RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FOOD AND DRUGS AUTHORITY STRATEGIC PLAN 2021–2024

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Statement by the Chairman of the Board of Directors

I am pleased to introduce a four-year Rwanda Food and Drugs Authority (FDA) Strategic Plan (SP) (2021–2024) on behalf of the Board of Directors (BoD). Development of this plan has taken into account critical framework documents, including the National Strategy for Transformation (NST1), the National Health Policy (2015), the Health Sector Strategic Plan (HSSP) IV for the Ministry of Health (MOH) of Rwanda, the National Pharmacy Policy (NPP) 2016, the National Food and Nutrition Policy (2014), and Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

The primary mandate of the Rwanda FDA is reflected in the authority's mission, which is "to regulate human and animal medical products, processed foods, household products, and tobacco and tobacco products to ensure their quality and safety so as to protect the population of Rwanda from defective, falsified, and substandard products." This mission is in line with the National Health Policy (2015) and National Food and Nutrition Policy (2014). I anticipate that the implementation of this SP will demonstrate the extent to which the Rwanda FDA's vision of "being a world class regulatory authority effectively protecting and promoting public health" will be realized.

This SP outlines strategies and interventions to be undertaken and resources needed for their implementation. Funds are derived from fees and charges on services offered by the Rwanda FDA, Government subvention, and contributions from development partners.

Apart from addressing issues specifically focusing on the safety, efficacy, and quality of regulated products, fundamental issues have also been emphasized in relation to improving social services for employees, and considerations for gender, environmental protection, HIV/AIDS services, and management of non-communicable diseases have been included. Furthermore, implementation of the National Anti-Corruption Strategy has been taken into consideration.

The BoD will provide the necessary support, including liaising with the MOH, to facilitate thorough execution of this plan. In this respect, I ostensibly urge the Rwanda FDA management and staff to embrace the core values stipulated in the plan as the Rwanda FDA's hallmark and closely monitor and manage resources to achieve the objectives and subsequently the targets set out in the plan.

I wish the Rwanda FDA management and staff successful implementation of this four-year SP (2021–2024).

This was done at Kigali, Rwanda, on this 20th day of February Two Thousand and Twenty-One.

Dr Etienne KARITA
Chairman Board of Directors
Rwanda Food and Drugs Authority

Statement by the Director General

This SP covers a period of four years from January 2021 to December 2024. The plan sets out objectives, strategies, and targets necessary to achieve the authority's mission of protecting and promoting public health by ensuring the quality and safety of food, human and veterinary medicines, cosmetics, and medical devices and diagnostics. It also sets out key performance indicators (KPIs) to monitor the progress and success toward achieving established objectives and targets.

We are embarking on our journey to become a world-class regulatory authority that effectively protects and promotes public health. As Rwanda's economy continues to develop, we must respond to the rapid pace of innovation; the tighter integration of global supply chains; and the increasing demands of our citizens for safe, effective, and quality food, cosmetics, and health-related products.

We expect to meet these challenges by making informed decisions based on scientific evidence and by building effective partnerships with the private sector, government entities, and international partners. We commit to earning the trust of the people of the Republic of Rwanda by engaging proactively with the public and building a high-performing, efficient, and innovative organization that allows our staff to be the best in all they do.

In November 2018, the World Health Organization (WHO) conducted a benchmarking assessment on the capacity of the Rwanda FDA to regulate medical products. The assessment provided useful input in the development of this strategic plan (SP), and stakeholders were involved at different stages of its development, discussions, and finalization.

Implementing these Rwanda FDA strategies is of paramount importance to meet, and where possible, exceed the expectations of its customers and the public at large. In this regard, the Rwanda FDA management is committed to provide the necessary resources for successful implementation of this SP. The monitoring and evaluation of the plan will be done to ensure that anticipated performance results are achieved.

I feel indebted to the Rwanda FDA management and employees who contributed ideas, suggestions, experiences, expertise, and time to the development of this SP. In a special way, I thank the management of the Ministry of Health (MOH), chairperson, members of the Board of Directors, and all stakeholders for their continued support and cooperation toward achieving the Rwanda FDA's vision and mission. I also thank the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) program for its technical support in the finalization of this SP and the Global Health Supply Chain – Procurement and Supply Management support to initiate the development of Rwanda FDA strategic plan.

Dr Charles KARANGWA
Ag. Director General
Rwanda Food and Drugs Authority

Executive Summary

The Rwanda Food and Drug Authority (FDA) Strategic Plan (SP) was developed to ensure proper implementation of the Authority's mission provided under Law N° 003/2018 of 09/02/2018, which is to protect public health by regulating human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials. The SP lays out the strategic objectives and interventions to achieve targeted regulatory and health outcomes in the next four years, from 2021 to 2024.

The Rwanda FDA's SP was developed through a multidisciplinary process of consultations among Rwanda FDA divisions and departments and validation with all key sector stakeholders. The SP is organized into four chapters. The first chapter provides background on the establishment of the Rwanda FDA and its organization and management. The second chapter describes the current situation and provides context for the regulation of processed food, veterinary medicines, cosmetics, household chemicals and human medicines and pharmaceutical products. The third chapter presents the Rwanda FDA's vision, mission, core values, and strategic framework (i.e., objectives, interventions, targets, and key performance indicators). The last chapter covers the implementation framework and monitoring and evaluation plan.

The SP is structured according to the following three strategic priority areas. The strategic results for each strategic priority area and the strategic objectives under each are summarized below:

1) **Strengthen the Rwanda FDA's role to ensure compliance to specified standards and requirements for regulatory processes and regulated products**

- **Strategic Result:** Strengthened regulatory functions and roles that will support the Authority to execute its mandate and guide the regulated industry to comply with regulations for the benefit of the Rwandan people. Rwanda FDA has the core responsibility of ensuring the safety, efficacy, and quality of drugs, food, cosmetics, and tobacco products in an effective and efficient manner. Therefore, the Authority intends to focus on building confidence in the population by putting in place a regulatory framework that will increase investment opportunities and improve regulatory and health outcomes while meeting stakeholders' expectations.
- **Strategic Objectives:**
    - Strategic Objective 1: To develop and ensure compliance with FDA's regulations and guidelines through regulatory licensing and inspection of premises for regulated products
    - Strategic Objective 2: Enhance product registration/marketing authorization processes according to best practices and international standards
    - Strategic Objective 3: Regulate and provide clinical trials oversight on medicines, including herbal medicines, vaccines, biological products, and medical devices
    - Strategic Objective 4: Strengthen the system of pharmacovigilance and post-market surveillance for effective regulation of medicines and related health products

- Strategic Objective 5: Establish the Rwanda FDA laboratory and develop the regulatory framework to perform post-market surveillance testing of all regulated products

2) Collaborate effectively with the public and private sectors and national and international partners

- **Strategic Result:** Efficient customer service, stakeholder management and engagement, improved public image, and fair and balanced regulatory decisions. It is the responsibility of the Authority to serve the people of Rwanda and meet stakeholder expectations. This can be achieved by enhancing service coverage; communicating and publishing the regulatory framework; applying regulatory decisions in a fair, transparent, and accountable manner; responding in a timely manner to customer needs; and constructively collaborating and partnering with national, regional, and international agencies and institutions that contribute to the core responsibilities of the Rwanda FDA
- **Strategic Objectives:**
  - Strategic Objective 1: Engage proactively with the public and private sectors (including the regulated industries) and other national stakeholders to ensure the quality and safety of all regulated products
  - Strategic Objective 2: Harness collaboration and partnership arrangements with international organizations in areas of mutual interest and benefit to strengthen Rwanda FDA's regulatory capacity

3) Enable an accountable, high-performing, innovative, and sustainable organization

- **Strategic Result:** A high-performing organization that delivers efficient and innovative regulatory services with highly motivated and competent staff using an effective governance framework with appropriate infrastructure and sustainable financial management that fosters institutional accountability, risk management, and continuous performance improvement. The Authority will continuously invest in research and development and workforce development to provide a platform for innovative service delivery. It will also strive to achieve the highest standards of corporate governance and put in place the right infrastructure. It will establish a risk management, logistics, and procurement system; performance management system; and financial management for effective implementation of the authority's mandate. Rwanda FDA shall continue the development of the workforce, systems, and infrastructure needed to address the emerging, complex challenges brought by the current operating environment.
- **Strategic Objectives:**
  - Strategic Objective 1: Strengthen organizational management and capacity building framework for developing, attracting, and retaining talent to ensure effective implementation of the Rwanda FDA's mandate
  - Strategic Objective 2: Strengthen governance structure and financial management to enhance accountability and sustainability and improve efficiencies

- Strategic Objective 3: Establish mechanisms to promote operational research on all regulated products, foster innovation, and enhance the use of modern information management systems to improve decision making

Rationale, interventions, targets, milestones, and key performance indicators (KPIs) (both output and outcome indicators) have been developed for each of the 10 strategic objectives corresponding to the three priority areas identified. Specific, Measurable, Achievable, Realistic, and Time-bound (SMART) targets and indicators have been crafted for each objective to facilitate monitoring and evaluation and easy measurement of performance. The monitoring and evaluation plan, results framework matrix, and reporting plan have been developed to bring about responsibility and accountability in the implementation of this plan.

Acronyms

ADR	adverse drug reaction
AEFI	adverse event following immunisation
AMA	African Medicines Agency
AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization
BOD	board of directors
CRP	Collaborative Registration Procedure
CTD	Common Technical Document
EAC	East African Community
EDPRS	Economic Development and Poverty Reduction Strategy
FDA	Food and Drugs Authority
GBT	Global Benchmarking Tool
GDP	gross domestic product
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
HSSP	Health Sector Strategic Plan
IPPIS	integrated payroll and personnel information system
ISO	International Organization for Standardization
IVP	veterinary immunological products
KPI	key performance indicator
LIMS	Laboratory Information Management System
M&E	monitoring and evaluation
MA	marketing authorization
MOH	Ministry of Health
MTaPS	Medicines, Technologies, and Pharmaceutical Services program
NPP	National Pharmacy Policy
NST	National Strategy for Transformation
OIE	World Organization for Animal Health
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIRS	performance indicator reference sheets
PMS	post-marketing surveillance
PRIMS	Pharmaceutical Regulatory Information Management System
PV	pharmacovigilance
QMS	quality management system
RAB	Rwanda Agriculture Board
RARDA	Rwanda Animal Resources Development Authority
RMS	Rwanda Medical Stores
RSB	Rwanda Standards Board
RWF	Rwandan franc
SMART	Specific, Measurable, Achievable, Realistic, and Time-bound
SME	small and medium enterprise
SOP	standard operating procedure
SP	strategic plan
SWOT	strengths, weaknesses, opportunities, and threats
USAID	US Agency for International Development
WHO	World Health Organization

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Chapter I: Introduction

1.1 Background

The 1994 Rwanda genocide against the Tutsi destroyed almost all economic, legal, and social infrastructure, leading the country into near-total ruin. After this period, the country's rehabilitation required an adequate legal framework to manage the situation of post-genocide and war. Rwanda's framework for development, Vision 2020, and the Economic Development and Poverty Reduction Strategy (EDPRS) II 2013–2018 set the target to achieve income status by 2020 with an annual growth rate of 11.5% and a per capita gross domestic product (GDP) of USD 1,200. In line with its policy of economic development and good governance, in 2018, the Government of Rwanda established the Rwanda Food and Drug Authority (FDA) to contribute to the achievement of the country's socio-economic goals and protection of public health. The Rwanda FDA is an autonomous entity mandated by Law N° 003/2018 of 09/02/2018 to protect public health by regulating human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials.

This is the first strategic plan for the Rwanda FDA since its establishment in 2018. The FDA Strategic Plan (SP) is aligned with the authority's mandate and critical framework documents, including the National Health Policy (2015), the Health Sector Strategic Plan (HSSP) IV for the Ministry of Health (MOH) of Rwanda, the National Pharmacy Policy (NPP) 2016, the National Strategy for Transformation 1 (NST1) 2017–2024, the National Food and Nutrition Policy (2014), and Law N° 47/2012 Of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products. The alignment of Rwanda FDA's strategic priorities and objectives, NST 1, and the health sector's goals and objectives is included in Annex 1.

The Rwanda FDA's comprehensive set of laws and regulations is publicly available on the Rwanda FDA website. The authority's legal framework, including approved laws, regulations, guidelines, standard operating procedures (SOPs), and forms for regulatory oversight, presents an opportunity to build a strong regulatory system with a solid foundation. The Rwanda FDA aims to streamline revenue streams through its operations so that it can sufficiently function without much reliance on government funding.

Rwanda FDA works closely with local government, Rwanda National Police, Rwanda Investigation Bureau, and international organizations to coordinate enforcement of and compliance with regulations to ensure maximum impact for the public welfare. The Authority also develops partnerships, as appropriate, with the private sector, including regulated industries, academic institutions, trade organizations, advocacy groups, and nongovernmental organizations. By leveraging resources from organizations and individuals with shared interests, Rwanda FDA is better able to accomplish its mission through strategies that minimize administrative and financial burdens and increase benefits to the public. Recognizing the importance of border trade and engagement with regional and international regulatory bodies, the Rwanda FDA will work with local, regional, and international players to ensure that the objectives of this plan are achieved.

