



RWANDA FOOD AND DRUGS AUTHORITY
2024–2029
STRATEGIC PLAN

July 2024

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LIST OF ABBREVIATIONS

ASF	Animal Source Foods
ASF	African Swine Fever
AMRH	African Medicines Regulatory Harmonisation
BoD	Board of Directors
BSC	Balanced Scorecard
CFO	Chief Finance Officer
DALYs	Disability-Adjusted Life Years
DG	Director General
EAC	East African Communities
EAC-MRH	East African Medicines Regulatory Harmonisation
EMA	European Medicines Agency
FCTC	Framework Convention on Tobacco Control
FMD	Foot-and-Mouth Disease
GMP	Good Manufacturing Practices
HSSP IV	Health Sector Strategic Plan IV
ISO	International Organization for Standardization
IT	Information Technology
ICT	Information and Communication Technology
ICDRA	International Conference of Drug Regulatory Authorities
ML4	Maturity Level Four
M&E	Monitoring and Evaluation
MEAL	Monitoring, Evaluation, Accountability, and Learning
MERL	Monitoring, Evaluation, Research and Learning

MINICT	Ministry of Information Technology and Communication and Innovation
MOH	Ministry of Health
MOUs	Memorandum of Understanding
NIRDA	National Industrial Research and Development Agency
NCDs	Non-Communicable Diseases
NFNP	National Food and Nutrition Policy
NPP	National Pharmacy Policy
NST1	National Strategy for Transformation 1
POSE	Phyto Social Enterprise Project
PAS	Performance Appraisal System
PMAS	Corporate Performance Appraisals Systems
QMS	Quality Management Systems
Rwanda FDA	Rwanda Food and Drugs Authority
ROI	Return on Investment
RWF	Rwandese Franc
SLAs	Service Level Agreements
SSA	Sub-Saharan Africa
SMART	Specific, Measurable, Achievable, Realistic and Time-bound
SP	Strategic Plan
SWOT	Strength, Weaknesses, Opportunities and Threats
TCAM	Traditional, Complementary, and Alternative Medicine
WHO	World Health Organization

Table 1: List of Abbreviations

STATEMENT OF CHAIRPERSON OF RWANDA FDA BOARD OF DIRECTORS

The 21st century has witnessed a mounting trend towards the application of new management approaches particularly the use of strategic planning and result-based management. It is from this standpoint that organizations including Rwanda FDA have been developing Strategic Plans as important frameworks and governance tools to communicate the organizational goals, actions needed to achieve the goals and other critical elements required to stimulate growth, development and sustainability.

This 2nd Rwanda FDA Strategic Plan is set to describe the current state of affairs of the Authority, desired future outcomes, priorities and resources required to realize the vision. We at Rwanda FDA strongly believe that there is no other concrete strategy to accomplish and fulfil the mandates, functions and activities that meet national and international standards without having a clear and comprehensive strategic planning.

As the Chairman of the Board of Directors, I would like to uphold the desire, enthusiasm and commitment of the Rwanda FDA Management in discharging its functions. The right Vision that is projected towards improving and transforming the organization through a more results-oriented management approach is furthermore acknowledged. I have no doubt that the same spirit and vigour will be translated into implementation of this new five-year Strategic Plan (2024-2029).

Throughout the implementation phase, the Board of Directors will provide full support to the Rwanda FDA Management in realizing the Vision and objectives set. The strategies, deliverables and milestones set in this Strategic Plan are not only relevant but also vital to attaining the Mission of Rwanda FDA. Henceforth, on behalf of the Board of Directors, I would like to assure the general public, stakeholders and customers that Rwanda FDA is fully committed to use this Strategic Plan as a means or vehicle that will take us to the next performance level.

Dr Etienne KARITA
Chairperson of Rwanda FDA Board of Directors



STATEMENT OF THE DIRECTOR GENERAL

Rwanda FDA is mandated to regulate the quality, safety and effectiveness of food and drugs products. The Rwanda FDA is a Regulatory Authority established by Law N° 003/2018 of 09/02/2018, with a mission to protect public health by regulating food and drugs products. To effectively discharge these mandates and attain its objectives, it is apparent that Rwanda FDA needs a well-articulated and comprehensive strategy to chart out a strategic direction for continuous organizational growth and development.

It is from this background that the formulation, implementation and evaluation of strategic plans are integral parts of the governance, management and good practices at Rwanda FDA. Staff, Management and the BoDs believe strongly that the observed performance, stability, growth, development and sustainability are the result of effective implementation of previous Strategic Plans (SP). With the same spirit, I believe that the implementation of this new SP will be an impetus to steer further stability, development and growth of Rwanda FDA for the wider interests of the population.

This 2nd Rwanda FDA Strategic Plan (2024 – 2029) a five-year strategic plan highlights a number of strategic objectives, strategies and targets that are pivotal in attaining Rwanda FDA's Mission of protecting and promoting public health by ensuring safety, quality and effectiveness of food and drugs regulated products. This SP has outlined key performance indicators which will be measured according to the set targets.

In realizing its mission of protecting and promoting public health by ensuring quality and safety of products regulated by Rwanda FDA with its vision of being a globally recognized food and drugs authority; five thematic pillars have been derived and mapped to KPIs to anchor the realisation of the corporate strategic aspirations as well as the national socio-economic development goals. The thematic pillars are; Establish A Fully Functional Globally Recognized Regulatory System; Position Rwanda FDA in the Heart of National Health Research; To Scale up Current Institutional Capacity to Build a Sustainable Workforce; To Significantly Improve Value-Chain Management; and Leveraging Technology /digitalization for efficient services.

Achievement of the strategic objectives will depend on the capacity to deliver services effectively and efficiently. In this regard, the Management is committed to providing leadership and resources throughout the implementation of the Plan.

I feel indebted to all staff of Rwanda FDA for their contribution and readiness to implement this plan. Many thanks are extended to the BoDs for their guidance, support and endorsement of this new Strategic Plan (2024-2029).


Dr Emile BIENVENU
Director General

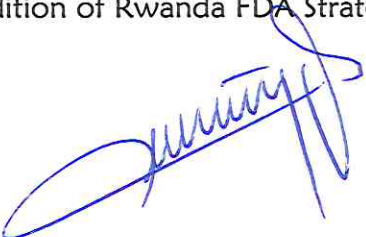


ACKNOWLEDGEMENTS

A number of individuals have contributed towards successive development of the Rwanda FDA five-year Strategic Plan which is to be implemented from 2024 to 2029 financial years. First and foremost, I wish to sincerely express my gratitude to a team of staff from Planning, Monitoring and Evaluation Unit for the hard work, efforts and time devotion during the initial drafting, compilation and ensuring thorough completion of this Strategic Plan.

Special thanks are also bestowed to the team from Horizon Business Solutions for their technical inputs and support, commitment and dedication throughout the whole process of developing this plan. Contributions, guidance and active participation of Rwanda FDA management as well as fruitful comments, critics and opinions from Rwanda FDA staff and stakeholders in enriching this plan particularly its objectives and strategies are irrefutably acknowledged. My appreciation goes to Enabel through Kwigira Project for financial support towards the development of this 2nd important strategic plan

I would like to express my heartfelt appreciation to the members of the Board of Directors at Rwanda FDA for their valuable guidance, constructive inputs and eventual approval of this 2nd edition of Rwanda FDA Strategic Plan


George NTAGANDA
Chief Budget Manager of Rwanda FDA



EXECUTIVE SUMMARY

The Rwanda FDA is a Regulatory Authority established by Law N° 003/2018 of 09/02/2018, with a mission to protect public health by regulating food and drugs. The Rwanda FDA 2nd Strategic Plan 2024-2029 has been conceptualised, developed and positioned as an enabler, joint development blueprint to support and facilitate the realisation of Rwanda's strategic aspirations as set out in Vision 2050; National Strategy Transformation 2 (NST-2) 2024-2029; Health Sector Strategic Plan (HSSP) V among other socio-economic development blueprints. The plan is structured around 4 thematic areas cascaded from the national development aspirations in health including positioning Rwanda as a bio-manufacturing hub and knowledge centre. The major national strategic aspirations as enshrined in the Country's socio-economic development blueprints include; **to be a Leading Bio-Manufacturing Centre in Africa, to become a Knowledge-Intensive Economy in Africa, to become a Regional Logistics Hub, and to achieve Universal Health Coverage.** In addition, the NST 2 cascaded from Vision 2050 provides 5 strategic priority areas; namely creating decent and productive jobs, boosting exports, reducing stunting and malnutrition, enhancing public service delivery, and improving quality of education. Effective communication is a critical enabler of Rwanda FDA's mission to protect public health and ensure regulatory compliance. A comprehensive communication strategy will support the Rwanda FDA's efforts in stakeholder engagement, transparency, and public awareness. By leveraging multi-channel approaches, Rwanda FDA will ensure that regulatory information reaches key stakeholders, enhances public understanding, and fosters compliance across sectors.

Rwanda FDA's strategic aspirations cascaded therefrom include;

- a) **To Establish a Fully Functional Regulatory System Globally Recognized** by attaining WHO Maturity Levels 3 and 4 (ML3 & ML4) and further be designated as WHO listed Authority (WLA) by 2029. Further, Rwanda FDA intends to comply with FAO-WHO food control assessment criteria in addition to be ISO 17020 certified.
- b) **To Scale up current institutional capacity to build a sustainable workforce** to be able to provide required regulatory oversights of the agri-food and pharmaceutical industries intended to become competitive regionally and globally. Rwanda's Vision is to become a *bio-manufacturing hub* and a *regional leader for pharmaceutical production*, to develop an *advanced food industry*; all these imposing Rwanda FDA to develop its regulatory capacities to support this Rwanda's vision.
- c) **To position Rwanda FDA in the Heart of the National Health and Research Centers:** Rwanda aspires to become a hub for research and development in health sciences, while it hosts the emerging multinational regulatory and research hubs. It is therefore imperative to strengthen linkages between Rwanda FDA and these hubs hosted in Rwanda.
- d) **To Significantly Improve Value-Chain Management:** Rwanda FDA is committed to enhancing the management of food and drug value chains to ensure efficiency, traceability, and safety by implementing digital traceability systems, improving quality control at each

stage of the supply chain, and fostering collaborations with local and international partners etc.

- e) **Leveraging technology /digitalization for efficient services** by continuing its efforts to modernize and optimize its processes, performance and efficiency through the use of IT tools and other technologies, in order to rapidly adapt to changing external environment, combined with a growing need for efficiency and effectiveness.

Based on the strategic aspirations, five thematic pillars have been derived and mapped to KPIs to anchor the realisation of the corporate strategic aspirations as well as the national socio-economic development goals. The thematic pillars are; **Establish A Fully Functional Globally Recognized Regulatory System; Position Rwanda FDA in the Heart of National Health Research; To Scale up Current Institutional Capacity to Build a Sustainable Workforce; To Significantly Improve Value-Chain Management; and Leveraging Technology /digitalization for efficient services.** The strategic pillars have been cascaded into an implementation matrix that outlines the Objectives, Outputs, outcomes, responsibility, budget and the timelines is provided. The strategic plan implementation framework is anchored on a thorough situation analysis that defines Rwanda FDA's organisational structure, governance mechanisms, human resource management practices, contextual analysis, analysing food and drugs regulatory landscape and strategic alignment and investment opportunities. A SWOT analysis covering the strengths, Weaknesses, Opportunities and Threats informed the development of strategic objectives and initiatives. The Plan outlines the Authority's key priorities and initiatives for effective strategy implementation.

A strategic Risk analysis was conducted based on the overarching institutional risk framework to enhance proactive risk monitoring and management. The key strategic risk focus areas include; **Operational Risks: Financial Risks: Reputational Risks: Strategic Risks: Technological Risks: Global Health and Supply Chain Risks.** For each strategic risk category, appropriate set of risk mitigation and management strategies have been proposed. This is then mapped to the institutional, sustainable MEAL and performance management framework (BSC) has been established to track progress, measure outcome, by aligning its capabilities and resources to national development priorities. The MEAL framework is designed to be adaptive, with mechanisms for regular monitoring, evaluation, and feedback to ensure continuous improvement and alignment with strategic goals. The BSC framework translates the vision and strategic goals into a set of measurable performance indicators. This will ensure alignment across various functional areas, supports effective decision-making, and enhances accountability. The balanced scorecard framework is structured around four key perspectives: financial, customer, internal processes, and learning and growth. The plan defines resource mobilisation strategies to ensure sufficient resources for implementation. Developed through a participatory approach, the plan incorporates lessons from the previous strategy and aligns with global best practices. It emphasises strategic partnerships, resource mobilisation, and stakeholder collaboration to achieve its goals.



CHAPTER 1: INTRODUCTION

1.1 Background

Building on the gains made during the implementation of the maiden 2021-2024 strategic plan, the Rwanda FDA developed this transformative 5-year (2024-2029) strategic plan. This strategic plan sets the stage for structured and strengthened regulation of foods and drugs in Rwanda. In 2018 the Government of Rwanda established the Rwanda FDA through the enactment of Law N° 003/2018 of 09/02/2018 determining its mission, organisation, and functioning. The establishment of the Authority ushered Rwanda into a new dispensation in food and drug regulation and compliance calling for strategic alignment between the Authority's strategies with other national, sector and corporate plans to ensure effective regulation. The 1st Rwanda FDA strategic plan created structures for development and implementation of future strategic plans.

This 2nd (2024-2029) Rwanda FDA Strategic Plan is aligned with Rwanda's national legal framework, socio-economic development blueprints, health sector policies and strategic frameworks including; Vision 2050, National Strategy for Transformation 2 (NST2), the National Health Policy (2015), Health Sector Strategic Plan (HSSP) V, National Pharmacy Policy (NPP) 2016, National Food and Nutrition Policy (2014), and Law N° 47/2012 of January 14, 2013 relating to the regulation and inspection of food and pharmaceutical products, the UN SDGs etc. The plan is anchored by a strong and sound, enabling legal and policy framework that not only legitimises the Authority by acting as a cornerstone for building a resilient and agile regulatory environment but also guides its strategic plan, including key elements of the planning process and outcome.

Communication plays a vital role in the successful implementation of Rwanda FDA's strategic objectives. Rwanda FDA will prioritize the development and execution of a structured communication strategy that ensures timely, accurate, and transparent information dissemination to all stakeholders, including the public, manufacturers, health professionals, and international partners. This strategy will be integral to promoting compliance and fostering stakeholder trust.

Rwanda FDA will continuously strengthen strategic partnerships with local government entities, law enforcement agencies, regional and international organizations in its regulatory compliance efforts, to ensure maximal compliance and impact for public good as well as to strengthen resource mobilisation and technical support for full implementation of this strategic plan. Linkages with the private sector, academic institutions and non-governmental institutions will foster research, learning and development to accelerate gains in regulatory enforcement and market conduct.

1.2 Vision, Mission and responsibilities of Rwanda FDA

The Rwanda FDA was established vide Law N° 003/2018 of 09/02/2018. The vision, mission and responsibilities of Rwanda FDA are as stated below;

1.2.1 Vision

To be a globally recognized food and drugs authority.

1.2.2 Mission

The mission of the Rwanda FDA is to protect and promote public health by ensuring quality and safety of products regulated by Rwanda FDA.

1.2.3 Responsibilities

Rwanda FDA has the following responsibilities:

- (a) To register and issue marketing authorization for products regulated by Rwanda FDA;
- (b) To establish and publish the list of regulated products for which marketing authorization has been granted;
- (c) To ensure, through regulatory inspections, that facilities intended to be used for the manufacture, storage or sale of regulated products, comply with good practices and standards relating to manufacturing, storage and distribution
- (d) To grant licence to facilities that manufacture, sell, distribute store regulated products;
- (e) To regulate raw materials used in the manufacture of regulated products;
- (f) To control importation and exportation of regulated products;
- (g) To establish and publish a list of prohibited substances and products regulated by Rwanda FDA;
- (h) To regulate the management of unfit regulated products, and their safe disposal;
- (i) To conduct pharmacovigilance and post-market surveillance for safety and quality of regulated products;
- (j) To regulate and analyse information used in the promotion, advertising and marketing of products regulated Rwanda FDA;
- (k) To follow up, analyse and disseminate information to the concerned members of the health professionals and the general public on quality, safety and use of pharmaceutical products that are subject to global drugs safety monitoring; as well as other products regulated by Rwanda FDA;
- (l) To provide laboratory services including testing for regulated products and report test results for regulatory purpose;
- (m) To perform lot release function for vaccines and other biological products regulated by Rwanda FDA;
- (n) To regulate and inspect clinical trials conducted on regulated products;
- (o) To regulate and inspect pre-clinical studies conducted on regulated products for the purpose of discovering new treatments or therapies.
- (p) To regulate prices and mark-ups for pharmaceutical products;

- (q) To collect and analyse data, and publish findings to facilitate evidence-based decisions, system improvement and promote investment for products regulated by Rwanda FDA;
- (r) To enter into partnerships and cooperation for harmonization of practices with national, regional and international bodies with similar mandate, and with academic institutions on projects of common interest;
- (s) To advise the Government on matters regarding the products regulated by Rwanda FDA.

