Ethiopian Food and Drug Authority (EFDA)

Food and Health Products Regulatory Sector Transformation Plan II

FHRSTP-II

2020/21-2024/25

Addis Ababa, Ethiopia

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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	Europian Union
FAO	Food and Agricultural Organization
FCTC	Framework Conversion on Tobacco Control
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 marketting 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

Ethiopia is engaged in a rapid and comprehensive development schemes to transition from poverty to sustainable and reliable growth and prosperity. The Government has therefore invested heavily in health system strengthening guided by its pro-poor policies and strategies, in the past two decades, 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 plans 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 burden coupled with the 2020 COVID 19 pandemic, led the country to ever increasing demand and urged the Government to be increasingly focused on addressing communicable diseases like HIV/AIDS, TB, malaria, respiratory infection, and diarrhea which are still the serious challenges, besides the COVID 19 prevention and control. With a growing middle class, we are facing an increase in non-infectious diseases such as cancer, diabetes, heart diseases, high blood pressure, mental health and eye problems.

Under the Health System Transformation Plan following the second Growth and Transformation Plan (GTP II), the MOH is implementing changes to various aspects of the healthcare system. The 2020 impact-level targets for the Health System Transformation Plan (HSTP) are to: - reduce infant and neonatal mortality rates; decrease HIV contraction and achieve zero new infections among children; lessen the number of TB deaths and incidence; diminish malaria case incidence and mortality rate. It has also set targets to stabilize and reduce deaths and injuries from road traffic accidents, which are significantly high.

The area of importance to the ministry has been leading the transformation of agencies such as the Ethiopian Food and Drug Administration (EFDA) and the Pharmaceutical Supply Agency (PSA). Both Agency being strengthened through close follow up and monitoring of the Ministry's Executive Committee to provide increased regulatory oversight with the responsibility of promoting and protecting public health by ensuring the safety and quality of health products and working on the public procurement of pharmaceuticals, medical supplies, and equipment, which have predominantly been registered by EFDA, respectively.

With all the commitment of the leadership and the health programs workers, I am confident that the outcomes of the HSTP II and FHRSTP II will herald tremendous successes and achievements to our government and the population at large.

Lia Tadesse (Dr.)

Minister, Ministry of Health

Foreward by Director General

Safe, effective, and quality assured health products are instrumental 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. 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 to take the responsibility of ensuring the safety and efficacy of medicines and medical products and ensuring safety of food through implementation of enforceable legislation, regulations, guidelines, and operational procedures.

As a Director General of EFDA, I am proud to highlight the key achievements of the HRSTP I in the last few years and the highlights of the FHRSTP II. The Authority has developed a comprehensive proclamation that would successfully lead the interventions in the system to sufficiently protect the public from risks associated with Food, medicines, medical devices, alcohol consumption and tobacco use and also developed related directives and new guideless paving the way for implementation of regulation and registration of new products like vaccines and biological products for the domestic market. EFDA has been restructuring itself since 2018 and all the federal and branch offices have been restructured with the related ports of entries.

It has also increased the capacity of regulators to use quality information on medical products for decision-making, digitizing the importation and registration of health commodities to Ethiopia using the online application systems like i-register for application of market authorization and product registration and i-import for importers to apply for import of health commodities, implemented Risk-Based Post-Marketing Quality Surveillance with focuses on food products that present the greatest risks to public health and substandard and falsified medical products across the country, implemented medicines strategy leading to fast track registration and market authorization for essential medicines. We have recently been registering protective devices for prevention of COVID 19 and currently working on the preliminary requirements and application of COVID 19 vaccine. These have been supported with good governance principles throughout our quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health.

Some of our immediate priorities include: - Playing our regulatory part in the provision of COVID 19 vaccine starting with the vulnerable groups of the society; Strengthening the capacity of food and

medicines Laboratories in analytical quality control methods; sustainably improve the Registration, inspection, and licensing functions of food and medicines and reducing the prevalence of unsafe food available in the market, prevalence of illegal food products, food adulteration prevalence in the market; increasing evidence-based decision-making; supporting the Multispectral Coordination Group, which is the primary AMR governance body to the Ministry of Health's (MOH); providing response to medical device reports of suspected device-associated serious injuries and malfunctions, reported by manufacturers, device user facilities, and importers; Using Mobile Technologies to Detect Poor-Quality Medicines and to screen suspicious pharmaceuticals in the country's commodity pipeline including substandard, falsified, unregistered medical products.

We believe that the successful implementation of this FHRSTP II will help us achieve the desire of our population of getting quality ensured food and medicines in the markets to come. Therefore, I call up on our people, health professionals, civil societies, development partners and all stakeholders to put a coordinated effort to realize the FHRSTP II goals. 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 meet our FHRSTP II goals and targets.

Heran Gerba

Director General, Ethiopian Food and drug Authority

Executive Summary

This is the second Food and Health products Regulatory Sector Transformation Plan (FHRSTP-II) covering the period between July 2020 and June 2025. It has been developed as the first 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 HRSTP-I and takes into consideration the country`s development plan and the health sector long term priorities and strategies in consideration.

During HRSTP-I (July 2015 – June 2020) significant achievements were made despite ongoing 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 HRSTP-I period was marked by encouraging improvements in Sustaining medicine lab accreditation and efforts to get WHO prequalification, Deployment 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 proclamation number 1112/2019, which enabled the reform of health regulatory sector to product based (food and drug) regulation.

This FHRSTP-II is developed based on the current 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 on the successes of the HRSTP –I period, and taking into its stride the lessons from its implementation.

An inclusive and active participatory process was adopted for the development of FHRSTP-II. This included iterative process 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 FHRSTP-II are: protecting the public from unsafe food; falsified, substandard and ineffective health related products; tobacco and alcohol related health risks and 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 their major 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 and alcohol 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 Food and health products regulatory infrastructures
- Improve quality management system
- Improve formulation and implementation of legal frameworks

FHRSTP-II 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, 18.12 billion ETB is required for five 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 designed 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 Millennium Development Goals (MDGs) earlier from the designated target years, and the first growth and transformation plan.

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 health regulatory sector transformation plan (HRSTP-I) 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 has brought in the regulatory sector. These achievements were brought due to the different high initiatives and strategies implemented through flagship programs, multisectoral collaboration, and community mobilization. Similarly, the key challenges and bottlenecks were identified through periodical and planned evaluations. The COVID-19 pandemic has caused an important impediment on the performance of HRSTP-I.

This strategic plan is developed based on the current reform taken place in the health regulatory sector to protect the public from health risks due to substandard and poor-quality food and health products.

The second Food and Health products regulatory sector transformation plan (FHRSTP-II) is the next five-year national food and health products sector strategic plan, which covers the period between 2013-2017 Ethiopian fiscal years (July 2020 – June 2025). 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 performance of HRSTP-I. This transformation 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 of food and health products regulatory sector. The identified long-term goals /objectives have passed series of consultations with the private sector (food and health products manufacturers, importers and whole sales), academia, professional associations, other government sectors and development partners. The feedback received from these consultations and reviews have been carefully incorporated.

The objectives and strategic directions were developed based on the situational analysis of the HRSTP-I and the baseline and targets were set based on recent surveys and in consultations with respective functions. The costing was developed using one health tool and excel-version-19.

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 6 describes 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 30oN and 150oN Latitude and 330o E and 480o 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: Performance of the Food and Health Products Regulatory Sector Transformation Plan I (FHRSTP I) – Situational Assessment

The HRSTP-I has depicted what the regulatory sector was intended to achieve by the year 2019/20. As the execution period has ended, the performance review and the identifying the achievements, failures and lessons learned throughout the implementation periods is vital and has paramount importance to indicate strengths and weaknesses, and to put as a basis for the next 5 years plan. The flow of the situational analysis report is organized as per the HRSTP-I plan organization, the structure has twelve strategic objectives.

3.1. Improve the satisfaction level of the community on health regulation

According to the 2017 National Community satisfaction level on health regulatory Service assessment, 48% of the population was satisfied with the availability of safe and quality medicine in the market. Seven out of ten (70%) were satisfied while experienced buying medicine from pharmacy, drug vendor, health center and drug store and also 75 % were satisfied with information of counseling given during dispensing. More over result of the survey showed only 53% of them were satisfied with the efficacy of medicine found in the market.

Results of the same study showed that satisfaction on the availability of safe and quality food items (commonly consumed) in the market ranged from 27 % to 65 % (i.e., for biscuits (65%), soft drink (62%), bottled water (61%) and edible oil (52%). Least satisfaction was found with infant formula and supplementary food (27%), juice (33%) and milk (37%). Over all the study results with its limitation showed that most of the key findings of the community satisfaction level by different areas of regulation are low from expected plan 70%, therefore, using these key findings at different level of the regulatory sector is crucial for planning & interventions

3.2.Improve public ownership

Improving Community Ownership was taken as one of strategic objectives to create community awareness on health regulation and, empower them and, be able to protect their own health from unsafe food and health products. It was planned that 50 % of the population would be aware on the legal frameworks of the health regulation, but an assessment conducted in 2017 on community satisfaction showed that only 46% of the population were aware on legal frameworks of the health regulation. The result also revealed that, even though the regulatory sector has made a great effort to provide regulatory

information on food and health products through different electronics, print and social media to the community, there is still a lot remain to work. In addition, the community that has been aware on legal frameworks, was expected to provide information and tips off to the regulatory body on illegal food and health product trade and other issues but the community satisfaction survey showed that only 19% of the population has given information and tip off to the regulatory body about illegal trade and other issues.

The other important target of this strategic objective was to create 35 model public wing bodies to improve the public ownership on the health regulation but, only 13 public wing bodies has got recognition. The result indicated that the performance was unsatisfactory due to some challenges such as insufficient commitment of regional health regulatory bodies and, lack of awareness and poor capacity of public wings.

3.3. Improve efficiency and effectiveness

EFDA has been allocating resources properly to improve efficient utilization, and tracking and controlling of resources. It has been involving stakeholders and mitigate dual efforts in resource allocation and implement effective procurement and financial management systems in place. However, the EFDA grant management system was not IT supported and has limited the expediting of financial utilization system as well as ensures the justified resource allocation among core activities, programs and regions have been also considered in the plan.

As the figure below revealed, the trend of financial absorption capacity was 70.14% in 2018/19 and 85.33% in 2019/20, which has shown a great improvement compared with 57.86% absorption capacity in 2017/18. Significant improvements have been observed in liquidation of treasury budget. The close follows ups, supervisions and ad hoc evaluation meetings on grant liquidations held by the management bodies and deploying of new financial management systems, like IFMIS has improved in treasury budget liquidation. The grant management system EFDA has implemented, especially the budgets follow up disbursed to regions in collaboration with branch offices has been successful both in budget liquidation and bringing the required results.

The resources allocated to programs were made logically and on the common consensus among departments. It has focused on the core functions which had direct impact on the health of the public. The improvements in resource absorptive capacity have decreased wastage of resources significantly.

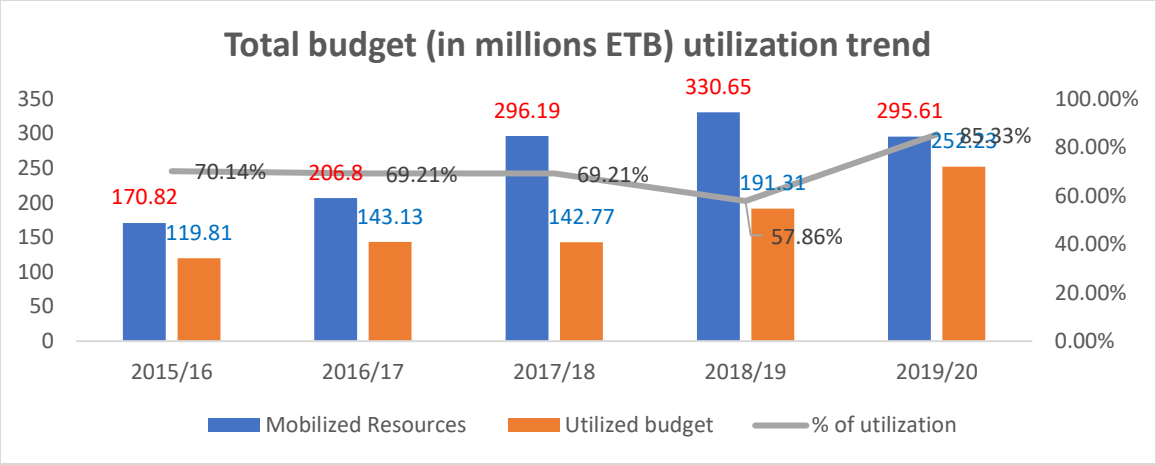


Figure 1: budget utilization trend

3.4. Improve quality and safety regulation of food

3.4.1. Food registration and market Authorization

Increasing access to safe and quality food was one of the transformation agendas of HRSTP-I. Efforts were undertaken to increase availability of registered and market authorized food items on the market. During the last five years, a total of 1998 (which was 0 in the baseline) food items were registered, that includes: infant formula, dietary supplements, water treatment tabs & equipment and other selected food items based on their risks. (As shown in the figure – 2)

In addition, different strategic documents and electronic registration system have been developed to expedite the registration and licensing system of the selected food items.

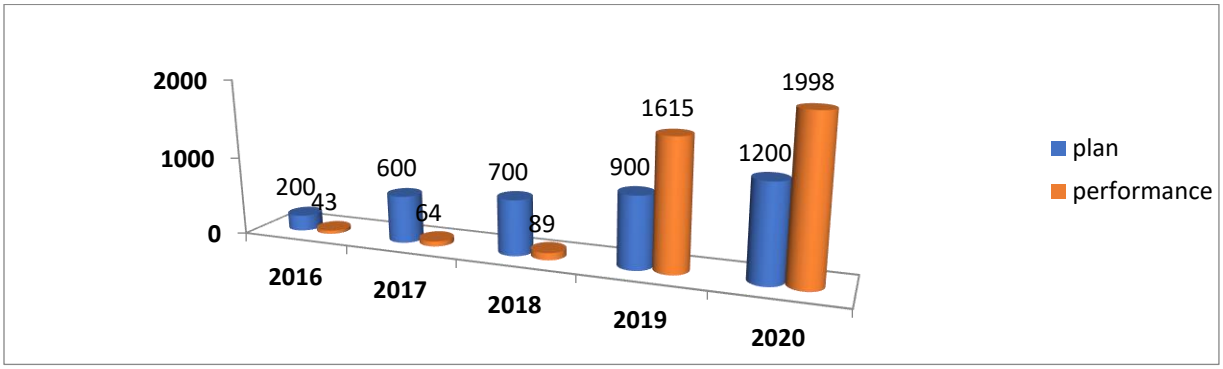


Figure 2: Number of registered foods from 2016/17 – 2019 /20

(Source: from EFMHACA annual report (2008 -2012 EFY)

However, several challenges remain, among the major challenges are: low willingness to register food both by importers and local manufacturers, presence of foods that do not have national standard, weak

connection with other foreign country regulatory bodies and international organizations like CODEX, ISO, WHO, FAO and others, and also lack of easy access to information about registered foods.

3.4.2. Food inspection and enforcement

3.1.2.1 Food facilities inspection and internal quality management system

Inspection is one of the components in regulation system of food to ensure its safety. By the end of five year the coverage of national inspection for food facilities was 70 %, which was 60% compared to HSTP-I. These food facilities have been inspected at least yearly bases and /or twice a year.

