



**RWANDA FDA**  
Rwanda Food and Drugs Authority

**RWANDA FOOD AND DRUGS AUTHORITY ANNUAL  
REPORT FY 2024-2025**

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## LIST OF ABBREVIATIONS

<b>ADR</b>	Adverse Drug Reaction
<b>AEFI</b>	Adverse Events Following Immunization
<b>ANPP</b>	Algeria National Pharmaceutical Authority
<b>ABMed</b>	Benin National Medicines Regulatory Authority
<b>AfCFTA</b>	African Continental Free Trade Area
<b>AVAREF</b>	African Vaccine Regulatory Forum
<b>BOMRA</b>	Botswana Medicines Regulatory Authority
<b>CAPA</b>	Corrective and Preventive Actions
<b>CEPI</b>	Coalition for Epidemic Preparedness Innovations
<b>EAC:MRP</b>	East African Community Medicines Regulatory Programme
<b>EDA</b>	Egyptian Drug Authority
<b>GCP</b>	Good Clinical Practice
<b>GMP</b>	Good Manufacturing Practice
<b>GPPQCL</b>	Good Pharmaceutical Practices and Quality Control Laboratory
<b>iRIMS</b>	Integrated Regulatory Information Management System
<b>ISO 9001:2015</b>	ISO Standard for Quality Management Systems
<b>ISO/IEC 17025:2017</b>	International Standard for Competence of Testing and Calibration Laboratories
<b>MoU</b>	Memorandum of Understanding
<b>NPAC</b>	National Pharmacovigilance Advisory Committee
<b>PBRER</b>	Periodic Benefit Risk Evaluation Report
<b>PSUR</b>	Periodic Safety Update Report
<b>QMS</b>	Quality Management System
<b>SAHPRA</b>	South African Health Products Regulatory Authority
<b>SKCP</b>	Smart Kigali Command Post
<b>TWG</b>	Technical Working Group
<b>VigiMobile</b>	Vaccine and Medicine Safety Mobile Reporting System
<b>VigilLyse</b>	WHO Global Safety Database for Medicines and Vaccines
<b>WHO</b>	World Health Organization

## FOREWORD

On behalf of Rwanda Food and Drugs Authority (Rwanda FDA), I am pleased to present the Authority's Annual Report for the Fiscal Year 2024-2025. This report outlines the progress made in fulfilling our mandate of safeguarding public health by ensuring that medicines, vaccines, food, cosmetics, medical devices, and other regulated products circulating on the Rwandan market are safe, effective, and of assured quality. Our work continues to align with national priorities under the Health Sector Strategic Plan, the National Strategy for Transformation (NST2), and global commitments such as the Sustainable Development Goals and the WHO Global Benchmarking requirements.

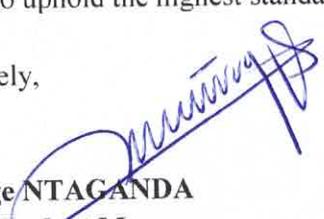
During the reporting period, Rwanda FDA registered significant achievements despite resource and operational challenges. The Authority successfully strengthened post-market surveillance through inspections at borders and within the domestic market, expanded adverse drug reaction reporting under pharmacovigilance, and advanced the digitalization of regulatory processes through the Integrated Regulatory Information Management System (IRIMS). Progress was also made towards enhancing laboratory testing capacity, training regulatory professionals, and fostering international collaborations, including the EU-Twinning project, WHO technical support, and partnerships with development agencies. These milestones reflect the dedication of our staff and the trust placed in us by our stakeholders.

Despite facing challenges inherent to regulatory environment, Rwanda FDA remained proactive and resilient. The Authority advanced its mission by introducing risk-based approaches, broadening stakeholder consultations, and strengthening communication with the public. This was achieved through diverse channels, including the Authority's website, media platforms, television and radio programs, a mobile-enabled customer support system, and a toll-free hotline. These efforts enhanced transparency, responsiveness, and community engagement, underscoring our commitment to safeguarding public health.

We extend our sincere appreciation to the Government of Rwanda for its unwavering support, which has been instrumental in enabling the Authority to achieve its objectives. We are equally grateful to the Rwanda FDA Board of Directors for their technical and managerial guidance, as well as to our local and international partners for their invaluable contributions in strengthening our regulatory capacity.

Looking ahead, Rwanda FDA remains committed to consolidating the progress achieved while addressing identified gaps. Our priorities for the coming fiscal year include strengthening laboratory services, advancing iRIMS automation, deepening international collaborations, enhancing risk-based regulatory oversight, and building staff competencies. With the continued support of our stakeholders and partners, we are confident in our ability to advance towards WHO Maturity Level 4 and to uphold the highest standards of regulatory excellence in protecting public health.

Sincerely,



**George NTAGANDA**  
**Chief Budget Manager**

## EXECUTIVE SUMMARY

Rwanda FDA, established under Law N° 003/2018 of 09/02/2018, continues to safeguard public health by regulating human and veterinary medicines, vaccines, biologicals, processed foods, medicated cosmetics, medical devices, household chemicals, tobacco products, and clinical trials. During FY 2024-2025, the Authority achieved significant milestones across regulatory oversight, product registration, inspections, capacity building, and emergency preparedness, reinforcing its commitment to ensuring the safety, quality, and efficacy of health products in Rwanda. Notably, Rwanda FDA has achieved WHO Maturity Level 3, reflecting stable, well-functioning, and integrated regulatory system.

In regulatory performance, Rwanda FDA conducted 41 GMP inspections, surpassing the annual target, including 8 local manufacturers, 30 foreign manufacturers, and 3 joint inspections with regional and international partners. In addition, 32 reliance inspections and 40 desk assessments facilitated timely handling of applications from foreign manufacturers. Across sectors, 1,180 premises licenses were issued, and 166 unauthorized premises were closed, demonstrating proactive enforcement and adherence to regulatory timelines. Registration rates across key sectors included 28.5% for human medicines and medical devices, 63.9% for veterinary medicines and devices, 59.1% for food products, and 57.6% for cosmetics and household chemicals.

Capacity-building efforts strengthened regulatory competencies across all functions. Staff were trained in clinical trial oversight, quality management systems, and digital traceability tools to enhance supply chain integrity. Targeted workshops on pharmacovigilance, laboratory testing, and inspection processes further reinforced technical expertise. Rwanda FDA advanced the national pharmaceutical traceability system through TWG initiatives and international benchmarking, and coordinated emergency use authorizations, including Mpox vaccines, ensuring rapid access during public health emergencies. These achievements collectively supported operational efficiency, robust decision-making, and compliance with international best practices.