1.3 Rwanda FDA's Strategic Aspirations

1.3.1. To Establish a Fully Functional Regulatory System Globally Recognized

Rwanda FDA is targeting to achieve international recognition by attaining WHO Maturity Levels 3 and 4 (ML3 & ML4) where its core regulatory functions will be fully functional in stable manners and meet the criteria and standards set through the WHO Global Benchmarking Tool (GBT). Rwanda FDA further targets to be designated as WHO listed Authority (WLA) by 2029. In food sector, Rwanda FDA intends to comply with FAO-WHO food control assessment criteria in addition to be ISO 17020 certified.

1.3.2. Scale up current institutional capacity to build a sustainable workforce

Rwanda's vision is *to become a centre for biomedical research, a bio-manufacturing hub and a regional leader for pharmaceutical production* to turn the country from importing to exporting to other countries. Indeed, pharmaceutical industries both in distribution and manufacturing are being attracted; the example being BioNTech for mRNA Vaccine Manufacturing. On the other hand, Rwanda targets *to create a competitive Agri-food Industry*. Indeed, the agriculture sector has important implications for food security, nutrition, exports, and has linkages to industry development. By 2050, Rwanda aspires to establish a manufacturing and commercial agriculture sector that is regionally and globally competitive, with access to modern, high-quality, and cost-effective services as inputs. Therefore, an advanced food industry will be established in the country to develop safer processed and packaged foods for the local, regional and global markets.

Thus, Rwanda FDA aspires to develop its capacities to support this Rwanda's vision on the pharmaceutical sector, as well as required capabilities to provide oversight of emerging technologies and new therapies (nanotechnology-, cell, gene-based etc.) and new components in the regulatory domain such as local production, supply chain (quality assurance and cross-border value chain monitoring). At the same time, Rwanda FDA aspires to enhance its regulatory capacities to support Rwanda's vision to establish a modernized and competitive agri-food industry. In line of the above Rwanda's vision on the pharmaceutical and agri-food industries, Rwanda FDA intends, in the coming five years, to build, attract and retain a sustainable critical mass of staff with the right skills delivering on the regulatory requirements today and properly responding to the future. This requires to plan for lifelong learning and quick growth of Rwanda FDA staff; engage diverse workforce to bring a broader range of skills, perspectives and experience, as well as transfer of

knowledge; develop talent acquisition and competency development programs; and implementing career progression and staff mobility mechanisms.

1.3.3. To position Rwanda FDA in the Heart of the National Health and Research Centers

Rwanda aspires to become a hub for research and development in health sciences, focusing on innovation, knowledge creation, value chain management, collaboration, and capacity building. Rwanda hosts enabling institutions such as African Medicines Agency (AMA); The International Vaccine Institute (IVI); The African Pharmaceutical Technology Foundation (APTF); The Africa Bio-Manufacturing Institute (ABI); The Rwanda Heart and Research Centre; IRCAD (Research Institute against Digestive Cancer), etc. It is therefore imperative to strengthen linkages between Rwanda FDA and the emerging multinational regulatory and research hubs hosted in Rwanda.

1.3.4. To Significantly Improve Value-Chain Management

Rwanda FDA is committed to enhancing the management of food and drug value chains to ensure efficiency, traceability, and safety by implementing digital traceability systems, improving quality control at each stage of the supply chain, and fostering collaborations with local and international partners etc.

1.3.5. Leveraging technology /digitalization for efficient services

Rwanda FDA has embarked on a large-scale digital transformation to improve its level of service. With a rapidly changing external environment, combined with a growing need for efficiency and effectiveness, it is essential for Rwanda FDA to continue its efforts to modernize and optimize its processes, performance and efficiency through the use of IT tools and other technologies. Thus, capacity- building on digital skills, for staff at all levels, will also be a focus, to ensure speed and consistency in the delivery of services.

1.4 Strategic Plan Development Process

A participatory and consultative approach was adopted in the development of this 5-year Rwanda FDA strategic plan. Following the inception meeting, a series of other meetings were held with the Rwanda FDA team to clarify the mission and vision, set up strategy priority areas, agree on activities and clarify other essential aspects of the plan. A detailed desk review was conducted to understand the Authority's legal/policy, institutional and market framework in a targeted situational analysis. This process also supported the alignment of the strategic plan with the national socio-economic development blueprints and agenda as well as global best practices in Drug Authority strategic plan development, implementation and MEAL. Consequently, a review of the implementation of the Authority's maiden strategic plan was done to distil and extract key lessons to inform better development and implementation of the 2nd Rwanda FDA strategic plan. Data was collected from senior managers to help align the vision, strategic direction and institutional framework for effective and inclusive development of the plan. A strategic plan was

developed on the basis of the information gathered from various sources and the interactions with key stakeholders. These were then incorporated into the fair draft to produce the final strategic plan complete with the strategic priority areas, SMART objectives, implementation matrices, resource mobilisation strategy, MEAL Framework, Strategic Risk Analysis and other salient aspects. The draft SP was reviewed, refined and validated prior to formal adoption and implementation by the Authority.

1.5 Organization of this Strategic Plan

This Strategic Plan is organised into three key sections (preliminaries, main strategic plan body and the annexes), each with various subsections. The preliminaries section has the List of Abbreviations, the Foreword from the Rwanda FDA DG and the executive summary. The main body of the strategic plan comprises of the Introduction, Overview of the authority (policy and country context, situation analysis), Strategic Framework (Vision, mission, values and guiding principles), Strategic Priorities Areas, Objectives, Targets, and Strategic Initiatives, Implementation arrangement, Risk analysis and mitigation strategy, Costing, Monitoring and Evaluation Framework and Conclusion. The annexes are mainly the detailed tables on the 3 key strategy priority areas. This Strategic Plan sets out a coherent, systematic, and sustainable roadmap for anchoring Rwanda FDA strategic intents and translating them into operational initiatives for the development of the 2nd Rwanda FDA Five Year (2024-2029) Strategic Plan.

CHAPTER 2: SITUATION ANALYSIS

To understand the contextual factors affecting the Authority as well as the development and implementation of the strategic plan, a detailed but precise situation analysis was conducted. At the first level, Review of the Implementation of the Maiden (2021-2024) Rwanda FDA Strategic Plan was conducted to gain an understanding of how much was done, how it was done, the success factors as well as the barriers/impediments to successful implementation. This is followed by a review of the legal/policy framework, national socio-economic development blueprint and best practices to inform alignment of the plan with these frameworks. Consequently, a sector-wise analysis of the key sectors (Food, Pharma, Tobacco, Traditional medicines, Veterinary products, Medicated Cosmetics and Household Chemical Products). A SWOT (Strength, Weaknesses, Opportunities and Threats) analysis is then conducted to gain a 360° view of the operating environment.

2.1 Review of the Implementation of the Maiden Rwanda FDA Strategic Plan

2.1.1 Level of Implementation

The implementation of the maiden 3-year strategic plan was assessed, tracking down the performance along the key strategic priority areas and the KPIs established. The average implementation status of the maiden (2021-2024) Rwanda FDA strategic plan is about 70%.

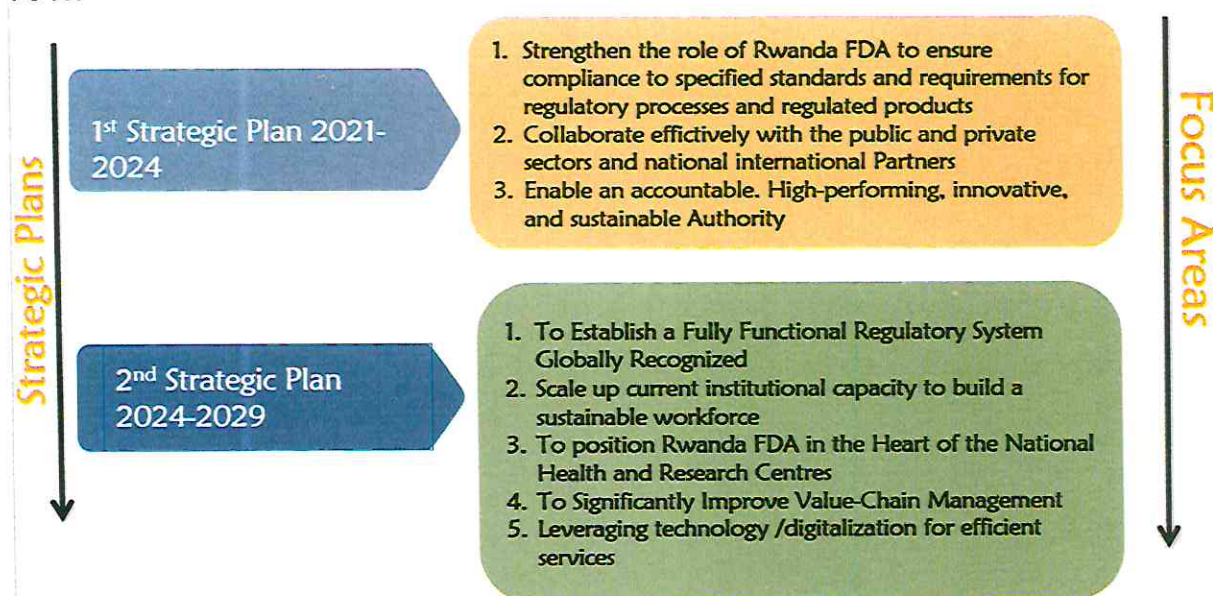


Figure 1: Rwanda FDA Strategic Planning Progress

This successful implementation of the maiden SP was attributed a number of factors including;

1. Cascading of strategic activities into annual work plans and implementation of the work plans on a rolling basis.
2. Aligning individual performance targets and performance to the corporate performance through the annual work plans.
3. Enhancing staff capacity by increasing the number of staff and investing in staff training and capacity building.

4. Targeted secretarial interventions including effective regulation of product quality and strengthening compliance measures. Removal of substandard products from the market and managed to register many previously unregistered products, despite the outstanding backlog in drug products registration. Staff capacity was increased from around 194 to 312 employees, which continues to strengthen enforcement of standards. Additionally, the use of the WHO global benchmarking tool contributed to improved compliance.

The Rwanda FDA is aspiring for maturity level three (ML3), maturity level four (ML4); WLA (World Health Organisation Listed Authority); ISO 17020; ISO 9001; ISO 31000 and FAO/WHO food control system assessment regulatory standards standing. In this regard, there has been significant investment in collaborative partnership as well as institutional capacity building to enhance research capabilities for evidence-based research and decision-making. The Authority has invested in creating structures and building partnerships to secure and sustain financial and administrative independence. Rwanda FDA is planning to construct a new laboratory, to get ISO 17025 accreditation as well as WHO pre-qualification. Rwanda FDA will strengthen its pursuit of organisational excellence by enhancing staff competencies and organisational capabilities through a culture of continuous improvement for eventual regulatory excellence.

Table 1: Rwanda FDA Strategic Planning Progress

Strategic Goals	Targets	Extent of Realization	Explanation for the Level of Realization
Strengthen Rwanda FDA's compliance with specified standards and requirements for regulatory processes and regulated products	- Ensure 100% of products comply with standards. - Register all products - Implement progressive licensing scheme.	Applications 4,500 (100%). Registration 830 (45%) Pending 2,648 (59%) Compliance to GxP (GSDP and Licensing, GCP and GMP) Inspections for premises suitability conducted: (93%) GxP certificates and licenses (83%) Testing Laboratory capacity is at the medium level of 48%	Insufficient human resource to conduct assessment of applications of all regulated products, and conduct inspections for compliance seven of the eight regulatory functions are on track towards achieving Maturity Level 3 status, with ongoing efforts to address the necessary corrective actions for the remaining function which will lead to the achievement of the ML3 Delays in the procurement of laboratory equipment
Collaborate effectively with the public and private sectors and national	Establish MOUs with key national and international partners	Rwanda FDA expanded its international collaborations by signing Memoranda of	Lack of a communication strategy;

and international partners	Strengthen public awareness campaigns	Understanding (MoUs) with several health regulatory authorities Few public awareness campaigns conducted	Budget constraints to conduct public awareness campaign
Enable an accountable, high-performing, innovative, and sustainable organisation	- Achieve full system automation - Implement robust M&E mechanisms - Develop sustainable revenue sources	50-60% All functions are not fully automated and the system is being developed and when completed and functional it will support the Authority to provide services to its clients using the IT system.	The process of the development of the IRMIS took long due to the availability of three developers and budget constraints to support the development of the IT solution

Table 2: Level of implementation

2.1.2 Challenges Experienced

The key challenges faced in the implementation of the maiden strategic plan include;

1. Young and evolving monitoring and compliance enforcement systems and mechanisms.
2. The plan was not very detailed, especially concerning IT strategies and automation as well as the attainment of maturity level 3.
3. Limited collaboration with local institutions. The Rwanda FDA had not established formal collaboration agreements with key local entities such as academic and research institutions and others. This lack of formal partnerships restricted opportunities for collaborative research, mutual support in testing processes, and shared use of resources. The absence of these collaborative efforts hindered the potential for innovative regulatory practices and limited the ability to address complex regulatory issues through joint efforts.
4. Infancy stages of adoption of digital resources in the organisation. Although some progress was made, with modules like imports being fully automated and functioning effectively, other critical modules were not automated. This nascent digitalization affected the overall efficiency of the Rwanda FDA's operations. The lack of a fully automated system led to delays and inefficiencies in regulatory processes execution, thereby impacting the timely delivery of regulatory services. The need for a comprehensive digital transformation was evident to streamline operations and enhance the agency's responsiveness.
5. There were resource limitations such as gaps in equipment, staff, training and availability of testing equipment/products, necessary to meet international accreditation standards as well as conducting thorough and timely regulatory assessments.
6. Procurement challenges including limited financial resources, inefficient procurement processes, inadequate supply chain management, and underutilization of digital tools, leading to delays and inefficiencies in acquiring essential equipment and materials

These factors slowed down the implementation of the plan and constitute key learning points for the implementation of the current strategic plan.

2.1.3 Response/Solutions to the Challenges

The following insights on how to improve the implementation of the SP were gathered;

1. Strengthen partnerships and collaboration between internal stakeholders (inter-departmental), with local academic and research institutions, development partners and other key agencies and stakeholders in key Rwanda FDA regulatory areas.
2. Institutionalise clear guidelines and processes for inter-departmental collaboration to streamline operational and regulatory processes. Nurture a strong culture of collegiality and collaboration to facilitate effective regulation, teamwork, and enhance partner development and collaboration.
3. Complete, full automation of processes to streamline regulatory processes, reduce delays, and improve responsiveness. Continued improvements to the IRIMIS and other core systems at Rwanda FDA are necessary to achieve full digitalization to enhance data management, improve regulatory oversight and provide more efficient services to stakeholders.
4. Strengthen resource mobilisation and investment in equipment, training, reagents, ICT systems/equipment and other support systems to ensure effective and efficient processes and systems that meet international accreditation standards.
5. Enhance sustainability and accountability frameworks through performance reviews aligned with regulatory objectives to ensure continuous improvement and accountability.
6. Advocate for realignment of the PP laws and processes to unique challenges faced by Rwanda FDA and other similar agencies.

2.2 Strategic Alignment with Global and National Development Blueprints

2.2.1 Alignment with Vision 2050

Rwanda's Vision 2050 articulates the long-term strategic direction for “the Rwanda we want” and outlines the enabling pathways to achieve this ambition. The vision emphasises promoting economic growth, prosperity, and a high quality of life for all Rwandans. It is anchored around five key pillars: Human Development, Competitiveness and Integration, Agriculture for Wealth Creation, Urbanization and Agglomeration, and Accountable and Capable State Institutions.¹ The Rwanda FDA 2nd Strategic Plan (2024-2029) aligns closely with these objectives by focusing on enhancing regulatory frameworks for health and nutrition, fostering research and innovation, promoting organizational excellence, and establishing Rwanda as a regional bio-manufacturing hub, which are essential components of the Vision 2050 agenda. These efforts support Vision 2050's pillars of human development, competitiveness, accountable state institutions, and economic growth by ensuring the safety and quality of health-related products, enhancing regulatory compliance, and driving technological advancements. Through its commitment to strengthening regulatory compliance, fostering research, and development, promoting

¹ Rwanda Vision 2050.

https://www.minecofin.gov.rw/fileadmin/user_upload/Minecofin/Publications/REPORTS/National_Development_Planning_and_Research/Vision_2050/English-Vision_2050_Abridged_version_WEB_Final.pdf



organisational excellence, the Authority aims to play a pivotal role in realising the goals set forth in Vision 2050, ultimately contributing to the transformation of Rwanda into a prosperous and competitive nation.