The Rwanda FDA's SP was developed through a multidisciplinary process of consultations among Rwanda FDA divisions and departments and validation with all key sector stakeholders. The SP

is organized into four chapters. The first chapter provides background on the establishment of the Rwanda FDA and its organization and management. The second chapter describes the current situation and provides context for the regulation of processed food, veterinary medicinal products and human medicinal products, medicated cosmetics, pesticides, chemicals, and poisons. The third chapter presents the Rwanda FDA's vision, mission, core values, and strategic framework (i.e., objectives, interventions, targets, and key performance indicators). The last chapter covers the implementation framework and monitoring and evaluation plan.

This four-year SP will be used to develop annual action plans with resources, designated roles and responsibilities of key actors, and measurable milestones. The SP will be evaluated two years after its implementation to assess its progress and realign priorities as needed.

1.2 Rwanda FDA's Institutional Framework

The specific functions of the Rwanda FDA are prescribed in article 8 of Law N° 003/2018 of 09/02/2018 (listed below). Several other legal and regulatory instruments enable the Rwanda FDA to discharge its responsibilities in each sector to be regulated.

Rwanda FDA's Mandate

i. Regulate pharmaceutical products, vaccines and other biological products, human and veterinary processed foods and food supplements, food fortificants, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical, and food products and clinical trials
ii. Regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labelling, packaging, and raw materials used in the manufacture of products regulated under this Law
iii. Regulate laboratory and cleaning chemicals and pesticides as well as premises involved in the manufacture of products regulated under this Law
iv. Establish, approve, and publish the list of human and veterinary food and pharmaceutical products as well as other products regulated under this Law for which marketing authorization (MA) has been granted
v. Establish and publish the list of prohibited cosmetics
vi. Establish the quality assurance and quality control of products regulated under this Law through designated quality control laboratories when necessary
vii. Regulate and inspect clinical trials
viii. Ensure that processed food, food supplements, and fortified food meet the prescribed quality standards before they are placed on the market
ix. Conduct pharmacovigilance (PV) and post-marketing surveillance for safety and quality of products regulated under this Law
x. Follow up and analyse information on the use of pharmaceutical products that are usually subject to global drugs safety monitoring
xi. Regulate and analyse information used in the promotion, advertising, and marketing of products regulated under this Law
xii. Regulate the use of unregistered products regulated under this Law for clinical trial purposes or compassionate use

xiii. Disseminate information on quality and safety of products regulated under this Law to health professionals and other concerned persons
xiv. Conduct operational research and studies on food and pharmaceutical products and publish the findings to contribute to the investment promotion
xv. Build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions
xvi. Advise the Government on all matters regarding the products regulated under this Law

Management, Structure, and Staffing

The management bodies of the Rwanda FDA are the Board of Directors (BOD) and the executive organ. The BOD is the supreme management and decision-making organ, with full authority over administration, human resources, and property of the Rwanda FDA to fulfil its mission. The executive organ of the Rwanda FDA comprises the director general, who is appointed by a presidential order, and other staff members recruited in accordance with relevant laws. A presidential order may also be used to appoint deputy director general and determine their powers and duties. The executive organ of the Rwanda FDA has the responsibility to monitor and coordinate daily duties and activities and to perform other duties as assigned by the BOD and in accordance with the Rwanda FDA's mission. The director general reports to the BOD and has the power to make decisions regarding the administrative and financial management of the Rwanda FDA. He or she also coordinates and directs the activities of the Rwanda FDA. The senior management team of the Rwanda FDA comprises the director general, department heads, and division managers.

The Rwanda FDA's functions are executed through three departments: The Food and Drugs Assessment and Registration Department, the Food and Drugs Inspection and Safety Monitoring Department, and the Finance and Administration Department. These three departments are supported by five divisions:

- Drug and Health Technologies Assessment and Registration,
- Food Assessment and Registration,
- Pharmacovigilance and Food Safety Monitoring,
- Drug and Food Inspection and Compliance,
- and Quality Control Laboratory

In the quest for continuous improvement in the performance of individual staff members and the institution as a whole in terms of scope and depth; a revised organizational chart has been developed and approved by the Cabinet, in its meeting of 14/12/2020, the Prime Minister's Order N° 162/03 of 21/12/2020 Determining Organisational Structure of Rwanda Food and Drugs Authority was also published in the official Gazette n° 41 of 21/12/2020. The new structure for the Rwanda FDA aims to allow a re-organization of the institutional arrangement for increased efficiency and performance toward effective implementation of the authority's legal mandate. Both the previous and the revised organizational charts are included in Annex 2.

The previous organizational structure of the Rwanda FDA dated 2017 included 155 staff while the new approved structure has 194 staff. In addition to the increase of staff members by 39 within the new structure; the positions of Directors were upgraded to Division managers, Specialists

upgraded to Analysts and Officers for technical departments also upgraded to Specialists. Considering that the restructuring process is not a one-day activity but rather a process; Rwanda FDA shall be implementing both structures concurrently while staff placement/recruitment in the new positions is ongoing in line with relevant laws, however, the Authority should have all staff members in place as per the new structure by December 2021.

1.3 Rwanda FDA Quality Policy Statement

The Rwanda FDA is committed to providing the highest standard of regulatory service to all customers through the implementation of a quality management system that complies with International Organization for Standardization (ISO) 9001:2015.

Timely and reliable service; compliance with all applicable statutory and regulatory requirements; continual improvement of processes, systems, and procedures; and meeting customer requirements underlie all our efforts in ensuring the quality, safety, efficacy, and wholesomeness of all regulated products used in Rwanda.

This is achieved through product assessment and registration, licensing, control of imports and exports, pharmacovigilance (PV), post-marketing surveillance, clinical and field trials, control of publications and advertisements, laboratory testing, inspection, and enforcement.

The Rwanda FDA shall therefore commit adequate financial, human, physical, and technological resources for implementing, maintaining, and continually improving the quality management system to achieve set objectives and maintain an adequate workforce that is trained, motivated, facilitated, and empowered to achieve results.

Quality objectives, processes, systems, and procedures that support this quality policy are established and reviewed every 3 years for continuing suitability.

This Rwanda FDA quality policy statement aligns with Rwanda quality policy aimed at delivery of quality products and services through establishment of quality management systems in all government institutions.

1.4 Risks and Mitigation Measures

The Rwanda FDA recognizes that internal and external risks to the authority could deter the successful implementation of this SP. Risk and likelihood rating scales have been developed in alignment with the Rwanda FDA risk management framework and are summarized in Table 1. The identified risks and potential mitigation strategies are included in Table 2.

Table 1. Risk Likelihood and Risk Impact Rating Scale

Risk Likelihood (Rank)	Score	Risk Impact (Rank)
Very High *(Almost Certain)*	**5**	Very High *(Catastrophic)*
High *(Likely)*	**4**	High *(Major)*
Moderate *(Possible)*	**3**	Moderate *(Possible)*
Low *(Unlikely)*	**2**	Low *(Minor)*
Very Low *(Rare)*	**1**	Very Low *(Insignificant)*

Table 2. Identified Risks and Mitigation Measures

Risk	Likelihood	Impact	Mitigation Response
Lack of understanding and ownership of the strategic goals and objectives by those who are involved in SP implementation	**3**	**4**	• Secure early engagement with stakeholders through consultations during the development of the SP
Lack of commitment from the authority's top management	**2**	**5**	• Establish accountability measures for leadership in SP implementation
Lack of coordination among all implementers	**4**	**4**	• Development of annual plans with detailed activities • Mapping of stakeholders • Establishment of a coordination mechanism within the Rwanda FDA
Delayed approval and implementation of activities	**2**	**3**	• Periodic review and reporting of activity status • Develop action plans that include mitigation measures for delayed implementation
Inadequate funding	**3**	**5**	• Authority has allocated annual budgets • Develop a diverse pool of funding sources to sustain the authority's operations, including revenue collected for regulatory processes and government and donor funding

Risk	Likelihood	Impact	Mitigation Response
Gap of skilled staff and high turnover	**5**	**4**	• Development of human resource plan for managing and retaining staff (including training, assessment of working conditions, staff recognition, and incentives)
Significant changes in National Health Sector Policies	**3**	**3**	• Continuous engagement with health sector policy makers • Adjustment of strategic and implementation plans to reflect current health policy priorities
Unstable macroeconomic environment	**3**	**3**	• Adjustment of the implementation plan to reflect the macroeconomic environment
Lack of political stability and social harmony	**1**	**3**	• Suspend implementation of the SP where necessary

Chapter 2: Situation Analysis

The Rwanda FDA management team, which includes representatives from all of the authority's departments, carried out a series of brainstorming sessions and consultative meetings to identify internal and external factors that may facilitate or hinder the Rwanda FDA's vision and mandate. Salient observations from the situation analysis are captured on the strengths, weaknesses, opportunities, and threats (SWOT) framework, included in Table 4 in Section 2.8 of this document. This chapter also includes stakeholders expected to play a role in the implementation of the SP. A comprehensive list of all critical stakeholders and expected levels of participation can be found in Annex 3.

2.1 Economic and Agricultural Sectors

Following the events of the 1994 genocide, great achievements have taken place, which are reflected in the continuing progress of the country's economy. According to the milestone analysis of EDPRS II, in 2018, Rwanda was tenth among the fastest growing economies around the world with a sustained growth rate of 8%. A review of the implementation report of the EDPRS I revealed an economy shielded from external financial shocks, especially the 2009 global financial distress that affected most economies around the world. Rwanda was among the few African countries leading in the achievement of the Millennium Development Goals. By the end of 2015, the country had successfully halved the proportion of people suffering from hunger and had made good progress toward reducing by half the proportion of people living below the national poverty line and those living in extreme poverty. Yet about 55% of the Rwandan population is still within the poverty brackets.[1]

The Rwandan government has made tremendous effort in ensuring food security. In 2010, the Rwandan government established the National Strategic Reserve with four main objectives:[2]

1) Providing emergency food assistance to transitory food insecure
2) Supporting communities and farmers with storage facilities
3) Assisting producers to secure a minimum price for their produce at harvest time
4) Providing domestic consumers price support (market intervention) to procure food at a reasonable price.

The National Strategic Reserve also provides oversight of the private sector in relation to the consumer market and is instrumental in ensuring that food entering the Rwandan market is tested, registered, and safe for consumption. However, according to the 2018 Comprehensive Food Security and Vulnerability Analysis survey, the Rwanda subsistence population (i.e., people that grow food crops to meet the needs of themselves and their families) remains vulnerable to food insecurity. This sector of the population cultivates small pieces of land of less than 0.1 hectare, engages in casual labor, and in most cases is alienated from the transport network.

[1] The World Bank in Rwanda. 2020. https://www.worldbank.org/en/country/rwanda/overview.

[2] Kelly S., Mbizule, C. 2014. Institutional procurement of staples from smallholders: The case of common purchase for progress in Rwanda. Accessed on July 14, 2020: http://www.fao.org/3/a-bc575e.pdf.

Agriculturists in Rwanda depend entirely on rainfall for their activities, and seasonal weather variations define the food security situation of many households. With an anticipated annual growth rate of 2.6%, Rwanda has the second-highest population density in Africa with 499 people per square km. The implication of increasing density, including the strain on the available land resources, and increased human settlement, is that the increase in agricultural activities will pose a threat to food security and safety. Food security and safety issues are macroeconomic issues that require multidimensional dissection and review. Therefore, the prism from which we construct our perspective will include poverty reduction, employment creation, demographic trends, infrastructure development, and private-sector development, among others. Economic prospects, regional integration, infrastructural development, and revamping of the private sector remain paramount issues in food security and safety in Rwanda.

2.2 The Food Sector

When food is not fit for human consumption, its availability is reduced, which leads to food insecurity. Consumption of such food has a cascading negative effect on public health, productivity, and national expenditure on remedial interventions. This plan considers strategic directions for enhancing food security and strengthening Rwanda's market to ensure food quality and safety and that impacts to the environment from the food production process are mitigated.

Ensuring food security and nutrition in Rwanda requires the simultaneous efforts of different sectors. Through the Rwanda FDA, the central government plays a critical role in food security and safety by ensuring security vigilance, providing oversight of testing and product registration, putting in place environmental policies, and developing the infrastructure necessary for the production and transportation of food and raw materials. Moreover, government agencies such as the Ministry of Trade and Industry, Rwanda Standards Board (RSB), Ministry of Agriculture and Animals Resources and its agencies (Rwanda Agricultural Board and National Agricultural Export Board), MOH, and Ministry of Local Government work with the Rwanda FDA to enforce food safety regulations in the country.