Key challenges included persistent limitations of digital platforms, notably iRIMS, which affected application tracking, inspection scheduling, and data management. Staff shortages impacted pharmacovigilance follow-up and monitoring activities, while resource constraints occasionally limited outreach and training activities. In response, Rwanda FDA will focus on stabilizing digital systems, enhancing staff technical capacity through continuous training, and strengthening inspection, monitoring, and enforcement mechanisms to maintain high standards of regulatory oversight.

The fiscal year 2024-2025 demonstrated Rwanda FDA's commitment to rigorous regulatory oversight, effective stakeholder engagement, and continuous institutional development. By consolidating achievements in inspections, registrations, capacity building, and emergency preparedness, the Authority remains dedicated to protecting public health, ensuring compliance, and fostering a resilient regulatory environment aligned with international standards, setting a strong foundation for FY 2025-2026.

## **1. RWANDA FDA OVER VIEW**

### **1.1. Strategic Overview**

Rwanda Food and Drugs Authority hereafter designated as the “Authority”, was established by the law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of the Authority is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products

### **1.2. Vision**

To be a globally recognised food and drugs Authority

### **1.3. 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.

### **1.4. Core values**

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

1. Serving with professionalism for excellent service delivery
2. Continuously working with integrity
3. Promoting accountability at all times
4. Nurturing teamwork to achieve common objectives
5. Striving for innovation to create value for our stakeholder and other interested parties.

### **1.5. Rwanda FDA Quality Policy Statement**

Rwanda FDA is committed to providing the highest quality of regulatory services that consistently meet customer requirements and expectations through the implementation of a robust Quality Management System (QMS) that complies with ISO 9001.

This is achieved through assessment and registration, inspections and licensing, control of imports and exports, vigilance, post-market surveillance, oversight for clinical trials, control of promotional materials and advertisements, laboratory testing and lot release. These functions are implemented to ensure the quality, safety, and efficacy of regulated products, through enforcement of applicable laws and regulations.

Rwanda FDA therefore, commits adequate financial, human, physical, and technological resources to effectively implement, maintain, and continually improve the QMS. We strive to attract and retain a competent, motivated, facilitated, and empowered workforce to achieve our quality objectives and mission.

The objectives, processes, systems, and procedures supporting this policy are established and regularly reviewed to ensure continuous improvement of the QMS.

## **2. THE AUTHORITY MANAGEMENT**

Rwanda FDA is governed by a Board of Directors (BoD) and an Executive Organ. The BoD serves as the highest management and decision-making body, with full authority to oversee the Executive Organ and provide strategic direction to fulfill the Authority's mission. FDA is affiliated with and reports to the Ministry of Health.

### **2.1. Rwanda FDA Board of Directors (BoD)**

The Board of Directors (BoD) consists of seven members: a chairman, a vice-chairperson, and five additional members. Among its key responsibilities, the BoD oversees the functioning of the Executive Organ and provide strategic guidance to be followed in the fulfilment of its mission

### **2.2. Rwanda FDA Executive Organ.**

The Executive Organ of Rwanda FDA comprises the Director General (DG), Deputy Director General (DDG) appointed by Presidential Order, Heads of Departments (HODs), Division Managers, Directors, Legal Analyst, and the Chief Finance Officer (CFO). The Director General, as the chief executive, provides overall leadership and coordination of the Authority's daily operations.

In accordance with the Law governing public finance, the CFO serves as the Chief Budget Manager, ensuring sound financial planning, budget execution, and compliance with administrative and regulatory requirements. The Executive Organ collectively executes additional duties assigned by the Board of Directors that are consistent with the Authority's mandate to safeguard public health.

## **3. IMPLEMENTATION OF ACTIVITIES FY 2024-2025**

Rwanda FDA's performance in the fiscal year 2024-2025 reflects a strong commitment to its mission of protecting public health. Guided by its Strategic Plan, national health sector priorities, the National Transformation Strategy (NST1 and NST2) priority areas, and other sector-level strategies, the Authority implemented its core regulatory functions with measurable impact. All activities carried out during the year fall under the two major areas of assessment and registration of regulated products and inspections for compliance, ensuring that only safe and effective products reach the market while safeguarding the public from unsafe consumption.

### **3.1. Assessment and Registration**

#### **3.1.1. Human Medicines and Medical Devices**

In FY 2024-2025, the Authority received 1,237 applications for human medicines and medical devices, representing a 100.5% increase compared to 617 applications in FY 2023-2024. This substantial rise was largely driven by the Authority's proactive engagement with stakeholders

through several meetings, which encouraged clients to submit their applications. Additionally, the assessment process was streamlined, with a three-month completion time for products from stringent regulatory authorities (SRAs) and those assessed under reliance recognition mechanisms.

During the same period, the Authority handled a total stock of applications comprising 2,648 carried over from FY 2023-2024 and the newly received 1,237 applications. Out of the 1,569 applications assessed, 448 were successfully registered, reflecting a registration rate of 28.5%. Despite this progress, 2,239 applications remained pending and will be carried over to FY 2025-2026 for further assessment.

The assessment and registration processes were entirely managed by the Authority's staff and local professionals. The East African Community (EAC) joint dossier assessment was conducted, adhering to the reliance recognition framework. The assessment encompassed a variety of applications, including variations, renewals, and medical devices, and provided technical review recommendations based on the results.

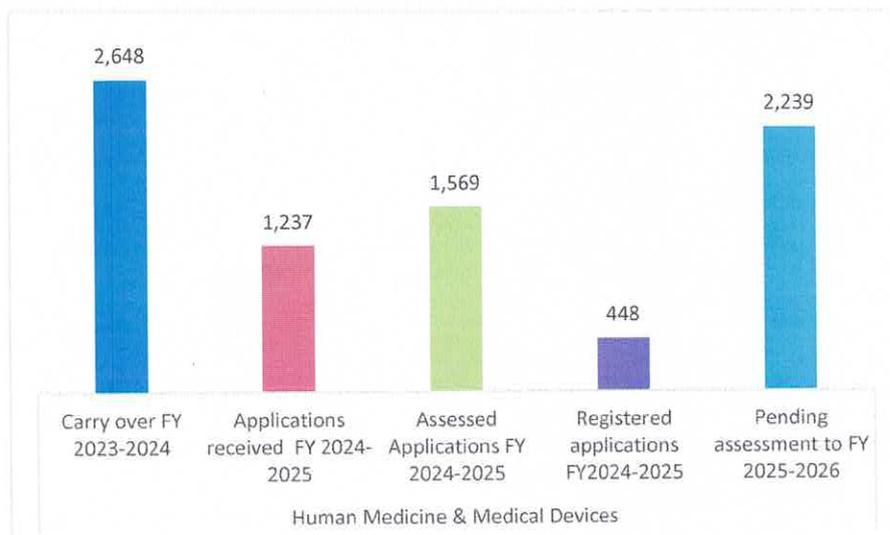


Figure 1: Human Medicine assessment and Registration

### 3.1.2. Veterinary Medicines and Devices

A total of 57 veterinary medicine and medical device applications were received in FY 2024-2025, representing a 16.2% decrease from 68 applications in the previous year. Together with 72 applications carried over from FY 2023-2024, the Authority managed a total stock of 129 applications during the reporting period. Out of these, 61 were assessed, of which 39 were successfully registered, resulting in a registration rate of 63.9%. At the close of the fiscal year, 76 applications remained pending and will be carried over to FY 2025-2026 for further assessment.