With the need to shift from routine inspection to auditing inspection services, some initiatives were carried out during HRSTP-I. These initiatives include implementation of internal quality management system and risk-based inspection. In this regard the IQMS implementing food facilities have been increased from 0 % to 36 %.

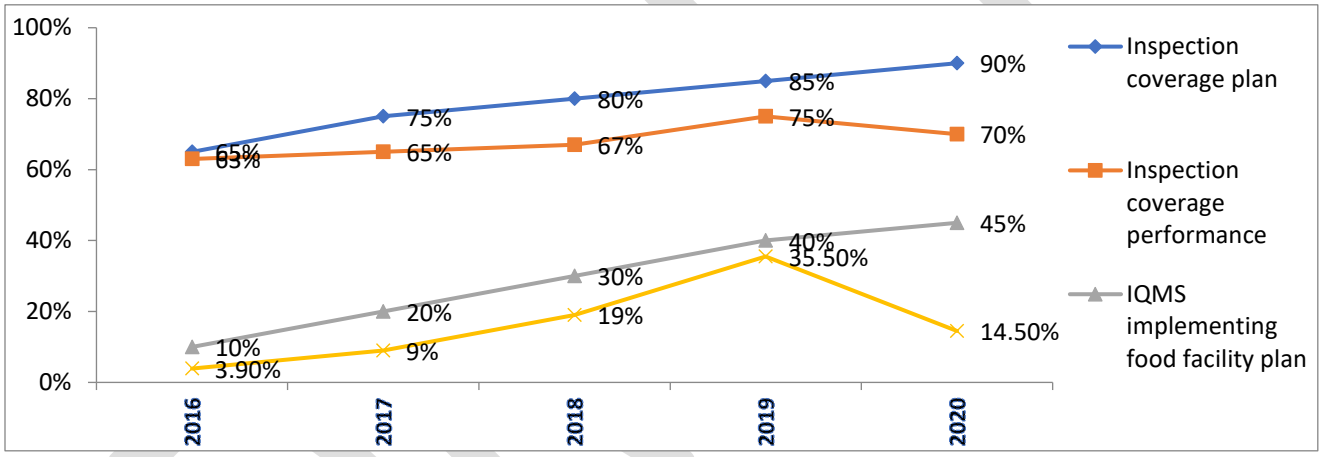


Figure 3: **Status of Food facilities inspection coverage and internal quality management system from 2015/16 – 2019/20**

(Source: EFMHACA annual report (2008 -2012 EFY)

In addition, development of risk based internal quality management guidelines and revision of food licensing directive was carried out based on capacity such as Small, medium and large scale and- pre- and post-inspection and licensing for food manufacturing facilities.

In the case of controlling illegal food trade and food adulteration in the market, two approaches were used; market assessment and surveillance, and intelligence-based operations in collaboration with stake holders like regional health regulatory body, code enforcement and police on selected food items like candies, edible oil, injera, red pepper, butter, honey and others. 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.

Though, several efforts have been exerted to strengthen inspection and enforcement, there are persisted gaps in governing the regulation. Among the major gaps are: absence of updated national central data based system for food institution based on their capacity and product nature and low usage of modern technology for inspection at facilities, market and at the port of entry , increasing issue of intentional food adulteration and loosen enforcement laws implementation, interference and conflict of interest, inadequate skilled, experienced and well equipped (onsite verification kits) experts on food quality and safety regulation at federal and regional levels and low awareness of the community towards regulation of food, and loose integration and collaboration amongst different sectors are areas that need to be act up on.

3.1.2.2 Food product and raw material inspection at port of entry

One of the major activities in the food regulation and enforcement is inspection of food products and raw material inspection at port of entry for imported food products and raw material.

During the last five years food items that inspected and allowed to enter to the country 19,619,244.31 in tons

In addition, a total of 2,146,104.98 imported food raw materials are being inspected allowed to enter.

Some of the major challenges are: - inadequate skilled, experienced and well equipped (onsite verification kits) experts on food quality and safety regulation at all entry and exit port, Due to the fast-going technology of food industry and production of new food products are coming to our country our inspectors are not capable of inspecting these products, inadequate infra structure and absence of health regulatory where custom control practiced.

3.4.3. Administrative measures taken

After inspection conducted at food facilities, in the market and at port of entry administrative measures have been taken based on the finding of inspection which violates the regulatory and statutory requirements.

3.4.3.1.Administrative measures taken on food facilities

In the last five year after food facility inspection has been conducted 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	70	42	659
2	Suspension	110	74	129
3	Revocation/ cancellation	11	34	-
4	Recall	6	11	-

(Source: from EFMHACA annual report 2008 -2012 EFY)

3.4.3.2.Administrative measures taken on Food products

In the last five year after market assessment, surveillance, inspection at port of entry and local food institutions administrative measures were taken on the following products which are substandard, expired, mislabeled, damaged, adulterated and illegal;

Table 2: Administrative measures taken on Food products

No	Food items	Amount disposed
1	Edible oil	180,788.8L
2	Rice	246.78 tones
3	Wheat flour	2788.55tones
4	Decorticated peas	74.14 tones
5	Sugar	4533.53 tones
6	Juice	19,710.1 tones
7	Food raw material	758.48 tones
8	Other food items	1705.6 tones

(Source: from EFMHACA annual report (2008 -2012 EFY)

3.4.4. Food laboratory testing

Food consignment and post marketing surveillance are two major strategic initiatives which are used to assure the quality and safety of food products imported, locally produced and available on the market. Food items covered under both initiatives are selected based on their food safety risk considering the nature, perish-ability, mass consumption, end user of the product and others criteria. The food items were covered both under PMS and Consignment are Edible oil and salt, powdered and pasteurized milk, peanut butter, packed juice, vegetables, raw and canned fish, rice, child food,

Ketchup, water and others. Based on these 28 and 31 food items have been covered under consignment and PMS respectively.

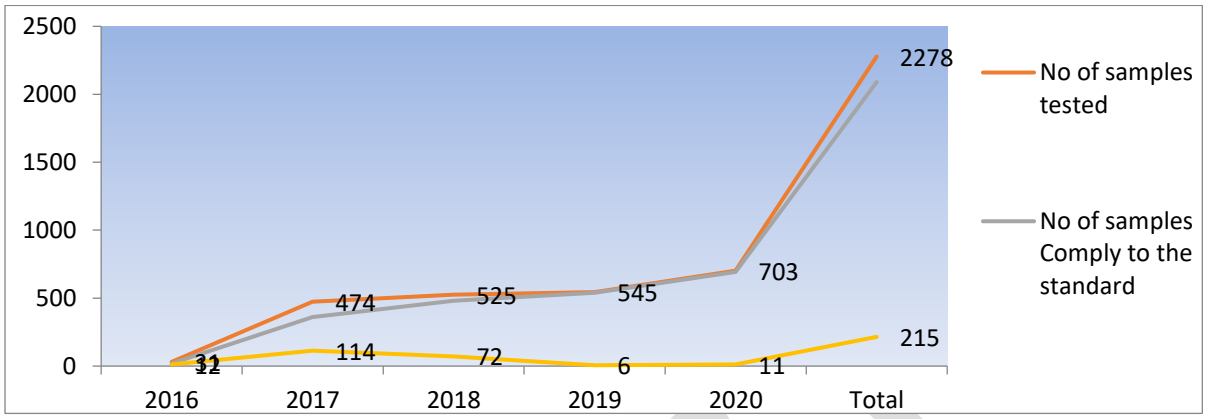
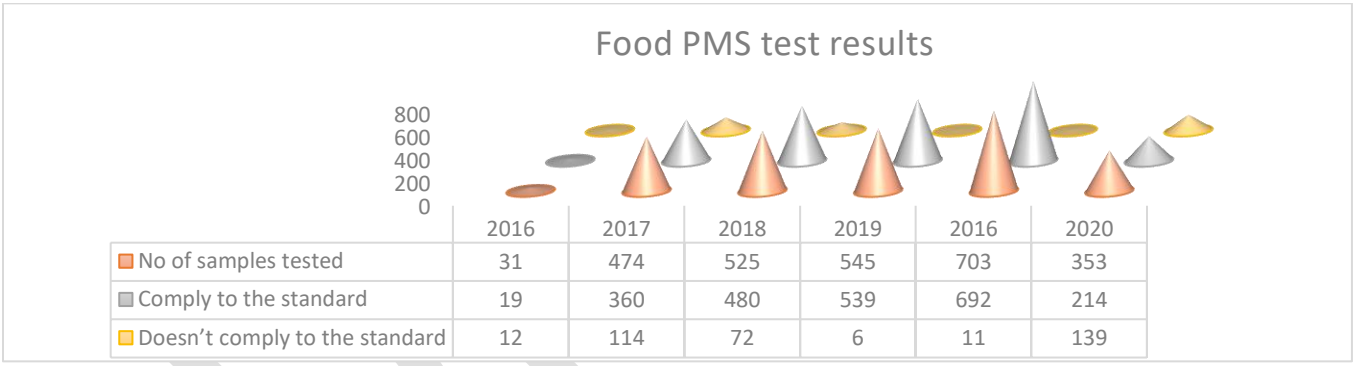


Figure 4: Food consignment test results
(***Source: from EFDA annual report (2008 -2012 EFY)***

The five-year performance showed that consignment test was 100 % and in case of PMS 87 % was achieved through strengthening the current EFDA food quality and safety laboratory and using locally available governmental and private laboratories.



	2016	2017	2018	2019	2016	2020
No of samples tested	31	474	525	545	703	353
Comply to the standard	19	360	480	539	692	214
Doesn't comply to the standard	12	114	72	6	11	139

Figure 5: Food PMS test results
(***Source: from EFDA annual report (2008 -2012 EFY)***

In addition to consignment and PMS, tests have been performed on suspected food products like edible oil, salt, alcohol, peanut butter, infant formula, packed juice, butter, honey, soft drinks and others. These suspected products are very low in number compared to the food safety issues that exist in the country.

Table 3: Suspected food products laboratory test results

Year	Suspected food items	Complies to the standard	Doesn't comply to the standard
2016	70	36	34
2017	98	26	72
2018	70	22	48
2019	127	90	37
2020	306	144	162

(Source: EFDA Annual plan report (2008 -2012 EFY)

Apart from the achievement's history made in the HRSTP- I the following are major challenges includes: limitation in addressing food safety chemical hazards like pesticide and veterinary drug residue, PCB's (polychlorinated biphenyls) food contact material testing due to lack of well-trained expertise, high-tech equipment's, reference standards and certified reference materials. Moreover, problem aroused from food adulteration and delay of laboratory test results need to be executed.

3.5. Improve Regulation of Health Products

3.5.1. 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 zero backlog was one of the main flagship initiatives during the last five-years. 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 medicine registration system (eRIS). These resulted in reducing backlogs, reducing lead-time for registration, helped the authority to focus on areas that pose greater health risk to the public and ultimately reducing poor and unsafe medicines from the market.

In 2014/2015, the numbers of registered medicines in the country were only 1375 and the Authority planned to register 5,000 medicines in the year 2015/2016-2019/2020. At the end of the fifth year, 3,981 (79.6%) new medicines were registered (Figure 6). Compared to 2014/15, significant achievements have been gained in registration of medicines. The improved access to medicines that comply standards in the market protected the public from health risks resulted from poor quality and unsafe medicines.

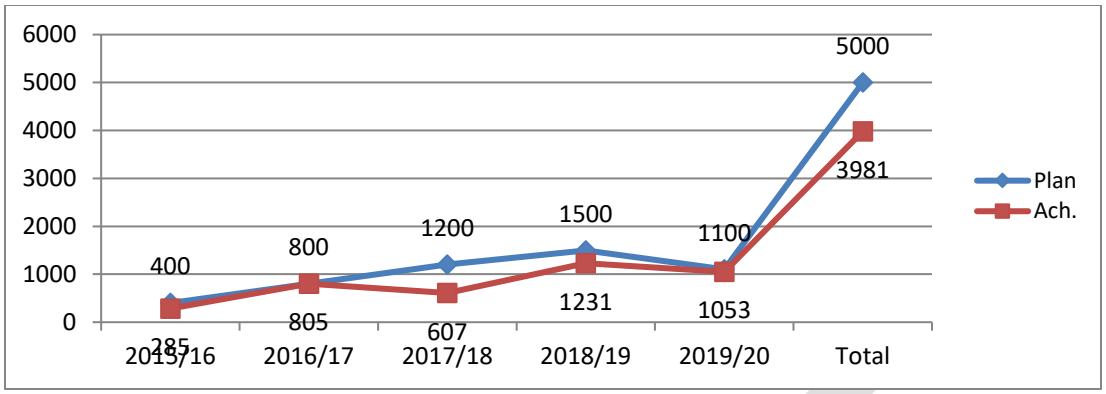


Figure 6: Number of registered medicines in Ethiopia, 2015/16-2019/20

However, limited capacity, number and mix of human resource, 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. There were also gaps in evaluation of biologics, biosimilars and traditional medicines. Furthermore, risk-based classification of products for registration, and collaboration and harmonization with other countries and regions need to be strengthened.

3.5.2. 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. The Authority adapted medical devices marketing authorization strategies and aligned its registration requirements with international practices. The Authority has implemented fast-track registration approach for critical public health concerns such as condom, HIV RDT's, malaria RDT's and etc., SRA procedures for dossier assessment, and WHO collaborative approach. These procedures were automated using electronic medical device registration system. These resulted in reducing lead-time for registration and reducing availability of poor quality and unsafe medical devices from the market. Though there were no clear strategic targets set in the five-year strategic plan, the Authority registered 4527 medical devices in the years 2015/16 to 2019/20 **(Figure 7).**

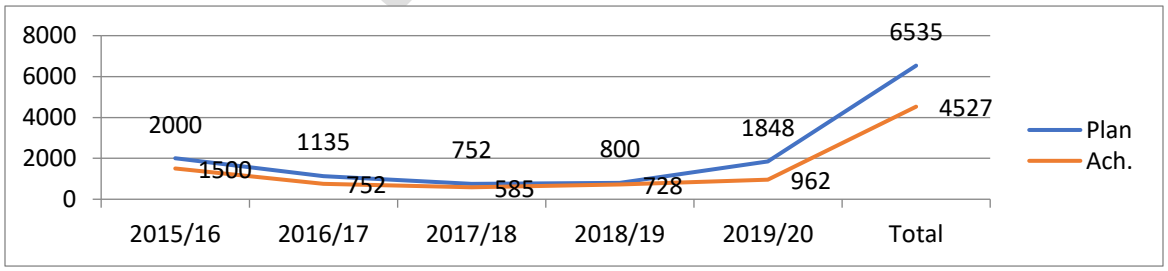


Figure 7: Number of registered medical devices in Ethiopia, 2015/16-2019/20

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.

3.5.3. 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 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 8)**. 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 9)**. 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 are 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.