In addition, the Rwanda FDA has developed an ecosystem of partners that have been instrumental in executing the Authority's mandate. Partnerships with local stakeholders and international bodies, such as ISO and Codex Alimentarius, are critical for ensuring quality and food safety standards. Harmonization of local and international regulations therefore becomes paramount given these partnerships, which enable regional and international trade. The Rwanda FDA has engaged both international and local stakeholders in the formulation and enforcement of regulations. ISO is responsible for more than 19,000 standards that are recognized globally, of which nearly 1,000 focus specifically on food safety and quality. Development of technical regulations will be based on these standards to ensure the promotion of cross-border trade. For example, in 2010, the ISO 22000-2005 food safety management system was introduced into the Rwandan food market through a training session conducted by the United Nations Industrial Development Organization. The Codex Alimentarius (i.e., the commission for collecting internationally adopted food standards) operates under the umbrella of the Food and Agriculture Organization in conjunction with the World Health Organization (WHO). The primary aim of this commission is to establish harmonized international food standards and ensure that the health of consumers of food products is protected and that players in the food industry practice fairly.

To develop strategies that will be championed in the next four years, in addition to identifying the critical players at the different stages of Rwanda's food value chain, this SP considers findings from Rwanda's 2020 mapping of food processing industries and importers.[3] The mapping highlights findings from 448 food processors that were visited during the mapping exercise. In general, beer, bakery, and general foods industries represent the highest proportion of mapped processors in Rwanda. Of the 448 facilities inspected, almost 30% (n=128) did not qualify for registration and licensing and their closure was recommended, whereas 71% (n=320) of the inspected facilities qualified for licensing and registration. According to Law N° 47/2012, around 80% (n=364) of food-processing industries included in the mapping did not hold a standardization mark (S-Mark, the product certification attesting that attributes, characteristics, quality, or status of goods is in accordance with established standards). With regard to food quality and safety, repeated cases of poor-quality agriculture and animal-based products were reported by both inspectors and consumers, as were counterfeit products, poor packaging, and storage conditions, forcing various food products to be recalled from the markets.

Based on the findings from the assessment, the main recommendations consisted of:

- A second inspection of the facilities recommended for closure to assess the severity of the hygiene and sanitation violations and determine whether measures could be taken to improve their inspection scores
- A regulatory approach based on the FDA criteria rather than the S-Mark certification since the S-Mark does not necessarily align with FDA compliance requirements
- Developing legal requirements for all personnel in direct contact with food products to be trained in food safety; the Rwanda FDA could develop training courses and programs and/or work with an affiliated institution to deliver food safety trainings
- Increasing sample testing at the retail or wholesale level
- Implementing strategies to encourage potential investors to manufacture appropriate food packaging materials
- Boosting technology and innovation in the food industry to optimize production and sales
- Investing in research, data analysis, and development for sustainable solutions that not only look to protect consumers but also lead to the development and marketing of new products.

2.3 Tobacco Products

The Law N° 08/2013 of 01/03/2013 relating to the control of tobacco regulates authorisation to manufacture tobacco and tobacco products, and authorisation to import and to export tobacco and tobacco products. Rwanda FDA also regulates tobacco and tobacco products. The assessment and registration office has developed guidelines for registration and an assessment report template. The office has registered seven (7) tobacco brands. Two (2) other tobacco brands are still undergoing assessment. There are other brands on the market, which must be traced so that their importers or manufacturers can comply with the requirements for registration of the products.

[3] Voice for Change Partnership Project (V4CP). 2020. Mapping of the food processing industries and importers in Rwanda.

2.4 The Pharmaceutical Sector

The pharmaceutical sector in Rwanda has made significant progress in the last decade in line with important developments in the health sector and the growth of the country's economy. Significant achievements have been recorded in areas such as supply and access to health commodities; human resource professionalization; and private-sector development and partnership. However, quality assurance and control measures, appropriate use of medicines and technologies, and long-term affordability, are lagging behind. Since almost 100% of pharmaceutical products used in Rwanda are imported from Asia, Europe and other parts of the world, a strong regulatory system with adequate and skilled personnel is required to ensure the quality and safety of all pharmaceutical products, including those imported from abroad.

The MOH Pharmaceutical Services team under the General Directorate of Clinical and Public Health Services has led various key policy, legislative, and governance initiatives to guide and strengthen the pharmaceutical sector in Rwanda. The team also served as the MOH's coordinating and liaising unit in multisectoral or interministerial activities requiring input on pharmaceutical products and health technologies. Over the past decade, the team has issued key guidance for the pharmaceutical sector, including the 2016 NPP, the 2018 Traditional Medicine Policy, and various strategic implementation plans, and supported legislation and guidelines that advance the mission of the pharmacy sector in the country (e.g., the 2017 guidelines for pharmaceutical procurements by health posts). While supporting the establishment of the Rwanda FDA, the MOH Pharmaceutical Services team performed essential regulatory functions that are now fully taken up by the Authority. Furthermore, the team ensured Rwanda's contributions to the harmonization of medicines registration in the East African Community (EAC), as well as the regulation of pharmacy health professionals, through the establishment of the National Pharmacy Council (Law N° 45/2012). Other notable achievements of the team include the set-up of product registration and premise licensing systems, including an online interface portal, and the establishment of inspection units working with police and the RSB to monitor pre- and post-market product quality.

The Government of Rwanda has taken strides over the last decade to systematically address the issue of quality assurance and quality control of pharmaceutical products and health technologies. In addition to laws, ministerial orders, and guidelines developed to reinforce regulatory functions, a major achievement was the approval by Parliament of the law establishing the Rwanda FDA (February 2018). The establishment of core regulatory systems by the MOH includes:

- Establishment of medicines evaluation and registration criteria, in line with the EAC harmonized registration policy, although there is still a need for criteria pertaining to registration for medical devices.
- Establishment of an online registration portal for all interested suppliers and importers—the Products Regulatory Information Management System (PRIMS). PRIMS has significantly streamlined the process for review and approval of qualified products and suppliers, including ensuring compliance with quality assurance standards and requirements.
- Licensing and inspection of pharmaceutical establishments in the private and public sectors, including a team of inspectors working in collaboration with law enforcement authorities. The ability to seize medical products that are not compliant with regulations is a critical function for effective and developed regulatory agencies.

- Awareness creation of SOPs for medicine quality assurance and for monitoring compliance at all levels of health service, such as referral hospitals, district Rwanda Medical Stores (RMS) branches, district hospitals, and health facilities.
- The upgrade of the RSB medical and pharmaceutical quality control laboratory in December 2017, increasing national testing capacity from 35 types of drugs to 100, including locally manufactured and imported drugs.
- The creation of a reporting system for adverse drug reactions (ADRs) and suspected poor quality pharmaceutical products.
- Conducting routine but random inspections and supervisions of public and private health facilities under an initiative of the MOH and partners to proactively identify illegal or poor-quality products.

Finally, in Rwanda, inappropriate use of medicines has been linked with self-medication practices and antibiotic abuse. In this regard, important achievements have been made to promote the appropriate use of medicines in Rwanda, including the development and dissemination of the 6th edition of the National List of Essential Medicines for Adults (2015) and 1st edition of the National List of Essential Medicines for Paediatrics, the publication of standard clinical guidelines for the treatment and management of prevailing health conditions, and the National Formulary (1st edition, 2007). Despite these efforts, adherence to guidelines and protocols must be improved.

2.5 Situation of Rwanda FDA Regulatory Functions

In November 2018, the Rwanda FDA's regulatory system was assessed using the WHO Global Benchmarking Tool (GBT). Major findings included the high implementation of indicators related to strategic planning with clear objectives (83%) as well as indicators related to understanding the financial resources needed to perform regulatory activities (75%). Significant room for improvement was identified in the areas of arrangement for effective organization and good governance (50%); regulatory systems supported with leadership and risk management (50%); human resources to perform regulatory activities (50%); mechanisms to promote transparency, accountability, and communication (50%); legal provisions, regulations, and guidelines required to define the regulatory framework (45%); and a quality management system (QMS) that includes risk management principles (29%). The overall regulatory system maturity level was Level 1. Table 3 corresponds to salient findings of the assessment by regulatory function.

Table 3. GBT Findings by Regulatory Function

Regulatory Function	Components in Place	Areas for Improvement
National Regulatory Systems	• Rwanda FDA law approved and published in the country's official gazette • Developed organizational chart forming the basis for the operationalization of Rwanda FDA • Authority's SP with objectives and a roadmap for its implementation is in its final development stage • Financial needs and cost of operationalization of Rwanda FDA have been clearly identified • Many GBT sub-indicators can be fully implemented within few months (i.e., "low-hanging fruit")	• Despite leadership commitment for QMS implementation and becoming ISO 9001:2015 certified, the authority is in need of a QMS, including risk management principles • Significant room for improvement was identified in the areas of arrangement for effective organization and good governance (50% of sub-indicators implemented); human resources to perform regulatory activities (50% of sub-indicators implemented); and mechanisms to promote transparency, accountability, and communication (50% of sub-indicators implemented)
Registration and Marketing Authorization	• Most legal provisions in place • Open-ended pre-registration status was issued to products once without a validity period • Currently issuing finite registration license certificates • Submission of dossiers in Common Technical Document (CTD) format • Reliance: EAC joint review outcomes are applied locally, occasionally relying on the Swiss medic procedure for MA for global health products	• Guidelines yet to be developed include registration of products in emergency situations, timelines for processing of MA applications and related tracking system, and reliance on the MA decision of other national medicines regulatory authorities/international organizations • Human resource constraints hampering the effectiveness of activities
Vigilance	• PV center with legal mandate to carry out its functions under the Rwanda FDA's law • Developed guidelines pending approval • Regulations and SOPs in place	• Designated staff to carry out PV activities • Implementation of national database for collating ADRs • Establishment of advisory committee to advise on causality assessment • Development of communication strategy • Low submission of ADR reports to the Uppsala Monitoring Centre (e.g., no reports were received at the centre in 2018, and 30 reports have been submitted to the centre's database since 2012) • Stakeholder engagement in PV activities, particularly with public health programs (e.g., HIV, TB, malaria, vaccines)

Regulatory Function	Components in Place	Areas for Improvement
Market Surveillance and Control	• Legal framework and provisions drafted (i.e., regulations, guidelines, SOPs) but awaiting approval for implementation • Human resource documentation developed (i.e., job descriptions with expected experience and qualifications, training plan) • Required procedures to perform market surveillance and control activities (e.g., SOPs, risk-based post-marketing surveillance program guidelines) drafted but awaiting approval	• Need for guiding documents that facilitate transparency and communication of the market surveillance outcomes to the public • Required staff to perform market surveillance and control activities not yet recruited
Licensing Establishments	• Application requirements (i.e., forms, checklists, guidelines, any administrative information) developed and implemented • QMS to standardize operations developed and in place	• Required staff not yet recruited; training plan yet to be developed • Guidelines yet to be developed or approved (e.g., guidelines for inspection and licensing of premises, regulations on the variation of premises)
Regulatory Inspection	• Legal provisions developed and publicly available • Centralized document control system enabling standardization and control of documents produced by the authority is in place	• Required staff not yet recruited • Training of personnel and qualification and evaluation of the effectiveness of training should be prioritized • Most regulatory inspection operations performed are not documented, especially procedures or documentation to show implementation of enforcement activities (e.g., investigations into quality issues) were not available

Regulatory Function	Components in Place	Areas for Improvement
Laboratory Testing	• Food laboratory, medical devices, veterinary medicines, and household chemical testing is planned to be established • Availability of adequate and well-maintained facilities for performing the testing • QMS is in place according to ISO 17025 • Competent and motivated staff	• Additional appropriately trained staff are needed for the development of microbiological testing • Need for regulation describing the mechanism of quality control of medicines, including the official issuance of laboratory testing results • Memorandum of understanding defining the process of recognition of and reliance on the results of other laboratories needs to be enforced • MA information needs to be made available to laboratory staff to ensure that testing is in accordance with the manufacturer's methods • Guidance on nonconformities and how to communicate with MA holders and other interested parties needs to be provided
Clinical Trials Oversight	• Law mandating the authority to regulate clinical trials in the country is in place • Clinical trials oversight currently undertaken by the Rwanda National Ethics Committee	• Drafted legal provisions need to be revised in accordance with the provisions of Law N° 003/2018 of February 9, 2018 • Rwanda FDA is not involved in the regulation of clinical trials except for the issuance of a license for importation of medical products for clinical trials • Limited number of human resources to carry out clinical trial oversight activities

2.6 Regulation of Veterinary Products

Veterinary products have become an important tool in the prevention and control of animal diseases, but their residues can persist in animal-derived foods and present potential food safety risks. To ensure effective and sustainable animal disease control while minimizing risks to humans and animals, the government of Rwanda is expected to provide appropriate regulations on the operation of a veterinary pharmacy, and the manufacture, distribution, import, export and use of veterinary products through its institutions. Significant legislation to regulate veterinary products have been put in place such as Reviewed Law N° 41/2006 of 30/09/2006 establishing the responsibilities, structure and functioning of Rwanda Animal Resources Development Authority (RARDA); Law Nº 54/2008 of 10/09/2008 determining the Prevention and Fight against Contagious Diseases for Domestic Animals in Rwanda; Ministerial Order N° 008/11.30 of 18/11/2010 determining the Organization of Veterinary Pharmacy Practice; Law N° 38/2010 of 25/11/2010 establishing Rwanda Agriculture Board (RAB) and determining its responsibilities, organization and functioning; Law N° 56/2013 of 09/08/2013 establishing Rwanda Council of Veterinary Doctors and determining its mission; Reviewed Law N° 14/2017 of 14/04/2017 establishing Rwanda Agriculture and Animal Resources Development Board (RAB) and

determining its mission, organization and functioning. However, some areas, such as quality assurance and control, and prudent use of veterinary products require further development.