The assessment encompassed a variety of categories, including medicines, immunologicals, biologicals, medical devices, and in vitro diagnostics (IVDs). Looking ahead, the Authority intends to launch sensitization campaigns to improve stakeholder awareness regarding the registration process for veterinary products.



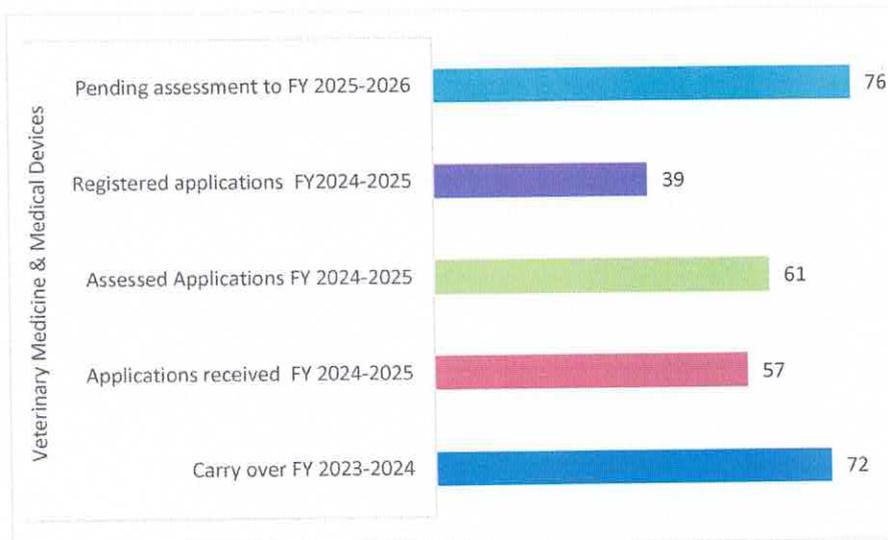


Figure 2: Veterinary Medicine & Medical Devices Assessment Registration

### 3.1.2.1. Recognition & Collaboration

During the fiscal year, Rwanda FDA made significant progress in the regulation of veterinary medicines and medical devices through regional, international, and domestic engagements. At the regional level, staff participated in EAC-MRP activities, including workshops to validate draft guidelines for registration of veterinary devices and medicines and the 27<sup>th</sup> Technical Working Group meeting on harmonized labeling of veterinary ectoparasiticides. Additionally, two Technical Working Group members and one staff from the GMP unit took part in a regional GMP validation workshop and joint assessment of pending GMP applications in Dar-es Salaam, Tanzania. Globally, Rwanda FDA was represented at the 17<sup>th</sup> Veterinary International Cooperation on Harmonization (VICH) Forum and the 7<sup>th</sup> VICH Public Conference, reinforcing alignment with international standards and best practices.

### 3.1.3. Cosmetics and Household Chemicals

During FY 2024-2025, the Authority received 118 applications for cosmetics and household chemicals, a modest increase of 5.4% compared to 112 applications in FY 2023-2024. This growth is linked to rising consumer demand and increased awareness of regulatory requirements following market surveillance and sensitization activities. Together with 54 applications carried over from FY 2023-2024, the Authority managed a total stock of 172 applications during the reporting period. Out of the 144 applications assessed, 83 were successfully registered, translating into a registration rate of 57.6%. At the close of the fiscal year, 47 applications remained pending and will be carried over to FY 2025-2026 for further assessment

Several factors contributed to this substantial rise in applications for FY 2024-2025. Enhanced awareness among business operators, manufacturers, importers, and the public played a crucial role. Furthermore, meetings with business stakeholders to clarify regulatory requirements and emphasize the benefits of product registration, combined with targeted reminders to key

stakeholders via email and updates from mapping exercises and database records, effectively stimulated greater interest in applications.

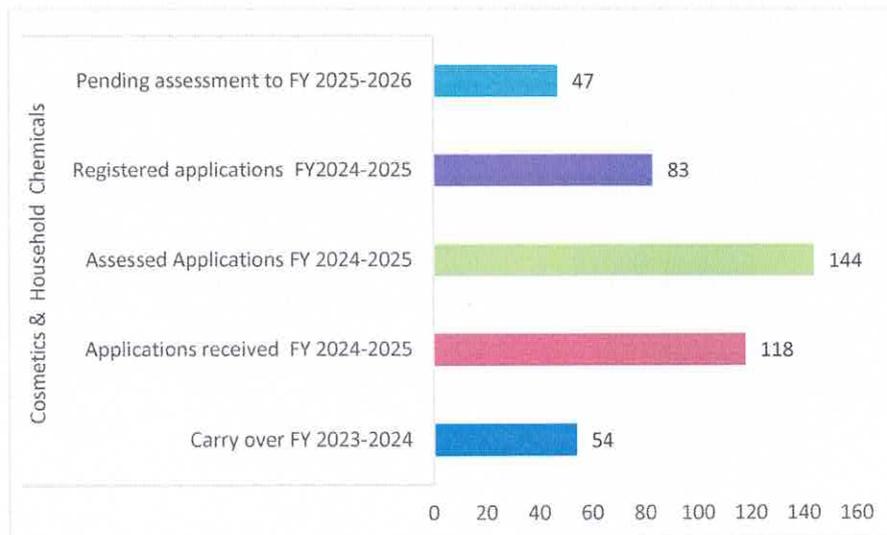


Figure 3: Cosmetics & Household Chemicals Assessment And Registration

### 3.1.3.1. Research & Mapping

During the fiscal year, 400 establishments dealing in cosmetics and household chemical products were mapped in Bugesera, Ngoma, and Kirehe Districts, covering pharmacies, supermarkets, manufacturers, and retail shops. The survey revealed key regulatory gaps such as unregistered and prohibited products on the market, non-licensed local manufacturers, and limited stakeholder awareness of Rwanda FDA’s mandate. To address these issues, Rwanda FDA strengthened regulatory inspections, removed non-compliant products, and initiated awareness programs in collaboration with local government officials.

In addition, research was conducted in Musanze and Rubavu Districts to identify barriers to product registration, while a study on knowledge, attitudes, and practices towards skin-whitening cosmetics was completed and is under journal review.