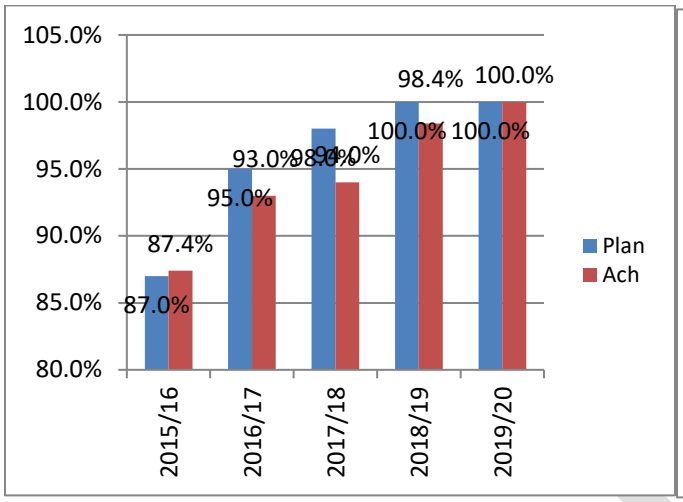


Figure 8: Inspection coverage of medical products manufacturers, importers and wholesaler, 2015/16-2019/20

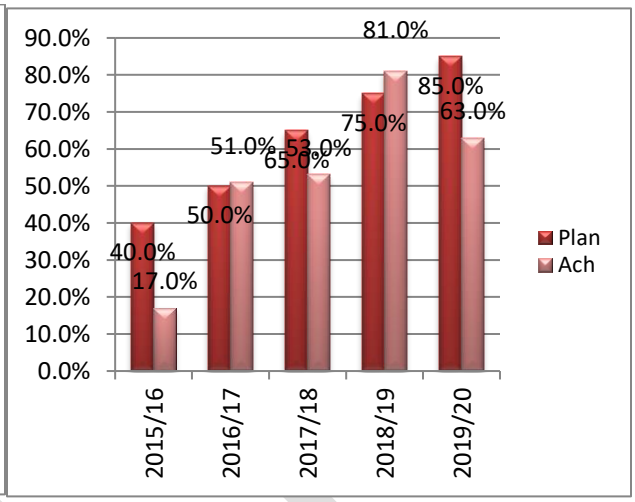


Figure 9: Number of medical products manufacturers, Importers and suppliers that implement quality assurance, 2015/16-2019/20

Cosmetic products are currently one of the most popular consumer products used by all people, of all age. 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 controlling through licensing. 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 distributers 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 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.

3.5.4. 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. The physicochemical unit is under the process of WHO pre-qualification. Currently physicochemical, physical and microbiological quality control tests are conducted for medicines, condoms, 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 10).**

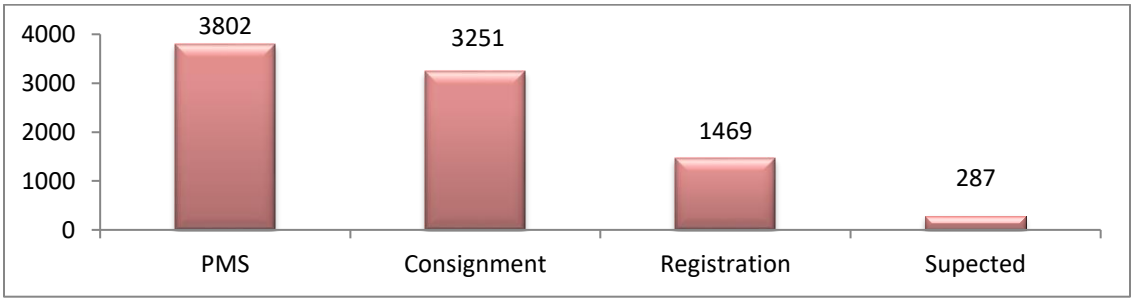


Figure 10: Number of samples tested (2015/16 - 2019/20) by physicochemical, condom and microbiology units.

According to the HRSTP I (2015/16 - 2019/20), the Authority has planned to test 25% of health products arriving at the port of entry (consignment samples) and 55 % of health products (by type) from the market (PMS samples). At the end of the fourth year, 19.3% consignments samples were tested (96.5% of the plan) and 48.6% of health products of PMS were tested (97.2% of the plan). Consignment and PMS testing coverage at the beginning of the HRSTP-I were 3.4% and 3% respectively (Figure 11).

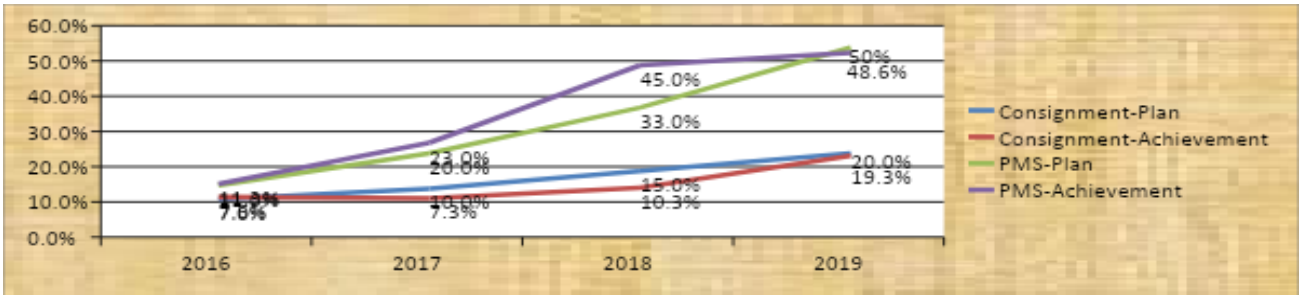


Figure 11: Comparison of the plan and achievement for Consignment and PMS sample testing (2015/16 - 2018/19).

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 2015/16 -2018/19.

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 and proper maintenance problems (especially HPLCs); 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.

Hence, expanding scope (test parameters) of QC testing and starting new testing parameters including testing for impurities (related substances); biological products, traditional medicine and cosmetic products; expanding testing of medical device need improvements.

3.5.5. 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 5000 healthcare professionals, necessary tools necessary such as ADE 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 of roadmap, development of electronic reporting and mobile application, carry out investigations on serious adverse drug events, performing of causality assessment, active surveillance on ART medicines, safety monitoring of MDR-TB medicines and anti-helminthic in mass drug administration (MDA) programs were performed during this period. Besides this, training, assessment and supportive supervision to strengthen Adverse Event Following Immunization (AEFI) have been performed.

However, the number of reports received were increased from 411 in 2014/15 to 2096 in 2019/20 which is very low as compared to the standards (Figure 12). 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.

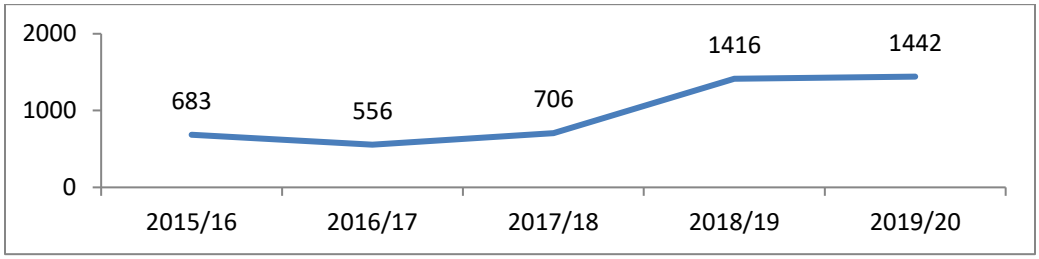


Figure 12: Number of adverse drug events (ADE) received, 2015/16 -2019/20.

Poor knowledge and attitude regarding the importance of pharmacovigilance, poor level of awareness of electronic reporting, weak collaboration between public health programs**,** structural arrangement, and low number of staff at the PV center were the main challenges observed.

3.5.6. 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 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.

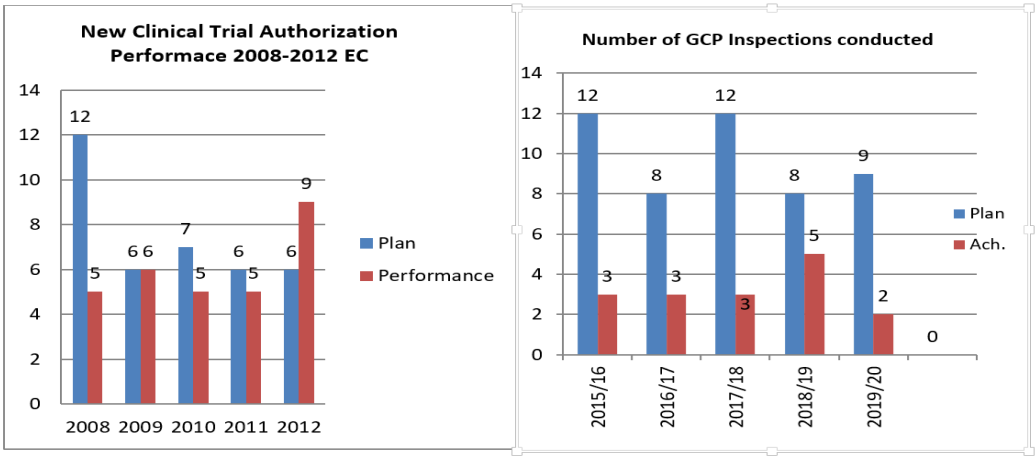


Figure 13: Performance of clinical trial authorization and GCP inspection

3.6. Improve Tobacco Regulation

Tobacco Regulation is a multi-sectoral issue, and EFDA's role is coordination of different stakeholders through a National Tobacco Steering committee. The government of Ethiopia has been committed to protect the public health by strongly regulating tobacco products. Comprehensive system, and appropriate and strong legal frame work has been introduced in this regard. As part of the HRSTP, it was expected that 75% public places would be tobacco smoke free. Despite the encouraging performances have been made, the percentage of tobacco smoke free public places in 2019/20 was 45% as compared to the plan 75%.

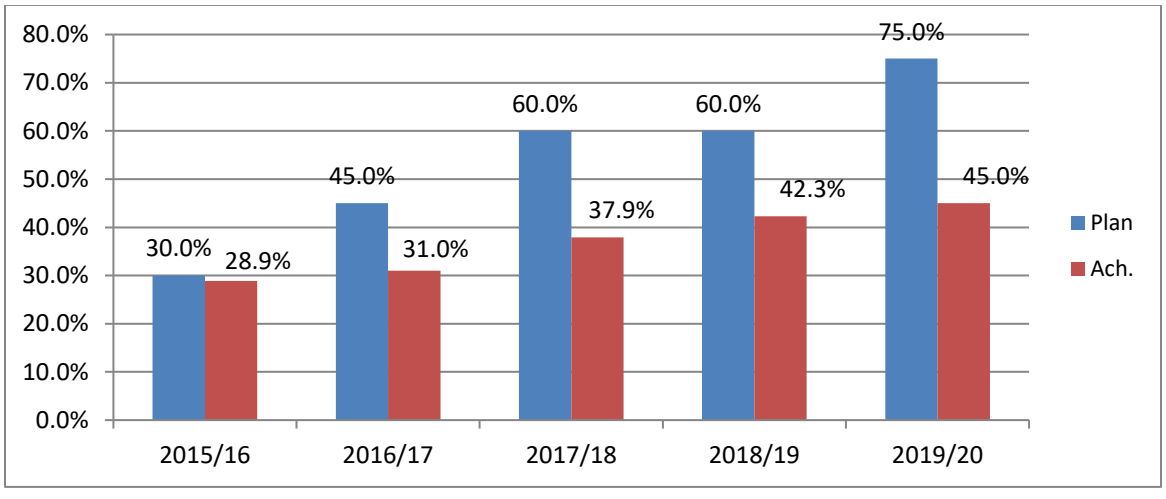


Figure 14: Percentage of tobacco smoke free public places in Ethiopia

3.7. Improve partnership, and engagement of community and stakeholders

A health regulation without the participation and engagement of the community and other stakeholders could not be effective and sustainable. Therefore, this objective was formulated to ensure the participation and engagement of community and other stakeholders in planning, implementation, monitoring and evaluation of health regulation.

To participate and engage the key stakeholders on health regulatory activities, it was planned that to create 100% integrated system with relevant stakeholders to improve their participation and engagement and improve the regulatory operation efficiency. The performance was found to be 100%. In addition, it was also planned to increase the participation and engagement of stakeholders on planning, implementation and evaluation of Health regulatory activities from 59% to 100%, and the performance was found to be 100%. This shows that, all the relevant key stakeholders were being fully participated on planning, implementation and evaluation of the regulatory activities. Some of the achievements were: - a joint inspection was conducted with different stakeholders; an integrated system has been created with five neighboring countries on illegal food and medicine trade; and a joint inspection and surveillance was done with INTERPOL, Customs, Federal Police, TCCPA and regional regulatory bodies. Not engaging all stakeholders equally was the major gap identified in the implementation period.

The other performance measure for this strategic objective was to implement health regulatory operations at 50% of health development army structures in the country and the performance was found to be 98%. In addition, it was planned to aware 80% of the public on regulatory laws and operations through different awareness creation discussions (events, electronics, print and social media) and the performance was found to be 77.9%.

3.8.Improve human resource development and administration system

Improving human resource development and administration system was one of the strategic objectives to have a regulatory work force equipped with the necessary knowledge, skill and attitude. The main focus of this strategic objective was providing short- and long-term trainings to build the capacity of regulatory work force**,** implement different motivational schemes and Create favorable work environment and minimize attrition rate.

One of the performance measures for this strategic objective was to increase the percentage of model regulatory worker force with regulatory competency and ethics from 8% to 50% and the performance was found to be 39.2%, and that seems good. Some of the achievements were: - the regulatory science master program has been started in collaboration with Addis Ababa University and more than 23 professionals are currently learning health regulatory science in master program; more than 34 regulatory work forces has joined master program in different higher education universities in different disciplines; and based on the identified gap, various short term capacity building training has been given to fill the gap on skills, knowledge and attitude within and outside the organization.

The other performance measure for this strategic objective was to increase the percentage of women's decision-making positions to 40%, and the performance showed that women has got 37 % of decision-making positions in the Ethiopian food and medicine authority which was a good achievement. It was also targeted to increase the motivation schemes for the regulatory work force at all levels from 4 to 15, and the motivation schemes was only increased to 7 which is 47% from the plan. The reason behind the low performance was due to the government direction that some motivation schemes were not allowed to implement as a scheme in the organization.

In addition, it was planned to decrease attrition rate of employee from 6% to 2%, and the performance at the end of the strategic period was 1.3 % which was an excellent achievement of the authority. Moreover, it was also planned to increase the employee satisfaction level to 90% and according to the 2019 employee satisfaction survey, it was found to be 38.1% and that was very low. The reason behind the low performance was due to lack of adequate incentives, lack of benefits related with work hazarders and lack of adequate salary for the regulatory work force which cannot be answered by the authority.

3.9.Strengthen good governance

The focus of this strategic objective was to 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. One of the key steps taken as a strategic step towards achieving this strategic objective was to strengthen the transparency, grievance and feedback system, while another strategic step was to implement the ISO Quality Management System and become a center of excellence.

During the strategic implementation period, a lot of work has been done to update the services and make efficient service available to the customer. The registration and licensing system for food, medicine, and medical devices has been improved by making the service delivery system faster and more efficient, assuring drug quality. A number of manuals, operating systems have been developed to update the Inspection System, and training has been provided to several personnel on manuals and operating systems and is in progress to be certified to ISO 17020 Quality Management.

Accordingly, one of the performance measures of this strategic objective was to reduce service-related complaints by 85%. However, it has been observed that 84% has been achieved. In addition, the assessment of customer satisfaction survey showed a significant gap in the reporting and the complaint handling system. The other performance measure for this strategic objective was to make 80% of the legal framework accessible to the concerned parties, and according to a 2016/17 survey, the performance was found to be 36.5%, which is very low and a great effort is needed to improve it. In addition, it was planned to increase the satisfaction level of customers to 90 %, but the 2019 customer satisfaction survey indicated, their satisfaction was 35.71%, which is also very low and needs due attention.