2.2.2 Alignment with National Strategy for Transformation 2 (NST-2) 2024-2029

Rwanda's National Strategy for Transformation (NST-2) is the country's overarching development blueprint for the period 2024-2029. Building on the successes and lessons learned from the previous NST-1, NST-2 aims to propel Rwanda further towards its long-term development vision as articulated in Vision 2050. The key priority areas of NST-2 are: Creating decent and productive jobs; Boosting exports; Reducing stunting and malnutrition; Enhancing public service delivery; and Improving quality of education. The Rwanda FDA strategic plan 2024-2029 aligns closely with Rwanda's National Strategy for Transformation (NST-2) 2024-2029. Strengthening regulatory compliance and market conduct supports NST-2's goals of "creating decent and productive jobs", "boosting exports", and "Made in Rwanda" by ensuring the safety and quality of food, medicines, and other regulated products. This helps build consumer confidence, facilitate trade, and promote local manufacturing.

The plan's focus on research, development, and digital transformation aligns with NST-2's aims of "developing skills for the future" and "universal access to e-government". By leveraging technology and innovation, the Rwanda FDA can enhance its regulatory capabilities and provide efficient, digitised services. Initiatives under the "Scale up current institutional capacity to build a sustainable workforce" priority area directly support NST-1's objective of "enhancing public service delivery". By strengthening the FDA's institutional capacity and stakeholder engagement, the plan contributes to improving the overall quality and responsiveness of regulatory services. Furthermore, the Rwanda FDA strategic plan's alignment with national health, food, and nutrition policies addresses NST-2's goals of "reducing stunting and malnutrition" and "quality healthcare for all". Effective regulation of food, medicines, and related products is crucial for improving population health outcomes.

2.2.3 Alignment with National Health Policy (2015)

The 2nd Rwanda FDA strategic plan is aligned with the overarching goals of the Rwanda National Health Sector 2015 based on the WHO's seven building blocks of health system strengthening, which include; To improve accessibility to, quality of and demand for maternal Health, Family plan, rep. Health, Nutrition services; To consolidate, expand and improve services for the disease and promotion of health and to consolidate, expand and improve services for the treatment and control of disease. The plan addresses key areas such as regulatory compliance, research, development, organisational excellence, advocacy, capacity building and Manufacturing and Value chain. *Strategic Priority Area 1: Establish a Fully Functional Globally Recognized Regulatory System* resonates with the health sector's goal of ensuring universal access to quality health services that are safe, effective, and compliant with international standards. It addresses the need to establish robust regulatory frameworks and compliance mechanisms, ensuring that health products, medicines, and services meet global quality standards. This aligns with the health policy's principle of offering people-centred services that are affordable and of high quality, thereby supporting the broader objectives of patient safety, public health, and regulatory

excellence². **Strategic Priority Area 2: Position Rwanda FDA in the Heart of National Health Research and Development** directly supports the health sector's objectives of strengthening health support systems and expanding research capacity to enhance essential health services. The integration of digital transformation initiatives will improve the efficiency and effectiveness of regulatory and health service delivery, aligning with the health policy's goal of leveraging technology and innovation to maintain high standards of care, even in the context of limited resources. This priority area addresses the health sector's needs for improved surveillance, data management, and evidence-based policy-making, which are crucial for addressing maternal, neonatal, and child health issues, as well as communicable and non-communicable diseases. By fostering institutional linkages and research collaborations, this strategic priority also contributes to generating scientific evidence that informs public health interventions and regulatory decisions. **Strategic Priority Area 3: Scale Up Current Institutional Capacity to Build a Sustainable Workforce:** The National Health Policy (2015) emphasizes the importance of strengthening the health workforce as a key pillar for improving healthcare delivery and regulatory oversight. RFDA's strategic priority to scale up institutional capacity by building a sustainable workforce aligns with this policy by focusing on enhancing the skills and competencies of staff involved in the regulation of food and pharmaceutical products. This effort ensures that the workforce is equipped to meet emerging challenges, enforce safety standards, and improve service delivery. By investing in continuous professional development and capacity-building initiatives, RFDA supports the policy's goal of developing a well-trained, motivated, and sustainable health workforce, ultimately contributing to the improvement of public health outcomes. **Strategic Priority Area 4: To Significantly Improve Value-Chain Management:** The National Health Policy (2015) emphasizes the need for strengthening health systems and ensuring the quality, safety, and availability of essential health products and services. The RFDA's strategic 2nd priority to significantly improve value-chain management directly aligns with this policy by ensuring that food and pharmaceutical products are managed efficiently throughout the supply chain. By implementing enhanced value-chain management practices, RFDA ensures that these products maintain high-quality standards from production to consumption, which contributes to the safety and well-being of the population. This is particularly aligned with the policy's focus on improving service delivery and ensuring that health products meet regulatory standards, ultimately enhancing the health outcomes of the nation. **Strategic priority area 5: Leveraging Technology/Digitalization for Efficient Services:** The National Health Policy (2015) advocates for the integration of technology to strengthen the health sector's efficiency, particularly in service delivery and the management of health information systems. RFDA's strategic priority of leveraging technology and digitalization to enhance services is in direct alignment with this aspect of the policy. By adopting digital systems for traceability, monitoring, and regulatory enforcement, RFDA improves operational efficiency, reduces delays in service delivery, and ensures real-time data for decision-making. This technological approach supports the National Health Policy's objective of enhancing efficiency and responsiveness within the health sector, making services more accessible and effective in promoting public health.

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[https://www.google.com/search?q=national+health+policy+\(2015\)+in+rwanda&og=&gs_lcrp=EgZjaHJvbWUqCQgAECMYJxiqAijJCAAQlxgnGOoCMgkIARAJGcCY6glyCQgCECMYJxiqAijJCAMQlxgnGOoCMgkIBBAjGcCY6glyCQgFECMYJxiqAijJCAyQlxgnGOoCMgkIBxAjGcCY6gLSAQsyNjAyMTc0ajBqN6gCCLACAQ&sourceid=chrome&ie=UTF-8](https://www.google.com/search?q=national+health+policy+(2015)+in+rwanda&og=&gs_lcrp=EgZjaHJvbWUqCQgAECMYJxiqAijJCAAQlxgnGOoCMgkIARAJGcCY6glyCQgCECMYJxiqAijJCAMQlxgnGOoCMgkIBBAjGcCY6glyCQgFECMYJxiqAijJCAyQlxgnGOoCMgkIBxAjGcCY6gLSAQsyNjAyMTc0ajBqN6gCCLACAQ&sourceid=chrome&ie=UTF-8)

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2.2.4 Alignment with Health Sector Strategic Plan (HSSP) V

The purpose of HSSP V is to accelerate progress and ensure equitable improvement of health outcomes through evidence-based prioritization of high-impact interventions. The development of HSSP V was based on a deep-dive analysis of the health sector data that informed the prioritization and built on the new reforms in the health sector. It considered the lessons from the COVID-19 pandemic response and the implementation of HSSP IV. HSSP V is aligned with the National Strategy for Transformation 2024/25-2028/29 (NST2) and Vision 2050 which aims to ensure that Rwanda has a healthy and productive population to attain upper-middle and high-income country status by 2035 and 2050 respectively. HSSP V also responds to the cross-cutting areas emerging from other sectors that are enshrined in the NST2 by embedding them within the HSSP V strategic interventions, including nutrition; capacity development; environment & climate change; disaster management; disability & social inclusion; gender & family promotion including teenage pregnancy reduction; innovation, technology, & digitalization; research & development; regional & international positioning.

2.2.5 Alignment with National Pharmacy Policy (NPP) 2016

This plan is closely aligned with the National Pharmacy Policy (NPP) 2016. NPP's goal of ensuring the quality, safety, and efficacy of pharmaceuticals and health products is directly aligned to the Rwanda FDA strategic priority are 1. By focusing on strengthening regulatory systems and compliance, the FDA supports the development of robust quality assurance systems that ensure the safety, effectiveness, and efficacy of health commodities, aligning with the NPP's objectives of quality assurance and pharmacovigilance. The emphasis on research and development aligns with the NPP's goals of enhancing the health product information system and promoting the rational use of health commodities. 2. The priority on organizational excellence and capacity building bolsters the FDA's ability to improve pharmaceutical sector performance and sustainability, which is crucial for maintaining a steady supply of quality health products. 3. By prioritizing the establishment of a bio-manufacturing hub, the Rwanda FDA contributes to the NPP's objective of promoting investment in local manufacturing, ensuring the availability and accessibility of affordable, high-quality health. The NPP emphasises the need for robust regulatory frameworks and enforcement mechanisms to safeguard public health.³. Such initiatives are consistent with the NPP's objectives to modernise the pharmaceutical sector and harness technology for better health services delivery⁴. The NPP requires competent regulatory bodies and well-trained personnel to effectively implement and enforce pharmaceutical policies in alignment with the Rwanda FDA strategic priority area 3.

2.2.6 Alignment with the National Family and Nutrition Policy (2024)

The National Family and Nutrition Policy aims to promote prosperous and stable families in Rwanda, enhance family members' wellbeing and contribute to a peaceful, capable and inclusive society. The policy is aligned with the national development goals outlined in Vision 2050, the Law governing Persons and Family, the Fourth Health Sector Strategic

³ Rwanda Ministry of Health, 2016

⁴ Rwanda Ministry of Health, 2016

Plan (HSSP IV, 2018-2024), the Fourth Strategic Plan for the Transformation of Agriculture (PSTA4, 2018-2024), the National ECD Policy (2016), and other national strategic documents, as well as International development framework such as the Sustainable Development Goals, the Agenda 2063 of the African Union, and the Scaling-Up Nutrition Movement. The policy will focus among other strategies on legal frameworks and market regulations for safe, nutritious, and affordable food products and services. The policy also increases interventions that address micronutrient deficiencies among children, adolescent girls, women of reproductive age, young adults, senior citizens, and elderly individuals. By improving organizational excellence and capacity building, the FDA ensures effective implementation of food safety regulations and promotes public awareness, aligning with the National Food and Nutrition Policy's focus on market regulations for safe food products. Establishing a bio-manufacturing hub supports the National Food and Nutrition Policy's goal of enhancing food security by encouraging local production of safe and nutritious food products, contributing to the broader aim of improving public health and reducing malnutrition in Rwanda.

2.2.7 Alignment with the Law N° 47/2012 Relating to the Regulation and Inspection of Food and Pharmaceutical Products

This plan is aligned with Law N° 47/2012 of January 14, 2013, which governs the regulation and inspection of food and pharmaceutical products. By prioritizing **Establishing a Fully Functional Globally Recognized Regulatory System – Strengthening Regulatory Systems and Compliance**, the strategic plan directly supports the Law's mandate for rigorous regulatory frameworks and compliance mechanisms to ensure the safety, quality, and efficacy of food, medical products, medicated cosmetics, and household chemicals (Article 5 and Article 9). The focus **To Scale up current institutional capacity to build a sustainable workforce** aligns well the law that speaks to Organisational Excellence, Advocacy, and Capacity Building reflects the Law's requirements for building a competent and sustainable organization capable of effective regulation and public engagement (Article 3 and Article 7). **Positioning Rwanda FDA in the Heart of National Health Research and Development** enhances the Law's objectives of fostering innovation and evidence-based decision-making while embracing technology for improved efficiency and automation in regulatory processes. Aiming **To Significantly Improve Value-Chain Management services** aligns with the Law's that aim to promote local manufacturing and supply chain oversight, ensuring quality assurance and fostering a competitive industry landscape. Lastly, **Leveraging technology /digitalization for efficient**. By implementing digital traceability systems and enhancing quality control, Rwanda FDA can ensure better oversight and efficiency in the value chain, aligning with the legal mandate to maintain effective inspection and regulatory standards. This alignment ensures that the Strategic Plan not only complies with but also strengthens the legislative framework for food and pharmaceutical product regulation in Rwanda.

2.2.8 One Health Strategic Plan 2021-2026

The Rwanda FDA Strategic Plan aligns with the One Health Strategic Plan 2021-2026 by integrating a multidisciplinary approach to public health, which is essential for effectively managing health risks that arise at the intersection of humans, animals, and the environment. Under Law N° 003/2018 of 09/02/2018, Rwanda FDA is tasked with protecting public health through the regulation of human and veterinary medicines,

vaccines, biological products, processed foods, and other critical areas. This mission supports the One Health approach by ensuring that health regulations encompass both human and animal health sectors, promoting a coordinated response to health threats, and contributing to the prevention and control of zoonotic diseases. Manufacturing and Value Chain collectively contribute to objective 6: 'Ensure that there is a clear, systematic, predictable, sustainable and well-coordinated approach to mobilizing, acquiring, utilization, management, reporting, monitoring and evaluating domestic and external resources'⁵. By improving surveillance systems and ensuring efficient resource management Rwanda FDA's regulatory activities are crucial in advancing the One Health agenda by fostering collaboration across sectors and disciplines, thereby enhancing the overall health security of the nation.

2.2.9 Alignment with WHO Global Strategy for Food Safety 2022-2030:

The Rwanda FDA Strategic Plan aligns closely with the WHO Global Strategy for Food Safety 2022-2030, particularly in its mission to protect public health through the regulation of processed foods, among other products. Under Law N° 003/2018 of 09/02/2018, Rwanda FDA is mandated to regulate human and veterinary medicines, vaccines, biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco, and tobacco products. This regulatory framework supports the WHO strategy's goals by strengthening national food safety systems and enhancing global cooperation. Rwanda FDA's focus on ensuring food safety through robust regulation, capacity building, and stakeholder engagement mirrors the WHO's emphasis on comprehensive food safety systems, promoting good practices across the food supply chain, and fostering international collaboration to harmonise standards and improve global health outcomes. It also supports the strategy's objective to improve food safety throughout the food chain. Ensuring that manufacturing processes and value chains adhere to safety standards enhances the overall safety and quality of food products.

2.2.10 Alignment with FAO Strategic Framework 2022-2031:

The strategic priority areas of the Rwanda Food and Drugs Authority (RFDA), such as improving value-chain management, enhancing digital traceability systems, and strengthening quality control, align closely with FAO's global regulations and standards. RFDA's goal to ensure traceability and safety throughout the food and drug supply chains reflects the FAO's Codex Alimentarius standards, which focus on food safety, labelling, and fair-trade practices across the supply chain. The implementation of digital traceability systems is in line with FAO's emphasis on transparency and traceability to improve food safety and consumer trust. Moreover, RFDA's focus on quality control aligns with FAO's guidelines on Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP), which ensure that food production and handling minimize health risks. RFDA's efforts to collaborate with local and international partners also resonate with FAO's sustainability standards, which promote global cooperation to secure food safety and agricultural sustainability. By adhering to these international regulations, RFDA not only enhances local

⁵ <https://faolex.fao.org/docs/pdf/rwa210403.pdf>

food safety and pharmaceutical standards but also strengthens Rwanda's alignment with global food security and health goals.

2.2.11 Alignment with ISO certifications ISO 22000/ ISO 9001 for food safety management systems.

The strategic Objective to achieve required ISO certifications within RFDA's framework aligns with both FAO and WHO global strategies focused on enhancing food safety standards and quality control. FAO promotes the adoption of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), and other standards aligned with ISO certifications to ensure safety and quality throughout the food and pharmaceutical value chains. Achieving ISO certifications, such as ISO 22000 for food safety management systems or ISO 9001 for quality management, is crucial for RFDA to meet internationally recognized benchmarks of operational efficiency, traceability, and compliance with global food safety regulations. This effort mirrors the FAO's commitment to improving production systems and ensuring global food security through rigorous safety and quality standards

2.2.12 Alignment with Food Safety Strategy for Africa 2022-2036

The Rwanda FDA Strategic Plan is well-aligned with the Food Safety Strategy for Africa 2022-2036, reinforcing the continent-wide effort to enhance food safety systems and public health. Under Law N° 003/2018 of 09/02/2018, Rwanda FDA is mandated to protect public health by regulating processed foods, among other critical products. This mission directly supports the objectives of the African strategy by strengthening national food safety systems, enhancing regulatory frameworks, and promoting safe agricultural practices. Rwanda FDA aligns with the objective to strengthen research, innovation, technology development, and transfer by promoting cutting-edge research and innovations that improve food safety practices and technologies. Rwanda FDA's commitment to rigorous food safety regulation and its focus on capacity building, surveillance, and risk management align with the broader continental goals of reducing foodborne diseases, ensuring the integrity of food products, and facilitating safe trade within and beyond Africa. It also aligns with the objectives to **improve trade and market access** and **establish and strengthen coordination mechanisms** by ensuring that food production and distribution systems meet safety standards, thus facilitating better market access and coordination at various levels. Through its regulatory activities, Rwanda FDA plays a vital role in advancing food safety in Rwanda, contributing to the overall success of the Food Safety Strategy for Africa.