### 3.1.4. Food Products registration

The Authority received 404 applications for registration of food products in FY 2024-2025, marking a sharp increase of 164% compared to 153 applications in FY 2023-2024. This surge is largely attributed to intensified inspections and enforcement measures that compelled businesses to regularize their products, as well as growing compliance awareness among food operators. Together with 5 applications carried over from FY 2023-2024, the Authority managed a total stock of 409 applications during the reporting period. Out of 364 applications assessed, 215 were successfully registered, resulting in a registration rate of 59.1%. At the end of the fiscal year, 45 applications remained pending and will be carried over to FY 2025-2026 for further assessment.

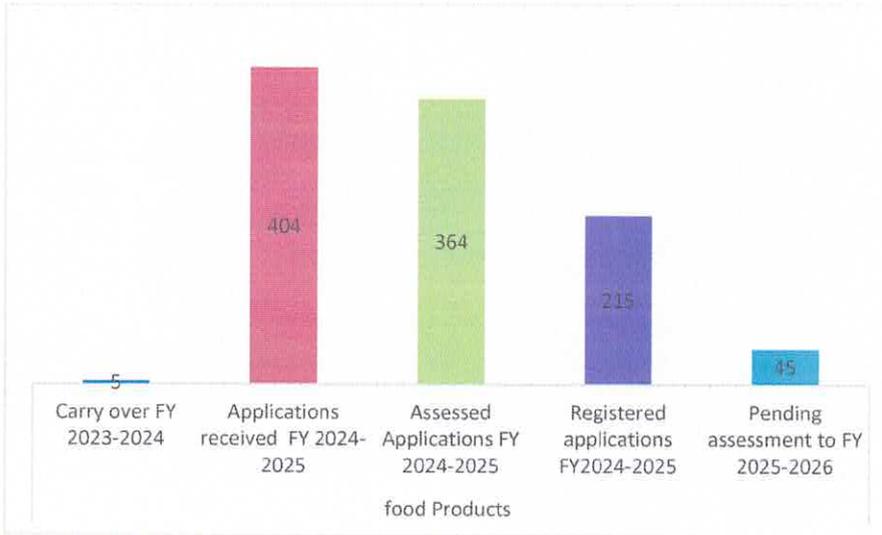


Figure 4: Food products Assessment and Registration

### 3.1.4.1. Information Control

During the year, Rwanda FDA processed 29 applications for authorization of promotion and advertisement of food products. Of these, 13 applications were approved. In addition, inspections were carried out across 78 food premises in 18 districts of Kigali City, Northern, Southern, and Eastern Provinces, where non-compliant advertisements were identified and regulatory awareness was raised.

## 3.2. Inspection and Licensing of Facilities

### 3.2.1. Pharmaceutical Facilities

Rwanda FDA plays a pivotal role in ensuring the safety, efficacy, and quality of medical products in the country. During FY 2024-2025, the Authority continued to strengthen regulatory oversight over pharmaceutical establishments, including manufacturers, distributors, wholesalers, retailers, and clinical trial sites. These activities encompassed licensing, inspections, and enforcement, guided by Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Storage and Distribution Practices (GSDP). A risk-based inspection approach enabled prioritization of high-risk establishments, ensuring efficient use of resources while safeguarding public health.

### 3.2.2. Applications and Licensing

During the year, Rwanda FDA received a total of 1,450 applications for premise licensing, license renewals, and license variations. Out of these, 1,171 licenses were issued, reflecting a compliance rate of approximately 81%, while 279 applications (19%) were queried or found non-compliant, requiring additional documentation or corrective action.

Process Name	Applications Received	Licenses Issued	Queried / Non-compliant Premises
Premise Licensing	182	147	35
Premise License Renewal	1,049	839	210
Premise License Variation	219	185	34
<b>Total</b>	<b>1,450</b>	<b>1,171</b>	<b>279</b>

Table 1: Summary of Applications and Licenses Issued

### 3.2.3. Inspections and Compliance

Rwanda FDA conducted **714 inspections** during the year, covering licensing, GSDP, relocation, enforcement, safe disposal, variations, and re-inspections. Enforcement inspections on non-compliant premises led to regulatory actions, including 166 closures, 12 administrative fines, 6 license suspensions, and 2 revocations, reinforcing compliance and public safety.

Inspection Category	Number Conducted
Premise Licensing	208
License Renewal	101
GSDP	64
Relocation	21
Enforcement	309
Variation	2
Safe Disposal	7
Re-inspection	2
<b>Total</b>	<b>714</b>

Table 2: Overview of Inspections

### 3.2.4. Good Manufacturing Practice (GMP) Inspections and Certification

#### 3.2.4.1. GMP Inspections conducted

During FY 2024-2025, Rwanda FDA continued to strengthen regulatory oversight of pharmaceutical manufacturers through Good Manufacturing Practice (GMP) inspections and certification. The Authority received a total of 127 GMP inspection applications (9 local and 118 foreign), covering human medicines, veterinary medicines, and medical devices. Human medicines accounted for the largest share (119 applications, 93.7%), underscoring the growing demand for quality assurance in this sector.

Across the financial year, Rwanda FDA conducted a total of 45 physical GMP inspections, surpassing the initial annual target of 20 and demonstrating proactive regulatory oversight. These inspections comprised 42 human medicines facilities, 2 veterinary medicines facilities, and 1 medical device facility. In addition, 6 joint inspections were carried out in collaboration with

regional and international partners, including the East African Community (EAC), ANSM-France, and the African Medicines Regulatory Harmonization (AMRH) initiative.

To optimize resources and benefit from international regulatory expertise, 53 desk assessments were conducted, while reliance on reports from WHO-listed and other stringent regulatory authorities facilitated certification decisions.

### 3.2.4.2. GMP Certificates Issued

As a result of these efforts, Rwanda FDA issued 56 GMP certificates during the year: 52 for human medicines, 4 for veterinary medicines, and none for medical devices. These outcomes reflect the Authority’s continued commitment to ensuring compliance with international quality standards and safeguarding the supply of safe, effective, and quality-assured medical products in Rwanda

Product type	Received applications	Pending	Total	Physical inspections	Joint inspections	Desk assessments	Certificates Issued
Human Medicines	119	101	220	42	6	47	52
Veterinary Medicines	4	5	9	2	0	5	4
Medical devices	4	5	9	1	0	1	0
<b>Total</b>	<b>127</b>	<b>111</b>	<b>238</b>	<b>45</b>	<b>6</b>	<b>53</b>	<b>56</b>

Table 3: Table showing GMP Inspections and Licenses issued

### 3.2.4.3. GMP Deficiencies

A total of 283 GMP deficiencies were identified across all inspections. These were categorized as follows:

Deficiency Type	Number of Findings	Common Areas of Concern
Critical	2	Production, data integrity
Major	172	Documentation, equipment, utilities, QC labs, quality management systems
Minor	109	Personnel practices, self-inspections, premises, documentation
<b>Total</b>	<b>283</b>	

Table 4: Categorization of GMP Deficiencies

the average time for issuing inspection reports exceeded the 30-day target, and only a proportion of CAPA plans were submitted and implemented within the required timelines. These gaps highlight areas for improving follow-up and response efficiency in clinical trial oversight.