3.10. Improve resource mobilization

This was intended to 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 17, the resource mobilization to implement the health regulatory sector plan was 3.48 billion birr for five years. The allocated budget for EFDA, the federal health regulatory body, increased from 129.8 million in 2015/16 to 208.8 million birr in 2018/19, and 230.25 million birr in 2019/20. Regarding the resources mobilized from developmental partners, the amount increased from 90 million birr in 2015/16 to 194.6 million birr in 2018/19, and 107.1 million in 2019/20. Similarly, the revenue which was collected from service provision was increased from 16 million birr in 2015/16 to 43 million birr in 2018/19, and 89.11 million in 2019/20.

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.

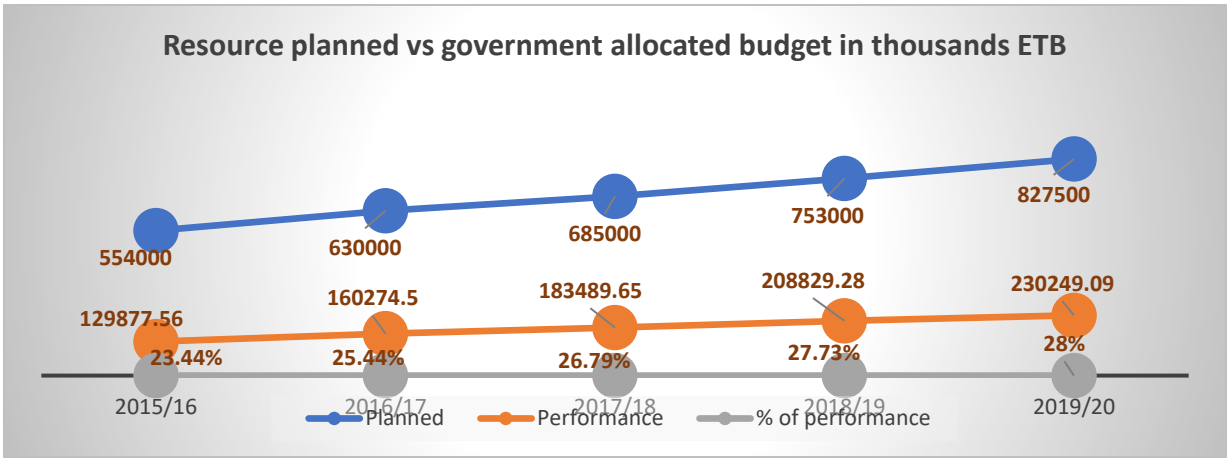


Figure 15: resource planned vs government allocation (from gov`t, revenue and donor)

The achievement trends by the last five 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 directive 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.

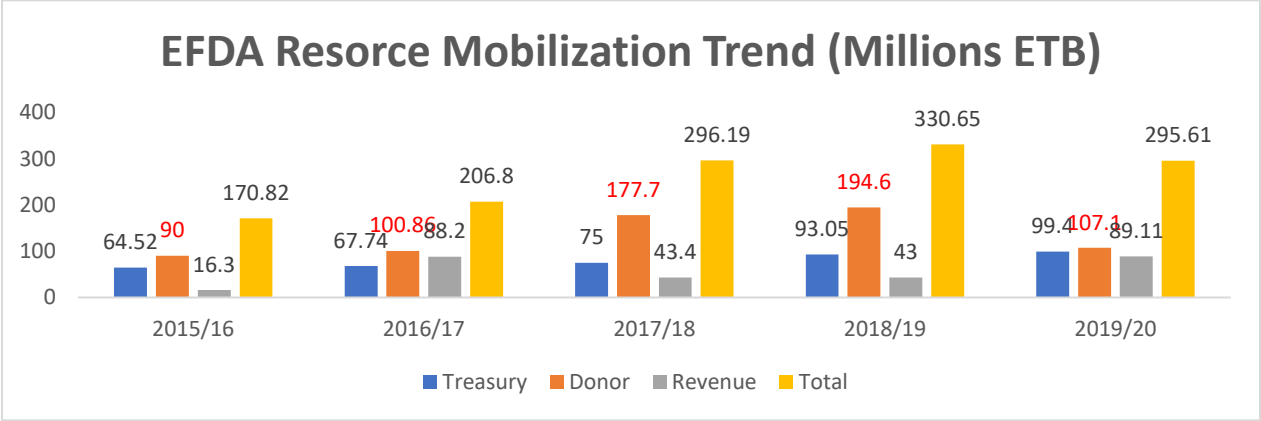


Figure 16: resource mobilization trend

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.

3.11. Strengthen regulatory infrastructures

By the last five years, EFDA has planned to build center of excellence. The design works has been completed and the overall performance reached only 5%. The resource limitation and absence of project office were major challenges that hindered the performance. Similarly, it was planned to build one branch laboratory at North East Ethiopia Branch Office, Kombolcha. Since the absence of decision on the location of the branch office, the laboratory was not built as per the plan. In addition, mini-labs and offices at ports at entry/exit ports were not built because of the decisions in the application of one window system with Custom Authority.

Regarding equipping and furnishing of quality control laboratories of the EFDA, South West Ethiopia branch laboratory has been built and equipped to start quality control tests. On the other hand, the other laboratories, both head lab and branch laboratories, has been equipped with highly advanced laboratory equipment to improve the existing tests and start new parameters. In addition to equipping the laboratories, maintenance and calibrations were undertaken regularly. However, underutilization of procured advanced lab and inspection equipment and limitations of proactive actions towards lab renovations were the main challenges.

EFDA has implemented electronic regulatory information system (eRIS) that enabled to transform the manual services to electronic and online systems, which has reduced the cost of customers as well as regulatory efforts. In addition, the Authority has started corporate mail address which harmonized the regulatory activities. Databases such as MRIS has been developed and applied. ERIS included (medicine, medical device, food registration system and licensing system) i-Register, i-Import, i-License, e-reporting ADR) electronic regulatory information system. The preliminary work was done for traceability. But the planned Software developments for planning and reporting automation (BSC), i-License for regional regulatory bodies, Inspection system, Software procurement for LMIS, deploy traceability Implementation Systems were not implemented as per the plan.

3.12. Improve preparation and implementation of legal frameworks

EFDA has planned to develop 130 legal frameworks within the strategic period which envisages proclamation, regulation, directives, standards, formulary list, specification and other list, in contrary to the conventional meaning.

Based on proclamation No. 661/2009, the federal and regional health regulatory bodies have been mandated by laws to regulate products, premises, professionals and practices. However, following the adoption the food and medicine administration proclamation No. 1112/2019 on February 2019, the mandate of the EFDA has been limited to product regulation. This impacted the development and implementation of legal frameworks within the strategic period, as the areas are relatively narrow. But regional regulatory mandated remain the same and the Authority has been developing and implementing legislation focusing on products.

Table 4: Legal frameworks developed in each year

Title	**2008 e.c**	**2009 e.c**	**2010 e.c**	**2011 e.c**	**Total**
Proclamations			1	1	2
Regulations	1		1		2
Directives	6	8	6	9	29
Standards (preparation)**	12	2	7		21+47**
Total					101

** In the strategic period 25 standards, 11 specialty Center list, 10 Medical Device Specification and 1 formulary list were developed. This also considered to evaluate the performance of the Authority. The Authority have planned to develop 130 legal frameworks and developed 101 legal frameworks within the last four years. Based on this figure, its performance is 77.692.

In the process of developing legal frameworks, the sector has faced numerous challenges. Some of the challenges were: prolonged process of the law-making, the process required involvement of various participants and bringing all to the same floor was difficult, it also required full engagement of lawyers and different technical experts. However, due to shortage of these professionals, EFDA was unable to undertake all activities per the plan. The other bottleneck identified was poor communication or delayed response of concerned directorate and institutions in forwarding input or facilitating of the process for adoption of a draft legislation.

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 5: Strength, Weakness, Opportunities and Threats of the Regulatory Sector

	ENABLERS	PAINS
	STRENGTHS	WEAKNESSES
INTERNAL	• Development and facilitating the adoption of the Food and Medicine Proclamation No. 1112/2011, Tobacco and Alcohol proclamations. • Sustaining accreditation and efforts to get WHO prequalification. • Deployment of e-RIS (e-registration, e-licensing, e-ADE reporting, electronic service in port of entry) • Availability of regulatory legal frame work. • Start-up audit and Risk based inspection. • Conducting food product market survey • Starting MSC Education program in regulatory science in AAU. • Starting of enforcement 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. • Preparation of institutional development plan and beginning implementation. • Development of communication strategy and IT Policy. • Strong collaboration with stake holders such as Police & customs. • Increasing & sustaining foods and medicines lab tests for both consignments (external labs) and post marketing. • New Market authorization strategy. • Initiatives in the Organizational Style and culture.	• Fragmented structure and not fully autonomous food and health prodcuts regulatory body which resulted in weak integration, coordination and execution of the regulatory laws. • Insufficient support from the regional governments to strengthen the regulatory system especially at zonal and woreda level. • Shortage / absence of budget allocation, vehicles to the sector and limited capacity to mobilize resources. • Limited/ Inadequate engagement of health extension workers, 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 technology to identify adulterated food, substandard and falsified health products. • Weak boarder control of illegal food and medicines products. • Loosen enforcement laws implementation and decision-making problems on concrete regulatory findings. • Weak communication and international relations. • Weak commitment and interest of staffs to work on the regulatory system and presence of high attrition rate especially at regional & woreda. • Lack of accredited 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.

	ENABLERS	PAINS
		• Lack of tracking and tracing capacity in the regulatory system. • Absence of QMS in place and gap in Implementation of ISO 9001/2015 and 17020/2012. • Absence of rapid test kits at port of entry, exit and inspection. • Absence of testing of health products like cosmetics, medical devices, and traditional medicines. • Fragmented food safety regulation. • Lack of standards for regulated products. • Inadequate cosmetics, traditional medicines and medical device regulation.
	OPPORTUNITIES	THREATS
EXTERNAL	• Availability of International food safety management schemes. • Endorsement of food and nutrition policy. • Commitment of the government to bring change in the organization. • Willingness of the existing partners to continue and strengthen their support. • Increasing trend of community participation and availability of public wing and health extension program. • Industrialization (increase in local production of drugs and equipment, local manufacturers of food, etc.) • Increased number of radio /TV and social media plat forum with capacity to accommodate multiple language with positive sense of social responsibility. • Availability of alternative regulatory means like private and university labs & their willingness. • Improved access to education. • Technology advancement and Globalization. • Emerging of Food safety issues as global agenda. • Inter-sectoral and regional collaboration.	• Fast going of food industry and production technology which results complex regulated products. • Existence of pores boarders 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 neighbor countries. • Climate change. • Increase issues of intentional food adulteration. • Absence of well capacitated public and private laboratories.

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 6: 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	Draft legal frameworks, executing the authority and responsibility properly, 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	Timely Plan and performance report, execute our authority and responsibility	Integration, collaboration, and leadership support	Accountability, lack of leadership support and loss of trust	Strong monitoring and evaluation system, MoU
Line ministries (Revenue, of Trade, Industry, agriculture, Science and higher education etc.), and Agencies (EPSA, Custom, Airports org. Trade Competition and Consumers Protection Authority etc.)	Multi-sectoral collaboration and engagement, exchange up-to-date information, technical support	Collaboration, transparency, technical support	Fragmentation, Dissatisfaction and considering food and medicine safety and quality assurance a low priority	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

Stakeholder	Their interest	Behaviors we desire	Resistance issues	Response of the FMRS
Ministry of Peace, Judiciary bodies and Federal and Regional Police Commissions	Collaboration, Detailed legal framework, Awareness on legal instrument, Technical support, up to date information	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 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 Health Professionals and Traditional and alternative medicines	Collaboration, engagement, good governance, technical support	Collaboration, engagement, technical support and advocacy	Dissatisfaction unethical practices	Advocacy, awareness, MoU, good governance and collaboration and engagement
Public wings, 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	Report non-compliance, 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 Transformation Plan-II

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. Objectives

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 FHRSTP II is to protect and promote public health through realization of the following objectives:

1. Protect the public from unsafe food
2. Safeguard the public from falsified, substandard and ineffective health products
3. Protect the public from tobacco and alcohol related health risks
4. Attain public confidence on food and health product regulation

1. Protect the public from unsafe food

Description

Improving food safety is necessary to augment the efforts to increase food security, increase which exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food, which meets their dietary needs and cultural preferences to have an active and healthy life.

The recent WHO report on the global burden of Food Born Diseases found that 31 FBD agents (biological and chemical hazards) accounted for around 420,000 deaths in developing countries, imposing a burden of around 33 million DALYs each year. *(Havelaar et al. 2015).*

Therefore, an effective national food safety and quality regulation system is significant to protect public health by reducing the risk of food-borne illnesses and consumption of substandard, unwholesome, illegal or adulterated food. Moreover, it contributes to economic development by maintaining consumer confidence in the food supply system for domestic and international food trade.

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 reducing food borne morbidity & mortality arising from unsafe food as well as contribute to economic development.

Targets

1. Decrease the prevalence of unsafe food available in the market from NA to 25%
2. Decease the prevalence of illegal food products in the market from NA to 30%
3. Reduce the percentage of food adulteration prevalence in the market from NA to 30%

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

Description

This objective is defined based on the sector's vision and Sustainable Development Goal Three (SDG-3) related with safety, quality and performance of health products. Safeguarding the 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, cosmetics, antiseptics and disinfectants; and public health pesticides. The need to resolve challenges posed by innovative new products and increased globalization require well-functioning pre-market and post-market regulatory systems that demonstrates 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; 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 the percentage of Substandard and Falsified medicine and medical devices in the market from 8.6% to 5% and from NA to 10 %, respectively.
2. Increase the Percentage of Good Dispensing Practice at retail outlets from 50% to 65%
3. Increase the Percentage of Administrative measure taken against any regulatory non-compliance from 95% to 99%.

3. Protect the public from tobacco and alcohol related health risks

Description

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. It is also intended to safeguard the vulnerable groups such as children, youth and women due to the excess use of tobacco and alcohol. 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 and alcohol leads to reduction of mortality and morbidity.

Targets

1. Reduce the prevalence of tobacco smoking and use from 5% to 3%
2. Reduce the prevalence of alcohol use from 41% to 39%

4. Attain public confidence on food and health product regulation

Description

One of the most important mission of the sector is to safeguard the health of the public from health risks associated with food, medicines, medical devices and other regulated products marketed in the country. This objective guides the implementations through capacity building the regulatory sector through internal process optimization, ensuring greater coordination and partnership, establishing harmonization better regulatory standards and greater information sharing among the regional counter parts and the local public through continuous improvement of systems, leadership capacity, skilled workforce, regulatory infrastructure, institutional visibility, integrated and agile management systems and can best gain staff and public confidence, boost its reliability, increase community and stakeholders' engagement and public satisfaction by improving the responsiveness of the regulatory system to the expectations and needs of the public.

This objective therefore, will be proactively working to upgrade the authority to promote an adaptive, risk-informed, and cost-effective management system to lead to organizational excellence, effective performance and accountability, through strengthened quality management system aligned with regulatory policies, legal frameworks and assist the regulatory functions to climb the ladder to higher maturity levels. The objective also focuses on raising the awareness of the public on the regulatory strategies used to protect the public from the risks emerging from the health products largely consumed by the public, increasing the involvement and participation of the public on the regulatory activities with ultimate goal of creating empowered community, leading the public to viable participation in proactive reporting on the availability of illegal products in the market and defective ones at health facilities. This in its turn will strengthen the mutual understanding between the community and the regulatory authority though building trust and bringing about community ownership ultimately achieving sustainable public confidence.