2.2.13 Alignment with United Nations Sustainable Development Goals (UN-SGDs)

The United Nations Sustainable Development Goals (SDGs) are a set of 17 interrelated global goals adopted by the United Nations in 2015. The SDGs provide a shared blueprint for peace and prosperity for people and the planet, now and into the future. They are designed to be a "blueprint to achieve a better and more sustainable future for all." The Rwanda FDA's mandate includes regulating human and veterinary medicines, vaccines, and other biological products, which directly contributes to ensuring access to quality essential healthcare services and medicines. The plan's focus on strengthening regulatory systems and compliance, as well as enhancing oversight to ensure product safety and effectiveness, aligns with the goal of promoting healthy lives and well-being for all (SDG 3: Good Health

and Well-being). Additionally, the strategic plan's focus on research, development, and digital transformation indicates a commitment to promoting innovation and building resilient infrastructure within the food and drugs regulatory sector, which aligns with SDG 9: Industry, Innovation, and Infrastructure. The plan's coverage of the food sector, tobacco and tobacco products, traditional medicines, and medicated cosmetics and household chemical products suggests an alignment with the goal of ensuring sustainable consumption and production patterns (SDG 12: Responsible Consumption and Production). Furthermore, the strategic plan emphasises the importance of strategic partnerships and stakeholder engagement, which is crucial for the successful implementation of the plan and the achievement of the SDGs, aligning with SDG 17: Partnerships for the Goals.

2.3 Rwanda FDA's Aspirations

National Aspirations	Strategic Aspirations	RFDA Aspirations	Objectives	What Needs to be done
To be a leading bio-manufacturing centre in Africa HSSP V Pillar 5: Research, Innovation, Bio-manufacturing, Regulation and Digitalization Vision 2050 Pillar 2: Competitiveness and Integration; A diversified economy built upon future industries NST-2 Goal 4: Made in Rwanda		To Establish a Fully Functional Regulatory System Globally Recognized	(a) Achieve WHO ML3, ML4, and WHO Listed Authority (WLA) by 2029. (b) Comply with FAO-WHO food standards. (c) Achieve required ISO certifications.	✓ Strengthen legal frameworks of Rwanda FDA. ✓ Implement a Quality Management System, and risk management for adaptability. ✓ Meeting the criteria and standards set through the WHO Global Benchmarking Tool (GBT). ✓ Meeting the FAO-WHO food standards. ✓ Achieving ISO 17020 certification for food controls. ✓ Obtain required ISO for the laboratory and process certifications. ✓ Standardize regulatory processes and adopt a risk-based approach. ✓ Enhance staff skills through training and foster a culture of innovation to build expertise in all regulatory areas, as well as in regulatory science. ✓ Invest in infrastructure and technology for efficient regulatory operations.
To become a knowledge-intensive economy in Africa - Vision 2050 Pillar 2: Competitiveness and Integration; Knowledge-intensive economy		Scale up current institutional capacity to build a sustainable workforce	Develop a competitive agri-food and pharmaceutical industry	✓ Develop required capabilities to provide oversight of emerging technologies and new therapies (nanotechnology-, cell, gene-based etc.) and new components in the regulatory domain such as local production, supply chain to

- NST-2 Goal 6: Developing skills for the future. - HSSP V Pillar 5: Research, Innovation, Bio-manufacturing, Regulation and Digitalization			support the bio-manufacturing and food industries. ✓ Develop required regulatory capacities to support establishing a modernized and competitive agri-food industry in Rwanda. ✓ Attract and retain a sustainable critical mass of skilled staff, including engaging diverse workforce. ✓ Develop a lifelong learning program and competency development mechanisms. ✓ Develop talent acquisition programs. ✓ Implement career progression and staff mobility systems. ✓ Establish institutional linkages with international stakeholders like BioNTech, African Medicines Agency (AMA), and African Pharmaceutical Technology Foundation (APTF). ✓ Implement continuous professional development programs for Rwanda FDA staff and healthcare providers. ✓ Enhance infrastructure and resources for training programs for both Rwanda FDA staff and health providers.
		Establish organisational Excellence and Advocacy	✓ To ensure that Rwanda FDA has an Adequate, Competent and Motivated Workforce. ✓ To Enhance Resource Mobilization and Prudent Financial Management. ✓ To enhance Corporate Governance Practices. ✓ Enhance Brand Identity, Awareness and Customer Satisfaction.
To achieve universal health coverage - Vision 2050 Pillar 1: Human Development;	To position Rwanda FDA in the Heart of the National	Enhance Rwanda FDA's linkages with multinational	✓ Build and strengthen partnerships with international health research centres. ✓ Strengthen Rwanda FDA's regulatory services provided to

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Universal access to high quality health care - NST-2 Goal 3: Open for business - HSSP V Pillar 2: Health Infrastructure Modernization - HSSP V Pillar 3: Quality of Care Based on Primary Health Care	Health and Research Centres	regulatory and research hubs hosted in Rwanda.	research hubs such as IRCAD, Rwanda Heart and Research Centre, etc. ✓ Collaborate with AMA, APTF and ABI, as well as with research institutions like the University of Rwanda, IVI, etc. for health studies.
To become a regional logistics hub - Vision 2050 Pillar 2: Competitiveness and Integration; Competitive manufacturing anchored to a regional hub - NST-2 Goal 3: Open for business - HSSP V Pillar 5: Research, Innovation, Bio-manufacturing, Regulation and Digitalization	To Significantly Improve Value-Chain Management	Strengthen Rwanda FDA's oversight on food and drug value chains	✓ Review and update regulatory frameworks to align with international standards. ✓ Establish strategic partnerships with local and international organizations, international education & research institutions, and regulatory bodies. ✓ Facilitate workshops for stakeholders on quality assurance best practices.
		Implementation of digital traceability systems that can monitor and track products throughout the supply chain	✓ Develop and deploy a centralized digital platform for supply chain tracking. ✓ Implement digital traceability systems for efficiency, traceability, and safety. ✓ Train stakeholders on the use of digital systems for tracking and reporting.
		Enhancing the quality control measures at each stage of the value chain, from production and processing to distribution and retail	✓ Conduct regular audits and inspections to ensure compliance with quality standards. ✓ Improve quality control measures at each stage of the supply chain. ✓ Implement a comprehensive quality management system (QMS). ✓ Facilitate workshops for manufacturers and distributors on best practices in quality control.

		Enhance Research and Development To develop a knowledge centre for health and health sciences	✓ Enhance Rwanda FDA's research and development capabilities. ✓ Increase funding for research into local health challenges and solutions. ✓ Establish partnerships with academic and research institutions for collaborative studies. ✓ Promote innovation in health technologies and practices. ✓ Invest in research facilities, building on existing laboratory infrastructure
To achieve a digitalized economy and e-Government services - Vision 2050 Pillar 4: Innovations and Technological Advancement - NST-2: ICT Hub and Knowledge-based Economy - HSSP V Pillar 5: Research, Innovation, Bio-manufacturing, Regulation and Digitalization	Leveraging technology /digitalization for efficient services	Implement a digital transformation to optimize processes and performance through the use of IT tools and other technologies.	✓ Modernize regulatory processes through digital tools and technologies. ✓ Build digital skills capacity of staff at all levels. ✓ Implement centralized digital platforms for regulatory management. ✓ Invest in IT infrastructure and data management systems to support service delivery. ✓ Foster a culture of digital innovation and continuous improvement within Rwanda FDA.

Table 3: Rwanda FDA Strategic Aspirations

2.4 Sectorial Analysis and Harmonisation with Rwanda FDA Strategic Priorities

2.4.1 The Food Sector

In 2010, the global burden of 31 food hazards was found to be 33 million DALYs (A.H. et al., 2015)⁶. Children under five years bore 40% of the burden. The global burden of animal source foods (ASF) was 168 DALYS per 100,000 population (Li et al., 2019). Foodborne diseases in low- and middle-income countries cost about USD 110 billion a year with sub-Saharan Africa (SSA) accounting for US \$16.7 billion (Jaffee et al., 2019). Foodborne diseases are a significant health concern in Rwanda, with diarrheal diseases among the top causes of morbidity and mortality, particularly affecting children under five. A WHO/Joint External Evaluation in 2018 highlighted that 83% of diarrheal diseases in the past five years were related to food and waterborne illnesses such as typhoid fever, shigellosis, cholera, and food poisoning. This situation underscores the need for a robust food sector regulatory environment to ensure food safety and public health. Rwanda's food sector regulation has

⁶ A.H., H., MD, K., PR, T., HJ, G., T, H., & Lake RJ, et al. (2015). World Health Organization global estimates and regional comparisons of the burden of foodborne disease in 2010. PLoS Medicine, 12(12), e1001923.

significantly evolved, with the Rwanda FDA playing a crucial role under Law N° 003/2018 of 09/02/2018. The Authority has made strides in improving regulatory compliance, increasing facilities operating under good manufacturing practices (GMP) from 250 to above 1,000 and developing a licensing scheme for food manufacturers. Despite these advancements, challenges such as instilling a stronger food safety culture among manufacturers, addressing unapproved water sources, and improving under-resourced inspection systems remain. The Authority aims to enhance regional coordination on food trade and standards and further develop its organisational capabilities, including process automation, ISO certification and attaining ML4 status and FAO/WHO food control system assessment.

2.4.2 The Pharmaceutical Sector

The WHO sets global standards for pharmaceutical regulation to ensure the safety, efficacy, and quality of medicines. WHO guidelines cover Good Manufacturing Practices (GMP), Good Storage and Distribution Practices (GSDP), Good Clinical Practices (GCP), pharmacovigilance, quality control, marketing authorization, and regulatory oversight, aiming to harmonise practices worldwide and combat substandard and falsified medicines. Initiatives like the International Conference of Drug Regulatory Authorities (ICDRA) and the Prequalification Program facilitate international cooperation and strengthen regulatory systems in member states. In East Africa, WHO regulations have significantly shaped national pharmaceutical policies and enhanced regulatory capacities, and capabilities. Countries in the region, including Kenya, Uganda, Tanzania, Rwanda, and Burundi, have collaborated under the East African Community (EAC) to harmonise pharmaceutical regulations through the East African Medicines Regulatory Harmonization (EAC-MRH) program. Rwanda's pharmaceutical sector, though relatively small compared to larger African economies, has been steadily growing with public and private investments. The government is committed to improving health outcomes and reducing disease burdens by ensuring access to safe, effective, and affordable medicines. With over 99% of pharmaceuticals imported, efforts are underway to build local manufacturing capabilities through special economic zones offering incentives

2.4.3 Regulation of Tobacco Products in Rwanda

The regulation of tobacco products has evolved globally due to the significant health hazards associated with tobacco use, which the WHO identifies as one of the leading causes of preventable death, causing over 8 million deaths annually, particularly in low- and middle-income countries.⁷ Tobacco-related diseases, including cancer, cardiovascular, and respiratory conditions, pose a substantial global health burden. The Rwanda Non-Communicable Disease Risk Factor Report highlights use of tobacco products as a leading risk factor for non-communicable diseases (NCDs) in the country.⁸ Many countries, including Rwanda, have enacted stringent tobacco-products use regulations. These typically cover advertising restrictions, packaging and labelling requirements, taxation, and smoking bans in public areas. The Rwanda FDA, under Article 9 of Law No. 003/2018, issued new regulations to strengthen tobacco product control, focusing on processed tobacco goods

⁷ World Health Organization (WHO). (2021). Tobacco. <https://www.who.int/news-room/fact-sheets/detail/tobacco>

⁸ Rwanda Ministry of Health. (2015). Rwanda Non-Communicable Diseases Risk Factors Report.



like cigarettes and smokeless tobacco products. These new regulations specifically target the quality, safety, and packaging of these products, ensuring they comply with international health standards. The measures include mandatory graphic health warnings on all packaging, clear product labelling, and strict oversight of the importation and distribution of tobacco products to minimize their impact on public health. The Ministry of Health, through its Tobacco Control Unit, enforces measures aligned with the WHO Framework Convention on Tobacco Control (FCTC), to which Rwanda is a signatory.⁹ These measures include banning tobacco advertising and requiring graphic health warnings on packaging. In 2022, the Rwanda FDA issued new regulations under Article 9 of Law No. 003/2018 to strengthen tobacco control.¹⁰

2.4.4 Regulation of Traditional Medicines

The WHO emphasises the role of Traditional, Complementary, and Alternative Medicine (TCAM) in global healthcare, aiming to integrate it into health systems while ensuring safety and efficacy. The WHO Traditional Medicine Strategy (2014-2023) recognizes that TCAM usage varies widely, from 24% to 71.3%, influenced by cultural acceptance, accessibility, and integration with conventional healthcare. In East Africa, TCAM is crucial, especially in rural areas with limited access to conventional medical facilities. While some countries are working to regulate and integrate TCAM into formal health systems, challenges like regulation gaps and quality assurance remain, necessitating further research on its safety and efficacy. The regulation of traditional medicines has advanced with the establishment of the Rwanda FDA and the Rwanda Standards Board (RSB), guided by the National Policy of Traditional, Complementary, and Alternative Medicine (TCAM) of 2019. However, concerns about herbal medicine safety persist, such as unclear expiration dates and inadequate dosage instructions. Initiatives like the Phyto Social Enterprise Project (POSE) by the National Industrial Research and Development Agency (NIRDA) aim to modernise herbal medicine production and ensure adherence to Good Manufacturing Practices (GMP), with ongoing efforts to integrate traditional medicine effectively into the national health system.

2.4.5 Regulation of Veterinary Products

In 2019, the global burden of livestock diseases and inadequate veterinary care was substantial, with economic losses reaching billions of dollars annually. Veterinary products, including pharmaceuticals, vaccines, and feed additives, are critical in managing animal health and preventing diseases. The global market for veterinary pharmaceuticals was valued at approximately USD 40 billion in 2020, with expected growth driven by increasing demand for livestock and pets, advancements in veterinary medicine, and rising concerns over animal health. In sub-Saharan Africa, including Rwanda, veterinary products play a crucial role in controlling livestock health, which is vital for food security and economic stability. For instance, the economic burden of livestock diseases in Africa, like Foot-and-Mouth Disease (FMD) and African Swine Fever (ASF) is significant, with estimates suggesting that livestock diseases can cost these regions billions annually in terms

⁹ WHO. (2015). WHO Framework Convention on Tobacco Control

¹⁰ Rwanda FDA. (2022). Regulations governing licensing to manufacture, import, and sell tobacco and tobacco products.

of lost productivity and increased veterinary costs.¹¹ The regulatory framework for veterinary products in Rwanda has seen significant developments in recent years. Under the powers conferred by the Law N° 003/2018 of 09/02/2018, which establishes the Rwanda FDA, regulations governing veterinary products have been put in place. These regulations, adopted in 2022, are designed to ensure the safety, efficacy, and quality of veterinary medicines and vaccines. They include provisions for the licensing and registration of veterinary products, as well as monitoring their use to prevent issues such as drug resistance and contamination.¹²

2.4.6 Regulation of Cosmetics and other public health Chemical Products

The regulation of medicated cosmetics and household chemical products is crucial for public health and safety, with global frameworks becoming increasingly harmonised to ensure these products' safety, efficacy, and quality. Key regulatory bodies like the U.S. Food and Drug Administration (FDA) oversee cosmetics under the Federal Food, Drug, and Cosmetic Act, with the U.S. cosmetics market valued at approximately \$93.5 billion in 2020.¹³ Similarly, the European Medicines Agency (EMA) regulates medicinal products, including medicated cosmetics, under the EU Cosmetics Regulation, with the EU cosmetics market worth about €80 billion in 2020.¹⁴ In Sub-Saharan Africa, the regulatory landscape for medicated cosmetics and household chemical products is diverse, with varying levels of regulatory maturity and infrastructure.¹⁵ Initiatives like the African Medicines Regulatory Harmonization (AMRH) aim to harmonise medicines regulation across Africa, with the African pharmaceutical market projected to reach \$70 billion by 2030. The East African Community (EAC), which includes Rwanda, works towards harmonising pharmaceutical regulations and launched the Medicines Regulatory Harmonization Initiative in 2018 to streamline regulatory processes.

2.4 SWOT Analysis

These SWOT analysis highlights Strengths and Opportunities the Authority can leverage and exploit to overcome the Weaknesses, and Threats in its operating environment for effective strategy implementation and ultimately the realisation of its statutory mandate.

STRENGTHS

Legal Mandate: The Authority was established vide Law N° 003/2018 of 09/02/2018 giving a strong legal basis for operating and support bolster strategic implementation and regulatory effectiveness.

¹¹ Otte, J., Roland-Holst, D., & Ly, M. (2021). The economic impact of livestock diseases in sub-Saharan Africa. *Preventive Veterinary Medicine*

¹² Rwanda FDA. (2022). Regulations governing the licensing, registration, and control of veterinary products.

¹³ Statista. (2021). Cosmetics market value in the U.S.

¹⁴ Cosmetics Europe. (2021). Cosmetics and personal care market overview.

¹⁵ East African Community (EAC). (2018). Medicines Regulatory Harmonization Initiative.

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Governance and leadership: The Authority has a qualified, competent and proactive Board in charge of governance issues. The Authority is also characterised with well-established internal governance structures and an enabling governance framework.

Strong workforce: The Authority enjoys progressive leadership from a well trained and experienced management team committed to building a leading and sustainable institution. Rwanda FDA has a competent, motivated and committed workforce committed to teamwork, to execute its mandate efficiently and effectively. Continuous recruitment, training and motivation

Functional ICT Systems and Platforms: Rwanda FDA has made significant investment in a number of ICT infrastructure, platforms and systems. Some of the ICT systems are at the development stage and need finalisation while some could require integration.