In 2014, the Rwanda Agriculture Board (RAB) built human resources capacity to enforce the existing laws and regulations put in place to regulate veterinary products through its Animal Resources Department. Rwanda, as a member country of the World Organization for Animal Health (OIE), is expected to follow international standards, guidelines and recommendations for veterinary products legislation as established by OIE. These reference documents can be found in the four following publications: Terrestrial Animal Health Code, Aquatic Animal Health Code; Manual of Diagnostic Test and Vaccines for Terrestrial Animals; and Manual of Diagnostic Test and Vaccines for Aquatic Animals.

Furthermore, Rwanda, as a member of the East African Community (EAC), through the RAB, with the support of the Livestock desk at the EAC Secretariat and EAC Partner States, has developed harmonized tools for registration of Veterinary Immunological Products (IVPs) and commenced harmonized registrations of IVPs within the EAC. Later, the EAC expanded the scope of harmonization of veterinary products to cover harmonized registration of Veterinary Pharmaceutical Products. The initiative aims at increasing the availability of affordable, safe and quality veterinary medicinal products to the EAC region within a short period of time, as opposed to national applications where the processes are varied and time consuming. Harmonized tools for the Mutual Recognition Procedures of the EAC can be accessed online from the EAC website: https://www.eac.int/documents/category/livestock

Subsequently, with the approval by Parliament of Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA) and determining its mission, organization and functioning, the responsibility of regulation of veterinary products was transferred from RAB to the newly established institution. With the establishment of Rwanda FDA, significant achievements have been made with respect to the regulation of veterinary products, including successful recruitment of staff in charge of veterinary products, publication of the list of Authorized Veterinary Medicinal Products, development of regulation governing the registration of veterinary medicinal products, guidelines on submission of documentation for Registration of Veterinary Medicinal Products, regulations governing licensing to manufacture veterinary pharmaceutical products or to operate as a wholesale or retail seller of veterinary pharmaceutical products, guidelines related to the manufacture of veterinary pharmaceutical products or to operate as wholesale or retail seller of pharmaceutical products, guidelines for Good Distribution Practices and guidelines for Good Manufacturing Practices (GMP) for veterinary pharmaceutical products. Despite these efforts, there is a need to create a strategy to implement the developed regulations and guidelines. In addition, pharmacovigilance mechanisms and a quality assurance system for these veterinary products need to be established or improved where necessary.

2.7 Regulation of Household Chemicals and Medicated Cosmetics

Cosmetics and household chemicals range from everyday hygiene products such as soaps, shampoos, detergents, deodorants, and toothpaste to luxury beauty items including perfumes and makeup products. These products are divided into medicated cosmetics and non-medicated/normal cosmetics. The word “medicated cosmetics” is a new term and was introduced in Rwanda in 2018 in the Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA. As some substances used

in some cosmetics and household products can pose risks to human health, these products must be controlled from the raw materials stage to the finished product stage and beyond through cosmetovigilance. Before the establishment of the Rwanda FDA, there was no agency to register and control cosmetics from raw materials through to post-marketing surveillance. In 2002, the Rwanda Bureau of Standards was established by Law N° 3/2002 of 19/01/2002 (revised in 2013) to create the Rwanda Standards Board by Law N° 50/2013 of 28/06/2013 to monitor the quality of products, including cosmetics, through the establishment of standards, testing, quality service certifications, and to monitor conformity for issued certifications. However, there was no system for post-marketing surveillance of cosmetics (cosmetovigilance). Based on this gap, the government of Rwanda has enacted various laws to improve cosmetics quality, safety, and efficacy, and prevent proliferation of substandard products. These laws include N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, the Organic Law N° 01/2012/OL of 02/05/2012 instituting the penal code in Article 598, Law N° 20/38 of 26/02/2016, determining the list of cosmetics whose use is prohibited in Rwanda. Most recently, the Rwanda FDA was established by the Law Nº 003/2018 of 09/02/2018 as the competent authority to regulate household chemicals and medicated cosmetics.

2.8 SWOT Analysis

A SWOT analysis was carried out to identify internal and external factors that could have an impact on the realization of the Rwanda FDA's mission and vision (Table 4). The strengths of the Rwanda FDA reflect its internal capacity to offer services pertaining to regulatory functions, while its weaknesses highlight areas that require intervention to improve the current situation. The identified opportunities are external factors that need to be leveraged for the benefit of the Authority, while threats are challenges that must be managed or turned into opportunities through intervention. Findings from the SWOT analysis informed the selection of appropriate strategic objectives and interventions.

Table 4. SWOT Analysis

SWOT Category	Strategic Implications
Strengths	
• Existence of Rwanda FDA law with clear mandate • Availability of legal framework • Existence of an information management system • Existence of regulations, manuals, guidelines, SOPs, and forms • Implementation of EAC cooperation agreement framework • Special status • Existence of BOD and technical committee • Existence of an integrated payroll and personnel information system (IPPIS) for managing staff recruitment and selected employee benefits • Supportive national, regional, and international harmonization on regulation of food and pharmaceutical products	• Proper regulation and coordination of food and drugs • Improved performance • Effective regulation • Efficient service delivery

SWOT Category	Strategic Implications
Weaknesses	
• Insufficient qualified human resource • Inadequate infrastructure related to the core functions of Rwanda FDA • Insufficient financial resources • Ineffective monitoring and evaluation framework for food and drugs • Lack of QMS implementation • Weak enforcement and compliance mechanism for regulated products • Weak PV and post-marketing surveillance systems • Weak systems for assessment and registration of food and drugs • Inability to conduct quality assurance and quality control of products regulated under Rwanda FDA law • Weak enforcement of promotional materials, advertising, and marketing of products regulated under Rwanda FDA law • Insufficient number of Hazard Analysis and Critical Control Points (HACCP)-certified local food manufacturers • Lack of formal stakeholder forum to discuss regulatory issues • Lack of communication strategy	• Underperformance • Inadequate space, equipment, and information communication technology infrastructure to facilitate the implementation of regulatory activities • Inability to implement some regulatory functions • Inability to monitor and measure the institutional performance • Inconsistent implementation of regulatory processes • Presence of unsafe, inefficacious, and poor-quality products • Inadequate information for decision making on safety and quality of products • Unregulated information that might mislead the public • Presence of unsafe and substandard food products on the market
Opportunities	
• Availability of qualified human resources on the market • Existence of external quality control laboratory for food and pharmaceutical products • A strong regulatory framework • Existence of harmonized EAC regulatory framework • Rwanda has shown interest to the African Union to host the African Medicines Agency (AMA) • Rwanda is an active participant in the Collaborative Registration Procedure (CRP) for WHO-prequalified products • Rwanda has been accepted to become an observer to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) • Growth in investment of food and pharmaceutical industries	• Easy access to required personnel • Assured quality products on the market • Increased collaboration, partnerships, and competence in implementation of the regulatory functions • Well-regulated products and services • Increased confidence in the regulatory functions of Rwanda FDA • Accelerated registration of WHO prequalified products
Threats	
• Resistance to new regulatory requirements for food and drugs • Existence of porous borders that allow entry of unauthorized products • Reliance on 100% importation of drugs • Litigation arising from regulatory decisions • Increased public concern about quality and safety of medicines and food	• Possibility of limited range of some essential products on the market • Existence of unregulated products on the market • Unavailability of adequate products on the market • Reduced trust for Rwanda FDA

Based on the situational analysis, the following areas were identified as critical for improvement and must be addressed in the plan:

- Automation and increasing efficiency and transparency of Rwanda FDA services
- Facilitating formalization of domestic manufacturing facilities, including small and medium enterprises (SMEs)
- Post-marketing surveillance on regulated products
- Public education on Rwanda FDA services
- Staffing and motivation
- Monitoring and evaluation of Rwanda FDA systems
- Regulation of medical devices and diagnostics
- Analysis of drugs, herbal medicines, food, and medical devices
- Financial sustainability
- Transformation of Rwanda FDA into a full self-sustaining authority
- Development of a communication strategy for Rwanda FDA

Chapter 3: Strategic Framework

The ultimate purpose of the SP is to support the achievement of the Rwanda FDA's vision and mission. The strategic direction for this plan is guided by the current situation and trends, in line with other national initiatives. Performance targets for strategic objectives are presented in the respective sections of this SP document. The SP will be implemented from 2021 to 2024.

3.1 Vision

A world class regulatory authority effectively protecting and promoting public health.

3.2 Mission

To regulate medical products, processed foods, household products, and ~~tobacco and~~ tobacco products to ensure their quality, safety, and efficacy so as to protect the population of Rwanda from unsafe, defective, falsified, and substandard products.

3.3 Core Values

The conduct and performance of the Authority is underpinned by the following five core values:

1) Serving with **Professionalism** for excellent service delivery
2) Continuously work with **Integrity**
3) Promoting **Accountability** at all times
4) Nurturing **Teamwork** to achieve common objectives
5) Striving for **Innovation** to create value for our stakeholder and other interested parties

3.4 Strategic Priority Areas, Strategic Objectives, and Priority Interventions

The Rwanda FDA's SP builds on three strategic priority areas that have been formulated using the results of various assessments and a performance scorecard. The section below details each priority area with the associated strategic objectives and interventions. A separate annual work plan will be developed with details on how the strategic interventions will be operationalized over the four-year implementation period.

Every four years, Rwanda FDA will update its SP and strategic priority areas. The Rwanda FDA senior management team contributed to the development of the plan's priorities, objectives, and strategic interventions. The Rwanda FDA senior management and the planning team ensured that the strategic plan aligns with Rwanda FDA's mission and vision. The plan's priorities and objectives describe the approach for focusing Rwanda FDA's efforts to achieve its public health mission and to fulfil its role in supporting the larger mission and strategic goals of the health sector. A crosswalk that highlights the relationship between the Authority and the Health Sector/ NST1 strategic priorities is found in Annex 1.

The Rwanda FDA will seek to meet the regulatory and health outcomes outlined in the SP. Key performance indicators (KPIs) have been synchronized with the MOH SP, the African Medicines Regulatory Harmonization (AMRH) initiative, EAC, Sustainable Development Goals, and other national indicators with mutual outcomes. In total, there are 17 KPIs.

3.4.1 Strategic Priority Area 1

Strengthen Rwanda FDA's compliance with specified standards and requirements for regulatory processes and regulated products

Strategic Results: Strengthened regulatory functions and roles that will support the Authority to execute its mandate and guide the regulated industry to comply with regulations for the benefit of the Rwandan people. Rwanda FDA has the core responsibility of ensuring the safety, efficacy, and quality of drugs, food, cosmetics, and tobacco products in an effective and efficient manner. Therefore, the Authority intends to focus on building the confidence of the population by putting in place a regulatory framework that will increase investment opportunities and improve regulatory and health outcomes while meeting stakeholders' expectations.

Rwanda FDA is responsible for regulating a diverse range of products, from new and innovative medical products to nicotine replacement therapies. Thus, the standards that are used to determine whether they are suitable to be marketed to the public are also diverse. Rwanda FDA's premarket responsibilities include making advancements in regulatory science needed to better evaluate new products; collaborating with private, public, and academic settings to facilitate product development; and ensuring that the product review process is as effective and efficient as possible. The Authority will regulate tobacco products, including premarket review of new tobacco products to determine if they are substantially equivalent to existing products, or whether they represent a more distinct type of product that presents a different standard for marketing review. To be clear, currently regulated tobacco products do not benefit health. Rwanda FDA's responsibility is not to improve access to tobacco products, but to safeguard that access by responsibly controlling it in accordance with existing regulation. Rwanda FDA protects the safety of consumers through detection and intervention activities, such as inspections of manufacturing or production facilities, active surveillance of adverse events, and monitoring and securing the supply chain, to make sure that unsafe manufacturing conditions are discovered, and unsafe products are removed from the supply chain before they can do harm to the public.

The Authority makes decisions based on the best available scientific data and uses the best tools, methods, and approaches to assess the safety, efficacy, quality, public health impact, and performance of regulated products, while fostering and advancing innovation. Rwanda FDA keeps pace with and uses these new scientific advances to protect and promote the nation's health. To advance these efforts, Rwanda FDA will use laboratories, scientific computing capabilities, and expertise, while leveraging resources and collaborating with domestic and international partners in government, academia, and the private sector to ensure that Rwanda takes part in international innovation. Rwanda FDA will continue to increase regulatory science capacity and effectively evaluate regulated products.