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
3. Increase transparency score from N/A to 9

4.5. Strategic Directions

For this transformation plan, 15 strategic directions are formulated and each is 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 and alcohol 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 Food and health products regulatory infrastructures
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.

For effective food safety regulation implementation, a national food control system 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 easily identification of food product in the market, for customer informed choices and to establish track and traceability 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 imported food registration process through GMP inspection on selected food items, 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 up 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 planned post market surveillance, intelligence- led market assessment, food vigilance, developing and networking rapid alert system with the regional and international organizations and strengthening food inspection at port of entry.

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 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 auditing 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: Laboratories are 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 ten years the food control laboratory will majorly focus on performing 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 realize international accreditation of the central laboratory on selected parameters, provide strong support and supervision for branch and regional laboratories, enhance the capacity and capability of the laboratory personnel, expand scopes, up grading the laboratory with existing scientific laboratory technology, create a strong partnership with local and international private and governmental food quality control laboratories and other relevant organizations.

Food safety vigilance and PMS: Post market surveillance and vigilance of food is a system for food safety assurance in the food safety control and enforcement. The primary purpose for conducting scientific based post market surveillance is to identify food products previously recognized and get assurance for the market has a positive effect in the market in current situation and also to response to the public raised as a compliant. Correspondingly to the post market surveillance conducting intelligence led market assessment also part of food safety regulation and enforcement activity. Track and tracing system like I-Verify for food products will be implemented for proper implementation of food safety management and vigilance system at national level. This supports a system to prevent, detects, and responded to food outbreak, illegal food trade and minimize burden of food born disease.

Interventions

Food product registration and facility licensing

- Develop and implement strategy and road map for food registration and notification system
- Conduct food product, registration and market authorization through advanced document evaluation techniques or via notification for identified food products and supported with GMP/HACCP/FSMS inspection for local and selected imported food products.
- Conduct house hold water treatment technologies registration and market authorization through advanced document evaluation techniques
- Implement fast tracking strategy for food products imported from countries which have stringent regulatory authority

- Develop relevant manuals, guidelines and SOP's for product registration and facility licensing.
- Conduct pre-licensing inspection and issue license and renewal for food facilities
- Take appropriate administrative measures based on the post licensing inspection, PMS and market assessment findings and advertisement evaluation
- Strengthen scientific infrastructure and technological capacity to support risk analysis decisions.
- Establish a strong food supply chain traceability system within the scope of food and health products regulatory.
- Establish a strong network of food database systems
- Strengthen public information systems.

Inspection and enforcement

- Develop strategies and road map for the implementation national safety inspection and enforcement
- Strengthen the existing inspection and enforcement system
- Create incentive mechanisms for food business actors to apply preventive control measures.
- Reinforce food business actors' responsibility to produce and place safe food on the market
- Conduct risk-based food safety auditing inspection on food facilities
- Enforcing implementation of national mandatory/compulsory food standards.
- Perform scientific interventions based on over all food safety regulation findings.
- Enforce implementation of IQMS in food manufacturing facilities.
- Ensure and enforce internal quality control system in small and medium level food products manufacturing.
- Conduct foreign GMP inspection on selected food items
- Develop relevant manuals, guidelines and SOP's for inspection and enforcement
- Enforce existing food advertisement directives
- Ensure food handlers health status related to food borne diseases; Enforce implementation of food safety practices such as good hygiene practices, good manufacturing practices, good storage practices, good service practices, good catering practices, good distribution practices and good food handling practice on food business operators (importers, exporters, wholesalers, retailers, street vendors and mass-catering services)

- Strengthen scientific infrastructure and technological capacity to support risk analysis decisions.
- Establish the national integrated food safety regulation system covering the supply chain from farm-to-table.
- Coordinate food safety agencies' oversight to ensure a unified approach along the food supply chain.
- Encourage food safety agencies to participate in a national integrated food safety Strategy implementation.
- Establishing integrated national communication channel among stakeholders.
- Acquire necessary inspection equipment for field staff to carry out their activities.
- Strengthen public information systems on inspection and enforcement.
- To be accredited in inspection and enforcement service by international accreditation bodies (ISO/IEC 17020)

Import control

- Design an efficient and effective risk-based regulatory process for importing food.
- Ensure the safety of imported food products through risk-based food safety inspection system, 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.

Laboratory testing

- Develop strategies and road map for strengthening national and branch food safety control laboratory
- Attain ISO 17025 accreditation of the central and branch food safety control laboratory on major or selected parameters, maintain and expand scopes

- Ensuring the safety and performance of imported food products, raw materials, house hold water treatment technologies and food contact materials through advanced laboratory consignment tests.
- Ensuring the safety of locally and imported food products, raw materials, food contact materials through post market surveillance supported with advanced laboratory tests.
- Perform advanced laboratory analysis on suspected food products.
- Perform advanced laboratory analysis for market authorization
- Develop, validate and verify laboratory test methods using advanced analytical techniques
- Develop relevant manuals, guidelines and SOP's
- Create a network of accredited laboratories.
- Strengthen the procurement and maintenance system for laboratory equipment and reagents through harmonization with other stakeholders.
- Create and maintain a food safety risks reporting database.
- Establish a laboratory information sharing network.
- Establish a food emergency response network to address laboratory surge capacity during emergencies.

Food safety vigilance and PMS

- Develop strategies and road map for strengthening national Food safety vigilance and PMS system
- Establish interagency networks for information sharing.
- Protecting public health through performing food safety risk Analysis (Assessment, Management and communication) across the value chain
- Establishing informative, concert and inclusive data base system at national level and disseminate up to dated information on food safety regulation and enforcement.
- Develop database, track and tracing system of food business operators
- Conduct scientific based post market surveillance
- Conduct intelligence led market assessment
- Establish a system to detect, prevent and response to food outbreak
- Developing and networking rapid alert system with the regional and international organization
- Develop relevant manuals, guidelines and SOP's on food vigilance and PMS.

- Establish IEC system on findings of vigilance and PMS

Targets

1. Increase the number of market authorized food products from 2739 to 12,213
2. Increase the percentage local food facilities audit inspection coverage from 76% to 100%
3. Increase the number of foreign on-site inspection conducted on selected food products manufacturing facilities from 2 to 110
4. Increase the coverage of food facilities implementing IQMS/Regulatory requirements from 35 % to 70 %
5. Increase the coverage of street vendor that implemented GHP from 0 to 50 %
6. Increase the coverage of mass Catering service that implemented GHP & GCP from 0% to 50%
7. Increase the number of food product types tested via PMS laboratory from 28 to72
8. Increase Number of food product types for consignment laboratory tests from 28 to 60

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, TCCPA, 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.

Interventions

Prevention of intentional food adulteration and illegal food

- Develop and implement food safety alerting system
- Establish control system to address food safety in informal markets
- Establish modern food safety track and traceability system
- Strengthen regulations at port of entry
- Creating a 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 community.
- Celebrating food safety day

Detection of intentional food adulteration and illegal food

- Create effective and efficient surveillance and vigilance system.

- Conduct risk-based intelligence led food surveillance,
- 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.

Response

- Take administrative and legal measure
- Information, education and communication
- Panel discussion

Targets

1. Increase the number of risk-based intelligence led food surveillance and operation from 4 to 10
2. Increase the number of risk-based market assessments from 12 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-based regulation, exercise responsibility sharing with in pharmaceutical establishments and adopt utilization of new technologies including the introduction of track and trace system. 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 surveillances, 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 Pharmacopoeial 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, good reliance practices such as SRA procedures, mutual recognition, conditional approval procedures, collaborative approach with WHO, regional harmonization and joint 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.

Interventions

Improving Registration systems

- Create platform for medicine shortage alleviation and monitoring at national level in collaboration with concerned stakeholders and partners.
- 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 IGAD harmonization.
- Establish regulatory-university, professional associations, industry linkage.
- Establish and implement Good Review Practices for market authorization.

- Revise and implement medicine registration strategies based on reliance and risk based classification schemes.
- Establish and implement registration systems of herbal products and other traditional health care products.
- Institutionalize 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 and place on public domain on regular basis.
- Establish and use medicine registration advisory panel.

Improving Inspection and Enforcement Systems

a) Manufacturing Sites

- Conduct full regulatory oversight to the implementation of NSPA so as to ensure compliance to critical 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.
- Conduct regular cGMP inspection of local manufacturers
- Establish systems for inspection and licensing of herbal medicine manufacturing
- Implement reliance and risk-based cGMP inspection of manufacturers outside of Ethiopia.
- Comply with international best practices in cGMP inspection and become a member of PIC/s

b) Import/Export and Distribution

- Conduct regular inspection and enforce compliance to Good Storage, Good Distribution, Good Documentation and Good Dispensing Practices by importers, wholesalers and retailers.
- Strengthen systems for effective licensing and certification of importers, exporters, wholesalers and retailers.
- Enforce track and trace system 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.
- Strengthening the effective implementation of repository and verification systems for safety features for medicines to ensure this operate as intended.
- Strengthening stringent import/Export controlling system and tightening boarder control.
- 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 mechanism to encourage model medicine establishments that excel regulatory requirements.

Improve laboratory testing services

- Increase testing capacity to cover biological products, APIs, vaccines, cosmetics, herbal products, traditional medicine and other regulated products.
- Expand test parameters to address performance and safety concerns on risk-based approach.
- Strengthen the branch laboratories testing capacity.
- Conduct quality assurance related research and training using the center of excellence.
- Conduct validation and verification to confirm the suitability of analytical methods used.
- Develop analytical methods as appropriate for new testing schemes.
- Sustain and scope expansion of current ISO accreditation of the central quality control laboratory by meeting all requirements and attain WHO prequalification.
- Obtain accreditation of ISO/IEC 17025 for branch laboratories.

Improve Clinical Trial Authorization and Oversight

- Review clinical trial protocols and authorization when ensured the fulfillment of all ethical and scientific aspects of clinical trials
- Conduct clinical and field trial inspections to maximize safety while facilitating access to new medicines and health care products.
- Develop local capacity on inspection of clinical trials/bioequivalence study sites for GCP and GLP.

- Establish and implement traditional medicines clinical trial approval schemes and site inspection
- Establish national clinical trial registry and register all clinical trials in the registry
- Establish and use clinical trial advisory panel
- Create platform for clinical trial results approval and endorsement for dissemination of finding.
- Establish platform for clinical trial harmonization and joint activities with international and regional initiatives.

Improve Post Market Quality Surveillance systems

- Systematize and expand the range of products for post marketing surveillance considering emerging threats and risk levels
- Strengthen and implement risk-based post marketing surveillances.
- Strengthening plans and surveys for implementation of market survey.
- Strengthening risk-based site identification, sample collection, testing and action taking.

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).
- Establish a mechanism to disseminate the safety and quality information obtained from international organizations and national regulatory authorities.
- Establish a system where pharmacovigilance function is a licensing and accreditation requirement of health facilities.
- Establish and strengthen pharmacovigilance risk assessment committee
- Strengthen the identification, evaluation and communication of safety information.
- 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.

- Strengthen active surveillance system and pharmacovigilance inspection.
- Establish patient reporting system for monitoring safety and quality
- Enhance the implementation of traceability system to ensure the quality of medicines.
- Establish and strengthen regional pharmacovigilance centers and conduct continuous performance auditing and evaluation.

Improve Control of Narcotic drugs and Psychotropic substances

- Strengthen and reorganize Control of Narcotic and psychotropic substances.
- Collaborates with National Drug Law Enforcers to control diversion into illicit trade and abuse
- Grants authorization for import of narcotic drugs, psychotropic substances and precursor chemicals
- Strengthen data collection about narcotic drugs and psychotropic substances from manufacturers, importers, wholesales and health facilities and organize consumption, demand estimations and other data and report to International Narcotic Control Board on the reporting schedules set by the board.

Improve Ensuring Proper Use of Medicines

- Strengthen enforcement of proper use of medicines including good prescribing, dispensing practice and patient use at all levels.
- Strengthen enforcement in prevention and containment of Antimicrobial Resistance (AMR)
- Strengthen system of providing up-to-date regulatory information
- Foster ethical promotion and use of medicines
- Revise national essential medicines list, OTC and emergency lists on regular basis.
- Categorize and revise the list of medicines to be handled by medicine retail outlets and different health facilities considering the level of care.
- Revise National Medicines Formulary on regular basis.
- Update regularly the list of registered medicines and make it accessible to the public.
- Develop and disseminate drug information to the public and health care professionals.
- Ensure safe disposal of expired or otherwise unwanted medicines.
- Establish system to prompt communication on emerging issues related to medicines to target audiences through different communication channels.

Targets

1. Increase the number of registered medicines from 4,729 to 9500
2. Increase the number of registered traditional medicines from 0 to 10
3. Increase the number of ADR Reports received per year from 1442 to 11000
4. Increase the number of serious adverse event investigated and causality assessment conducted from 12 to 29
5. Increase signal detection from 0 to 10
6. Percentage of inspection coverage of medicine importers and wholesalers from 100% to 100%; medicine retail outlet from 75% to 90%
7. Increase the percentage of inspected consignments at set targeted time frame at PoE from 100% to 100%
8. Increase the number of medicine manufacturing facilities inspected against the national GMP requirements per year from 120 to 300
9. Increase the percentage of medicines consignment tested against imported products from 21% to 55%
10. Increase the percentage of medicines PMS tested against marketed products from 22% to 55%
11. Increase the number of clinical trial applications approved from 13 to 200
12. Increase the number of clinical trials inspected from 2 to 200

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 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. Currently, the medical device regulation is under development. There are a number of challenges in the medical device regulation sector. To mention some, there are limited number of registered medical devices on the market and the risk of infiltration of illegal medical devices is high. Furthermore, the medical device quality control (QC) testing and Good Manufacturing Practice inspection is almost on its infant stage.

The Authority will implement risk-based regulation, share responsibility to medical device establishments and adopt utilization of new technologies including the introduction of unique device identification system. The regulatory functions shall 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 provided in establishing well organized quality control access and laboratory testing; and establishing risk based GMP inspection systems for devices that require GMP inspection such as condom, supplies and reagents. In addition, proper attention will be given to oversight of field trials, post-marketing surveillances and field safety corrective actions.

Interventions

Medical Devices Registration and Marketing Authorization,

- Speed-up implementation of fast-track registration system, risk-based dossier assessments, SRA approach, WHO prequalification schemes, use of external assessors, conditional approaches, joint assessments and harmonization etc.
- Implement Good Registration Practices in market authorization.
- Optimize registration and marketing authorization processes and tools.