WEAKNESSES

Lack of a Formal Multi-Stakeholder Coordination Policy/Framework: To execute its mandate effectively, Rwanda FDA requires the support and collaboration of multiple stakeholders. The absence of a formal stakeholder engagement, coordination and management framework reduces the effectiveness and potential benefits of current efforts.

Inadequate Financial Resources to Support All Functions: Despite significant government and development partner support, the Authority has many existing and emerging demands related to its core mandate including research, institutional development and capacity building that require much more funding.

Procurement Delays: Chronic delays in the procurement processes impact the timely acquisition of necessary resources and equipment. These delays can hinder the agency's ability to respond promptly to emerging food and drug safety issues.

Insufficient Human Capital: Rwanda FDA has grown its human capital significantly since inception in 2018. However, the number of regulatory processes, institutions, products and collaborative partners is increasing as well calling for continuous recruitment, on-boarding, development and motivation of technical staff to meet regulatory demand.

Inadequate Facilities: Inadequate laboratory facilities and insufficient equipment, limit the Authority's ability to effectively execute its mandate. These infrastructure gaps affect the monitoring and enforcement capabilities, making it challenging to ensure food and drug safety across the entire country.

Low Regulatory coverage: Herbal medicine, household chemicals, medical devices etc.

THREATS

Emerging Health Challenges: New and emerging diseases can strain the regulatory and monitoring systems established by Rwanda FDA.

Compliance Window-Dressing: Some regulates may "cheat" to comply with regulatory standards (borrow equipment and tweak process to meet regulatory standards) then revert to their default settings post inspection. This coupled with manufacture and/or importation of substandard products may complicate regulation. Strengthening surveillance and enforcement mechanisms is critical to combat this threat.

Global Supply Chain Disruptions: Disruptions in global supply chains can affect the availability of essential drugs and food products. Rwanda's dependence on import of drug and food items

makes it vulnerable to international market fluctuations, supply disruptions and the attendant compliance issues.

Cyber-security and other Digital Platform Threats: Rapid advancements in technology pose a dual threat: the need to constantly update regulatory frameworks and the risk of cyber threats compromising data integrity and operational efficiency.

Low Technology Savviness and Access by the Public: Low technology savviness and access may impede public use of Rwanda FDA digital platforms and services.

Global Health Crises: Pandemics can overwhelm regulatory and health systems, making it challenging for Rwanda FDA to maintain routine operations and respond to new threats effectively.

OPPORTUNITIES

Global Best Practice Benchmarking: Rwanda FDA can benchmark with leading global FDAs through adoption of global best practices in regulation e.g. Capability Maturity Model Integration (CMMI).

Government strong commitment and support: Government's strong commitment and legal support provide a solid foundation for Rwanda FDA's regulatory effectiveness and strategic growth.

Technology Enhancement: There are opportunities for systems integration and enhancement.

Reliance and Recognition Mechanisms: The reliance on reports and assessments from other countries for certain regulatory decisions underscores the need for more robust internal capacity. Building this capacity would enable Rwanda FDA to independently assess products, enhancing the reliability and efficiency of its regulatory activities.

Regulation of Traditional, Complementary, and Alternative Medicine (TCAM): The establishment of the African Medicines Agency (AMA) in Kigali presents an opportunity to regulate and promote TCAM.

Technological Advancements: Rwanda FDA can integrate existing systems through an array of API and other technology tools to enhance access to and functionality of its current and future technology systems.

Regional Integration: As East African countries work towards greater economic integration; Rwanda FDA can benefit from harmonisation of food and drug safety regulations. Initiatives like the EAC Medicines Regulatory Harmonization can standardise regulations, facilitate trade and improve public health outcomes across the region.

Strengthening Local Manufacturing: Supporting local manufacturing of regulated products is a significant opportunity to ensure the availability of affordable and quality medicines. This can reduce dependence on imports and enhance national self-sufficiency in healthcare.

Partnership Strengthening and Stakeholder Engagement: Collaboration with various stakeholders, including the Ministry of Health, Rwanda Biomedical Centre, international organizations, development partners, global regulatory bodies (WHO, WTO) etc. can enhance its ability to discharge its regulatory functions.

Consumer Education and Engagement: Expanding consumer education initiatives can empower the public with knowledge about food and drug safety. Engaged and informed consumers are more likely to comply with regulations and report safety issues, improving overall public health outcomes.

Investment in Research and Development: Encouraging research and development in food and drug safety can lead to innovations and improvements in regulatory practices.

Hosting of International, Continental and Regional Agencies: African Medicines Agency (AMA), BioNTech mRNA Vaccine Manufacturing Facility, Rwanda, The African Pharmaceutical Technology Foundation, The International Vaccine Institute (IVI), The Rwanda Heart and Research Centre, IRCAD (Research Institute against Digestive Cancer) Africa, etc.

Table 3: SWOT Analysis

CHAPTER 3: STRATEGIC MODEL

3.1 Core Values

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



Figure 2: Rwanda FDA Core Values

3.2 Quality Policy Statement

Rwanda FDA is committed to consistently provide the highest quality of regulatory services that meet customer and statutory requirements by implementing a Quality Management System that complies with ISO 9001:2015 requirements.¹⁶

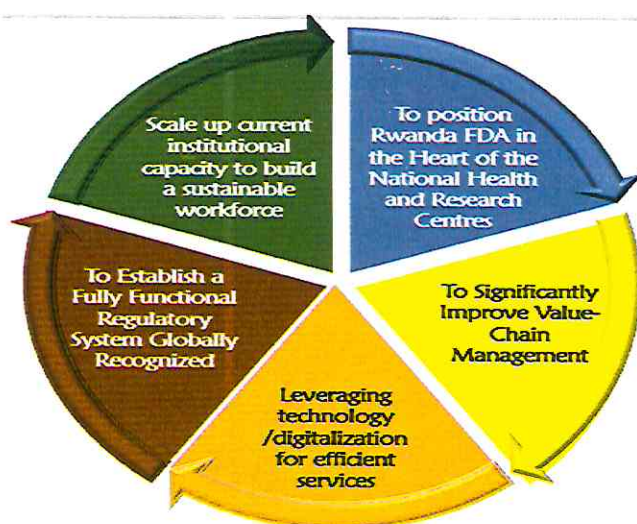
3.3 Strategic Priority Areas (Themes)

The Rwanda FDA has set 5 key priorities for the next five-years that speak to the strategic interventions and objectives.

1. To Establish a Fully Functional Regulatory System Globally Recognized
2. Scale up current institutional capacity to build a sustainable workforce
3. To position Rwanda FDA in the Heart of the National Health and Research Centres
4. To Significantly Improve Value-Chain Management
5. Leveraging technology /digitalization for efficient services

¹⁶

<https://rwandafda.gov.rw/quality-management-system/#:~:text=Rwanda%20FDA%20is%20committed%20to%20consistently%20provide%20the,Management%20System%20that%20complies%20with%20ISO%209001%3A2015%20requirements.>



These thematic areas are based on the Authority's strategic intents, historical assessments/evaluations as well as business environment dictates (including the legal framework). The section below details each priority area with the respective strategic objectives and interventions. A separate annual work plan will be developed detailing the strategic interventions that will be operationalized over the five-year implementation period.

Figure 3: Strategic Priority Areas [Themes]

RFDA Aspirations	Objectives
To Establish a Fully Functional Regulatory System Globally Recognized	a. Achieve WHO ML3, ML4, and WHO Listed Authority (WLA) by 2029 b. Comply with FAO-WHO food standards. c. Achieve the required ISO certifications.
Scale up current institutional capacity to build a sustainable workforce	a. Develop a competitive agri-food and pharmaceutical industry b. Establish organisational Excellence and Advocacy
To position Rwanda FDA in the Heart of the National Health and Research Centres	Enhance Rwanda FDA's linkages with multinational regulatory and research hubs hosted in Rwanda.
To Significantly Improve Value-Chain Management	a. Strengthen Rwanda FDA's oversight on food and drug value chains b. Implementation of digital traceability systems that can monitor and track products throughout the supply chain c. Enhancing the quality control measures at each stage of the value chain, from production and processing to distribution and retail d. Enhance Research and Development e. To develop a knowledge centre for health and health sciences
Leveraging technology /digitalization for efficient services	Implement a digital transformation to optimize processes and performance through the use of IT tools and other technologies.

Table 4: Strategic Priority Areas/ Themes Description

Table 4: Strategic Priority Area 1 – Establish a Fully Functional Globally Recognized Regulatory System

Strategic Objectives	Activity	Expected Output	Expected Outcome	Responsibility	Budget (RwF)	Time Frame
Enhance regulatory frameworks and guidelines with proper compliance mechanisms to ensure the safety, quality, and efficacy of products regulated by Rwanda FDA	Develop, review and update regulatory Frameworks and documents.	Updated Regulatory Documents.	Enhanced enforcement and compliance leading to a healthier Rwanda. Reduced malpractice.	Legal Office, Food/Drugs Departments/QMS	417,352,996	By 2026
	Streamline all regulatory processes.	Updated registration protocols, procedures and guidelines. SLAs and updated customer charter.	Enhanced regulatory enforcement and compliance. Reduced registration times. Recognition as a leading FDA in Africa.	Legal Office /Drugs/ Food Departments/QMS	259,908,452	By December 2025
	Apply for and comply with the Requirements for attaining and maintaining ML3 by 2024 and ML4 by 2029.	Maturity Levels 3 and 4 leading to strengthened regulatory capacity and processes.	Strengthened regulation and enhanced compliance. Recognition as a leading FDA in Africa.	QMS, RES and Drugs Department	833,423,110	By 2029
	Develop a comprehensive WHO Global Benchmarking Tool (GBT) compliance roadmap to achieve the status of a WHO Listed Authority (WLA) by 2029.	WHO GBT Compliance Roadmap developed and implemented?	Enhanced capacity to achieve WLA status. International recognized regulatory authority	QMS and Drugs Department	592,300,000	By 2029
Strengthen Registration, Inspection, and Enforcement	Adopt and implement ICT, legal provisions, guidelines and best practices.	Updated ICT policy and regulatory framework.	-Legal compliance. -Organisational efficiency and effectiveness.	IT Office/Legal Office	166,607,980	Continuous
	Conduct regular compliance and enforcement missions.	Inspection missions and reports.	Improved compliance. Reduced malpractice.	Drugs/ Food Departments.	3,082,247,673	Continuous

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	Apply for ISO 17025 lab accreditation.	ISO 17025 accredited lab standardised, benchmarked, excellent services.	Enhanced testing capacity and regulation. Regional leadership and continental recognition.	Laboratory Services department.	204,927,818	By 2025
	Apply for WHO prequalification.	Rwanda Laboratory with WHO pre-qualification.	Efficiency and efficacy of results from Rwanda Laboratories.	Laboratory Services department.	243,892,874	By 2025
	Apply for ISO 17020 certification.	ISO 17020 certification service provided.	Food Inspection services based on international best practices.	Food department.	204,927,818	By 2026
	Attain and Maintain ISO 9001 Certification.	ISO 9001 certification attained and renewed annually.	Improved operational efficiency and regulatory compliance.	CFO/QMS	1.364,713,978	Annually
	Compliance with WHO food control assessment criteria.	FAO-WHO food control certifications	Food regulatory system based on international best practices.	Food department.	204,927,818	By 2026

Table 5: Strategic Priority Area 1

Table 5: Strategic Priority Area 2 – To Scale up current institutional capacity to build a sustainable workforce

Strategic Objectives	Activity	Expected Output	Expected Outcome	Responsibility	Budget	Time Frame
To Ensure that Rwanda FDA has an Adequate, Competent and Motivated Workforce.	Conduct Institutional Human Capacity Assessment.	Human Resource Work plan. Optimal staffing levels with the required competencies.	Optimal staffing levels and optimal performance.	HR and Admin/CFO	45,000,000,000	By 2025 and Continuously
	Develop and Implement a Robust	Comprehensive talent management strategy that	Motivated and engaged workforce	HR and Admin/CFO	168,750,000	By 2024 and Continuously

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	Talent Management Strategy	includes recruitment, on boarding, training and development, performance management, and succession planning.	that is committed to achieving organizational goals.			
	Develop and Implement a Comprehensive Capacity Building Strategy	Comprehensive Capacity Building Strategy	Highly skilled and competent staff	HR and Admin/CFO	40,000,000,000	Annually
	Establish a Learning and Development Culture.	Organisational culture and learning development plans.	Continuous learning and development.	HR and Admin/CFO	3,125,750,000	Annually
	Attract, recruit, retain and engage diverse staff	Effective staff recruitment and retention system.	Stable, adequate, and motivated workforce.	HR and Admin/CFO	1,912,725,000	Annually
	Enhance a Positive and Supportive Work Environment.	Workplace culture that promotes employee well-being, engagement, and satisfaction.	High level of employee morale and retention.	HR and Admin/CFO	575,000,000	Continuously
	Develop and Implement a Comprehensive Environmental, Health, and Safety (EHS) Policy.	Well-defined EHS policy to protect the environment, safeguarding employee health, and ensuring workplace safety.	A safe work environment.	HR and Admin/CFO	204,125,000	Continuously

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	Implement staff mobility mechanisms to develop capacity	Employee engagement plan/systems.	Engaged and productive employees.	HR Admin/CFO	118,300,000	Continuously
To enhance Resource Mobilization and Financial Management Practices.	Develop and implement integrated budgets and resource mobilisation plans.	Annual, itemised budgets, work plans & procurement plans. Resource mobilisation plans.	Integrated work plans Adequate financial resources.	Planning and M&E Unit/CFO	161,300,000	Annually
	Implement a consolidated annual procurement plan.	Annual procurement plan.	Compliance with the procurement laws and timely, efficient procurement of goods and services.	CFO/Procurement Office	149,375,000	Annually
	Enhance resource mobilisation strategies.	Resource mobilisation strategy and plan.	Adequate OPEX and CAPEX resources.	CFO/RES	86,350,000	Annually
Encourage and adopt new technologies to continuously transform and improve operational efficiency.	Conduct regular assessments to review performance and identify emerging technologies.	Comprehensive plan outlining steps, timelines and resources required.	Improved operational efficiency	HR Admin/QMS Division.	58,501,250	Annually
	To conduct Staff training on the use and maintenance of new technologies	Training program, and staff competence matrix.	Increased adoption of new technologies	ICT/CFO	125,000,000	Continuously

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	Review and restructure organisational processes.	Restructured organisational processes.	Enhanced organisational efficiency and effectiveness	HR and Admin/ CFO	171,912,500	By 2026 and continuously
To enhance Corporate Governance Practices.	To conduct governance framework review	Revised governance framework	Improved governance practices	HR and Admin/ CFO	150,320,000	By 2025
	To review risk management framework Ensure implementation and monitoring of the SP. Undertake mid-term and terminal review of the SP.	Updated risk management plan Governance performance report and action plan Annual work plan review reports. M&E Reports	Reduced corporate risk Effective implementation of the Strategic Plan	ICT/CFO Internal Audit Office /CFO Planning and M&E Unit/DG/DGG/ CFO	230,851,250	Annually/Mid-term/End-term
	Risk assurance	Continuous assessment and mitigation plans.	Monitoring and control of risks	Internal Audit	96,700,000	Annually
Enhance Brand Identity, Awareness and Customer Satisfaction.	Develop and implement a communication strategy.	Communication Strategy.	Enhanced visibility of the brand and enhanced regulatory compliance.	Communication Office /CFO.	390,625,000	2025 and continuously
	Public education and awareness campaigns.	Increased public awareness.	Higher regulatory compliance.	Communications Office.	1,600,001,250	Annually

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Position Rwanda as knowledge hub.	Develop, implement and review a stakeholder engagement strategy.	Stakeholder engagement strategy.	Enhanced stakeholder engagement. Enhanced regulatory compliance.	Regulatory Ecosystem Strategy Division /CFO.	356,125,625	Biennially
	Develop and implement an organisational CSR strategy.	CSR Strategy	Enhanced public engagement and brand visibility.	QMS Division/CFO.	148,625,625	Annually
	Implement a customer relationship management system.	Customer relationship management system.	Enhanced customer satisfaction.	QMS Division/CFO.	212,501,250	By 2026
	Undertake customer satisfaction surveys.	Customer satisfaction survey index.	Enhanced customer satisfaction.	QMS Division/CFO.	106,070,000	Biennially
	Develop policies, linkages, curricula, platforms and processes for enhancing individual, corporate and national information, knowledge and competence in health and health regulation.	Policies, linkages, curricula, platforms and processes.	Enhance knowledge and management practices. Position Rwanda as a knowledge hub. Promotion of bio-manufacturing.	DG/DGG/CFO	867,456,700	Year 1 and continuously.