Findings from the GCP inspections primarily included major and minor deficiencies related to informed consent procedures, data quality, risk mitigation, and record-keeping. Across the inspected sites, corrective and preventive actions were taken, including the issuance of warning letters where necessary. Lessons learned emphasized the need for flexible planning to accommodate public health emergencies, site readiness, and investigator availability, ensuring continuity of oversight even under challenging circumstances.

### 3.2.5. Food Premises Inspections, Licensing, and Safety Monitoring

#### 3.2.5.1. Inspection and Licensing

During the reporting year, Rwanda FDA received a total of 1,635 application dossiers from food manufacturing facilities, food supplement shops, and wholesalers of regulated food products. Of these, 1,268 required physical inspections, while the remainder were processed without inspections, including notifications, complaints, and CAPA reports.

To ensure compliance, the Authority conducted 860 inspections covering initial licensing, renewals, re-inspections, follow-up visits, and sample collections. These inspections were distributed across 474 food manufacturing facilities, 52 food supplement shops, and 334 wholesalers and outlets.

As a result of these regulatory activities, Rwanda FDA issued 668 premises licenses, of which 380 were new and 288 were renewals. Specifically, 292 licenses were granted to food manufacturing facilities, 159 to food supplement shops, and 217 to wholesalers and outlets. In addition, 2 cases requiring product disposal were addressed, while 442 compliance feedback letters were issued to guide facilities in meeting regulatory requirements.

Overall, these outcomes reflect strengthened regulatory oversight, with inspections effectively driving compliance and ensuring that licensed food businesses operate within the required standards to safeguard public health.

Category	Applications Requiring Inspection	Inspections Conducted	New Licenses Issued	Renewal Licenses Issued	Total Licenses Issued
Food manufacturing facilities	929	474	185	107	292
Food supplement shops	50	52	19	140	159

Wholesalers / Outlets	287	334	176	41	217
Disposal	2				
<b>Total</b>	<b>1,268</b>	<b>860</b>	<b>380</b>	<b>288</b>	<b>668</b>

Table 6: Summary of Food Facility Inspections and Licensing (FY 2024–2025)

### 3.2.5.2. Joint Enforcement Activities

Rwanda FDA coordinated with governmental institutions, including the Smart Kigali Command Post (SKCP), Rwanda Investigation Bureau (RIB), Rwanda National Police (RNP), and local authorities to conduct 122 joint inspections across food establishments. These efforts focused on compliance verification, removal of unsafe products, and enforcement of penalties where necessary.

### 3.2.5.3. Post-Market Surveillance and Food Safety Monitoring

During the fiscal year 2024-2025, the Authority carried out 524 routine post-market surveillance inspections, ensuring compliance with safety standards and removing expired, substandard, or unsafe food products from the market. A total of 119 samples were collected and analyzed by the Rwanda FDA Quality Control Laboratory, informing regulatory decisions and reinforcing consumer protection.

### 3.2.5.4. Stakeholder Engagement

The authority prioritized collaboration and public awareness to promote food safety and regulatory compliance. Food safety messages were disseminated through local radio and public notices, complemented by the launch of the Rwanda FDA Food Safety Newsletter. Furthermore, stakeholder engagements were conducted with key institutions including local liquor manufacturers, RNP, RIB, National Intelligence and Security Service (NISS), Rwanda Revenue Authority (RRA), Rwanda Inspectorate, Competition and Consumer Protection Authority (RICA), Smart Kigali Command Post, and MINICOM. These partnerships played a critical role in combating counterfeiting, addressing smuggling, and improving industry compliance with regulatory requirements.

### 3.2.5.5. Risk-Based Inspection Planning and Strategic Initiatives

The Authority finalized the Risk-Based Inspection Plan for the period 2025-2030, aimed at enhancing regulatory efficiency by aligning inspection frequency with the level of risk posed by facilities. Under this framework, low-risk facilities will undergo one inspection every three years, medium-risk facilities will be inspected twice within five years, while high-risk facilities will receive four inspections within the same period. This classification approach is designed to optimize resource allocation, ensuring that regulatory efforts are focused where they are most needed to safeguard public health. Implementation of the plan is set to begin once the fiscal year budget is approved and allocated.

### **3.2.5.6. GMP Certification of Food Manufacturing Facilities**

During FY 2024-2025, Rwanda FDA conducted a total of 67 Good Manufacturing Practice (GMP) inspections across food manufacturing facilities. Of these, 25 GMP certificates were issued to compliant applicants, reflecting the Authority's ongoing commitment to ensuring adherence to manufacturing standards. Additionally, 64 feedback letters were provided to applicants to address queries and corrective actions, with remaining applicants actively responding to observations raised during inspections. The Authority is also advancing a risk-based inspection approach, designed to tailor inspection criteria according to the specific risk profile of each business, thereby enhancing overall compliance over time.

### **3.2.5.7. Destruction of Impounded/Expired Regulated Food Products**

Throughout the fiscal year, the Authority supervised the safe disposal of 38 batches of expired or substandard products from food manufacturers and establishments. These activities ensured the removal of unsafe products from the market, reinforced compliance with food safety regulations, and safeguarded public health.

## **3.2.6. Pharmacovigilance Activities and Safety Monitoring**

The Rwanda FDA plays a pivotal role in ensuring the safety of medical products through its robust pharmacovigilance system. The Authority actively collects, monitors, and evaluates safety reports from multiple sources, including marketing authorization holders (MAHs), hospitals, health centers, public health programs, local technical representatives, and patients. These reports cover adverse drug events (ADEs), adverse drug reactions (ADRs), and adverse events following immunization (AEFIs). Upon receipt, reports are recorded in a dedicated database, and serious local cases undergo causality assessment. Feedback is provided to reporters, and if safety signals are detected, they are analyzed and shared with MAHs for further investigation and action. Additionally, safety communications are issued to healthcare professionals to minimize risks and enhance patient safety.

### **3.2.6.1. Pharmacovigilance Reports and Case Investigations**

Over the fiscal year, Rwanda FDA received a total of 1,293 ADR/AEFI reports through spontaneous reporting from healthcare professionals and patients. Among these, 88 reports were classified as serious. Investigations of serious cases were conducted in collaboration with the National AEFI Committee, WHO staff, and other stakeholders.

Notable investigations included cases of contaminated normal saline 0.9% at King Faisal Hospital, which were confirmed to have a probable causal relationship with reported adverse events. Investigations of vaccine-related AEFIs highlighted the importance of distinguishing between coincidental health issues and genuine vaccine reactions. Causality assessments conducted by the national AEFI committee confirmed that several serious cases were coincidental, while others were linked to administered vaccines. These efforts underscore the importance of continuous monitoring to ensure public health safety and maintain confidence in immunization programs.