The timely review of the safety and effectiveness of new human and animal drugs, biologics, and medical devices is central to Rwanda FDA's mission to protect and promote public health. The

user fee programs for these medical products provide resources that enable Rwanda FDA to hire additional reviewers and support staff and upgrade information technology systems, which will improve the approval process and enable the Authority to speed the application review processes without compromising the Authority's high standards for ensuring the safety, efficacy, and quality of new medical products. Rwanda FDA further recognizes that increasing communication between the Authority and applicants during review has the potential to increase efficiency in the review process. Multiple review cycles are sometimes required for applications that contain outstanding deficiencies or demand further discussions between Rwanda FDA and the applicant. This represents an inefficient use of resources if resolution of these issues could have been achieved at the screening level. Rwanda FDA is working to make the review process more transparent and increase productive communication with clients.

Expected regulatory and health outcomes:

- Quality products on the market
- Availability of safe and efficacious medical products on the market
- Increased access to essential regulated products
- A functional legal and regulatory framework
- Affordability of regulated products
- Availability of registered products on the market

The KPIs selected to measure progress under Strategic Priority Area 1 are included below in Table 5. The strategic interventions for each of the five identified Strategic Objectives for Strategic Priority Area 1 are listed in Table 6.

Table 5. Strategic Priority Area 1: Key Performance Indicators and Targets

Key Performance Indicator	**Targets**		
	Baseline	**Midterm**	**Final**
SPA 1.1 Number of policies, laws, regulations, manual and other operational documents initiated (SOPs, STPs) developed and approved for implementation	47	60	98
SPA 1.2: % of premises inspected and licensed for regulated products	20%	40%	70%
SPA 1.3 % of import and export compliance and licenses issued for regulated products	20%	45%	98%
SPA 1.4 % of regulated products with current valid registration/marketing authorization	3%	10%	40%
SPA 1.5 Total number of regulated products for which notices of non-conformity (or similar document) issued	850	1500	2550
SPA 1.6 % of ADR/Adverse events following immunisation (AEFI) reports received and analysed	45%	70%	98%
SPA 1.7 Number of samples tested for Post-Marketing Surveillance (PMS)	425	25000	5000

SPA 1.8 Number of Food safety inspections conducted for compliance	50	1000	2000
SPA 1.9 Number of clinical trial sites inspected	6	18	30
SPA 1.10 Number of clinical trial applications reviewed within set timelines and authorizations issued	94	280	530

Table 6. Strategic Priority Area 1: Strategic Interventions by Strategic Objective

Strategic Objective 1: To develop and ensure compliance with FDA's regulations and guidelines through regulatory licensing and inspection of premises for regulated products	
i.	Development and regular update of regulations and guidelines for all regulatory functions carried out by Rwanda FDA
ii.	Develop SOPs and tools to support consistent and effective implementation of regulations
iii.	Perform assessments to ensure compliance to laws, regulations, and guidelines, including requirements for GxPs (e.g., GDP, GPP, GMP, GHP, GSP, GLP)* HACCP, and Codex Alimentarius
iv.	Establish and implement regulatory enforcement mechanisms for all regulatory functions
v.	Implement risk-based approaches to conducting inspections that maximize public health benefit by ensuring high rates of compliance
vi.	Increase the use of regulatory science to inform standards development, analysis, and decision making
vii.	Establish efficient and transparent inspection and licensing systems for premises handling regulated products
viii.	Review and improve systems for effective control of import and export of regulated products
ix.	Establish a system to supervise and monitor the safe disposal of pharmaceutical waste and waste from other regulated products
x.	Develop systems to improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents
xi.	Develop and implement systems to facilitate formulation of new food products to promote food safety and security
xii.	Develop a system to support the manufacture, production, distribution, and use of Rwanda FDA-regulated animal health products to facilitate access to safe and effective veterinary medicines and other animal health products
xiii.	Develop systems to evaluate and mitigate the risk of chemical exposures and microbiological hazards in food and feed products that may pose public hazard or regulatory concern
xiv.	Optimize rigorous, science-based premarket review to ensure that veterinary medicines and other animal health products marketed to the public are safe and effective
xv.	Adopt science-based regulations that protect food and feed supplies from contamination
Strategic Objective 2: Enhance product registration/marketing authorization processes according to best practices and international standards	
i.	Perform scientific evaluation of regulated products on the market, including utilization of good reliance principles and guidelines
ii.	Regularly update and issue the register of food, drugs, and health technologies on the market
iii.	Publish the list of unregistered, deregistered, withdrawn, and recalled products for public information
Strategic Objective 3: Regulate and provide clinical trials oversight on medicines, including herbal medicines, vaccines, biological products, and medical devices	
i.	Establish systems for clinical trial oversight and evaluation
ii.	Regulate clinical and field trial approvals to ensure efficacy and maximize safety of regulated products
iii.	Review and approve protocols for clinical trials and conduct good clinical practice inspections

Strategic Objective 4: Strengthen the system of pharmacovigilance and post-market surveillance for effective regulation of medicines and related health products	
i.	Develop guidelines, procedures, and tools to increase collection, management, analysis and use of safety data
ii.	Strengthen the PV reporting system for ADRs, adverse events following immunization (AEFIs) with vaccines (including COVID-19 vaccines) and other regulated products from public and private facilities, and the general public
iii.	Establish post-market surveillance systems, including track and trace systems, to monitor the quality of regulated products so as reduce circulation of substandard, falsified and illegally marketed products on the market
iv.	Establish procedures to promote and facilitate effective collaboration and timely communication with stakeholders on outcomes of PV and market surveillance issues, including use of information, education, and communication programs as necessary
v.	Enhance Rwanda FDA's capacity for data-driven, risk-based post-market surveillance of food, medicines, and related health products to understand and assess changing use and intake patterns, emerging toxicological data, and adverse event reports
vi.	Develop improved methods for rapidly detecting, investigating, and stopping foodborne contaminants
Strategic Objective 5: Establish the Rwanda FDA laboratory and develop the regulatory framework to perform post-market surveillance testing of all regulated products	
i.	Establish a functional quality control laboratory with adequate facilities for effective testing of food, drugs, and other regulated products
ii.	Attain accreditation of ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
iii.	Attain WHO Good practices for pharmaceutical quality control laboratories prequalification for drug testing laboratory
iv.	Foster the development of rapid and advanced technologies to accurately identify biological and chemical hazards through expansion of Rwanda FDA scientific expertise and laboratory capacity,
v.	Identify and develop new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new animal drug development

*Good Practices (GxPs) refer to regulatory quality standards and regulations, including distribution (GDP), production (GPP), manufacturing (GMP), hygiene (GHP), storage (GSP), and laboratory (GLP)

3.4.2 Strategic Priority Area 2

Collaborate effectively with the public and private sectors, national and international partners

Strategic Results: Efficient customer service, stakeholder management and engagement, improved public image, and fair and balanced regulatory decisions. It is the responsibility of the Authority to serve the people of Rwanda and meet stakeholder expectations. This can be achieved by enhancing service coverage; communicating and publishing the regulatory framework; applying regulatory decisions in a fair, transparent, and accountable manner; responding in a timely manner to customer needs; and constructively collaborating and partnering with national, regional, and international agencies and institutions that contribute to the core responsibilities of the Rwanda FDA.

Rwanda FDA recognizes the invaluable role it plays in providing the public with timely, accurate, and useful information about Rwanda FDA-regulated products. As consumers, patients, health professionals, and purchasers gain access to relevant information about foods, medical products, household products, and tobacco and tobacco products, they are better able to make informed

decisions about whether or how to use these products. For this reason, Rwanda FDA believes that clear communication about regulatory and scientific decisions, policies, and standards, as well as the regulated products themselves is vital. Rwanda FDA will continue to work in collaboration with local and foreign partners to determine innovative and effective ways to provide better information to the public and to develop outreach and strategies that can assist in better decision making. Rwanda FDA supports informed decision making with a foundation of rigorous science, thoughtfully applied, to communication about and review of Rwanda FDA-regulated products.

A Rwanda FDA communication strategy shall be developed and implemented to support the Authority's decision making and that of stakeholders, including health care professionals, patients, consumers, and regulated industry. The Public Relations & Communication Officer shall develop surveys and focus group inquiries to learn how target audiences respond to Rwanda FDA and industry communications, and how prospective users approach the use of regulated products. The Authority seeks to learn what stakeholders consider important factors for balancing the benefit and risk in making decisions related to the manufacture and use of pharmaceuticals and other Rwanda FDA-regulated products.

Today, most of the people in Rwanda depend on Rwanda FDA-regulated medical products to sustain their health; increasing amounts of regulated products are prescribed and consumed over time. Too many people, however, suffer unnecessary injuries, and some die because of preventable errors pertaining to the provision and use of medical products in the country. Rwanda FDA believes that many of these risks are manageable if parties committed to the safe use of Rwanda FDA-regulated medical products work together. Rwanda FDA will continue to pursue initiatives aimed at protecting public health through effective communication with efforts to enhance risk communication for drugs, biologics, and devices. The Authority recognizes that it is imperative that health professionals and patients have access to the right kind and amount of information necessary to make decisions about how to prevent, mitigate, or treat their medical conditions. Rwanda FDA will continue to explore potential analytical and communication approaches to develop and incorporate uncertainty in the assessment of benefits and risks for key stakeholders and the general public. Over the next four years, the Authority will improve access to benefit-risk information by enhancing communication of benefit-risk assessments for approved products; enhance patient access to prescription medication benefit and risk information; use and monitor social media, e-mail, and web sites to disseminate FDA risk communication alerts and safety information to stakeholders; ensure public and stakeholder awareness of medical product quality and integrity issues through effective consumer communications and through news media; and disseminate FDA product information through partnerships with stakeholders and outreach at national meetings and conferences.

Rwanda FDA is committed to promoting healthful dietary practices through truthful and informative labelling for human and animal foods so that the population can use this information to make healthier choices about their food, help reduce the risk of chronic disease, and facilitate optimal health. The Authority will also provide the public with factual and accurate information about tobacco and tobacco products, which allow the public to have information on the harmful and potentially harmful constituents in tobacco and tobacco smoke in a way that is understandable and not misleading to the public. The Authority will continue to develop a strategy to address the safety and health information needs and concerns of both internal and external audiences. Rwanda FDA will develop safety and health information to improve consumer access to and use of accurate

nutrition information; implement sustained public education campaigns on the harms of tobacco and tobacco products; and expand use of social media, the FDA website, and consumer updates to communicate safety and health information. The Authority will also develop safety and health information for consumers with limited English proficiency.

Expected regulatory and health outcomes:

- Improved customer satisfaction and confidence in the regulated products
- Value addition from partnerships and collaborations

The KPIs selected to measure progress under Strategic Priority Area 2 are included below in Table 7. The strategic interventions for each of the two identified Strategic Objectives for Strategic Priority Area 2 are listed in Table 8.

Table 7. Strategic Priority Area 2: Key Performance Indicators and Targets

Key Performance Indicator	Targets		
	Baseline	Midterm	Final
SPA 2.1 Communication Strategy developed and implemented (% implementation)	20%	50%	100%
SPA 2.2 % increase in customer satisfaction	30%	50%	80%
SPA 2.3 Number of partnerships, membership and collaborations established	12	30	50
SPA 2.4 Public education campaigns on the harms of tobacco products conducted	0	10	20
SPA 2.5 Effective risk communications related to outbreaks and contamination incidents conducted	10	20	40

Table 8. Strategic Priority Area 2: Strategic Interventions by Strategic Objective

Strategic Objective 1: Engage proactively with the public and private sectors (including the regulated industries) and other national stakeholders to ensure the quality and safety of all regulated products	
i.	Develop and maintain systems for effective customer service provision and timely information dissemination
ii.	Improve collaboration and information-sharing among FDA and domestic and international partners on response efforts
iii.	Develop proactive communication processes with industry and the public, including consumers of limited English proficiency
iv.	Strengthen existing communication and feedback mechanisms with the public to enable consumers to play a proactive role in minimizing food safety risks
v.	Develop guidelines and establish processes to foster public private partnerships
vi.	Strengthen existing partnerships with local and central government institutions to improve the effectiveness and efficiency of the FDA's food safety program for government and industry
vii.	Establish communication channels and processes to regularly inform internal and external stakeholders about the Rwanda FDA's efforts to understand and ensure the healthfulness and safety of all regulated products
viii.	Increase leveraging of internal resources through collaboration with national stakeholders, including academia, industry, and other regulatory bodies
ix.	Disseminate the laws and regulations to stakeholders
x.	Conduct effective risk communications related to outbreaks and contamination incidents
xi.	Implement sustained public education campaigns on the harms of tobacco products
Strategic Objective 2: Harness collaboration and partnership arrangements with international organizations in areas of mutual interest and benefit to strengthen Rwanda FDA's regulatory capacity	
i.	Establish collaborations and cooperative agreements with international organizations for improved regulation and harmonization of compliance processes in line with existing regional and international trade agreements, protocols, and policies
ii.	Foster mutually beneficial partnerships for capacity-building, collaboration, and sustainability in laboratory testing
iii.	Collaborate with regulatory counterparts to leverage resources and avoid duplication of inspections as well as build a model for mutual reliance by sharing inspection reports.
iv.	Participate in regional and international fora for capacity building, information sharing, and institutional development
v.	Institute mechanisms to support regulatory harmonization and reliance initiatives, including aligning and harmonizing national, regional, and international requirements on regulated products

3.4.3 Strategic Priority Area 3

Enable an accountable, high-performing, innovative, and sustainable organization

Strategic Results: A high-performing organization that delivers efficient and innovative regulatory services with highly motivated and competent staff using an effective governance framework with appropriate infrastructure and sustainable financial management that fosters institutional accountability, risk management, and continuous performance improvement. The Authority will continuously invest in research and development and workforce development to provide a platform for innovative service delivery. It will also strive to achieve the highest standards of corporate governance and put in place the necessary infrastructure to support fulfilment of its mission and vision. It will establish a risk management, logistics, and procurement

system; performance management system; and financial management system for effective implementation of the authority's mandate. Rwanda FDA shall continue the development of the workforce, systems, and infrastructure needed to address the emerging, complex challenges brought by the current operating environment.