Table 6: Strategic Priority Area 2

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Table 6: Strategic Priority Area 3 – Position Rwanda FDA in the heart of National Health Research

Strategic Objective	Activity	Expected Output	Expected Outcome	Responsibility	Budget	Time Frame
Leverage research to innovate and make evidence-based decisions.	Develop a policy framework and platforms to encourage and reward research, development and innovation.	Innovation policy and platforms. New innovative products and processes.	Continuous improvement. Evidence based decision making. Enhanced regulatory capability. Enhanced knowledge management.	Planning and M&E Unit,	182,320,000	By 2025 and continuously.
	Invest in modern facilities and technologies to spur research and innovation.	Facilities and technologies to spur research and support research and innovation.	Continuous improvement. Evidence based decision making. Enhanced regulatory capability.	Planning/CFO/ICT.	3,675,000,500	By 2026 and continuously
	Sensitise, train and enable staff for better research and innovation.	Number of staff sensitised, trained and enabled.	Improved research and innovation capabilities. Enhanced product quality, research, and regulatory processes. Strengthened regulation.	QMS Division/HR.	1,336,560,300	Annually
Foster Institutional Linkages, Collaborations, and Partnerships between the Health	Strengthen institutional partnership and collaboration in research and development.	MoUs with international research hubs and innovation institutions such as AMA, APTF, ABI, and others. Collaborative agreements with academic and research institutions.	Increased research, innovation and development funding. Better research and innovation capabilities. Strengthened regulation and partnerships.	Planning and M&E/Regulatory Ecosystem Strategy Division	493,500,450	By 2025 and continuously

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Industry and Research Institutions to Enhance Evidence-Based Regulatory Decision-Making.	Create a centralized Health Research Hub to serve as a focal point for national and regional health research and innovation initiatives.	Rwanda FDA Health Hub established and operationalized.	Increased capacity for conducting and coordinating health research.	Regulatory Ecosystem Strategy Division/ Planning Unit	715,200,000	By 2026
	Facilitate collaboration and knowledge exchange between the Rwanda FDA and key international health research bodies to enhance research and compliance.	Knowledge-sharing platforms and collaborative research programs.	Enhanced research capacity and international recognition.	Planning and M&E Unit/ Regulatory Ecosystem Strategy Division	482,750,000	By 2026
	Facilitate collaboration and knowledge exchange between the Rwanda FDA and key international health research bodies to enhance research and compliance.	Knowledge-sharing platforms and collaborative research programs.	Enhanced research capacity and international recognition.	Planning and M&E Unit/ Regulatory Ecosystem Strategy Division	482,750,000	By 2026
Advance Scientific Knowledge through Health Research and Innovation for Improved Public Health Outcomes.	Conduct evidence-based applied research and implement the findings.	Research studies conducted, findings published, and recommendations implemented.	Enhanced decision-making based on scientific evidence. Improved public health outcomes through evidence-based regulation.	CFO/Planning and M&E Unit	1,311,400,000	Continuous
	Establish a comprehensive research database to streamline data sharing and knowledge management across research institutions.	Health research database established and operational.	Improved data management and access for research and regulatory decision-making.	Regulatory Ecosystem Strategy Division/ IT Unit	594,500,000	By 2025
	Organize national and regional health research and innovation symposiums.	Annual health research symposiums organized. Collaborative	Enhanced visibility of Rwanda FDA in the regional health research landscape.	Regulatory Ecosystem	467,320,000	Annually

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		platforms for knowledge exchange established.	Strengthened collaboration with local and international research institutions.	Strategy Division		
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Table 7: Strategic Priority Area 3

Table 7: Strategic Priority Area 4 - To Significantly Improve Value-Chain Management: Rwanda FDA

Strategic Objectives	Activity	Expected Output	Expected Outcome	Responsibility	Budget	Time Frame
Regulatory Support for the Establishment of Rwanda as a Bio-Manufacturing Hub	Promote the export of locally manufactured products by ensuring compliance with international standards.	Harmonized Regulatory Framework And Enhanced Regulatory Capacity	Increased quality of Exports and Improved Market Access.	Regulatory Ecosystem Strategy Division	265,000,000	By 2026
	Conduct regular training programs and workshops to educate manufacturers on regulatory compliance requirements.	Comprehensive training materials developed, significant number of manufacturers trained and increased Opportunities for manufacturers to network with regulatory experts.	Increased compliance, Export Opportunities	Regulatory Ecosystem Strategy Division	123,750,000	By 2025
	Establish a dedicated team at Rwanda FDA to manage regulatory assistance and providing timely support and guidance to manufacturers	Standardized procedures for handling regulatory inquiries. Clear roles and responsibilities for team members.	Increased compliance of manufacturers with regulatory requirement	Drugs Department	1,800,001,250	Continuous
	Foster collaboration with international regulatory bodies to harmonize	Shared Best Practices and Negotiation and implementation of MOUs	Reduced Trade Barriers and Improved Regulatory Efficiency	Drugs Department	113,750,000	Continuous

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	standards and facilitate trade.	with regional and international regulatory bodies.	Enhanced Expertise in biomanufacturing			
	Build capacity and train regulatory staff to enhance their expertise in biomanufacturing.	Tailored Training Programs.	Regulatory in biomanufacturing	Drugs Department	255,000,000	Annually
	Support the development of local manufacturing industries and value chains.	Forums and collaborations with local manufacturers	Growth of Local Manufacturing	Regulatory Ecosystem Strategy Division / Drugs Department	123,750,000	Continuous
Strengthen Rwanda FDA's Oversight on Food and Drug Value Chains	Review and update regulatory frameworks to align with international standards.	Regulatory frameworks updated.	Strengthened oversight and compliance with international standards.	Regulatory Ecosystem Strategy Division	185,500,000	By 2025
	Establish strategic partnerships with local and international organizations, education and research institutions, and regulatory bodies.	Strategic partnerships formed.	Enhanced collaboration and knowledge sharing.	Planning and M&E Regulatory Ecosystem Strategy Division	250,000,000	Continuous
	Facilitate workshops for stakeholders on quality assurance best practices.	Number of workshops conducted. Increased awareness of quality assurance best practices.	Improved control across value chains.	QMS Division / HR	140,000,000	Annually

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Implementation of Digital Traceability Systems	Develop and deploy a centralized digital platform for supply chain tracking.	Centralized digital platform operational.	Improved efficiency, traceability, and safety in value chains.	ICT Unit / Regulatory Ecosystem Strategy Division	625,000,000	By 2026
	Implement digital traceability systems for efficient product monitoring throughout the supply chain.	Traceability systems implemented.	Enhanced transparency and product safety.	ICT Unit / Planning and M&E Unit	375,000,000	By 2025
	Train stakeholders on the use of digital systems for tracking and reporting.	Number of stakeholders trained in digital traceability systems.	Improved supply chain management and accountability.	ICT Unit / HR	105,000,000	Continuous
Enhancing Quality Control Measures at Each Stage of the Value Chain	Conduct regular audits and inspections to ensure compliance with quality standards.	Audit reports and inspection results.	Improved compliance with quality standards.	QMS Division / Drugs Department	275,000,000	Annually
	Improve quality control measures at each stage of the supply chain.	Enhanced quality control mechanisms established.	Improved product quality and safety.	QMS Division	235,500,000	Continuous
	Implement a comprehensive quality management system (QMS).	Comprehensive QMS operationalized.	Enhanced regulatory oversight and product quality.	QMS Division	265,000,000	By 2026
Enhance Research and Development	Facilitate workshops for manufacturers and distributors on best practices in quality control.	Workshops conducted. Best practices disseminated.	Strengthened quality control across supply chains.	QMS Division / HR	315,000,000	Annually
	Enhance Rwanda FDA's research and development capabilities.	R&D capacity strengthened.	Innovative solutions and improved regulatory practices.	Regulatory Ecosystem Strategy Division	405,000,000	By 2025

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	Increase funding for research into local health challenges and solutions.	Increased R&D funding for local health challenges.	Enhanced research capacity and public health outcomes.	CFO / Planning and M&E Unit	400,000,000	Continuous
	Establish partnerships with academic and research institutions for collaborative studies.	Collaborative research partnerships established.	Improved innovation and evidence-based decision making.	Planning and M&E Unit	275,000,000	Continuous
	Promote innovation in health technologies and practices.	Innovation programs initiated and promoted.	Improved public health outcomes through technological advancement.	Regulatory Ecosystem Strategy Division	285,000,000	Continuous
	Invest in research facilities, building on existing laboratory infrastructure.	Research facilities upgraded and expanded.	Increased capacity for health research and development.	CFO / Planning and M&E Unit	950,000,000	By 2026
	Establish a knowledge centre for health and health sciences.	Knowledge centre operationalized.	Enhanced knowledge sharing and research capabilities in health sciences.	Planning and M&E Unit	450,000,000	By 2026

Table 8: Strategic Priority area 4

Table 8: Strategic Priority Area 5 - To Scale Leveraging technology /digitalization for efficient services

Strategic Objectives	Activity	Expected Output	Expected Outcome	Responsibility	Budget	Time Frame
Modernize regulatory processes through digital tools and technologies	Develop and deploy a centralized digital platform for regulatory management	Fully functional digital platform for regulatory processes	Streamlined regulatory procedures and faster service delivery	IT Department/Regulatory Ecosystem Strategy Division	400,000,000	By 2025

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	Automate compliance monitoring and reporting systems	Automated systems for compliance checks and reporting	Improved efficiency and accuracy in compliance monitoring	IT Department/Quality Control Division	250,000,000	By 2024
Build digital skills capacity of staff at all levels	Conduct regular training programs on digital tools and data management	Number of staff trained on digital systems and data analysis	Increased staff proficiency in digital systems and improved performance	Human Resources/IT Department	100,000,000	Annually
	Facilitate workshops and e-learning sessions for continuous learning	Comprehensive digital skills training programs	Enhanced digital literacy and innovation within Rwanda FDA	Human Resources/IT Department	60,000,000	Annually
Implement centralized digital platforms for regulatory management	Integrate all regulatory systems into a single digital platform	Unified platform connecting all regulatory services	Centralized regulatory data and processes	IT Department	300,000,000	By 2025
	Implement digital systems traceability across the supply chain	Digital systems that track products from production to retail	Enhanced traceability and safety of regulated products	IT Department/Quality Control Division	220,000,000	By 2024
Invest in IT infrastructure and data management systems to support service delivery	Upgrade IT infrastructure and improve data storage solutions	Enhanced IT infrastructure and reliable data storage systems	Improved operational efficiency and data security	IT Department	350,000,000	Continuous
	Develop a secure digital database for regulatory information and compliance data	Fully secured and accessible database	Better data accessibility and decision-making	IT Department	200,000,000	By 2025
Foster a culture of digital innovation and continuous improvement	Establish a digital innovation unit to explore new technologies	Creation of a digital innovation team	Continuous exploration of cutting-edge technology solutions	IT Department/Innovation Unit	120,000,000	Continuous

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	Implement a feedback loop for staff to propose digital improvements	Feedback system implemented and regularly reviewed	Increased engagement in digital transformation efforts	Human Resources/IT Department	50,000,000	By 2024
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Table 9: Strategic Priority Area 5

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CHAPTER FOUR: IMPLEMENTATION FRAMEWORK

This chapter presents the framework for effective implementation of the 2nd Rwanda FDA strategic plan. The implementation framework serves as a blueprint to operationalizing the Rwanda FDA's vision and strategic objectives. It outlines the institutional and departmental structures necessary to support the execution of the strategic plan; a stakeholder mapping and engagement plan; and a detailed resource mobilisation plan essential for the successful execution of the strategic objectives.

4.1 Institutional Framework

4.1.1 Governance, Management and Staff Structure

The Rwanda FDA is steered by the **Board of Directors (BoD)**, responsible for setting the vision of the Authority and providing strategic direction. The BoD will also be responsible for ensuring the funding and full implementation of the strategic plan through guiding the resource mobilisation strategies and ensuring sufficient monitoring of the plan implementation process. The **Executive Organ** is led by the **Director General (DG)** who is appointed by presidential order. The DG reports directly to the BoD, exercises decision-making authority, and directs the Authority's activities in alignment with its mission.

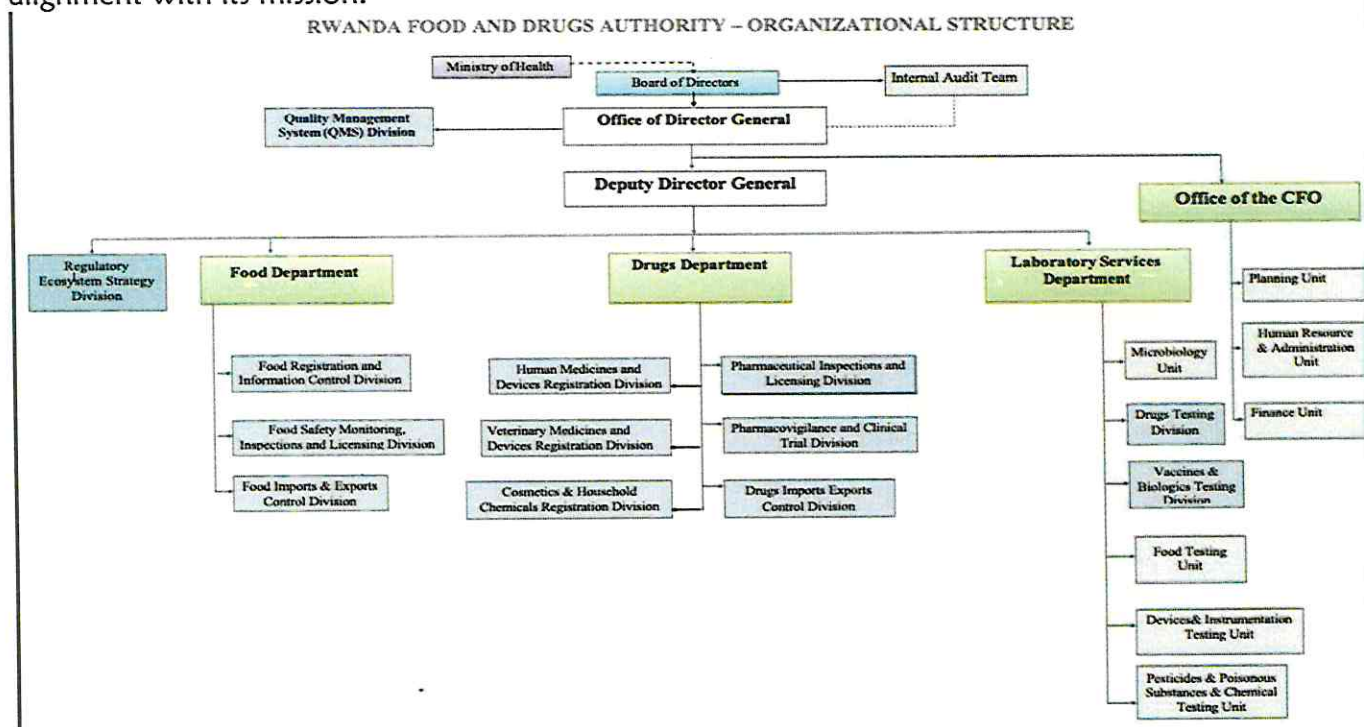


Figure 4: The Rwanda FDA Organogram

The DG will bear the overall responsibility for the implementation of the strategic plan, working closely with the Board to ensure the strategic focus is maintained; budgets are prepared, funded and monitored; annual work plans are developed and implemented and that reporting is done at all levels. The senior management team comprising the DDG, CFO, Heads of Departments,

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Division Managers and Directors, will be responsible for the technical coordination and implementation of strategic activities. They will be responsible for development of departmental work plans, individual work plans and performance targets, MEAL and other strategic plan tracking management reports, report and act on variances and advise the DG and the Board on possible corrective actions. The Authority's structure has three technical departments:

- 1) Food.
- 2) Drugs.
- 3) Laboratory services.

The departments form the operational backbone of the Authority, that will facilitate the effective implementation of the strategic plan through activities contained in their annual work plans (cascaded from the strategic) plan as well as their performance targets. Supporting these departments are specialised divisions, each tasked with distinct responsibilities to ensure comprehensive regulatory oversight and enforcement. Together, these departments and divisions collaboratively administer regulatory processes, facilitate market access for safe and quality products, and uphold public health standards. The technical staff will be run the day-to-day operations ensuring all the activities in the strategic plan are;

4.2 Implementation Approach

This section presents an implementation mechanism and coordination framework for effective implementation and coordination of the Strategic Plan. It acknowledges the role of Rwanda FDA's organisational structure, stakeholders in the execution of its mandate. Innovation, team spirit and professionalism are key drivers in the implementation of this Plan. The strategic implementation and coordination mechanism will include four approaches: phasing and sequencing, performance management framework, implementation management structure and implementation framework. Phasing & sequencing and performance management framework are reviewed succinctly below;

4.2.1 Phasing and Sequencing

The implementation of this Strategic Plan will be in tandem with the government planning cycle. Rwanda FDA will therefore develop subsequent Annual Work Plans from the Strategic Plan. The work plans will peg the Authority's operations on the financial, human and other resources available in each financial year. The corporate Annual Work Plans will be actualized by the Departmental Work Plans, which will in turn be cascaded through the assignment of specific roles and responsibilities to individual members of staff. This approach will enhance performance management at individual, departmental and organisational levels.