### **3.2.6.2. PSUR/PBRER**

During FY 2024-2025, the PV-CT division received 89 Periodic Safety Update Reports (PSURs) and Periodic Benefit-Risk Evaluation Reports (PBRERs) from MAHs. These reports were screened, analyzed, and recorded in the database for further assessment. PSURs are essential for evaluating the benefit-risk balance of medicinal products and monitoring emerging safety concerns based on clinical use and post-marketing surveillance.

### **3.2.6.3. National Pharmacovigilance Advisory Committee (NPAC) Activities**

The NPAC convened to review serious ADRs and AEFIs, including cases of adverse events linked to contaminated normal saline at King Faysal Hospital. Causality assessments were conducted using WHO methodologies, and regulatory recommendations were provided. Key actions included random sampling and testing of imported medical products, enhancing public awareness, strengthening post-market surveillance, and improving communication to healthcare providers and patients.

### **3.2.6.4. Supportive Supervision**

Rwanda FDA conducted supportive supervision visits to 220 health facilities nationwide in collaboration with WHO and Rwanda Biomedical Centre (RBC). During these visits, 347 previously unreported adverse events were identified from health facility registries and patient records and subsequently reported through the VigiMobile system to Rwanda FDA and shared with WHO's Vigilyse database.

### **3.2.6.5. Post-Marketing Surveillance of Medical Products and Cosmetics**

During the year, the Authority received reports of 51 suspected poor-quality medical products, all of which were thoroughly investigated. Routine post-marketing surveillance activities were conducted on 16 occasions, covering a total of 94 medical products. Surveillance included sampling for laboratory quality control testing, both at the Rwanda FDA Quality Control Laboratory and, for certain projects such as BREDME and MINILAB, at partner laboratories in Tanzania. In total, 120 product samples were submitted for laboratory analysis. Key surveillance activities included inspections following media alerts and project-based sampling, such as the PMS inspection for Benylin syrup after detection of diethylene glycol (DEG) and the BREEDIME and Minilab projects.

In addition to pharmaceuticals, Rwanda FDA conducted post-marketing surveillance for cosmetic products. A total of 47 cosmetic products were visually inspected, including complaints received from the SKCP. Investigations identified instances of unauthorized manufacturing, expired products, and products lacking manufacturer or shelflife information. Feedback from these inspections and laboratory analyses was provided to the relevant stakeholders, ensuring compliance with Rwanda FDA regulations.

### **3.2.6.6. Recalls of Medical Products**

During FY 2024-2025, the Authority took decisive action to remove non-compliant or unsafe medical products from the market. A total of 10 recall activities were initiated, including both voluntary and statutory recalls. The recalled products included batches of Fluconazole powder for suspension and other identified non-compliant pharmaceuticals. A countrywide recall audit was conducted to verify that all recalled products were fully removed from the market, targeting facilities based on distribution lists provided by suppliers. This rigorous follow-up ensured the protection of public health and reinforced compliance among suppliers and healthcare facilities.

### **3.2.6.7. Product Information, Promotion, and Advertisement**

The Authority monitored the promotion and advertisement of regulated medical products to ensure ethical marketing, prevent misinformation, and protect public health. Rwanda FDA received 28 applications for promotional and advertisement materials during the year. Of these, 22 applications were approved, 1 was rejected, and 5 had queries requiring feedback from applicants. Approved applications included Direct Healthcare Professional Communications (DHPCs) such as Roche's clarification on Atezolizumab combined with Bevacizumab, which emphasized that the product is not approved as adjuvant therapy for hepatocellular carcinoma at high risk of recurrence.

Inspections of non-approved promotional materials were conducted at wholesale and retail pharmacies, cosmetic shops, and local markets, targeting herbal medicine promotions and social media campaigns. A total of 66 facilities were vetted, identifying cases of non-compliance. Corrective actions included raising awareness, issuing warning letters, and recommending follow-up inspections.

### **3.2.7. Clinical Trial Oversight**

Rwanda FDA continues to strengthen regulatory oversight of clinical trials to ensure the safety, efficacy, and ethical conduct of medical research. During FY 2024/2025, the Authority received and reviewed a total of 16 new clinical trial applications. Among these, 4 clinical trials were approved, while several applications required additional information, and 7 were issued query letters to the principal investigator or sponsor.

The Authority also processed 20 clinical trial amendment applications, approving 13 and issuing 7 queries for further clarification. Additionally, 4 applications for annual renewal or extension of approved clinical trials were received, with 2 approvals issued and 2 queries sent to applicants.

Clinical trial staff actively monitored safety through recording and analysis of 129 safety reports from authorized clinical trials, including key studies such as BREATHE, KALUMA, VIBRI, MEPLAZUMAB, KARISMA, CASPAR, HOPE II, RTS,S/AS01E GSK Malaria Vaccine Trial, and EBOLACOV. Coordination was maintained through 27 internal clinical trial technical committee meetings, comprising pre-approval meetings and grading of Good Clinical Practice (GCP) inspection findings.

Activity	Number
New clinical trial applications screened and reviewed	16
Ongoing clinical trial applications reviewed (additional data)	8
Clinical trials approved	4
Clinical trial amendments reviewed and approved	13
Clinical trial amendments reviewed and queried	7
Applications for annual renewal/extension received	4
Approvals issued for renewal/extension	2
Safety reports recorded and analyzed	129
Progress/site close-out reports reviewed	75
Internal clinical trial technical committee meetings	27
Training and induction programs attended	5

Table 7: Clinical Trial Oversight Statistics FY 2024/2025

### 3.2.8. Drugs Import and Export Control

During the fiscal year 2024-2025, Rwanda FDA, through the Drugs Import and Export Control Division, continued to regulate the importation and exportation of medical products and related commodities using the Integrated Regulatory Information Management System (iRIMS). The authorization process initially involved two steps import visa followed by import license with importers required to first obtain a visa to confirm orders before applying for an import license. However, beginning in the second quarter, the Authority streamlined the procedure by removing the visa requirement, thereby reducing administrative steps and facilitating a more efficient importation process without compromising regulatory accuracy.

#### 3.2.8.1. Import & Export licenses issued

In the first quarter, the Authority received 1,704 applications for import visas, of which 1,531 (89.8%) were approved. Across the entire year, a total of 11,428 import license applications were received, and 10,844 (94.9%) were granted. These applications covered a broad range of regulated products, including human and veterinary medicines, vaccines, biosimilars, medical devices, cosmetics, chemicals, disinfectants, tobacco and tobacco products, packaging and labeling materials, and raw materials for local production. The Authority also processed 92 export license applications, approving 86 licenses (93.5%) across various product categories.