Improving Inspection and Enforcement System

a) Manufacturing Sites

- Conduct full regulatory oversight to the implementation of QMS to ensure compliance to global and/or National Quality management system requirements.
- Strengthen effective licensing of local manufacture of medical devices.
- Provide skilled regulatory oversight for the new industries inhabited in the newly built pharmaceutical industry parks and the existing industries.
- Support the review and approval of investment proposals for compliance to cGMP (ISO 13485) requirements.
- Conduct regular quality audit/ cGMP inspection of local manufacturers
- Implement risk-based quality management audit/cGMP inspection to manufacturers outside of Ethiopia.
- Ensure that procedures for accrediting third part auditors and auditing organizations are in place.
- Comply with international best practices in quality audit inspection and become a member of GHWP

b) Import/Export and Distribution

- Conduct regular inspection and enforce compliance to Good Storage, Good Transportation and Good Distribution practice.
- Strengthen systems for effective licensing importers and wholesalers.
- Establish and enforce track and trace systems/unique device identification in the supply chain.
- Establish and strengthen Field Alert System to monitor substandard and counterfeit medical devices.
- Strengthening the effective implementation of repository and verification systems for safety features for medical devices to ensure this operate as intended.
- Strengthening stringent import/Export controlling system and tightening boarder control.
- Establish mechanism to encourage model medical devices establishments.
- Strengthening market surveillance of medical devices

Clinical Trial authorization and Oversight

- Create a system to oversight clinical trials on new investigational medical devices.
- Review clinical investigation applications; approve where relevant and monitor progress.

P**ost-market surveillance of Medical devices**

- Expand the range of products for post marketing surveillance considering emerging threats and risk levels.
- Strengthen and implement risk-based post marketing surveillances.
- Establish risk-based site identification, sample collection, testing and action taken.
- Establish a system for adverse events and incidents reporting, and recall of medical devices
- Establish system for monitoring of reported recalls of medical devices by other agencies.
- Establish system for creating awareness in reporting adverse effect
- Establish a mechanism to disseminate the safety and quality information obtained from international organizations and national regulatory authorities.
- Establish and strengthen medical devices vigilance risk assessment committee
- Establish active surveillance system and vigilance inspection.
- Ensure that all healthcare facilities implement Healthcare Technology life cycle Management (HTM) for their medical equipment.

Laboratory access and testing for medical devices,

- Strengthen and expand scope of laboratory testing in terms of test parameters and type of medical device.
- Enhance the scope of accreditation for testing new medical device.
- Strengthen consignment and post-market surveillance testing.
- Establish workshop to test functionality and performance of medical equipment.
- Enhance equipment management system including equipment calibration & maintenance.
- Perform analytical method verification and validation.

Oversee medical device promotion and advertisement

- Review pre-approval of promotional activities.
- Monitor advertisements of medical devices in collaboration with appropriate body.

Targets

1. Increase the number of registered medical devices from 4527 to 10050
2. Increase the number of types of medical devices consignment tested from 1 to 25
3. Increase the number of types of medical devices PMS tested from 1 to 25
4. Percentage of inspection coverage of medical devices importer and wholesaler from 100% to 100%; retail outlet from 75% to 90%, respectively
5. Increase the number of medical devices facility GMP inspection conducted /audited per the national standard from 6 to 65
6. Increase the number adverse device events reports received per year from 0 to 430
7. Increase the number of clinical trial/ investigation applications approved from 3 to 80
8. Increase the number of approved medical devices inspection at port of entry (import /export) from 2600 to 10000
9. Reduce percentage of ineffective, defective and malfunctioning medical devices in the market from NA to 30%

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, implement strong market control and surveillance systems, introduce safety laboratory testing, implement notification procedure, tighten port and boarder control, introduce 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.

Interventions

Improving the notification system:

- Establish and implement cosmetic notification system
- Establish and update notified cosmetic products central database.
- Monitor prohibited ingredients during notification

Strengthen Licensing and Inspection:

- Strengthen licensing system of cosmetic facilities
- Strengthen inspection system of cosmetic facilities
- Strengthen market control and surveillance
- Strengthen regulation of cosmetics at port of entry
- Implement risk based inspection of cosmetic supply chain.

Establish 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 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 risk assessment committee
- Establish consumers reporting system for monitoring safety

Targets

1. Increase the number of issuances of notification notes from 0 to 3000
2. Increase the percentage of suspected cosmetic products tested for safety from 0 to 100%
3. Increase the percentage of inspection coverage of the supply chain from 30% to 60%

6. Strengthen tobacco and alcohol control system

Description

This strategic direction aims to improve 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. The strategic direction primarily complements to 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 life style.

This will abet 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 tobacco control measures that reduce the use of tobacco and tobacco products and exposure to cigarette smoking. 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 & advertisement, control of content disclosure and pictorial graphic health warning; and related aspects of tobacco products.

During the FHRSTP II, this strategic direction will also focus on alcohol regulation. Licensing and inspection of alcohol manufacturers and distribution channels, control sale of alcohol in prohibited places, market surveillance activities, control of illegal sell, control of promotion & advertisement, control of health warnings on alcohol products are the focus areas of this strategic direction.

Interventions

- Sensitize, familiarize and advocate regulatory laws and activities about tobacco and tobacco products, alcohol products
- Strengthen systems for effective licensing of importers, wholesalers and retailers.
- Conduct regular inspection and enforce compliance to requirements by manufacturers, importers, wholesalers, and retailers.
- Establish intelligence capability and conduct operations focusing on public health impact.
- Enhance stringent import controlling system and tightening boarder control.
- Institute the detection and control of illicit tobacco and tobacco products, and illegal trade of alcohol products
- Enforce smoke-free environments and control sale of alcohol in prohibited places
- Enforce rotating health warnings and messages that are comprised of combined images and full-color pictures on tobacco products in every two years
- Enforce 70% PGHW on tobacco product label and health warnings on alcohol products
- Enforce disclose of ingredients of tobacco and tobacco products
- Enforce tobacco & tobacco products, and alcohol products advertising, promotion and sponsorship
- Conduct regular monitoring of tobacco industry interferences
- Enforce ban of sale of tobacco to/by minors under 21 years and sell tobacco to a person under the age of 21.
- Enforce ban of sale of alcohol to a person under the age of 21.
- Enforce ban of single stick sell of cigarette
- Enforce not to sell tobacco products within hundred meters of the premise of health institutions, schools, and youth centers
- Strengthen a national and regional coordination mechanism

Targets

1. Increase the number of smoke free public places from 109000 to 218000
2. Decrease illicit trade of tobacco from NA to 15%
3. Reduce the percentage of Advertisement, Sponsorship, and Promotion (ASP) of tobacco from 42% to 15%

4. Reduce the percentage of Advertisement, Sponsorship, and Promotion (ASP) of alcohol from NA to 25%
5. Reduce the percentage of alcohol sale in prohibited areas from NA to 50%

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.

Interventions:

- Ensure the implementation of good governance principles and its practices
- Make assessments by using WHO instrument on transparency and potential vulnerability to corruption in key regulatory functions
- Develop code of conduct based on the regulatory condition
- Design and implement anti -corruption strategy.
- Controlling corruption strictly in the sector by using different strategy
- Identify and manage the fundamental risks in regulatory sector (risk management)
- Improve compliant handling system

- Set standards of services to meet the needs and expectations of the citizens
- Promote gender equity in leadership and other roles
- Conduct customer satisfaction survey and take corrective action based on the finding

Targets

1. Increase the food and health products regulatory sector customer satisfaction level from 50.2% to 80%
2. Increase the percentage of regulatory services provided as per the standard from 80 to 100
3. Reduce the percentage of service delivery complaints from 84% to 100%
4. Increase the number of developed anti-corruption strategy 0 to 1

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 implementation of proper human resource management system and, bringing about competent and evolutionist food and health products regulatory workforce. This helps to develop sustainable capacity, promote professionalism, create learning culture in the regulatory sector, and to link the knowledge, skills and personal attributes to the organizational performance. On the other hand, 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 particular, in diversity, knowledge, level, resource and information, managements and strengthening of communication, partnerships and negotiation skills.

Hence, in this strategic direction the focus areas will be developing human resource development strategy, improve competence and skills of the regulatory workforce, improve motivation and commitment, leadership capacity, strengthen human resource management system including recruitment and selection, staff deployment, performance management. In addition, it will focus on ensuring safety and healthy workplace in alignment with national and international standards. Furthermore, this strategic direction will give special attention for women to capacitate and encourage there by creating room for leadership positions.

Interventions

- Undertake continuous organizational reform
- Develop human resource development plan and strategies
- Implement modular strategies for capacity building training
- Develop and implement human resource management strategy (forecasting, recruiting, selection, transfer, performance appraisal)
- Develop motivation schemes and strategy
- Create conducive work environment
- Strengthen Human Resources Information System (HRIS)
- Enhance gender mainstreaming
- Improve leadership capacity and develop succession strategy
- Develop employees hand book
- Encouraging and facilitating culture of learning
- Implement different motivational initiatives, such as motivation, talent development, and role clarity and personnel ownership

Targets

1. Increase employee satisfaction level from 38% to 65%
2. Increase the percentage of training effectiveness from NA to 80%
3. Decrease employee attrition rate from 3.4% to 2%
4. Increase organizational health status from 42% to 70%

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 creating 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 advance 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 inspections in order to improve efficiency of the regulatory system.

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

Interventions

- Conducting mapping of potential stakeholders
- Engages in partnerships with foreign governments, regulatory coalitions, development organizations, academic institutions, among others.
- Engage stakeholder's in the planning, implementation, monitoring and evaluation of the regulatory system
- Promote and create public private partnership
- Inform and engage all stakeholders through effective internal and external communication
- Collaborate with federal and local offices to detect and respond on illegal food and drug trade
- Prepare and implement memorandum of understanding (MOU) for partnerships and collaborations with international, federal, and local organizations
- Formulate and implement partnerships and collaborations strategy
- Establish harmonization with independent organizations like, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

Targets

1. Increase the percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities from 68 to 100
2. Increase the number of strategic partnership and collaboration established with international, federal, and local organizations from NA to 10

3. Increase the number of joint activities of regulatory function conducted with different stakeholders from NA to 45

10. Improve efficiency & effectiveness

Description

This strategic direction is designed to mobilize resources from government (treasury and revenues), and funds from external sources (donors) proactively in alignment with high level and long-term priorities and interventions. Moreover, it will be enhanced by encouraging and establishing a system for sustainable self-financing. In addition, this strategic direction entails optimum and rational utilization of both financial and non-financial resources through proper planning, management & execution of the procurement activities in line with budgeted financing schemes. Furthermore, this strategic direction aims to strengthen efficiency and reduce lead time for different processes such as medicine registration to make safe, effective medical products to expedite quality assured medicines in the market. The focus areas in this strategic direction will be proper implementation of strategies and achievement of strategic goals, an appropriate budget allocation/ costing to high impact and prioritized outcomes, proper & timely utilization and mitigate resource wastages at all levels, and timely financial reports for decisions, and strengthening of internal auditing system.

Interventions

- Develop resource mobilization strategy which will help to be self-reliance
- Strengthen M&E system.
- Strengthen internal audit system
- Develop a strategy to implement program budgeting properly
- Strengthening partners forum
- Implement transparent, accountable & sound resource utilization and financial tracking management system
- Implement effective IFMIS or other ICT method of procurement process
- Develop a strategy that can reduce lengthy processes for medicine registration

- Prepare standards for effective & efficient utilization system for all type of resources including technologies,instruments & other fixed asset/properties, and vehicles.
- Strengthen modern inventory & stock management system supported by modern ICT system, and establish a system that controls resource wastages
- Establish a modern contract management system for large & extended projects, programs/initiatives or works, & implement with necessary knowledge sufficiently for all the regulatory sector nation-wide to suport regional regulatories.
- Establish & Strengthen modern & easily accessible, efficient & customer oriented archive & secured documentation,and an information system supported by modern technologies.

Targets

1. Reduce medicine registration lead time (in days) from 90 days to 60 days
2. Increase the amount of resource mobilization (in million birr) from 97.5 to 1,977.5
3. Increase the percentage of budget utilization from NA to 95%

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 themselves 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.

Interventions

- Strengthen regulatory information dissemination through different online and mass medias to bring behavioral change among the public about safety and quality of food and health products, substandard products and measures taken.
- Enhance creating awareness and increase literacy of the public about food and health product regulation, legal frameworks and illegal food and health products.
- Improve regulatory communication system, strategies and mechanisms to disseminate information about food and health products regulation, findings and measures taken.
- Strengthen the participation and engagement of youth, women and civic forums.
- Introduce recognition schemes /mechanisms to best performers public wing and community civic forums

Targets

1. Increase the percentage of the population who are informed about regulatory measures, laws and activities from 46% to 70%
2. Increase the percentage of investigated tipoff, complaints and concerns from the public from 0.89% to 3%
3. Increase the percentage of population whose age above 13-year-old, who got regulatory information through media outlet.) from NA to 75%

12. Improve Evidence Based Decision Making

Description

This strategic direction focuses on the generation of quality evidence data and improve 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. Therefore, focus will be given on the improvement of the quality and availability of data, knowledge management and capacity to use information for action at all levels.

Interventions

- Strengthen monitoring and evaluation system for evidence-based decision making in the food and health product regulatory system.
- Establish evidence-based decision-making rapid response team // TWG /
- Strengthen the implementation of one plan and one report approach at all levels of the regulatory system
- Strengthen electronic regulatory information system,
- Strengthen survey and surveillance to measure performance and promote evidence-based decision-making practices.
- Enhance Knowledge Management practices at all levels
- Improve quality of data through comprehensive implementation of data quality assurance and auditing, and improving data demand.

Targets

1. Increase the % of expected reports received from reporting units on time from NA to 95
2. Increase the % of expected reports received from reporting units complete from NA to 80%
3. Number of conducted surveys NA to 86
4. Increase the number of produced peer-reviewed journals NA to 10

13. Strengthen Food and health products Regulatory Infrastructures

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, guest houses and utilities as the major buildings, that will serve for training center, and quality assurance laboratory. 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. It has also planned to establish and maintain branch/subnational 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 ergonometric system to improve workplace safety.

Interventions:

Construction, furnish and renovation of premises

- Construct the center of excellence in Addis Ababa
- Construct new branch office and laboratories in geographic areas where there is no Quality assurance lab nearby.
- Establish and strengthen medical device and vaccine labs at the head laboratory
- Establish mobile quality assurance laboratories at entry/exit ports
- Renovation of head and branch laboratory premises
- Furnish and equip the existing and newly established lab premises with the art of technologies
- Furnish the regulatory offices with ergonometric furniture

Information. Communication technology for regulatory sector

- Software upgrade for i-License (Implemented regional level)
- 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
- Software Development/upgrade and equipment
- Fleet management software: procurement, maintenance and service
- Software development for (inspection system Implemented regional level))
- Software procurement for LMIS
- Software for handling & retrieval of Documentation system
- Establish traceability system in the pharmaceutical supply chain
- Cascading the regulatory information system to branch, region and woreda level

- Hard ware 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
- Establish rapid alert system at national level by adopting the WHO alert system
- Establish risk analysis technology
- Equip the inspectors and intelligence professional with basic and high-tech equipment

Vehicles

- Procurement of vehicles for the federal and regional regulatory bodies
- Procure motorcycles for woreda and entry/exit ports

Targets

1. Increase the number of established, and well equipped and furnished center of food and health products regulatory excellence from 0 to 1
2. Increase the number of sub-national/branch laboratories and offices from 5 to 17
3. Increase the number of established and well-equipped mobile labs at entry/exit ports from 0 to 22
4. Increase well established national rapid alert system from 0 to 2
5. Increase the number of regional regulatory bodies that implemented i-license system from 0 to 12
6. Increase the number of automated systems implemented from NA to 4

14. Improve Quality Management System

Description:

This strategic direction describes about 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 enhancing 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.