4.2.2 The Performance Management Framework

Rwanda FDA has implemented a performance management framework to facilitate realisation of its corporate goals as well as the successful implementation of this Strategic Plan. The framework provides a basis for setting performance targets, evaluation and a reward and sanction scheme. The strategic objectives, strategies and activities in the Plan will be translated into departmental objectives, strategies and activities and further cascaded to individual performance targets. This will facilitate effective appraisal at the individual, departmental and institutional levels while

allowing for continuous improvement of performance and by extension, effective implementation of all of Rwanda FDA programmes. The performance management framework is a hybrid of the Balanced Scorecard (see chapter 6) and the corporate performance appraisals systems (PMAS) aligned to the Government of Rwanda performance contracting system and cycle.

4.3 Resource Mobilization Framework.

The implementation of the 2nd Strategic Plan will depend on substantial financial resources. The implementation of this Strategic Plan will be financed by both internal and external sources. The anticipated sources of finance include funding from the Government of Rwanda, development partners and internal (own source revenue from different services provided by the Authority).

4.3.1 Resource Requirements for Implementation.

A summary of the resources required to implement the 2nd Rwanda FDA strategic plan is provided in Table 7. Table 8 provides detailed, annualised resource requirements with additional columns for tracking budget allocation, deficits/gaps and explanations.

Strategic Priority Area/Themes	Budget 2024-2029 (RWF)
Establish a Fully Functional Globally Recognized Regulatory System	20,414,039,187
To Scale up current institutional capacity to build a sustainable workforce	96,016,365,450.00
Position Rwanda FDA in the heart of National Health Research	10,071,301,250
To Significantly Improve Value-Chain Management: Rwanda FDA	8,237,251,250
To Scale Leveraging technology /digitalization for efficient services	2,050,000,000
TOTAL BUDGET	116,374,917,950

Table 10: Summary Implementation Resource Requirements

4.3.2 Resource Mobilization and Management

The Strategic Objectives will be achieved through various strategies and activities as outlined in the strategic model (Chapter 3). The financial resources required for implementing the strategies and activities are outlined in the Implementation Matrix. The total amount required for the period 2024/19-2029 is RwF. **116,374,917,950.00**. The resources will be raised through a dedicated resource mobilisation strategy extracted from the guidelines provided in this strategic plan.

4.4 Stakeholder Analysis, Mapping and Management

The stakeholder analysis and mapping process has been developed to follow the power, urgency and legitimacy typology ranking. The three attributes define the stakeholder 'salience' as 'the degree to which managers give priority to competing stakeholder claims. These three attributes define the stakeholder 'salience' which is 'the degree to which managers give priority to competing stakeholder claims'. The more attributes (**power, legitimacy, and urgency**) a stakeholder is perceived to have the higher their salience. Power and legitimacy are interrelated and the three variables can overlap. The stakeholders are then mapped by ranking the attributes and fed into the stakeholder management process as outlined in the figure below;

	Red	Definitive stakeholders	Presence of all three attributes (power, legitimacy and urgency), high salience. Managers give immediate priority to these stakeholders.
	Amber	Expectant stakeholders	Two attributes, moderate salience. Rather passive, likely higher-level engagement with these stakeholders. Manage carefully otherwise frustration could make them “turn red”
	Green	Latent stakeholders	One attribute, low salience. Some level of attention and monitoring, otherwise they “go amber”

Table 11: Summary of Stakeholder Analysis, Mapping and Management

The guide emphasizes the importance of understanding and managing the needs, expectations, and contributions of these different stakeholder categories to ensure the successful implementation of the strategic plan. Table 10 contains a summary of the Stakeholder mapping and analysis.

STAKEHOLDER	BENEFIT TO RWANDA FDA	BENEFIT FROM RWANDA FDA	CLASS	STAKEHOLDER STRATEGY	MANAGEMENT
Management and Leadership	✓ Provide strategic direction. ✓ Allocate resources. ✓ Support resource mobilisation and strategy implementation.	✓ Strong environment. ✓ Full strategy implementation ✓ Success in executing mandate.	Red	✓ Involvement in planning and validation. ✓ Reports on implementation progress. ✓ Effective execution of mandate.	
Staff	✓ Implement the strategic plan and day to run operations. ✓ Regulatory implementation.	✓ Professional growth. ✓ Training opportunities. ✓ Conducive work environment.	Red	✓ Training and capacity building. ✓ Involvement in planning, decision making and recognition for achievements.	
Rwanda Government and Governmental Agencies.	✓ Collaboration for policy implementation, regulatory compliance enforcement and sharing resources and knowledge exchange.	✓ Strengthened regulation and regulatory compliance. ✓ Access to accurate information. ✓ A healthy, safe and sustainable Rwandan society.	Red	✓ Sharing progress reports and meetings to align goals. ✓ Seeking feedback for continuous improvement. ✓ Policy dialogue, advocacy and compliance.	
Healthcare, Pharmaceuticals, Food and Drug Sector Players and Professionals.	✓ Regulatory compliance and reporting. ✓ Access to industry and trends. ✓ Traceability in supply chains. ✓ Improved product quality.	✓ Improved patient care, access to safe drugs, foods and cosmetics boosting consumer confidence. ✓ A healthy, safe and sustainable Rwandan society.	Amber	✓ Proper regulation, inspection and enforcement. ✓ Awareness building, sensitisation and training on regulatory standards. ✓ Information sharing and feedback.	
Development Partners	✓ Secure funding and technical assistance for projects. ✓ Exchange expertise and best practices	✓ Realisation of development goals consistent with development partners. ✓ Data and information exchange or regulatory standards.	Amber	✓ Knowledge and information sharing. ✓ Joint research ventures. ✓ Align with development partners' priorities and reporting requirements. ✓ Transparency and accountability.	
Research and Academic Institutions	✓ Collaborative research, innovation and development. ✓ Organisational learning.	✓ Brand affiliation. ✓ Leverage institutional knowledge, assets and resources for research.	Amber	✓ MoUs and collaborative arrangements. ✓ Knowledge and skills exchange.	
Suppliers/Contractors	✓ Reliable, timely and quality goods/services.	✓ Profitable business opportunities. ✓ Timely payment	Amber	✓ Transparent and competitive procurement processes ✓ Proper contract management.	
Research partners	Research collaboration	Process improvement due to greater knowledge.	Amber	✓ Actively participate in trade association activities.	

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Global Standards Organisations	✓ Standards enhancement and certification.	✓ Information certification fees & brand building.	Red	✓ Adhering to certifications, sharing compliance reports, and participating in standard-setting discussions.
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Table 12: Stakeholder Analysis, Mapping and Management

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CHAPTER FIVE: STRATEGIC RISK ANALYSIS

Rwanda FDA faces significant risk arising out of its establishment instruments, external operating environment as well as its internal objectives and business operations (people, processes, products) that could impact its operations and ability to achieve its objectives. A proactive approach to strategic risk management is essential in anticipating and mitigating potential risks that could impede the realization of either specific attainable targets, strategic themes, general objectives or even Rwanda FDA's overall mandate. Factors such as evolving regulatory frameworks, technological advancements and market dynamics can influence the Authority's risk profile. By implementing effective risk management strategies, the Authority can enhance its resilience, adaptability and ability to realise its strategic objectives. For each risk, appropriate mitigation measures have been determined, and the mitigation measures have subsequently informed the implementation as well as the M & E framework. Risks have been classified as strategic, operational, reputational, supervisory or compliance and financial risk based on Rwanda FDA's overarching risk framework.

- 1) **Strategic risk** (including contagion and related party risk) is the prospective adverse impact on the business arising from poor strategic decisions, improper implementation of decisions; or lack of responsiveness to changes in the operational environment. Strategic risk encompasses the risk of; choosing and continuing to follow sub optimal strategies to meet objectives; not executing the strategies successfully; and treating the business-as-usual risks differently from expected.
- 2) **Operational risk** (includes people, compliance, information security risk, fraud risk, regulatory and legal risks). This is the risk of loss from inadequate or failed processes, people, systems or external events including, but not limited to, business continuity and disaster recovery, corporate governance, security, fraud and IT risks.
- 3) **Reputational risk** which is the risk of damage to corporate image.
- 4) **Supervisory/Compliance risk** defined as exposure to legal penalties, financial forfeiture and material loss arising out of failure to act in accordance with sectorial laws and regulations, internal policies or prescribed best practices.
- 5) **Financial risk** would emanate from failure to either mobilize adequate funds or lack of prudence in financial resource utilization and encompasses;
 - a) **Credit risk:** The risk of loss from a counterparty not meeting their contractual obligations as they fall due
 - b) **Liquidity risk:** Risk of being unable to meet cash flow obligations as and when they fall due.

For each risk, appropriate mitigation measures have been determined, and the mitigation measures have subsequently informed the implementation as well as the M & E framework. The risk analysis will also be an integral input in the subsequent development of a comprehensive risk management strategy to facilitate successful implementation of the Strategic Plan.

5.1 Risk Analysis

Risk Category	Mitigation Measures
Strategic Risks	
Strategic Misalignment and Failure to Realise Statutory Mandate: failure to align its strategic priority areas with the law, public expectation and global best practices could result in strategic misalignment.	1) Develop a strategic plan to guide realization of Authority's core mandate. 2) Alignment of the strategic plan and operations with relevant blueprints. 3) Implement the strategic plan and put in place a MEAL framework to ensure timely progress tracking.
Strategic Scope Creep: The Authority could also initiatives/interventions expand beyond their original scope, delays and potential failure to deliver on key objectives.	1) Continuous MEAL and taking corrective action. 2) Stakeholder Engagement. 3) Regularly review the Authority's strategic objectives with a view to realigning them with changes in operational environment and actual performance results.
Failure of staff and other stakeholders to buy into the vision and strategy leading to resistance, low morale and suboptimal performance	1) Inclusive visioning, strategic planning and strategy implementation. 2) Effective communication of the strategy and other organisational matters. 3) Stakeholder mapping, analysis and management. 4) Continuous training, development, motivation and recognition/incentives for staff.
Operational Risks	
Non-Compliance with Laws and Regulations.	1) Develop a compliance framework, systems and train staff. 2) Strengthen the internal audit function. 3) Implement a whistle-blower policy.
Internal Policy Non-Adherence Risk leading to inefficiencies, error and/or fraud.	1. Develop and implement policies aligned to the legal framework. 2. Continuous communication, monitoring, enforcement of policies and timely correction of deviations. 3. Foster a culture of accountability through regular internal audits and rewarding compliance.
System/technology failure	1. Implement the business continuity plan (BCP). 2. Regular backups to the national data centre. 3. Subscribing to reliable ISP(s) and acquiring non-redundant capacity. 4. Continuous acquisition and maintenance of new hardware to ensure resilience.
Public Health Emergencies	1. Public health emergency response strategy and team. 2. Automated value chain management to ensure continuous supply of essential supplies during emergencies.

	3. Foster partnerships with health organizations: Collaborate with other entities to enhance emergency response capabilities.
Inefficient Processes and Poor-Quality Process Output	1. Process improvement, automation and quality assurance to streamline operations and reduce waste. 2. Develop and monitor key performance indicators (KPIs), conduct regular process audits to identify and rectify inefficiencies and improve quality and quality monitoring. 3. Staff training on process improvement methodologies. 4. Institutionalise a culture of continuous improvement at Rwanda FDA.
Inaccurate data, data manipulation, mismatch of data, system/human errors etc.	1. Ensure Data encryption and utilize log tables 2. Install and update antivirus software, firewalls and other logical access controls 3. Set up a system for validating information collected from the various sources
Inadequate human, physical and other resources.	1. Hire additional competent staff 2. Retain, retrain and motivate current staff 3. Acquire more physical assets such as computers, vehicles, office space
Low awareness of Rwanda FDA's mandate and services	Increase public awareness of Rwanda FDA's mandate and services through targeted public education campaigns, aligned with the corporate communication strategy.
Failure to invest in new technology, inadequate ICT resources and technology obsolescence.	1. Develop sound policy for investment in new technology 2. Continuous acquisition of ICT resources. 3. Training of staff on new technology.
Reputational Risks	
Unauthorised sharing of organisational information.	i. Observing due process and protocol in information dissemination. ii. Verifying validity and accuracy of all information and credibility of information sources.
Negative Media Coverage	1. Develop a media relations policy and strategy that includes a crisis communication plan and clear protocols for media engagement. This will ensure that the Rwanda FDA can address negative media coverage swiftly, accurately, and consistently, minimizing reputation risks. 2. Engage with stakeholders to build trust and provide education on Rwanda FDA's role and activities. 3. Regularly publish positive stories and updates about achievements and public health initiatives.
Regulatory Failures such as lapses in enforcement or	1. Ensure strict adherence to regulatory standards and guidelines.

oversight, can erode trust and public image of the Authority.	2. Implement continuous professional development programs for staff to stay updated on regulatory requirements. 3. Establish an internal audit system to regularly review and improve regulatory compliance processes. 4. Foster a culture of accountability and transparency. 5. Collaborate with international regulatory bodies to benchmark and adopt best practices. 6. Develop and implement a risk management framework specifically tailored for regulatory compliance.
Downtime/hacking of the website	1. Ensure service level agreements with ISP providers 2. Regularly review the status of the website up/down time. 3. Firewalls and other cybersecurity controls.
Financial Risks	
Inadequate financial resources and over reliance on government for funds.	Proper budgeting and implementation of the resource mobilisation strategy through initiatives like diversification of income streams.
Inequitable resource allocation.	1. Prioritisation of resource allocation on the basis of the implementation matrix. 2. Continuous review of the Plan to ensure resource allocation for prioritised activities.
Low rates of absorption of allocated funds	1. Proper planning for expenditure and implementation 2. Continuous M&E of annual work plans against budgets and the strategic plan.

Table 13: Risk Analysis

CHAPTER SIX: MONITORING, EVALUATION, REPORTING AND LEARNING

Targeted Monitoring, Evaluation and Reporting will be done to ensure that the implementation of the Strategic Plan implementation runs to schedule and in the event of any deviation, appropriate and timely action is taken. Data will be collected on a continuous basis to inform periodic MERL reports (quarterly, semi-annual, annual, midterm and end-term). A Midterm review will be conducted to gauge the degree to which the planned results are on target and the areas that may require improvement. An end-line evaluation will be conducted to review this 2nd Rwanda FDA strategic Plan and assess its effectiveness, efficiency, impact and sustainability; to identify any problems or challenges encountered; to issue recommendations, and to identify lessons learned on design, implementation and management that will inform the 3rd strategic plan to be developed. The Monitoring, Evaluation and Reporting process will be undertaken at both Board and Management levels.

6.1 At the Board Level

The implementation of the Strategic Plan will be closely monitored to ensure its accomplishment. Monitoring, follow-up and control systems will be established at all levels. These will include review meetings, regular review of the budget systems and development of progress reports from the organization. Quarterly review meetings will be held between the Management and the Board. During these meetings, the Board will receive and review progress reports from the DG indicating overall progress made on key strategic objectives. The nature and scope of reporting will include: progress made against the Plan; causes of deviation from Plan, if any; areas of difficulties and suggested solutions to problems that may adversely affect implementation; and corrective measures to be undertaken. The input of these quarterly Council meetings will be the output from the Management meetings.

6.2 Managerial Level

Rwanda FDA's strategic plan implementation relies on effective monitoring and evaluation. Monitoring will involve routine data collection and analysis, with the Planning and M&E Unit coordinating these activities. A Monitoring & Evaluation Committee, chaired by the CBM, will oversee MERL activities, continuously monitoring and evaluating strategic activities and outcomes. Each department will monitor programs and projects within its area and submit reports to the Planning and M&E unit for review and overall reporting against targets. Monitoring will involve routine data collection and analysis on the progress of the Strategic Plan implementation. The results from the analysis will then be used to inform decision-making, including taking corrective action where deviations in implementation have been noted. The Planning and M&E Unit will provide technical support and facilitates MERL capacity building in liaison with the Human Resource Department. A system of disseminating the lessons learnt to users will be developed as part of the MERL Strategy. Annual customer satisfaction surveys will be undertaken to gauge the achievement of the set objectives. The Strategic Plan will be evaluated during and after implementation to gauge the extent of achievement of the intended results. The evaluation will be carried out using relevance, efficiency, effectiveness, sustainability and impact measures. A mid-term review will also be carried out. The implementation matrix will help track and monitor progress in the implementation of the Plan.

6.2.1 Management Control Function

The following initiatives will be undertaken by the Authority in executing the management control function:

1. Setting of performance standards and Targets, Indicators and Measures;
2. Regular Performance Evaluation/Appraisal;
3. Linkage of Rewards/Sanctions to Performance;
4. Budgets and Expenditure Review;
5. Management Reports;
6. Strategic Plan Implementation Programme/Matrix; and
7. Strategic Plan Review Meetings.

6.2.2 Strategic control mechanism

The control mechanisms that Rwanda FDA will deploy include:

1. Development of Annual Work Plans; and
2. Assessment of whether results produced by the implemented activities were those forecasted as outcomes and, whether they were achieved to the expected performance standards/measures.

