facilities implementing GMP/HACCP/FSMS requirements	output	35	70	40	45	50	Food inspe
SD1-5	Coverage of street vendor that implemented GHP	output	NA	50	10	20	20	Regions
SD1-6	Increase the coverage of mass catering service that implemented GHP & GCP	output	NA	50	10	20	20	Regions
SD1-7	Number of food product types tested via PMS laboratory	output	48	60	52	56	60	Food lab

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD1-8	Number of food product types for consignment laboratory tests	output	43	60	50	55	60	Food lab
Strategic direction 2: Strengthen detection, prevention, and response to food adulteration and illegal food products								
SD2-1	Prevalence of adulterated food available in the market	outcome	NA	24	44	36	24	Food lab
SD2-2	Number of illegal food products available in the market	outcome	91	36			36	Food inspe
SD2-3	Number of risk-based intelligence led food surveillance operation conducted and take administrative and/or legal measure	output	4	10	6	8	10	Surveillance
SD2-4	Number of risk-based market assessments and take administrative and/or legal measure	output	51	72	58	65	72	Food inspe
Strategic direction 3: Improve regulation of safety, efficacy, quality and proper use of medicines								
SD3-1	Number of registered medicines	output	3,644	7444	4844	6144	7444	Medicine regis
SD3-2	Approval of medicine with further request to MA in respective fiscal year	output	NA	60	60	60	60	Medicine regis
SD3-3	Public assessment report of registered medicines	output	80	80	80	80	80	Medicine regis
SD3-4	Number of registered traditional medicines	output	0	10	3	6	10	Medicine regis
SD3-5	Percentage of medicines tested through PMS	output	NA	55	30	50	55	Medicine lab

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD3-6	Inspection coverage of medicine importers and wholesalers	output	52.6	100	100	100	100	Branches and SA
SD3-7	Inspection coverage of medicine retail outlet	output	84	100	100	100	100	Regions
SD3-8	Percentage of medicine manufacturing facilities inspected against the applied for inspection per year	output	46	85	55	65	85	Medicine inspection
SD3-9	Percentage of medicines tested prior to distribution to the market (consignment tested)	output	28	55	40	46	55	Medicine lab
SD3-10	Number of ADR Reports received per year	Output	4354	11000	11000	11000	11000	PVCT
SD3-11	Number of AEFI reports received per year	output	9427	11000	11000	11000	11000	PVCT
SD3-12	Number of serious adverse event investigated per year	output	61	80	60	70	80	PVCT
SD3-13	Number of serious adverse event causality assessment conducted	output	40	190	46	50	54	PVCT
SD3-14	Signal detection	output	1	11	2	3	5	PVCT
SD3-15	Number of pharmacovigilance inspection conducted	output	0	10	2	3	5	PVCT
SD3-16	Number of clinical trial applications that get final decision per fiscal year	output	16	32	20	28	32	PVCT
SD3-17	Number of clinical trials inspected per fiscal year	output	8	30	10	22	30	PVCT
SD3-18	Evaluation of safety report for clinical trials per year	output	0	60		50	60	PVCT

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
Strategic direction 4: Strengthen Regulation of Safety, Quality and Performance of Medical Devices								
SD4-1	Number of registered medical devices (single and bundled)	Out Come	5420	8500	6220	7220	8500	MD regist
SD4-2	Number of types of medical devices consignment tested	Out put	4	10	6	8	10	MD lab
SD4-3	Number of types of medical devices subjected to PMQM	Out put	4	10	6	8	10	MD lab
SD4-4	Auditing Inspection coverage of licensed medical devices facilities (local manufacturers; importer and wholesaler)	Out put	99.3	100	100	100	100	MD inspection
SD4-5	Number of cGMP inspected overseas medical devices manufacturers per year	Out put	18	35	22	25	35	MD inspection
SD4-6	Number of adverse device events reports received per year	In put	14	56	25	45	56	MD inspect
SD4-7	Number of clinical trial/ investigation applications approved	output	3	20	7	13	20	MD inspect
SD4-8	Number of clinical trial GCP inspection	Out put	0	20	3	7	10	MD inspect
SD4-9	Types of medical devices checked for functionality at POE	Out put	0	3		1	2	Branches and SA
SD4-10	Number of FSCA notifications	In put	0	50		10	40	MD inspection
Strategic Direction 5: Improve regulation of safety of cosmetic products								

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD5-1	Number of issuances of notifications	output	1240	2440	300	400	500	PVCT
SD5-2	Percentage of suspected cosmetic products tested for safety	output	NA	100	100	100	100	PVCT
SD5-3	Percentage of inspection coverage of cosmetic establishments	output	30	60	40	50	60	PVCT
SD5-4	Number of cosmetics adverse events reports received per year	output	NA	1250	1250	1250	1250	PVCT
1. Strategic direction 6: Strengthen tobacco, alcohol and abuse NPS control system								
SD6-1	Evidence generated by GATS on the prevalence, exposure to Tobacco smoke, cessation, economic Impact and KAP of tobacco use	output	1	2	1			Med inspection
SD6-2	GYTS (13-15 years of age) and increasing the evidence generated by GYTS	output	1	3	1		1	Med inspection
SD6-3	Number of tobacco smoke free public places.	output	109000	174400	130800	152600	174400	Med inspection
SD6-4	Percentage of tobacco packs with the required 70% of pictorial health warning on legal tobacco products	output	100	100	100	100	100	Med inspection
SD6-5	Prevalence of illicit trade of tobacco	output	NA	15			15	Med inspection
SD6-6	percentage of Advertisement, Sponsorship, and Promotion (ASP) of alcohol	outcome	NA	25	15	20	25	Med inspection
SD6-7	Percentage of alcohol sale in prohibited areas	Output	NA	50	40	45	50	Med inspection