However, the Authority and the regional regulatory bodies did not implement QMS and the services and products they provide are not up to the expected standards. There are complaints in 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. This will lead the Authority to achieve the WHO maturity level three and four to become competent regulatory body in the Africa. Furthermore, the regional regulatory bodies are committed to implement ISO 17020 in their inspection processes.

In addition, the Authority and the regional regulatory bodies will properly sustain and maintain their certification/accreditation of their respective ISO families.

Interventions

- Conduct gap assessment and planning for development and implementation of the QMS.
- Develop QMS roadmap.
- Provide QMS and related training to EFDA and regional regulatory bodies' staff.
- Develop and implement the ISO/IEC 9001 at EFDA level including its branch offices.
- Develop and implement ISO/IEC 17020 at EFDA's inspection processes and regional regulatory bodies' inspection processes.
- Expand the scope of ISO/IEC 17025 for EFDA's laboratories.
- Attain WHO prequalified quality control laboratory at EFDA Head Quarter.
- Implement Global Benchmarking Tools (GBT) to achieve maturity level three and four.
- Prepare, review, revise and approve QMS documents.
- Conduct internal audits and management review meetings.
- Prepare Corrective and Preventive Actions (CAPA) and manage non-conformances based on external audits.
- Conduct compliant investigation and feedback analysis.
- Conduct risk analysis during the implementation of QMS.
- Monitoring and evaluation of the overall QMS.

Targets

1. Increase the number of EFDA inspection directorates (HQ and branches/ ISO 1720/ 2012 accredited from 0 to 8
2. Increase the number EFDA regulatory functions ISO 9001/2015 certified from 0 to 1
3. Increase the number of EFDA's laboratories ISO 170205/2017 accredited from 2 to 5
4. Increase EFDA laboratory maturity level recognition from NA to 3
5. Increase WHO prequalified quality assurance laboratory from 0 to 1

15. Improve formulation and implementation of Legal Frameworks

Description

Regulatory legal framework is one of the basic elements to establish food and health products regulatory organ. Strong legal instruments are crucial to have strong food and health products regulatory sector. Legal framework denotes all legal instruments that are enacted to regulate a sector or issues; whereas, legal instrument refers proclamation, regulation and directives. Within this understanding, the phrase legal framework and legal instrument encompasses laws that are applicable to the food and health products regulatory sector.

Strengthening formulation of legal framework means undertaking activities to improve how the legal instrument of the sector initiated, drafted, consulted and promulgated; whereas improving implementation of the legal framework is undertaking activities that enable for effective enforcement of the legal instruments. This strategic direction emphasis mainly on improving the system and process by which the legal instrument of the sector developed and improving the mechanism, manner and scale where enacted legal instruments implemented. In this regard, the scope of this objective is on the development of quality legal instruments of the sector and improving implementation of legal instruments in place.

The legal framework will pay high consideration for socio-economic, political, and cultural context of the society, the sector, the country, the international standards, and science. Also engaging professional with high experience and skill, stakeholders and community should be considered as part of improving the formulation system. When formulation system and process improved there will be high quality legal instruments; comprehensive and harmonized legal framework will be available across federal to region and region to regions and legal instruments that have social aspiration and meet international standards will be realized.

Effective implementation of the law equally matters as developing quality legal instruments. In undertaking activities to bring effective enforcement of the law; it is expected to achieve high rate

of law compliance, reduced illegal product and activities, accessibility to all legal instruments, transparent and accountable system in taking administrative measure and compliant reviewing system and strong collaboration and partnership among law enforcement organ at all levels.

Interventions:

- Establish internal procedure of legal instrument formulation that ensure high quality of the law;
- Conduct problem identification research for purpose of development of legal instruments;
- Prepare policy document, proclamation, regulations, and directives;
- Create a platform that enable sustainable engagement of the stakeholders and public in the preparation of legal instruments;
- Conduct legal impact assessment, and conduct legal audit;
- Identify non-compliance of regulatory and take administrative measures;
- Train law enforcement organs and regulatory sector professionals on regulatory legal frameworks, and provide technical support to law enforcement bodies;
- Conduct court litigation and respond to any claim against the regulatory organ;
- Establish a system to make accessible all legal instruments of the sector and disseminate as appropriate;
- Establish a body and develop a procedure for administrative measure review;
- Initiate, engage and support standard setting body for adoption of standards compulsory to the sector;
- Establish reviewing and monitoring procedure that protect the interest of the regulatory sector against any legal claim;
- Establish voluntary compliance scheme; and
- Form a plat form for information and evidence sharing purpose among law enforcement bodies.

Targets

1. Increase the number of legal instruments developed from 106 to 201
2. Increase percentage of follow-up, timely response to request and providing evidence to police and court for crime investigation and prosecution from NA to 94 %

3. Increased percentage of regulatory legal framework compliance and enforcement from NA to 100
4. Increase percentage of voluntary compliance from NA to 95
5. Increase rate of winning civil cases from NA to 95%

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 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 of 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 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 (eRIS), 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 eRIS such as i-Register, i-Import, i-Liccense, 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 7: 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: - 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.

Chapter VI: Costing and Financing

As part of the HSTP-II plan preparation, the costing of regulatory activities was carried out by using one health tool. But this tool has limitations to accommodate the food and health products regulatory part, that doesn`t have features for it. Hence, the regulatory interventions, as part of HSTP-II were considered as governance and Administration.

The costing part of this FHRSTP-II plan is computed both by one health tool and by developing appropriate format in micro soft excel version 19 that can accommodate possible cost items, and each intervention were costed independently and finally, consolidated together.

6.1. Cost Estimation for strategic Directions

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

The total cost estimation for FHRSTP-II is about ETB 18.12 billion for five years. As conveyed in table 8 and 9, the majority share goes to food safety regulations (33.02%). The second and third majority shares go to human resource development and management (25.7%) which included the salary and related budgets as well as the human resource development aspects of the regulatory sector, and Health regulator infrastructure (21.75%). The infrastructure costs are mainly for establishment of center of excellence, branch lab buildings and regulatory information communication infrastructures. On the other hand, improve efficiency and effectiveness, formulation and implementation of legal frameworks, and improve good governance have the least shares of the FHRSTP-II cost estimation.

Table 8: FHRSTP-II cost estimation of strategic directions (in millions of ETB)

	Strategic Directions	Estimated cost (in millions of ETB)					
		2020/21	2021/22	2022/23	2023/24	2024/25	1st 5 years
1.	Food Regulation	1,174.26	1,184.60	1,201.74	1,211.39	1,212.34	5,984.34
2.	Medicines	309.68	311.48	337.58	328.58	321.65	1,608.98
3.	Medical Devices	42.27	42.34	42.42	42.49	38.24	207.76
4.	Cosmetics	8.28	8.28	8.28	8.28	7.92	41.04
5.	Tobacco Regulation	200.89	200.89	204.49	200.89	199.09	1,006.27
6.	Quality Management System	34.27	40.32	49.38	89.82	107.78	321.57
7.	Good Governance	2.71	2.78	2.95	3.12	3.28	14.82
8.	Human Resource Development and Management	1,012.54	952.11	198.88	1,150.20	1,343.19	4,656.92
9.	Public Ownership	35.40	33.00	33.50	34.50	34.50	170.90
10.	Partnership and Collaboration	20.38	20.38	20.38	20.38	20.38	101.89
11.	Evidence Based decision making	5.00	13.25	3.28	7.31	3.34	32.20
12.	Formulation and Implementation of legal frameworks	3.24	3.30	5.40	2.33	1.88	16.16
13.	Food and health products regulatory Infrastructure	146.25	557.68	1,466.60	1,477.54	292.94	3,941.01
14.	Efficiency and Effectiveness	3.15	3.47	3.81	4.19	4.61	19.23
	Grand Total	2,998.32	3,373.90	3,578.69	4,581.02	3,591.14	18,123.08

Table 9: Cost estimation (in %) of strategic directions

	Strategic Directions	Estimated Cost (%)					
		2020/21	2021/22	2022/23	2023/24	2024/25	1st 5 years
1.	Food Safety Regulation	39.16%	35.11%	33.58%	26.44%	33.76%	33.02%
2.	Medicines	10.33%	9.23%	9.43%	7.17%	8.96%	8.88%
3.	Medical Devices	1.41%	1.26%	1.19%	0.93%	1.06%	1.15%
4.	Cosmetics	0.28%	0.25%	0.23%	0.18%	0.22%	0.23%
5.	Tobacco Regulation	6.70%	5.95%	5.71%	4.39%	5.54%	5.55%
6.	Quality Management System	1.14%	1.20%	1.38%	1.96%	3.00%	1.77%
7.	Good Governance	0.09%	0.08%	0.08%	0.07%	0.09%	0.08%
8.	Human Resource Development and Management	33.77%	28.22%	5.56%	25.11%	37.40%	25.70%
9.	Public Ownership	1.18%	0.98%	0.94%	0.75%	0.96%	0.94%
10.	Partnership and Collaboration	0.68%	0.60%	0.57%	0.44%	0.57%	0.56%
11.	Evidence Based decision making	0.17%	0.39%	0.09%	0.16%	0.09%	0.18%
12.	Formulation and Implementation of legal frameworks	0.11%	0.10%	0.15%	0.05%	0.05%	0.09%
13.	Food and health products regulatory Infrastructure	4.88%	16.53%	40.98%	32.25%	8.16%	21.75%
14.	Efficiency and Effectiveness	0.11%	0.10%	0.11%	0.09%	0.13%	0.11%
	Grand Total	100.00%	100.00%	100.00 %	100.00 %	100.00%	100.00%

6.2. Cost Estimation for interventions

The main intervention areas were identified and costed accordingly. These interventions are the key pillars for the achievements of the strategic directions, these in turn will determine the effectiveness of general objectives/goals.

As depicted in table 10, Human resource management and development, establishment of regulatory excellence center, facility inspection and auditing of food, medicine and medical devices take major shares of the cost estimation. On the contrary, good governance, legal frameworks and, improve efficiency and effectiveness have the least shares in the cost estimation of key interventions.

Table 10: HRSTP-II cost estimation (in millions of ETB) for key interventions

		Estimated Cost (in millions ETB)					
	Interventions	2020/21	2021/22	2022/23	2023/24	2024/25	1st five years
1	Food Regulation	1,174.26	1,184.60	1,201.74	1,211.39	1,212.34	5,984.34
1.1.	Food Registration	2.07	2.68	2.68	3.28	3.28	14.00
1.2.	Food Facilities inspection	503.27	515.78	520.05	511.95	514.43	2,565.47
1.3.	Food Facilities Auditing	499.67	497.42	501.69	504.39	506.87	2,510.03
1.4.	Food facilities Internal Quality management system (IQMS)	0.90	4.90	4.94	4.98	5.03	20.74
1.5.	Food Consignment laboratory tests	39.24	36.99	41.27	43.97	46.44	207.90
1.6.	Food Post Marketing Surveillance and Suspected tests	120.69	118.42	122.70	134.40	127.87	624.08
1.7.	Food Market Survey	8.42	8.42	8.42	8.42	8.42	42.12
2	Medicine Regulation	287.42	289.22	315.32	306.32	305.51	1,503.77
2.1	Medicines Registration	22.93	22.93	22.93	22.93	22.57	114.30
2.2	Medicines Facilities inspection	78.79	87.34	91.61	83.51	85.99	427.25
2.3.	Medicines Facilities Auditing	79.98	77.73	82.00	84.70	87.18	411.59
2.4.	Medicines facilities Internal Quality management system (IQMS)	0.40	0.40	0.40	0.40	0.40	2.02
2.5.	Medicines Consignment laboratory tests	32.58	30.33	34.61	37.31	39.78	174.60
2.6.	Medicines Post Marketing Surveillance	50.06	47.81	61.08	54.78	51.32	265.05
2.7.	Medicines Market Survey	8.60	8.60	8.60	8.60	8.60	43.02
2.8	Pharmacovigilance (ADR reporting, AMR)	14.07	14.07	14.07	14.07	9.66	65.94
3	Medical Device Regulation	42.27	42.34	42.42	42.49	38.24	207.76
3.1.	Medical Devices Registration	6.91	6.91	6.91	6.91	6.55	34.20
3.2.	Medical devices Facilities inspection	1.08	1.15	1.22	1.30	1.01	5.76
3.3.	Medical Devices Consignment and Suspected laboratory tests	10.44	10.44	10.44	10.44	10.44	52.20

		Estimated Cost (in millions ETB)					
	Interventions	2020/21	2021/22	2022/23	2023/24	2024/25	1st five years
3.4.	Medical devices Post Marketing Surveillance	16.64	16.64	16.64	16.64	13.04	79.60
3.5.	Survey on Medical Devices Proper use	7.20	7.20	7.20	7.20	7.20	36.00
4	Tobacco Regulation	200.89	200.89	204.49	200.89	199.09	1,006.27
4.1.	Advocacy	20.53	20.53	20.53	20.53	18.73	100.87
4.2.	Inspection	180.36	180.36	180.36	180.36	180.36	901.80
4.3.	Global Adult Tobacco Survey, Ethiopia	0.00	0.00	3.60	0.00	0.00	3.60
5	Cosmetics Regulation	8.28	8.28	8.28	8.28	7.92	41.04
5.1.	Inspection	8.28	8.28	8.28	8.28	7.92	41.04
6	Clinical trial regulation	1.37	1.37	1.37	1.37	0.65	6.12
6.1.	Clinical trial registration	1.04	1.04	1.04	1.04	0.32	4.50
6.2.	Clinical trial inspection	0.32	0.32	0.32	0.32	0.32	1.62
7	NPS regulation	16.02	16.02	16.02	16.02	10.62	74.70
7.1.	Narcotic and psychotropic Inspection	5.47	5.47	5.47	5.47	0.07	21.96
7.2.	Advocacy	10.55	10.55	10.55	10.55	10.55	52.74
8	SF products control	4.88	4.88	4.88	4.88	4.88	24.39
8.2.	Strengthening of regulatory intelligence works	4.88	4.88	4.88	4.88	4.88	24.39
9	Improve Regulatory infrastructure	146.25	557.68	1,466.60	1,477.54	292.94	3,941.01
9.1.	Establish Regulatory excellence center	0.00	360.00	1,123.50	1,147.50	28.50	2,659.50
9.2.	Construction of Branch quality assurance laboratories	0.00	29.00	145.00	145.00	87.00	406.00
9.3.	Construction and equipping of mobile labs at entry exit ports	0.00	7.50	15.00	10.50	0.00	33.00
9.4.	Furniture cost for all federal offices and labs	10.00	20.00	30.00	50.00	100.00	210.00
9.5.	ICT equipments and related costs	136.25	141.18	153.10	124.54	77.44	632.51

		Estimated Cost (in millions ETB)					
	Interventions	2020/21	2021/22	2022/23	2023/24	2024/25	1st five years
10	Quality Management System (lab Internal audit, ISO certification, WHO prequalification and GBT 3 processes)	34.27	40.32	49.38	89.82	107.78	321.57
11	Good Governance	2.71	2.78	2.95	3.12	3.28	14.82
12	Human Resource Development and Management	1,012.54	952.11	198.88	1,150.20	1,343.19	4,656.92
13	Public Ownership	35.40	33.00	33.50	34.50	34.50	170.90
14	Partnership and Collaboration	20.38	20.38	20.38	20.38	20.38	101.89
15	Evidence Based decision making	5.00	13.25	3.28	7.31	3.34	32.20
16	Formulation and Implementation of legal frameworks	3.24	3.30	5.40	2.33	1.88	16.16
17	Efficiency and Effectiveness	3.15	3.47	3.81	4.19	4.61	19.23
	Grand Total	2,998.32	3,373.90	3,578.69	4,581.02	3,591.14	18,123.08

6.3. Financial sources

The food and health products regulatory sector has three financial sources: treasury, revenue and external sources.