The Authority targets recruitment and retention flexibilities to establish and maintain a competent workforce and retain the nation's top talent. The Authority aims to ensure that it remains an employer of choice. Rwanda FDA will work in partnership with innovative organizations and leaders in the public and private sector to develop and implement large-scale improvements to its systems and infrastructure. The Authority affirms its commitment to create a positive work environment; evolve management systems that are robust and secure; and invest in the infrastructure needed to enhance our public health mission. Over the next four years Rwanda FDA shall recruit, develop, retain, and strategically manage a world-class workforce. A key component of Rwanda FDA's ability to respond to the emerging challenges presented by today's complex, globalized regulatory environment is our ability to attract and retain a talented and diverse workforce.

Rwanda FDA uses a fully integrated, agency-wide human capital management program to aggressively recruit, hire, develop, and retain skilled, high-performing employees so that it possesses the capabilities and capacities required to meet the breadth and depth of the legislative requirements. This management program includes leadership development, career management, performance management, and succession planning to harness employees' insights and experiences to help develop high-impact solutions to important public health and regulatory challenges. Rwanda FDA will continue to make progress by implementing the following strategies: hire and retain highly qualified scientific, medical, analytical, legal and management talent; track development and advancement of science and research expertise in the internal workforce through succession planning and executive development plans; and develop mechanisms to promote cross-disciplinary, regulatory-science training and research to address gaps and challenges posed by novel products.

Rwanda FDA shall take a horizontal and cross-cutting approach to management to improve overall operational effectiveness and efficiency. FDA will maintain a culture of continual business process improvement to identify opportunities to streamline and add value. These improvements will be supported by collaboration and knowledge management tools and will encourage input from stakeholders and advisory groups to help define and meet scientific, regulatory, and administrative needs and priorities. Collaboration supporting scientific outreach, training, and research and development activities will advance Rwanda FDA's mission with sister institutions, global regulatory partners, academia, innovators, and consumers. The ability to better coordinate efforts will increase quality, productivity, and transparency for mission-critical business processes. Rwanda FDA will continue to strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making; improve management and program effectiveness and make optimal use of resources; continue the development and implementation of quality approaches for review activities; development and implementation of an evidence-based resource planning model that connects performance measures and outputs to public health outcomes; establish a process and management structure to enhance risk-based decision making; provide information technology tools to enable collaboration; and implement robust compliance, internal

control, and risk management strategies, including compliance with ethical standards and avoidance of employee conflicts of interest.

Rwanda FDA shall invest in infrastructure to enhance productivity and capabilities and continue to prioritize crucial investments in both IT and laboratory infrastructure to better support its mission. FDA is finalizing the upgrade of PRIMS infrastructure to lay the foundation for modern, networked computing and shared data resources. This migration will enhance FDA's technical ability and provide high performance programs and data storage designed to allow for greater collaboration with stakeholders across government and globally while protecting systems from internal and external security and privacy threats. The Authority shall also install the Laboratory Information Management System (LIMS) to facilitate laboratory data management and the operation of its Quality Control Laboratory shall be at 80% by the end of this Strategic Plan period. Over the next four years, FDA will continue to provide infrastructure, in particular, modern laboratory equipment, that meets the demands of Rwanda FDA's scientific mission; implement an IT modernization program to provide state-of-the-art integrated information and shared data resources; develop/improve on methods to share data and informatics approaches within and outside of Rwanda FDA; and foster a secure, safe, and healthy work environment for FDA employees.

Expected regulatory and health outcomes:

- High-performing staff
- Financial stewardship
- Institutional effectiveness
- Good corporate governance

The KPIs selected to measure progress under Strategic Priority Area 3 are included below in Table 9. The strategic interventions for each of the three identified Strategic Objectives for Strategic Priority Area 3 are listed in Table 10.

Table 9. Strategic Priority Area 3: Key Performance Indicators and Targets

Key Performance Indicator	Targets		
	Baseline	Midterm	Final
SPA 3.1 Staff member placed/recruited as per new structure	10%	100%	
SPA 3.2 Staff retention strategy developed and implemented	10%	50%	80%
SPA 3.3 GBT maturity level attained by authority	ML1	ML3	ML3
SPA 3.4 % of staff trained (both short- and long-term) to fill critical needs in the regulatory functions	20%	60%	80%
SPA 3.5 % staff who attain their performance targets	50%	70%	80%
SPA 3.6 % budget allocated to Rwanda FDA's activities from internal generated revenues	50%	70%	100%
SPA 3.7 % relevant regulatory processes that are automated	20%	60%	80%
SPA 3.8 % internal and external audit recommendations implemented	20%	40%	80%

Key Performance Indicator	Targets		
	Baseline	**Midterm**	**Final**
SPA 3.9 Quality Control Lab operationalized (%)	20%	40%	80%
SPA 3.10 % certified/accredited management systems to relevant standards	10%	40%	80%
SPA 3.11 Number of publications for research conducted on regulated products	0	5	10

Table 10. Strategic Priority Area 3: Strategic Interventions by Strategic Objective

Strategic Objective 1: Strengthen organizational management and capacity building framework for developing, attracting, and retaining talent to ensure effective implementation of the Rwanda FDA's mandate	
i.	Develop and maintain systems for effective customer service provision and timely information dissemination
ii.	Improve collaboration and information-sharing among FDA and domestic and international partners on response efforts
iii.	Establish an effective human resource system and align the performance management and reward systems for effective SP implementation
iv.	Establish a performance management framework that is aligned with the authority's responsibilities
v.	Establish an enterprise risk management framework to monitor and inform decision making
vi.	Implement a QMS compliant with ISO 9001 to attain certification
vii.	Develop a staff management plan with measures to attract, retain, and optimally deploy a skilled workforce
viii.	Invest in leadership and human capital infrastructures
ix.	Promote an organizational culture of quality, cooperation, innovation, and accountability by enhancing open communication, encouraging creativity, and supporting employee recognition
x.	Enhance leadership development through continuous learning, performance management, and effective succession planning
Strategic Objective 2: Strengthen governance structure and financial management to enhance accountability and sustainability and improve efficiencies	
i.	Define roles and responsibilities for all leadership positions
ii.	Define or revise fee scheme to expand the authority's financial capacity
iii.	Establish appropriate structures and infrastructure for financial management to ensure effective performance by the authority
iv.	Perform costing and modelling of the Authority's services to inform appropriate financial management and planning
v.	Develop proposals and advocacy instruments for funding for financial support from government and potential development partners
vi.	Establish a robust procurement and logistics management system to enhance accountability and spur the Authority's performance
vii.	Establish a mechanism for effective asset management
viii.	Implement a transparent pricing policy and other related pricing mechanisms
ix.	Hire and retain highly qualified scientific, medical, analytical, legal and management talent
x.	Improve opportunities for continuous learning, career development, and work–life balance throughout the FDA workforce

Strategic Objective 3: Establish mechanisms to promote operational research on all regulated products, foster innovation, and enhance the use of modern information management systems to improve decision making	
i.	Develop protocols and guidelines and streamline mechanisms for conducting research on regulated products
ii.	Automate relevant Rwanda FDA functions for timely and efficient service delivery
iii.	Automate and integrate regulatory business processes
iv.	Increase research, data analysis, and systematic evaluation to improve the safety and effectiveness of food products in collaboration with stakeholders
v.	Support research to better understand the emergence, persistence, and spread of antimicrobial resistance (AMR)
vi.	Adopt innovative, risk-informed approaches to ensure that scientific research is directed at mitigating priority hazards and advancing public health
vii.	Improve cosmetics safety through oversight and increased efforts to fill gaps in scientific knowledge on the safety of cosmetics ingredients
viii.	Develop the necessary expertise and infrastructure to increase the Authority's regulatory science capacity
ix.	Implement robust compliance, internal control, and risk management strategies, including compliance with ethical standards and avoidance of employee conflicts of interest

Chapter 4: Implementation Framework

4.1 Implementation Strategy

The SP will respond to the enhanced scope of Rwanda FDA-regulated products and establish the required controls, structures, infrastructure, and human resources in its early stage of implementation to fulfil the Authority's mandate. The Plan activities will therefore be undertaken in line with the existing work plan aspirations. Later years will focus on harnessing the lessons learned and instituting effectiveness and excellence in service delivery. As a means of operationalizing the SP, each department will be responsible for formulating strategies to achieve the key strategic objectives and performance indicators enshrined within the SP to achieve the stated regulatory and health outcomes. The activities will be streamlined through the Rwanda FDA's annual budget, individual departments' annual work plans, and individual staff performance targets. The activities of the plan will cascade downward to the various service delivery offices for effective implementation of the strategies.

A stakeholder mapping exercise was conducted to identify the key players in each priority area (Annex 3). The exercise also helped to identify potential areas for stakeholder collaboration to leverage resources and eliminate duplication of efforts. The identification of stakeholders from the early stages of the planning process will help guide the implementation and evaluation of the plan.

4.2 Steering Committee

A steering committee to monitor implementation will be constituted and will include the three department heads, division managers, the director general, the director in charge of finance, and the officer responsible for monitoring and evaluation. The committee chair will be chosen by the members of the committee. The steering committee will determine its functioning rules and will mainly be in charge of monitoring and evaluating the implementation of this SP. More specifically, the following framework has been put in place to facilitate the smooth and effective implementation, monitoring, and evaluation of the current SP:

- Each responsible office will extract from this plan specific targets and provide implementation reports on a regular basis. The strategy will be translated into performance responsibilities by senior staff, who will ensure that detailed work plans of junior officers are set in conformity with the authority's mission and strategic goals and objectives.
- Annual performance contracts will be signed between each officer and supervisor based on the set strategic targets. It is against these contracts that employee performance will be assessed on a regular basis.
- A senior management meeting chaired by the director general will be held on a regular basis to evaluate progress on the SP
- The Rwanda FDA management will commission an annual review of implementation of the SP and incorporate any changes as needed.

4.3 Monitoring and Evaluation and Reporting Framework

The implementation of this SP will be monitored using the annual institutional work plan, which will include the performance undertakings for each department and unit. Annual institutional, departmental, and individual work plans will be derived from this plan. Management is responsible for implementation of this SP and will ensure that continuous monitoring and evaluation activities and processes are undertaken. The routines for monitoring the strategy implementation will include performance review reports and meetings on an annual basis, in addition to mid-term and end-of-term evaluations. Reports will be produced at the end of each review with recommendations to inform management's actions. A set of KPIs has been developed or adopted from other national strategies to monitor progress. The Rwanda FDA will use situational analyses and surveys to develop baselines and set targets as appropriate. KPIs will be monitored primarily on an annual basis. Selected KPIs will be monitored on a quarterly basis, pending available resources, to help monitor indications of progress. Rwanda FDA will develop Performance Indicator Reference Sheets (PIRS) for the KPIs to support development of a robust monitoring and evaluation plan for the implementation of the strategic plan.

4.3.1 Objectives of Monitoring and Evaluation

The monitoring and evaluation framework aims to:

- Track the realization of outcomes from the identified strategic objectives and strategic interventions over the SP period
- Ascertain whether resources earmarked for implementation of the initiatives are adequate and are delivering the desired outcomes
- Assess whether the expected outcomes from the strategies are being realized from the planned implementation process
- Establish whether there are any unanticipated challenges that might have arisen and seek ways to address them
- Ascertain whether institutional capacity in terms of the infrastructure, logistics, human resources, and financial resources is adequate to enable realization of the vision, mission, and objectives of the Rwanda FDA.

4.3.2 Action Plan

The Office of the Director of Planning and Monitoring & Evaluation (M&E) will coordinate all of the authority's planning and research activities. This office will be responsible for the annual preparation of an action plan that meets set strategic goals and objectives and realizes the vision and mission of the authority. This office will also be responsible for timely and systematic reporting on implementation as well as monitoring and evaluation of this SP by coordinating and guiding the preparation of a detailed annual action plan and annual activity-based budget in collaboration with the office in charge of finance management and other departments. A special emphasis will be on monitoring and evaluation activities. Timely and effective departmental involvement will be required to ensure that the authority is on track to fulfil its mission and vision as stipulated in this SP. An annual action plan will be drawn from the SP. The action plan will be based on the objectives as provided in the logical framework for each strategic priority area and

objective in this SP. The steering committee will organize semi-annual meetings to monitor the implementation of the action plan according to the expected key performance indicators.