6.3 Evaluation Tool

Rwanda FDA will use an evaluation tool to measure strategy implementation progress, highlighting strategic themes, objectives, timeframes, variances, responsibilities, and improvement programs. This tool will be used to measure the implementation of the strategy by highlighting the strategic themes, the objectives towards implementation of the strategic themes, the timeframe within which the activities were to be implemented, and any variances that may be noted in the implementation of the plan.

Strategic Objectives	Activity	Expected Output	Expected Outcome	Responsibility	Budget	Time Frame

Table 14: Monitoring and Evaluation Framework

6.4 Rwanda FDA Balanced Scorecard (BSC) Framework

The BSC framework will constrain the strategic planning process to help focus on its strategic goals, ultimately helping to prioritize resource allocation and performance measures. Rwanda FDA will adopt the framework to monitor and evaluate progress towards the strategic goals. The BSC will examine performance from four perspectives:

1. **Internal Process:** Improve efficiency and effectiveness of internal processes.
2. **Customer:** Enhance user satisfaction and meet stakeholder needs.
3. **Financial:** Implement cost-effective operations and maximize ROI.
4. **Learning and Growth:** Develop and maintain capabilities and employee skills.

5. **Social and Environmental Responsibility:** Ensure positive contributions to society and the environment.
6. **Innovation and Growth:** Foster innovation and support growth through R&D and technological advancements.

BSC Perspectives	Activities	Implementation matrix
Organization Learning and Growth Perspective The learning and growth perspective focuses on the development of the authority's workforce and organizational culture.		Strategic Aspiration: Scale up Current Institutional Capacity to Build a Sustainable Workforce
	1. Develop a comprehensive training program for regulatory staff	i. Conduct skills gap assessments across all departments. ii. Develop and roll out a competency-based training curriculum. iii. Provide continuous professional development opportunities. iv. Track the improvement in staff performance after training programs.
	2. Attract and retain skilled personnel	i. Develop a competitive recruitment process. ii. Implement an attractive benefits and retention program. iii. Monitor turnover rates and address retention issues. iv. Offer career growth and mobility opportunities to enhance retention.
	3. Create succession planning frameworks	i. Identify key positions requiring succession planning. ii. Develop leadership training for identified potential successors. iii. Conduct an annual review of succession plans. iv. Monitor the readiness of potential leaders through performance evaluations.
	4. Establish knowledge-sharing platforms across departments	i. Organize quarterly knowledge-sharing workshops. ii. Set up an internal knowledge management system. iii. Foster cross-departmental collaboration through shared projects. iv. Track the effectiveness of knowledge-sharing through regular feedback.
		Strategic Aspiration: To Position Rwanda FDA in the Heart of the National Health and Research Centres
	1. Strengthen linkages with multinational regulatory and research hubs	i. Sign MOUs with multinational research hubs. ii. Develop joint research projects with health centres like IRCAD and the African Medicines Agency. iii. Track collaborative outcomes annually. iv. Provide mutual resources to support regulatory and research innovations.
	2. Foster collaborative research with local and	i. Establish research grants for joint studies. ii. Host annual research conferences.

	international health institutions	iii. Develop shared research platforms for data and insights. iv. Foster knowledge exchange through international staff exchanges and study tours.
	3. Position Rwanda FDA as a centre of knowledge for health sciences	i. Create a dedicated knowledge hub within the FDA. ii. Publish research findings in international journals. iii. Host knowledge-sharing events with other regulatory bodies. iv. Set up a portal for public access to research findings.
Organization Internal Processes Business Perspective This perspective looks at the internal operational processes that contribute to the authority's effectiveness and efficiency. It encompasses the regulatory processes for drug approval, monitoring of product safety, and the management of inspection protocols.	Strategic Aspiration: Leveraging Technology /Digitalization for Efficient Services	
	1. Implement digital traceability systems for monitoring product safety across the supply chain	i. Develop and integrate a centralized digital traceability platform. ii. Train staff on using the traceability system for effective monitoring. iii. Regularly update the system to accommodate new regulatory needs. iv. Monitor compliance with traceability processes.
	2. Automate the regulatory processes, including licensing and inspection protocols	i. Design and deploy automation software for licensing and inspections. ii. Provide technical training to staff on the new systems. iii. Monitor the time saved by automation and process improvements. iv. Regularly review the automated processes for further optimization.
	3. Use digital tools to enhance pharmacovigilance and post-market surveillance	i. Implement a digital pharmacovigilance reporting tool. ii. Train healthcare providers on reporting through the digital platform iii. Ensure real-time monitoring of product safety reports. iv. Regularly analyse data to improve regulatory decisions.
	4. Strengthen cybersecurity measures to protect regulatory and consumer data	i. Install and regularly update cybersecurity software. ii. Conduct cybersecurity training for all employees. iii. Conduct regular penetration testing to identify vulnerabilities. iv. Create a protocol for handling security breaches and reporting incidents.
	5. Establish digital platforms to improve communication and	i. Build an integrated stakeholder communication platform. ii. Ensure access to real-time updates on regulatory matters. iii. Regularly collect stakeholder feedback for improvement.

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	engagement with stakeholders	iv. Provide training to stakeholders on using the digital platform effectively.
Innovation and Growth Perspective Emphasizes the importance of innovation in regulatory practices and public health initiatives. This perspective aims to ensure that the authority remains adaptive and forward-thinking in addressing emerging health challenges.	Strategic Aspiration: Leveraging Technology /Digitalization for Efficient Services	
	1. Invest in research and development (R&D) to support innovative regulatory practices	i. Allocate a budget for continuous R&D projects. ii. Establish partnerships with local and international research bodies. iii. Implement an annual review of R&D initiatives and outcomes. iv. Create innovation-driven regulatory guidelines based on research findings.
	2. Establish partnerships with academic institutions for collaborative research	i. Sign MOUs with academic and research institutions. ii. Develop a collaborative research framework. iii. Conduct joint research studies on regulatory advancements. iv. Organize annual workshops to showcase findings and innovations in regulatory practices.
	3. Enhance laboratory capabilities with modern technologies	i. Procure state-of-the-art laboratory equipment. ii. Train laboratory staff on new technologies. iii. Monitor and review the effectiveness of the upgraded technologies. iv. Establish benchmarks for testing standards based on new equipment.
	4. Foster an organizational culture of innovation and continuous improvement	i. Implement a reward system for innovative ideas. ii. Organize brainstorming sessions and innovation contests. iii. Provide incentives for departments that demonstrate continuous improvement. iv. Monitor the impact of innovations on regulatory efficiency.
	5. Promote the use of data analytics for decision-making	i. Implement data analytics tools for regulatory decision support. ii. Train staff on using data for regulatory insights. iii. Create a real-time data dashboard for monitoring regulatory performance. iv. Use predictive analytics to improve regulatory forecasting.
Financial Perspective	Strategic Aspiration: To Significantly Improve Value-Chain Management	

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This perspective focuses on the financial performance and the overall fiscal health of the Rwanda FDA. It examines value chain management, revenue generation, cost management, and budget efficiency to ensure that the authority can sustain its operations and effectively allocate resources for regulatory activities, public health initiatives, and infrastructure development.	1. Implement a digital traceability system to monitor the flow of regulated products	i. Develop a comprehensive digital system for tracking products. ii. Train value chain stakeholders on system usage. iii. Regularly review and optimize system performance. iv. Track the impact of traceability on compliance and safety across the supply chain.
	2. Strengthen financial planning and budgeting practices	i. Implement a financial planning tool to streamline budgeting processes. ii. Conduct quarterly financial reviews. iii. Monitor budget allocation for key regulatory activities. iv. Develop a performance-based budget allocation process to optimize resource use.
	3. Improve internal financial management through resource mobilization	i. Develop partnerships with external funders. ii. Create a resource mobilization strategy to expand funding opportunities. iii. Set financial KPIs to track resource mobilization efforts. iv. Evaluate funding allocations annually to ensure efficient use of resources.
	4. Foster collaborations with development partners to support value chain activities	i. Build partnerships with development organizations and donors. ii. Develop joint funding proposals for value chain support. iii. Track the impact of collaborative efforts on value-chain outcomes. iv. Publish the outcomes of partnerships in annual reports.
	Strategic Objective: To Establish a Fully Functional Regulatory System Globally Recognized	
Customer Perspective The customer perspective emphasizes the satisfaction and engagement of stakeholders, including the public, healthcare providers, and pharmaceutical	1. Achieve WHO Maturity Levels 3 and 4	i. Develop a roadmap for achieving WHO Maturity Levels. ii. Ensure compliance with WHO requirements for Level 3 by 2024 and Level 4 by 2029. iii. Conduct regular internal audits to measure progress. iv. Publish Rwanda FDA's progress reports on achieving maturity levels.
	2. Strengthen stakeholder engagement through workshops and public awareness campaigns	i. Organize quarterly stakeholder workshops. ii. Develop materials for public awareness on regulatory practices. iii. Monitor the reach and impact of public awareness campaigns. iv. Collect stakeholder feedback to improve engagement activities.

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companies. This involves enhancing service delivery, improving communication and transparency, and ensuring that the needs of the community are met through effective regulation and public awareness programs.	3. Foster transparency in the regulation of products	i. Publish all regulatory decisions in a public domain. ii. Develop an online platform for stakeholders to track the status of product approvals. iii. Create a transparent appeals process for regulatory decisions. iv. Ensure timely communication of regulatory updates.
	4. Conduct regular public health campaigns to raise awareness of regulatory efforts	i. Design public health awareness programs focused on product safety. ii. Partner with media organizations for wider reach. iii. Monitor public feedback on health campaigns. iv. Evaluate the effectiveness of each campaign and adjust strategies as needed.
Enhance regulatory frameworks and guidelines with proper compliance mechanisms to ensure the safety, quality, and efficacy of regulated processed food, medical products, medicated cosmetics and household chemicals in Rwanda.	5. Streamline all regulatory processes	i. Enhancing regulatory enforcement and compliance ii. Reduce registration times iii. Recognition as a leading FDA in Africa

Table 15: Balanced Scorecard (BSC) Framework

The BSC tracking mechanism will be complemented and propped by:

- ❖ **Accurate Performance Indicators:** The KPIs for each perspective will have to be continuously reviewed and updated to remain relevant, clear and SMART.
- ❖ **Data Collection and Analysis:** Systems for continuous, accurate data collection, analysis and reporting.

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- ❖ **Performance Monitoring:** Continuous performance assessment of progress against targets.
 - ❖ **Stakeholder Engagement:** Engaging with stakeholders to gather feedback and ensure that the strategic initiatives align with their needs and expectations.
- Continuous Improvement:** Promoting a culture of continuous improvement by identifying areas for enhancement and implementing best practices.

ANNEXES

Annexes 1

Implementation Matrix

No	Outcome	Indicator	Unit	Baseline	Annual Targets					Responsible	Data Sources	Means of Verification
					2024 / 25	2025/ 26	2026/ 27	2027/ 28	2028/ 29			
	Strategic Priority Area 1 – Establish a Fully Functional Globally Recognized Regulatory System											
1.	Achieving internationally recognized standards for regulatory practices, including certification by the World Health Organization (WHO) for various drug and health product registrations. This includes enhanced compliance monitoring and a streamlined registration process for pharmaceuticals, veterinary	% of human drugs registered within time period % of veterinary medicines registered within time period % of medicated cosmetics registered within time period % of food, feed, and supplements registered within time period % of medical devices registered	% % % %	20% (2024) 20% (2024) 20% (2024) 55% (2024) 20% (2024)	36% 36% 36% 64% 36%	52% 52% 52% 73% 52%	68% 68% 68% 82% 68%	84% 84% 84% 91% 84%	100% 100% 100% 100% 100%	Human Med Division Veterinary Medicines Division Cosmetics Division Food Registration Division Human and Veterinary Divisions	Registration Reports Registration Reports Registration Reports Registration Reports Registration Reports	Certificates issued Certificates issued Certificates issued Certificates issued Certificates issued

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	medicines, and food safety.	within time period	#	of inspections for drug safety control conducted	50 (2024)	100	100	100	100	100	Pharmacovigilance Division	Inspection Reports	Inspection logs
		# of inspections for food safety conducted	#	50 (2024)	100	100	100	100	100	100	Food Inspection Division	Inspection Reports	Inspection logs and Copies of Licenses
		% of premises with valid operational licenses	%		100	100	100	100	100	100	PIL, and Food inspections divisions	Report	Copies of licenses
		% of parameters accredited by international body	%	0% (2024)	5%	20%	50%	70%	90%		Lab Services Dept.	Certificate of accreditation	Accreditation certificates awarded
		WHO pre-qualification for RFDA Quality control laboratory	Status	Not prequalified (2024)		Rwanda FDA Lab pre-qualified					Lab Services Dept.	Certificate	Certificate
		ISO certifications achieved and maintained	Status	None (2024)		ISO certification achieved and sustained					QMS Division	Certificate	Certificate
		Maturity level four (4)	Level	ML2 (2024)			RFDA achieved				DG/DDG	Certificate	Certificate

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	or WHO Listed Authorities certification attained.	%	-									
	FAO/WHO food control system assessment	%	N/A	36%	52%	68%	Assessment passed by the Authority	<95 %	PV&CT	Food Dept.	Report	Assessment report
	Percentage of selected PMS human medicines complying with quality requirements	%	N/A	36%	52%	68%	84%	<95 %	PV&CT		Report	Quality compliance reports
	Percentage of selected PMS veterinary medicines complying with quality requirements	%	N/A	36%	52%	68%	84%	<95 %	PV&CT		Report	Quality compliance reports
	Percentage of selected PMS cosmetics and household chemicals complying with quality requirements	%	N/A	36%	52%	68%	84%	<95 %	PV&CT		Report	Quality compliance reports

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	Percentage of selected PMS food products complying with quality requirements	%	N/A	36%	52%	68%	84%	<95 %	PV&CT	Report	Quality compliance reports
	Percentage of selected PMS medical devices complying with quality requirements	%	N/A	36%	52%	68%	84%	<95 %	PV&CT	Report	Quality compliance reports
	Percentage of domestic medicines manufacturing facilities complying with GMP and Quality System requirements	%	N/A	36%	52%	68%	84%	<95 %	PIL	Report	GMP compliance certificates
	Percentage of clinical trials compliant to GCP standard	#	N/A	100%	100%	100%	100%	100%	PV&CT	Report	Compliance audit reports
	Percentage of clinical trials compliant with GCLP requirements	%	N/A	100%	100%	100%	100%	100%	PV&CT	Report	Compliance audit reports
	Percentage of inspected consignment	%	60% (2024)	95%	95%	95%	95%	95%	I&E control	Report	Inspection and

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	approved at Ports of Entry (POEs)																	approval logs	
	Public health advisory issuance timelines (average time taken to issue public health advisories or alerts following a significant food or drug safety concern)	N/A	1day	1day	1day	1day	1day	1day	1day	1day	1day	1day	1day	1day	1day	1day	Food and Drugs Dept.	Report	Advisory issuance records
	Number of awareness campaigns for quality and safety of regulated product	#	N/A	4	4	4	4	4	4	4	4	4	4	4	4	4	Food and Drugs Dept.	Awareness report	Campaign activity reports
Strategic Priority Area 2 – To Scale up Current Institutional Capacity to Build a Sustainable Workforce																			
2.	Developing a skilled and motivated workforce through comprehensive training programs, improved retention strategies, and a positive work	% of staff trained in key competencies	2024: 60%	65%	70%	80%	9%	100%	HR, Admin	Training logs	Skills assessments								
	Number of skills gaps assessments conducted	#	1	1	1	1	1	1	HR & Administration Unit	1	Assessment reports.								
	% of Rwanda FDA trained and capacitated	%	20%	30%	50%	75%	80	95%	HR & Administration Unit		Training records and evaluations								

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4	Enhancing the integrity and safety of the health product supply chain through improved tracking and monitoring systems. This includes implementing digital traceability, compliance with quality standards, and timely inspections to ensure that all regulated products meet safety requirements.	Proportion of drugs and vaccines manufactured locally	%	N/A	1%	2%	3%	4%	5%	Drugs Dept.	RFDA report	Field Visit
		Proportion of food supplement's manufactured locally	%	N/A	1%	5%	10%	15%	20%	Food Department	RFDA report	Field Visit
		Products traceability system established	#	N/A		Functional traceability system in Rwanda				Food and Drugs Depts.	Report	System implementation reports
		% Export of locally manufactured products to neighbouring countries and beyond	%	N/A	-	5%	10%	15%	20%	Food and Drugs Depts.	Report	Export records and trade reports
Strategic Priority Area 5 – To Scale Leveraging Technology/Digitalization for Efficient Services												
5	Modernizing regulatory processes through the adoption of technology and digital tools, leading to improved efficiency, faster	% of regulatory processes automated	%	N/A	80%	100%	100%	100%	100%	IT Office	Automation project reports	System audit
		Average processing time for applications	Days	N/A	2	1	1	1	1	IT Office	Internal tracking system	Process flow analysis
		% of stakeholders engaged via	%	N/A	20%	40%	60%	80%	95%	Communications Office	Stakeholder engagement reports	Engagement survey results

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