6.3.1. 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 FHRSTP-II 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.

6.3.2. 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 76 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.

6.3.3. 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 FHRTSTP-II costing. For the five years, efforts will be done to mobilize resources from external sources to implement the programs and key interventions, and it will get decreased after five years, as the regulatory revenue will increase dramatically, the completion of the excellence center will transform the revenue.

Chapter VII: Monitoring and Evaluation Plan

7.1. Monitoring and Evaluation System

Monitoring and Evaluation (M&E) system is an integral part of the FHRSTP 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 five 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 88 indicators are selected to monitor and evaluate the FHRSTP II. 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 5 years. Some indicators are analyzed on a monthly basis, others on a quarterly, annual, 2-3 years and 5 years' time period.

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 FHRSTP II. The common data sources used to measure and inform FHRSTP II 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 (ERIS), 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 FHRSTP II. 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 FHRSTP-II. 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 FHRSTP II 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 FHRSTP-II Monitoring

Table 11: Indicators and Targets

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
	Objective 1: Protect the people from unsafe food												
1.	Prevalence of unsafe food available in the market	Outcome	NA	25				25		assessment/ survey report	survey	4 years	FFID, FRLD, FQAD
2.	Prevalence of illegal food products in the market	outcome	50	30			40		30	survey report	survey	Every 2 and half years	FFID, FRLD, FQAD
3.	Percentage of food adulteration prevalence in the market	Outcome	NA	30				30		assessment/ survey	survey	4 years	FFID, FRLD, FQAD
	Objective 2: Safeguard the public from falsified, substandard and ineffective health related products												
4.	Percentage of Substandard and Falsified medicines	Outcome	NA	5			6.5		5	assessment/ survey report	survey	2 and half years	MFID, MQAD, MRLD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
5.	Percentage of Substandard and Falsified medical devices in the market	Outcome		10			12		10	assessment/ survey report	survey	2 and half years	MFID, MQAD, MRLD
6.	Percentage of Good Dispensing Practice at retail outlets	outcome	**50**	65		60			65	assessment/ survey report	survey	2 -3 years	MFID
7.	Percentage of administrative measures taken against any regulatory non-compliance	output	95	99	96	96.5	97	98	99	assessment/ survey report	Review of administrative reports	Annual	PSD/ MFID
	Objective 3: Protect the public from tobacco and alcohol related health risks												
8.	Prevalence of tobacco smoking and use	outcome	5	3				3		survey report	survey	5 years	PSD
9.	Prevalence of alcohol use	outcome	41	39				39					
	Objective 4: Attain public confidence on food and health product regulation												
10.	Percentage of community satisfaction on the regulatory sector	outcome	N/A	75				75		survey report	survey	5 years	PPCD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
11.	Public trust score	outcome	NA	4				4		survey report	survey	5 years	RGD
12.	Transparency score						7.5		9	survey report	survey	2 and half years	RGD
	Strategic direction 1: Strengthen food safety regulation												
13.	Number of market authorized food products	output	2739	12,213	2520	2550	2400	2350	2393	Performance Report	review of performance report	Monthly /Quarterly	FRLD
14.	Local food facilities audit inspection coverage	output	76	100	85	90	95	100	100	Performance Report	review of performance report	Quarterly	FFID
15.	Number of foreign on-site inspection conducted on selected food product manufacturing facilities	output	2	110	0	20	25	30	35	Performance Report	review of performance report	Quarterly	FFID
16.	Coverage of food facilities implementing IQMS/ Regulatory requirements.	output	35	70	40	45	50	60	70	Performance Report	review of performance report	Quarterly	FFID

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
17.	Coverage of street vendors implemented GHP	output	0	50	5%	10	25	35	50	Performance Report	review of performance report	Quarterly	FFID
18.	Coverage of mass Catering service implement GHP & GCP	output	0	50	5	10	25	35	50	Performance Report	review of performance report	Quarterly	FFID
19.	Number of food product types tested via PMS laboratory	output	28	72	33	40	50	65	72	Performance Report	review of performance report	Quarterly	FQAL
20.	Number of food product types for consignment laboratory tests	output	28	60	38	43	48	53	60	Performance Report	review of performance report	Quarterly	FQAL
	Strategic direction:2 Strengthen detection, prevention, and response to food adulteration and illegal food products												
21.	Number risk-based intelligence led food surveillance and operations conducted	output	4	10	2	2	2	2	2	Performance Report	review of performance report	Quarterly	FFID
22.	Number of risk-based market assessments conducted	output	12	72	12	12	12	12	12	Performance Report	review of performance report	Quarterly	FFID

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
	16. Strategic direction 3: Improve regulation of safety, efficacy, quality and proper use of medicines												
23.	Number of Registered Medicines	output	4,729	**9500**	1050	1070	1100	1150	1170	Performance Report	review of performance report	Quarterly	MRLD
24.	Number of Registered Traditional medicines	output	0	**10**	2	2	2	2	2	Performance Report	review of performance report	Quarterly	MRLD
25.	Number of ADR Reports received as per WHO standard	output	1442	**11000**	4000	7000	8000	9000	10000	Performance Report	review of performance report	Quarterly	PSD
26.	No of serious adverse event investigated and causality assessment performed	output	12	**29**	16	18	21	25	29	Performance Report	review of performance report	Quarterly	PSD
27.	Signal detection	Output	0	**10**	2	2	2	2	2	Performance Report	review of performance report	Quarterly	PSD
28.	Percentage of inspection Coverage medicine importers and wholesalers (retail outlets)	output	100 (75)	100 (90)	100 (78)	100 (82)	100 (85)	100 (87)	100 (90)	Performance Report	review of performance report	Quarterly	MFID

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
29.	Percentage of inspected consignments at set targeted time frame at PoE	output	100	100	100	100	100	100	100	Performance Report	review of performance report	Quarterly	Branch /Port offices
30.	Number of Medicine Facilities inspected against the national GMP requirements	output	120	**300**	150	180	220	260	300	Performance Report	review of performance report	Quarterly	MFID
31.	Percentage of medicines consignment tested against imported products	output	21	**55**	25	30	35	50	55	Performance Report	review of performance report	Quarterly	MQAD
32.	Percentage of medicines PMS tested against marketed products	output	22	**55**	25	30	35	50	55	Performance Report	review of performance report	Quarterly	MQAD
33.	Number of Clinical Trial applications approved	output	13	**200**	30	35	40	45	50	Performance Report	review of performance report	Quarterly	PSD
34.	Number of clinical trials inspected	output	2	**200**	30	35	40	45	50	Performance Report	review of performance report	Quarterly	PSD
	Strategic direction 4: Strengthen Regulation of Safety, Quality and Performance of Medical Devices												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
35.	Number of registered medical devices	output	4527	10050	6000	7000	8000	9000	10050	Performance Report	review of performance report	Quarterly	MRLD
36.	Number of types of medical devices consignment tested	output	1	**25**	4	10	15	20	25	Performance Report	review of performance report	Quarterly	MQAD
37.	Number of types of medical devices PMS tested	output	1	**25**	4	10	15	20	25	Performance Report	review of performance report	Quarterly	MQAD
38.	Inspection coverage (%) of medical devices importer and wholesaler (Retail outlets)	output	40	100 (75)	100 (90)	100 (78)	100 (82)	100 (85)	100 (87)	Performance Report	review of performance report	Quarterly	MFID
39.	Number of medical devices facility GMP inspection conducted /audited per the national standard.	output	6	**65**	8	10	12	15	20	Performance Report	review of performance report	Quarterly	MFID
40.	Number adverse device events reports received per year	output	0	**430**	30	100	100	100	100	Performance Report	review of performance report	Quarterly	PSD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
41.	Number of clinical trial/ investigation applications approved	output	3	**80**	5	10	15	20	30	Performance Report	review of performance report	Quarterly	PSD
42.	Approved medical devices inspection at port of entry (import /export)	output	2600	10000	3000	5000	7000	8000	10000	Performance Report	review of performance report	Quarterly	Branch /Port offices
43.	percentage of ineffective, defective and malfunctioning medical devices in the market	outcome	NA	30			35		30	survey report	survey	2-3 years	MFID
	Strategic Direction 5: Improve regulation of safety of cosmetic products												
44.	Number of issuances of notification notes	output	0	**3000**	500	500	500	500	1000	Performance Report	review of performance report	Quarterly	MFID
45.	Percentage of suspected cosmetic products tested for safety	output	0	100	100	100	100	100	100	Performance Report	review of performance report	Quarterly	MFID
46.	Percentage of Inspection coverage of the supply chain	output	30	60	40	45	50	55	60	Performance Report	review of performance report	Quarterly	MFID
	Strategic direction 6: People protected from risks related to tobacco and alcohol												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
47.	Number of smoke free public places	output	109,000	**218,000**	130,800	152,600	174,400	196,200	**218,000**	Performance Report	review of performance report	Quarterly	PSD
48.	Percentage of Illicit trade of Tobacco	outcome	NA	15				15		survey report	Survey	5 years	PSD
49.	percentage of Advertisement, Sponsorship, and Promotion (ASP) of tobacco	outcome	42	15				15		survey report	Survey	5 years	PSD
50.	percentage of Advertisement, Sponsorship, and Promotion (ASP) of alcohol	outcome	NA	25				25					
51.	Percentage of alcohol sale in prohibited areas	Output	NA	50				50					
	Strategic direction 7: Improve Quality Management System												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
52.	No of EFDA Inspection directorates (HQ and branches/ ISO 1720/ 2012 accredited	output	0	**8**	0	1	1	4	2	Performance Report	review of performance report	annual	QMU
53.	EFDA regulatory functions ISO 9001/2015 Certified	output	0	**1**	0			1		Performance Report	review of performance report	annual	QMU
54.	No of EFDA's laboratories ISO 170205/2017 Accredited	output	2	5	0			5		Performance Report	review of performance report	annual	QMU
55.	EFDA Maturity level 3 recognition	output	NA	3	1	1	3			Performance Report	review of performance report	annual	QMU
56.	WHO prequalified lab	output	0	**1**	0	0	0	1		Performance Report	review of performance report	annual	QMU
	Strategic direction 8: Enhance partnership and collaboration												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
57.	Percentage of stakeholders that participated in the planning, monitoring and evaluation of the regulatory activities	output	68	100	80	85	90	95	100	Performance Report	review of performance report	annual	
58.	Number of strategic partnership and collaboration established with international, federal, and local organizations	outcome	NA	10		5			5	assessment report	assessment	2-3 years	
59.	Number of joint activities of regulatory function conducted with different stakeholders	output	NA	45	9	9	9	9	**9**	Performance Report	review of performance report	annual	
	Strategic direction 9: Improve community ownership												
60.	Percentage of the population who are informed about regulatory measures, laws and activities	outcome	46	70			60		70	survey report	Survey	2-3 years	PSD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
61.	Percentage of investigated tipoff, complaints and concerns from the public.	output	0.89	3	2	2.3	2.5	2.7	3	Performance Report	review of performance report	Quarterly	PSD
62.	Percentage of population whose age above 13 years old, who got regulatory information through media outlet	output	NA	75	55	60	65	70	75	survey report	survey	annual	PRD
	Strategic direction 10: Strengthen Formulation and implementation of legal frameworks												
63.	Number of legal instruments developed	output	106	201	20	20	40	10	5	Performance Report	review of performance report	Quarterly	LPD
64.	Percentage of follow-up, timely response to request and providing evidence to police and court for crime investigation and prosecution	output	NA	94	90	90	92	92	94	Performance Report	review of performance report	Quarterly	LPD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
65.	Percentage of regulatory legal framework compliance and enforcement	outcome	NA	100			100		100	survey report	Survey	2-3 years	LPD
66.	Percentage of voluntary compliance	outcome	NA	95	80	95	95	95	95	survey report	Survey	annual	LPD
67.	Rate of winning civil cases	outcome	NA	95	75	80	85	90	90	survey report	Survey	annual	LPD
	Strategic Direction 11: Enhance good-governance												
68.	Customer satisfaction level	outcome	50.2	80	60	65	70	75	80	survey report	Survey	annual	RGD
69.	Percentage of regulatory services provided as per the standard	output	80	100	85	90	95	97	100	Performance Report	review of performance report	Quarterly	RGD
70.	Reduce percentage of service delivery complaints	outcome	84	100	88	90	93	95	100	survey report	Survey	annual	RGD
71.	Number of developed ant-corruption strategy	output	0	1		1				Performance Report	review of performance report	annual	RGD/ Ethics
	Strategic Direction 12: Improve human resource development and management												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
72.	Employee satisfaction level	outcome	38%	65%	45	50	55	60	65	survey report	Survey	annual	HRD
73.	Percentage of training effectiveness	outcome	NA	80	60	65	70	75	80	Assessment report	Assessment	annual	HRD
74.	Attrition rate of employees	outcome	3.4	2	3	2.8	2.5	2.3	2	Performance Report	review of performance report	annual	HRD
75.	Organizational health status	outcome	NA	70	50	53	58	63	70	survey report	Survey	annual	HRD
	Strategic Direction 13: Improve efficiency and effectiveness												
76.	Medicine registration lead time (in days)	output	90	60	85	80	75	70	60	Performance Report	review of performance report	Quarterly	MRLD
77.	Amount of resource mobilization (in million birr)	output	97.5	1,641.50	297.5	633.5	969.5	1,305.50	1,641.50	Performance Report	review of performance report	Quarterly	PPCD
78.	Improved percentage of budget utilization	output	NA	95	80	85	87	90	95	Performance Report	review of performance report	Quarterly	All Directotes /Branches
	Strategic Direction 14: Improve Evidence Based Decision Making												

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
79.	% of expected reports received from reporting units on time	output	NA	95	75	80	85	90	95	Performance Report	review of performance report	Quarterly	PPCD
80.	% of expected reports received from reporting units complete	output	NA	80	60	65	70	75	80	Performance Report	review of performance report	Quarterly	PPCD
81.	Number of conducted surveys/assessments	output	NA	56	7	7	15	56	7	Performance Report	review of performance report	Quarterly	PPCD
82.	Number of produced peer-reviewed journal	output	NA	10	1	2	2	2		Performance Report	review of performance report	Quarterly	PPCD
	Strategic Direction 15: Strengthen food and health products Regulatory Infrastructures												
83.	Established well equipped and furnished center of health regulatory excellence	output	0	1			1			Performance Report	review of performance report	Annual	PPCD
84.	Number of branch laboratories and offices	output	5	17		1	5	5	1	Performance Report	review of performance report	Annual	PPCD
85.	Established and well-equipped mini labs at entry/exit ports	output	0	22		5	10	7		Performance Report	review of performance report	Annual	PPCD/ MQAD /FQAD

S.N	Indicator	Indicator type	Baseline	target	Indicator Target Values					Data Source	Data collection methods	Frequency of data collection	Responsible
					2020/21	2021/22	2022/23	2023/24	2024/25				
86.	Established national rapid alert system	output	0	2		1			1	Performance Report	review of performance report	Annual	ITD
87.	Number of regional regulatory bodies that implemented i-license system	output	0	12	2	5	5			Performance Report	review of performance report	Annual	ITD
88.	Number of automated systems implemented	output	NA	4		2	2			Performance Report	review of performance report	Annual	ITD