#### 3.2.8.2. Controlled Substances

For controlled substances, Rwanda FDA received 245 applications for importation, of which 124 applications (50.6%) were approved, in alignment with national regulations and international conventions.

#### 3.2.8.3. Inspected Consignments

To safeguard public health, the Authority conducted inspection of 7,522 consignments at various

points of entry, with the following outcomes;

- 4,386 consignments directly released at border posts
- 2,563 consignments released under seal and later inspected at importer premises
- 573 consignments cleared for intra-regional transport

#### **3.2.8.4. Strengthening Customs Capacity through RRA Collaboration**

Furthermore, under the Memorandum of Understanding signed with the Rwanda Revenue Authority (RRA), the Authority strengthened collaboration by training customs officers at key border points, including Rusizi I, Rusizi II, Bugarama, Kagitumba, Cyanika, Petite Barrière, and Grande Barrière. This initiative enhanced efficiency in physical inspections and reinforced regulatory enforcement.

### **3.2.9. Food Import and Export Control**

#### **3.2.9.1. Import Licenses**

During FY 2024-2025, the Authority streamlined the import authorization process by removing the import visa requirement from Q2 onwards, allowing importers to apply directly for an import license. This reform simplified procedures while upholding strict regulatory oversight.

Over the year, Rwanda FDA received a total of 11,981 applications for import licenses, of which 11,249 (93.9%) were approved. These licenses covered a broad range of regulated products, including food products, food supplements, animal feeds, packaging materials, and raw materials for food production.

#### **3.2.9.2. Export Licenses**

The Authority processed a total of 616 export license applications, primarily for food products, food supplements, and animal feeds. Out of these, 560 licenses (90.9%) were granted after fulfilling the required standards, while 56 applications were rejected due to non-compliance.

#### **3.2.9.3. Inspected Consignments**

Rwanda FDA conducted inspections to ensure compliance with food safety standards for imported and exported consignments. Over the reporting period, a total of 10,755 consignments were inspected. Among these;

- 4,915 consignments were directly released at border posts.
- 5,691 consignments were released under seal for inspection at importer premises.
- 6 consignments of processed food were inspected at exit points and all approved for export.
- 1 consignment was rejected after failing to meet regulatory requirements.

#### **3.2.9.4. Strengthening Customs Capacity through RRA Collaboration**

In collaboration with the Rwanda Revenue Authority (RRA), Rwanda FDA trained customs officers stationed at border posts on inspection of regulated food consignments. The training also focused on the use of the newly integrated iRIMS platform for payment of services at the border, with support from finance staff. These sessions enhanced customs officers' technical capacity and efficiency in enforcement. However, challenges were observed, including limited warehousing facilities and difficulty in differentiating high-risk from low-risk food consignments.

### 3.2.10. Laboratory Testing Services

Rwanda FDA's Quality Control Laboratory ensures the quality and safety of regulated products including processed foods, human and veterinary medicines, cosmetics, biologicals, herbal medicines, and medical devices. The laboratory performs testing on samples from pre-market, post-shipment, and post-market surveillance, supporting evidence-based regulatory decisions and compliance with international standards (WHO GPPQCL, ISO/IEC 17025:2017).

#### 3.2.10.1. Laboratory Performance

At the Laboratory Services Department and FY 2024/2025; two indicators are considered to strengthen the testing capacity of the laboratory:

- i) The % of Rwanda FDA laboratory performance capacity increased, and
- ii) The number of parameters accredited by international accreditation bodies.

The details about the implementation of activities for each indicator are described below. Percentage (%) of Rwanda FDA Laboratory performance capacity increased. The target indicator of 66% was not successfully achieved in FY 2024/2025 as planned as some of the key activity to deliver to this output which was the purchase and installation of laboratory equipment to increase the laboratory testing capacity was not implemented:

With the main objective of strengthening the testing capacity of the Rwanda FDA- quality control laboratory a 5-years project was approved with a total budget of 10 billion Frw, effective date of its implementation was July 2020 to June 2025. Below is a summary of its implementation status as the project has ended by June 2025.

- *Annual budget spending: 18.2%;*
- *Cumulative spending: 37.7%;*
- *Lifetime execution: 100%;*
- *Physical progress: 65%.*

However, the laboratory procured and prepared specifications for the installation of new laboratory equipment, reagents, reference standards, and consumables. Capacity was further strengthened through staff training in analytical techniques, lot release of vaccines and biologicals, quality management systems, and ISO/IEC 17025 and ISO 9001 standards, alongside subscriptions to international pharmacopeias and official testing methods. These coordinated efforts collectively contributed to enhancing the Rwanda FDA laboratory's testing capability and readiness to meet regulatory standards.

### 3.2.10.2. Testing and release of test results

During FY 2024/2025, the Laboratory Services Department (LSD) received a total of 1,014 samples, comprising food products, human medicines, and medical devices. Of these, 935 samples were tested, while 79 samples remained in progress at the close of the fiscal year. No samples were subcontracted during this period.

From the tested samples, the Department issued a total of 857 Certificates of Analysis (CoAs). Among these, 609 samples passed, 238 failed, and 10 had no decision.

These results reflect the Authority's continued commitment to strengthening post-market surveillance, safeguarding public health, and ensuring that only quality and compliant products are available on the Rwandan market. The quarterly and unit-level breakdown of sample management and testing is presented in Table below

Unit / Division	Received Samples	Samples Tested	Samples in Progress	Untested Samples	Samples Subcontracted	Certificates Issued (CoAs)	CoAs – Passed	CoAs – Failed	Certificates – No Decision	Comments
Food Testing Unit – Registration & Information Control	208	197	11	0	0	197	140	52	5	High volume; minor in progress
Food Testing Unit – Import & Export Control	80	80	0	0	0	80	65	14	1	Mostly tested; minor failures
Food Safety Monitoring, Inspection & Licensing	498	466	32	0	0	466	308	158	0	<b>High failure rate</b> , key regulatory focus
PT Samples	8	6	2	0	0	4	0	0	4	Proficiency Testing pending evaluations
Devices & Instrumentation Testing Unit – Import & Export Control	29	27	2	0	0	27	23	4	0	Mostly passed, minor failures
Vaccines & Biologics Testing Division – Post Marketing Surveillance	1	1	0	0	0	1	1	0	0	Passed
Pesticides & Poisonous Chemicals Testing Unit	2	2	0	0	0	2	2	0	0	All passed
Drug Testing Division – Post Marketing Surveillance	188	156	32	32	0	80	70	10	0	Some samples untested due to duplication, <b>follow-up needed</b>
<b>Total</b>	<b>1,014</b>	<b>935</b>	<b>79</b>	<b>32</b>	<b>0</b>	<b>857</b>	<b>609</b>	<b>238</b>	<b>10</b>	<b>Reflects annual workload and trends; emphasizes need for regulatory enforcement</b>

Table 8: showing testing and release of test results



## Observations

- **High Testing Volume with Notable Failure Rates:** The Food Safety Monitoring, Inspection & Licensing stream handled the largest number of samples (498 received, 466 tested) and recorded a high failure rate (158 failed), highlighting persistent quality issues in food products and the need for intensified regulatory oversight.
- **Proficiency Testing and Follow-Up Requirements:** PT samples and some drug post-marketing surveillance samples remain in progress or untested (6 tested out of 8 PT samples; 32 untested drug samples), indicating the importance of completing proficiency evaluations and follow-up testing to support regulatory decision-making.
- **Overall Compliance and Risk Areas:** While most samples passed (609 out of 857 CoAs issued), the significant number of failed certificates (238) underscores ongoing compliance challenges across multiple units, emphasizing the need for strengthened enforcement, targeted inspections, and corrective actions.