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD6-8	percentage abuse of NPS from NA to 5%	Output	NA	5			5	Med inspection
Strategic Direction 7: Enhance good-governance								
SD7-1	Food and health products regulatory sector customer satisfaction level	outcome	89	100	90	95	100	Reform
SD7-2	Percentage of reduced service delivery complaints	output	90	100	95	100	100	Reform
SD7-3	Percentage of regulatory services provided as per the standard	output	84	100	90	95	100	Reform
SD7-4	Percentage of of women in to leadership	output	25	35	28	31	35	Gender
SD7-5	Organization's gender technical capacity scale	output	1.98	2.5		2.5		Gender
Strategic Direction 8: Improve human resource development and management								
SD8-1	Employee satisfaction level	outcome	38%	70%	50	60	70	HR
SD8-2	Percentage of training effectiveness	outcome	71	85	75	80	85	HR
SD8-3	Employee attrition rate	outcome	1.6	1	1.4	1.2	1	HR
SD8-4	Organizational health status	outcome	42	60	48	54	60	HR
Strategic direction 9: Enhance partnership and collaboration								

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD9-1	Percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities	output	91	100	95	100	100	Strategic Affairs
SD9-2	Number of joint activities of regulatory function conducted with different stakeholders per year	outcome	9	9	9	9	9	Strategic Affairs
SD9-3	Number of strategic partnerships established with international, federal, and local organizations	output	2	6	4	5	6	Strategic Affairs
Strategic Direction 10: Improve efficiency and effectiveness								
SD10-1	Amount of resource mobilization (in million birr)	output	90	214	127	165	214	Strategic Affairs
SD10-2	percentage of cumulative wastage of resources (human, material, financial ...)	output	NA	5	10	8	5	Strategic Affairs
SD10-3	Medicine registration lead time in days	output	83	60	75	67	60	Med regis
SD10-4	Medicine consignment test lead time in days		44	44		44	44	Med lab
SD10-5	Average medicine recall time in days	Output	NA			15	15	
Strategic direction 11: Improve community ownership								
SD11-1	percentage of the population who are informed about regulatory measures, laws and activities	outcome	46	70	55	60	70	PR
SD11-2	Number of investigated tipoff, complaints and concerns from the public	output	9806	21082	10296	17000	21082	PR

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD11-3	Percentage of population whose age above 13-year-old, who got regulatory information through media outlet	output	54	75		75		PR
SD11-4	Number of the population who reached and took action to inform the regulatory about unsafe and illegal food and health product as a result of engagement.	output	16911	55585	17756	18602	19227	PR
Strategic Direction 12: Improve Evidence Based Decision Making								
SD12-1	Percentage of expected reports received from reporting units on time	output	79.6	95	85	90	95	Strategic Affairs
SD12-2	Percentage of expected reports received from reporting units complete	output	79.4	90	83	86	90	Audit
SD12-3	Number of performance audit reports	output	3	5	4	5	5	Strategic Affairs
SD12-4	Number of media monitoring and analysis	output	1	12	12	12	12	PR
Strategic Direction 13: Strengthen food and health products Regulatory Infrastructures								
SD13-1	number of established, and well equipped and furnished center of food and health products regulatory excellence	output	0	1			1	Strategic Affairs
SD13-2	Increase well established national rapid alert system	output	1	2	1			ICT
SD13-3	number of regional regulatory bodies that implemented COC system for retail out let	output	0	12	4	4	4	ICT

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
SD13-4	Number of automated systems implemented	output	6	19	6	8	5	ICT
SD13-5	frequency of Audit and Validate the authority System	output	1	3	1	2		ICT
SD13-6	Increase the number of Integration of eRIS with other system	output	1	3	1	1		ICT
Strategic direction 14: Improve Quality Management System								
SD14-1	Maturity level 3 or WHO listed authorities certification attained (maturity level 2 to level 3)	output	2	3	3			QMS
SD14-2	Attained ISO/IEC 27001 accreditation of EFDA information security management system	output	0	1		1		QMS
SD14-3	Number of ISO/IEC 17025/2017 accredited EFDA's laboratories	output	3	5	1		1	QMS
SD14-4	Number of EFDA laboratories WHO prequalified	output	0	1	1			QMS
SD14-5	ISO 9001 certification of EFDA HQ attained	output	0	1		1		QMS
SD14-6	Scope of ISO/IEC 17025/2017 accredited test parameters of EFDA laboratories from 31 to 59 (food from 11 to 16, medicine from 11 to 16, medical device from 9 to 27)	output	31	59	9	9	10	QMS
SD14-7	Number of accredited EFDA inspection directorates (HQ and branches) for ISO 17020/ 2012	output	1	4	1	1	1	QMS

S/NO	Indicator	Indicator type	Baseline	target	Indicator Target Values			Responsible
					2023/24	2024/25	2025/26	
Strategic direction 15: Strengthen Formulation and implementation of legal frameworks								
SD15-1	Number of legislations on regulated products	output	120	170	10	20	20	Legal
SD15-2	Number of criminal cases instituted and follow-up made until decision is rendered by the court	output	48	195	60	65	70	Legal
SD15-3	Percentage of civil cases decided in favor of the regulatory	output	75	95	85	90	95	Legal
SD15-4	Percentage of Administrative measure taken against non-compliance	output	95	99	99	99	99	Legal
SD15-5	The impact of legislation on public health protection	outcome	NA	70		70		Legal