4.3.3 Annual Evaluation

The annual evaluation of achievements within the framework of the SP will be made during annual meetings and based on reports prepared by the director general's office. The annual evaluation will be conducted internally, and the self-evaluation committee will consist of the director general, department heads, division manager, and all Rwanda FDA unit directors. A workshop will be held to share the challenges and strategies for improvement to fully realize the expected results.

4.3.4 Mid-Term Evaluation

If required, the mid-term evaluation will be carried out after two years by an independent consultant to ascertain a neutral assessment of the implementation of the SP and any recommended adjustments to be made to reach expected outputs. The consultant's report will be submitted to the director general of the Rwanda FDA. Objectives will be assessed against the progress made. Recommendations in response to problems encountered during implementation will be formulated. These recommendations may lead to the adoption of the proposed strategies and alterations to the expected outputs as appropriate. A workshop will be held to share challenges and strategies for improvement to achieve the expected results as indicated in the SP.

4.3.5 Final Evaluation

A final evaluation, which may require the assistance of an independent consultant, will take place during the first half of 2024. The final evaluation report will include recommendations on new strategic orientations, which will be included in the 2025–2030 SP. This evaluation report will be submitted to the Rwanda FDA director general. The 2025–2030 SP will be prepared in the second half of 2024. A workshop will be held to share the challenges and strategies for improvement and to learn from the implementation of this SP for future planning initiatives.

4.4 Resources Requirements

Successful implementation of this SP will require both human and financial resources. An optimal level of staffing in terms of numbers, qualifications, skills, and experience will be fundamental. Annex 2 presents the organization structure that will facilitate achievement of the Rwanda FDA's vision during this period. The total budget for the SP will be 34,566,680,000, Rwandan Francs (RWF) excluding construction of new office premises. The budget will be planned annually as part of the Authority's annual action planning process. The Rwanda FDA will commit all of its efforts to ensure that the projected incomes are realized, to support full implementation of the SP activities planned for each period. If projected income will not be realized, prioritization of activities will be considered so that key result areas are given priority. As mentioned above, the implementation of this SP requires both financial and physical resources. The total cost of achieving the set objectives as detailed in the SP matrix is 34,566,680,000 over the four-year period, which represents an

average of RWF 8,641,670,000 annually. The law creating the Authority provides that the Rwanda FDA will rely on various revenue sources for the fulfilment of its mission. These include:

- Fees levied on application of licenses and registration of regulated products
- Grants and donations (fees for donation are not captured in the table below)
- All administrative fines imposed by the regulatory authority
- Loans
- Fees for services rendered by the Rwanda FDA
- Any other payment or property due to the Rwanda FDA in respect to any activity related to the regulated services.

It is the responsibility of both the regulatory board and management to ensure that there is no loophole in revenue collection.

Table 11. Projected Financial Performance (in Rwandan Francs)

Indicators	Projected Financial Performance (RWF)			
	2021	2022	2023	2024
Annual Income				
Ordinary budget	2,068,468,552	1,678,334,114	1,594,174,571	0
Internally generated revenue	4,385,891,448	5,856,025,886	8,030,185,429	11,977,310,477.75
Total budget	6,454,360,000	7,534,360,000	9,623,600,000	11,977,310,477.75
Annual Expenditure				
Operating Expenditure	2,236,308,000	4,236,308,000	5,006,308,000	6,236,308,000
Capital Expenditure	4,218,052,000	3,298,052,000	4,618,052,000	4,718,052,000
Total expenditure	6,454,360,000	7,534,360,000	9,623,600,000	10,954,360,000

Annex 1: Alignment of FDA's Strategic Priorities and Objectives, NST 1, and Health Sector's Goals and Objectives

Rwanda FDA Strategic Priority Areas	**1**	**2**	**3**
	Compliance to specified standards and requirement for regulatory processes and products	**Collaboration with public and private sectors, national and international partners**	**Accountable, high performing, innovative, sustainable organization**
Rwanda FDA Objectives:	1. Compliance with regulations and guidelines through Licensing and inspection of premises 2. Enhanced product registration/ Market authorization processes 3. Regulation, oversight of clinical trials 4. Strengthened system for PV and post-market surveillance 5. Rwanda FDA laboratory establishment and post-market surveillance testing	1. Engagement with public and private sector and other national stakeholders 2. Collaboration and partnership arrangements with international organizations in areas of mutual interest and benefit	1. Organizational management and capacity building framework for developing, attracting, retaining talent 2. Governance structure and financial management to enhance accountability, sustainability, and efficiencies 3. Operational research on regulated products, foster innovation, enhance use of IMS for decision making
Economic Transformation Priority: accelerating private sector-led economic growth and productivity	● A key objective of the NST is the industrialization and structural shift in Rwanda's export base to high-value goods with the aim of growing exports by 17% annually. The strategy includes the **establishment/ expansion of industries** to promote locally produced materials and "Made in Rwanda", including a pharmaceutical plant, a mosquito nets manufacturing plant, a chemical fertilizer plant, and industries for the production of packaging materials plant. **Strategic Priority Areas 1 and 2 will play a key part in ensuring achievement of this key strategy by:** 1) ensuring that Rwandan products meet both national and international standards for quality, safety, and value at all stages of the production and export value chain (inputs to outputs). 2) working with private sector supply, production, and distribution firms to align around common objectives. 3) engaging international organizations to leverage application of international standards. ● Considering that the NST's priority value chains of focus include agro-processing, and meat and dairy, the SP will consider alignment and coordination of its interventions under Strategic Priority Areas 1 and 2 to ensure NST objectives for these value chains are enabled/achieved. The NST strategy also targets the increase in productivity of agriculture and livestock through promotion of research and development of new seed varieties, with the ultimate goal of reducing reliance on imports. Strategic Priority Areas 1 and 2 will support this objective through application of products meeting required standards and certification.		

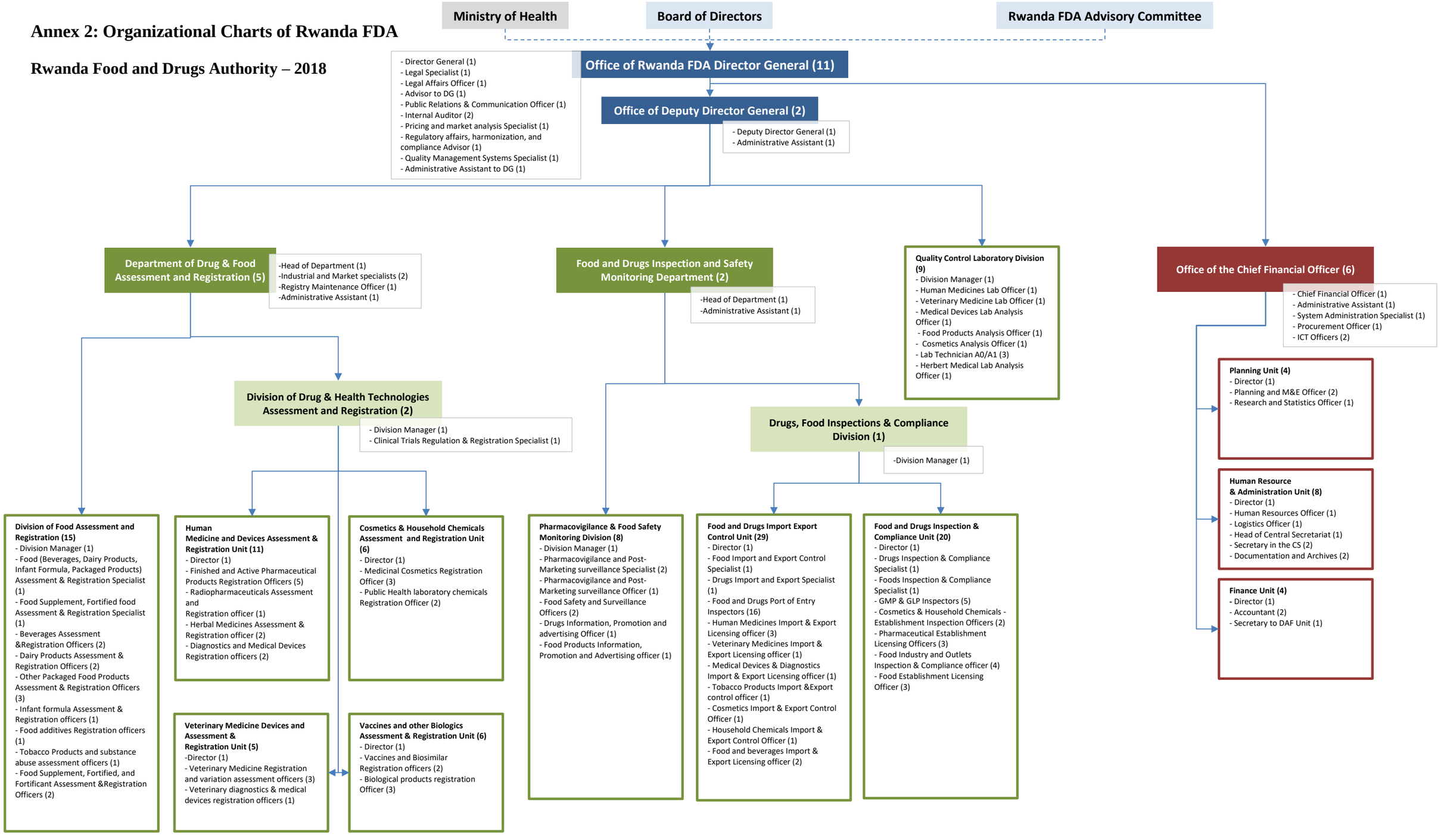
Social Transformation Priority: bringing qualitative change in all aspects of people's lives	● The NST, along with the accompanying sub-sector strategy on health, aims to ensure access to quality health for all, focusing on improving health care services at all levels of the health system. **The outcomes targeted by Strategic Priority Areas 1 and 2 of the Rwanda FDA SP are central to this objective,** by: 1) ensuring that health products, equipment, and health and pharmaceutical premises meet the required standards of quality and value. 2) focusing on standards and compliance for medical equipment that will be used in the NST's target to upgrade new and existing health facilities. 3) leveraging standards and guidelines that support the NST's promotion of manufacturing of medical equipment and support for medical research; interventions will align with those envisioned by NST's to invest in capacity building of priority sectors and suppliers and supporting technology acquisition and upgrading. ● In addition to strategic objectives defined under cross-cutting areas (see below), the NST's vision is to establish **model health centers of excellence** for treatment of NCDs that normally require treatment abroad such as cancer, cardiac surgery, and complex trauma among others. **Interventions under the SP's Strategic Priority 1 and 2, including partnership with the private sector, will consider adequately supporting the realization of this objective**, with beneficial social as well as economic impact for Rwanda. ● Finally, **Strategic Priority Area 3 aims to uphold the NST's focus on strengthening financial sustainability of the health sector** with a strategy to transition financing of its operational and capacity development requirements from government resources to internally generated revenues.
Transformational Governance Priority: consolidating and providing building blocks for equitable transformational and sustainable national development	● The NST underscores strengthening the capacity, service delivery and accountability of public institutions, enshrining a culture of dedicated service to citizens for fast and effective service delivery. **Strategic Priority Area 3 expects to espouse the shared values intended in this objective,** including among other things: 1) targeting 90% of relevant regulatory processes to be automated by 2024 as part of the NST's goal to e**nsure 100% of government services** are delivered online by 2024 (from 40% in 2017). 2) implementing 100% of internal and external audit recommendations and prospectively being considered among 80% of government entities expected to obtain unqualified audit opinion on financial statements and compliance with laws and regulations by 2023/24 (from 50% in 2016/17). ● Increased citizens' participation and engagement, particularly in development, is another objective of the NST. **Strategic Priority Area 2 expects to foster and leverage this strategy** through interventions that expand the use of social media, and mechanisms to enhance communication and feedback with the public.

Cross-cutting – Capacity Development & HIV/AIDS and NCDs Priorities	● **<u>Strategic Priority Area 3 will leverage as far as possible the NST's focus for capacity development</u>** in current and emerging sectors that are key economic drivers including agriculture, environment, and natural resources, manufacturing, and ICT. ● Strategic Priority Areas 1 and 2 expect to support the NST's increased focus on promoting HIV/AIDS self-testing methods. ● Strategic Priority Area 1 is expected to support the NST's targeted scale up of specialized treatment options, particularly for NCDs. As both public and private institutions undertake capacity development initiatives for their workforce in these options (under NST's Capacity Development priority), the Rwanda FDA expects to keep pace with the needed knowledge and research, to assess use and intake patterns, emerging toxicological data, and adverse event reports.
Cross-cutting – Regional Integration and International Positioning Priority	● Strategic Priority Area 2 fully aligns with the NST's continued strategic pathway to regional integration and international positioning to accelerate achievement of Rwanda's development goals. The strategy is first and foremost an economic one (supporting Economic Transformation pillar above) to increase value addition and competitiveness from trade partnerships; promote intra-Africa and global trade through continued advocacy to eliminate non-tariff barriers, and further mobilize resources to implement joint projects to facilitate trade. Strategic Area Priority 2 will leverage these integration opportunities to accelerate Rwanda FDA's objectives for capacity building, information sharing, institutional development, and leveraging of resources. The SP will consider partnership and integration opportunities highlighted in the NST, including: EAC, COMESA, the Economic Community of the Great Lakes Countries (CEPGL); the Economic Community of Central African States (ECCAS); the tripartite Agreement between EAC- COMESA-SADC and the African Union (AU); the Economic Partnership Agreements (EPA) and the Africa Growth and Opportunity Act (AGOA) with the EU and USA, respectively.
Full implementation of the main health programs (improve demand, access, and quality)	The Overall Objective (OO) of the health sector is to ensure universal accessibility (in geographical and financial terms) of equitable and affordable quality health services (preventative, curative, rehabilitative and promotional services) for all Rwandans that will have an impact of Improved health status of the country's population. Rwanda FDA's timely review of the safety and effectiveness of new human and animal drugs, biologics, and medical devices is central to Rwanda FDA's mission to protect and promote public health. The user fee programs for these medical products provide resources that enable Rwanda FDA to hire additional reviewers and support staff and upgrade the information technology systems which will improve the approval process and enable the Authority to speed the application review processes without compromising the Authority's high standards for ensuring the safety, efficacy, and quality of new medical products before approval. Rwanda FDA further recognizes that increasing communication between the Authority and applicants during review has the potential to increase efficiency in the review process

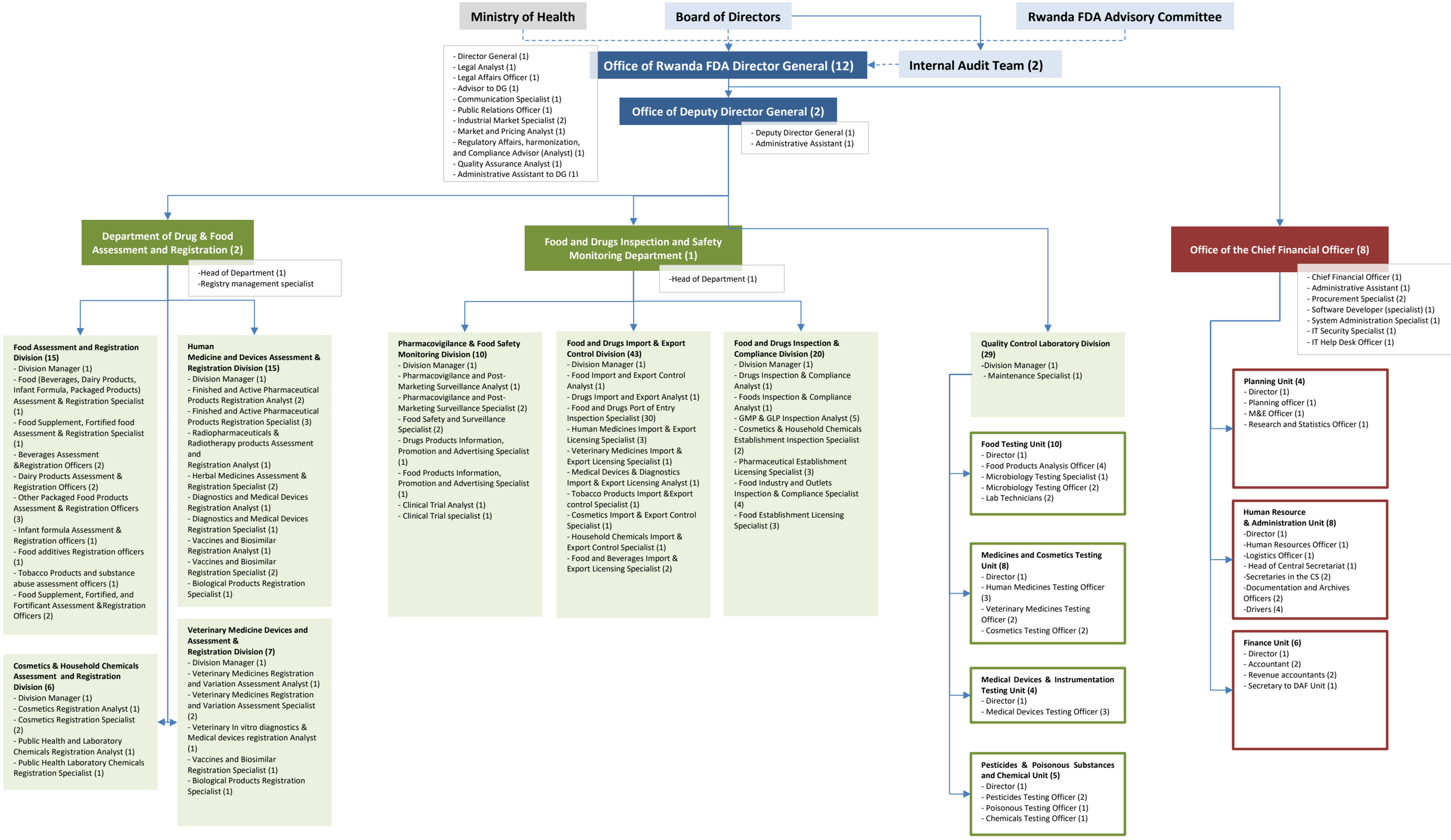
Strengthen all levels of service delivery (organise the services effectively at all levels, referrals)	Rwanda FDA shall take a horizontal and cross-cutting approach to management to improve overall operational effectiveness and efficiency. The ability to better coordinate efforts will increase quality, productivity, and transparency for mission-critical business processes. Rwanda FDA will continue to strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making, improve management and program effectiveness and make optimal use of resources, continue the development and implementation of quality approaches for review activities, development and implementation of evidence-based resource planning model that connects performance measures and outputs to public health outcomes.

Annex 2: Organizational Charts of Rwanda FDA

Rwanda Food and Drugs Authority – 2018



Rwanda Food and Drugs Authority Organizational Structure – 2020



Annex 3: Stakeholder Mapping and Commitment Matrix

Stakeholders	Areas of Support
Government	Maintain a robust and effective regulatory framework
	Carry out regulatory health impact assessments on a regular basis
	Enhance licensing framework and contribute to investment-conducive environment in the pharmaceutical and food sector
	Enhance monitoring of Rwanda FDA performance
	Establish the pricing mechanisms for the regulated products
	Financial support to Rwanda FDA
Rwanda FDA management	Regular review of human resources
	Manage staff emolument scheme to sustain competitiveness
	Training of staff
	Regular upgrade of institutional facilities and equipment to meet regulatory demands
	Continuous review of human resource policies and structures with a view to align the structure with the regulatory requirements
Pharmaceutical and food manufacturers, distributors, and retailers	Effective coordination with relevant government agencies and health sector players
	Comply with regulatory systems, policies, and procedures and put in place mechanisms for sharing information and engagement
Security teams	Establish a framework for collaboration with the security teams
	Support in enforcement of regulatory requirements where needed
Media	Promote visibility of Rwanda FDA through development of effective mechanisms for engagement with the media and the public
	Enforcement of regulation requirements in the advertisement of regulated products
Public	Provide feedback on regulatory processes and regulated products
Collaborating regulatory and oversight agencies (e.g., MOH, EAC, national health professional councils)	Enhance coordination and collaboration framework with other agencies
	Coordinate the professionals working with regulated products
Development partners and donors	Assist establishment of a sound regulatory framework that promotes transparency and accountability
	Assist the development and revision of regulations, standards, guidelines, and standard operation procedures to enhance products safety, efficacy, and quality
	Support Rwanda FDA infrastructure development

Annex 4: Key Terms in the Strategic Plan

Activity: Action taken, or work performed to produce a given target. Activities are what institutions do, and they describe processes that are largely internal to the institution. They describe how a target is to be achieved.

Appraisal: An overall assessment of the relevance, feasibility, and potential sustainability of a series of interventions prior to a decision to undertake or fund them.

Assumptions: Hypotheses about factors or risks that could affect the progress or success of an intervention.

Baseline indicator value: Historical value of an indicator. It includes an associated date called the baseline indicator date.

Capacity building: A process leading to skill upgrading (both general and specific), procedural improvements, or institutional strengthening. Capacity building refers to investment in people, institutions, and practices.

Competency: Ability of a company/institution/individual to achieve certain effects or to behave in specific ways. Competencies are one type of resources.

Effect: Intended or unintended change due directly or indirectly to an intervention.

Effectiveness: The extent to which an intervention's objectives were achieved or are expected to be achieved, taking into account their relative importance.

Efficiency: A measure of how economically resources/inputs (e.g., funds, expertise, time) are converted to outputs or results.

Evaluation: A periodic assessment of the efficiency, effectiveness, impact, sustainability, and relevance in the context of stated objectives.

Feedback: Transmission of findings generated through the evaluation process to parties for whom it is relevant and useful to facilitate learning. This may involve the collection and dissemination of findings, conclusions, recommendations, and lessons from experience.

Goal: A statement concerning the successful realization of an impact.

Governance: The way in which power and authority influence public life, especially economic and social development.

Impact: An effect on well-being or a significant long-term developmental change induced in the user of a service or product. May be direct or indirect, intended, or unintended.

Indicator: A number having a particular measurement purpose. A quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a party or institution. A

variable that allows the verification of changes in the development intervention or shows results relative to what was planned. Indicators are usually indirect measures of an underlying phenomena or quality (the way "smoke indicates fire") and are usually stated in SMART format. Indicators are often disaggregated to compare results and frequently have time-specified target and baseline values.

Input: The financial, human, and material resources used during the completion of an activity. Inputs are frequently measured in terms of financial costs

Milestone: An activity used to identify significant events in a schedule, such as the completion of a major phase. An activity tagged or singled out for special monitoring in terms of progress or completion. The milestone selected should be indicative of a larger or more important process. Milestones can be considered a form of indicator regardless of whether something has been produced within a particular deadline.

Monitoring: A continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing intervention with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds.

Objective: A broad statement of what is to be achieved and the improvements to be made. An objective describes an intended outcome or impact and summarizes why a series of actions have been undertaken.

Outcome: The likely or achieved short- and medium-term effects of an intervention's outputs. A direct but intermediary change or improvement in the welfare of the customer or beneficiary as a result of the use of a service (or output). Examples include improved health after visiting a dispensary or increased knowledge after completing school.

Output: The products, goods, and services that result from an intervention; may also include changes (usually of an immediate nature) resulting from the intervention that are relevant to the achievement of outcomes.

Performance: The degree to which an intervention or an implementer operates according to specific criteria/standards/guidelines or achieves results in accordance with stated objectives or plans.

Process: How something is done

Process evaluation: An evaluation of the internal dynamics of implementing institutions, their policy instruments, their service delivery mechanisms, their management practices, and the linkages among these.

Program: A time-bound intervention that differs from a project in that it usually cuts across sectors, themes, and/or geographic areas; uses a multidisciplinary approach; involves more institutions than a project; and may be supported by different funding sources.

Relevance: The extent to which the objectives of an intervention are consistent with beneficiaries' requirements, country needs, global priorities, and policies. Retrospectively, the question of relevance often becomes a question of whether the objectives of an intervention or its design are still appropriate given changed circumstances or observed effects.

Results: The output, outcome, or impact (intended or unintended, positive and/or negative) of an intervention.

Results chain: The causal sequence for an intervention that stipulates the necessary sequence to achieve desired objectives, beginning with inputs; moving through activities and outputs; and culminating in outcomes, impacts, and feedback.

Risk analysis: An analysis or assessment of factors affecting or likely to affect the successful achievement of an intervention's objectives. It may also mean a detailed examination of the potential unwanted and negative consequences to human life, health, property, or the environment posed by interventions; a systematic process to provide information regarding such undesirable consequences; or the process of quantification of the probabilities and expected impacts for identified risks.

SMART: Attributes of indicators, sometimes applied to other planning entities, such as targets or objectives. SMART stands for Specific, Measurable, Achievable, Realistic, and Time-bound; a means for assessing performance indicators.

Stakeholders: All of those who have an interest (direct or indirect) in an institution, its activities, and its achievements. These may include clients or customers, partners, employees, shareholders/owners, government, and regulators.

Strategic planning: A process that charts an institution's broad direction forward to achieve its objectives. Strategic planning looks at the big picture from a longer-term perspective; decides what it wishes to achieve and the main actions it will need to undertake in the future; clarifies institutional priorities; focuses away from day-to-day operations; and provides an opportunity to address important fundamental questions, such as: Where do we want to be? Where are we now? How will we get there? How will we know when we are there?

Sustainability: The continuation of benefits from an intervention after the intervention has been completed. The probability of continued long-term benefits obtained from an intervention. The resilience to risk of the net benefit flows over time.

Target: The goods or services produced over a given period of time by an institution to achieve its objectives.