### 3.2.10.3. Facility Maintenance and Environmental Monitoring

During the year, the Laboratory Services Department (LSD) ensured that laboratory facilities and environmental conditions are continuously monitored. All fixed assets were properly maintained, safeguarded, and secured, while cleanliness and security of the premises were consistently upheld. Preventive and curative maintenance was performed on specialized laboratory instruments, including 17 air conditioning units, ensuring optimal operating conditions. Additionally, calibration services were carried out for equipment measuring volume and temperature parameters, supporting the reliability and accuracy of laboratory testing processes.

### 3.2.10.4. Preparation for ISO/IEC 17025 Accreditation

Preparation for ISO/IEC 17025 accreditation was a key focus during the year. LSD staff received comprehensive training on ISO/IEC 17025:2017 and ISO9001:2015 standards, while internal audits were conducted to evaluate readiness. Staff also participated in international summer school sessions and hands-on practical training to reinforce competence in quality systems and analytical testing. Regular meetings with key partners, ensured alignment of laboratory procedures with accreditation requirements. These efforts enhanced the laboratory's capability to meet international standards and paved the way for formal accreditation in the near term.

## 3.3. Regulatory Ecosystem Strategy

### 3.3.1. Strategic Regulatory Partnerships and Collaborations

During FY 2024–2025, Rwanda FDA strengthened collaborations with national, regional, and international regulatory authorities to enhance regulatory efficiency, promote harmonization, and improve public health outcomes. Strategic partnerships focused on capacity building, knowledge exchange, and reliance-based regulatory frameworks, enabling faster and safer access to medicines,

vaccines, and other health products in Rwanda and the broader African region.

#### **3.3.1.1. Key Memoranda of Understanding (MoUs)**

During FY 2024/2025, Rwanda FDA formalized and advanced several MoUs to strengthen regulatory cooperation, harmonize practices, and enhance technical capacity at national, regional, and global levels.

#### **3.3.1.2. SAHPRA (South African Health Products Regulatory Authority).**

Rwanda FDA developed a draft implementation plan under the MoU with SAHPRA to strengthen collaboration on human and veterinary medicines, vaccines, medical devices, and in vitro diagnostics (IVDs). The Joint Technical Working Group (JTWG) facilitated discussions on registration requirements, clinical standards, inspectorate needs, and laboratory capacity development. The draft plan has been submitted and is currently under review.

#### **3.3.1.3. CEPI (Coalition for Epidemic Preparedness Innovations).**

The MoU with CEPI establishes a framework to support emergency vaccine regulatory activities, including recruitment of on-site vaccine experts and capacity strengthening in vaccine product review, inspection, and laboratory services. The Final version was completed and submitted for signature in Q4 FY 2024/2025 (June 2025).

#### **3.3.1.4. Algeria - ANPP (Agence Nationale des Produits Pharmaceutiques)**

Signed on June 3, 2025, this MoU promotes equality and mutual benefit, covering GMP audits, product registration, reliance-based approvals, and exchange of regulatory information and scientific knowledge.

#### **3.3.1.5. Egyptian Drug Authority (EDA).**

Signed on August 12, 2024, this MoU establishes a joint recognition framework for registered products, enabling reliance-based regulatory decisions aligned with WHO Maturity Level 3 standards.

#### **3.3.1.6. Other MoUs**

During FY 2024/2025, Rwanda FDA initiated several MoUs to strengthen regulatory cooperation and capacity building with regional and global partners

- Botswana (BOMRA) – A capacity-building workshop was hosted in January from 27<sup>th</sup> to 31<sup>st</sup>, 2025, culminating in the signing of an MoU. The agreement covers joint regulatory activities, expert exchange, capacity building, and support for WHO Maturity Level advancement.

- Benin (ABMed) – The final draft of the MoU was submitted on February 3, 2025, focusing on mutual recognition, information sharing, joint regulatory activities, and expert exchange. Signature is pending.
- Algeria, Kazakhstan, Poland and Somalia – Draft MoUs were initiated to facilitate regulatory information exchange, joint inspections, and capacity-strengthening initiatives. Signature dates are not yet finalized.
- HealthAI Global Regulatory Network – Draft collaboration framework was developed to support AI health solutions regulation and integration into a global regulatory network. Signature is pending.

### **3.3.2. Regulatory Compliance, Traceability, and Emergency Preparedness**

Rwanda FDA made notable progress in Regulatory Compliance, Traceability, and Emergency Preparedness during the reporting year. The Authority officially launched the Pharmaceutical Traceability Technical Working Group (TWG), aligning Rwanda with Global Standard 1 (GS1) and international best practices. Staff were trained on Traceability Implementation and Operational Procedures (TIOP) and Electronic Product Catalogue Information System 101 (EPCIS 101), building local capacity for effective implementation of traceability systems.

In addition, Rwanda FDA coordinated emergency use authorization (EUA) for Mpox vaccines through the AVAREF multi-country review process, ensuring timely access to critical vaccines during the public health emergency. A benchmarking mission to Turkey’s EPCIS-based traceability system provided valuable insights, guiding the development of a national digital traceability system to ensure supply chain integrity and strengthen regulatory oversight

#### **3.3.2.1. Pricing Policy and Industry Support**

Rwanda FDA advanced the implementation of the National Pharmaceutical Product Pricing and Cost Containment Policy. Key interventions included the introduction of regressive mark-up guidelines for high-cost medicines to improve affordability, the development of a digital pricing database, and capacity-building initiatives to ensure sustainable regulatory oversight. Public consultations and stakeholder engagement were conducted to enhance transparency, compliance, and stakeholder confidence. These efforts contribute directly to Rwanda’s universal health coverage goals by promoting equitable access to medicines.

#### **3.3.2.2. Industrial Support and Trade Facilitation**

Rwanda FDA also played a central role in Industrial Support and Trade Facilitation, actively participating in national and regional platforms such as Non-Tariff Barrier (NTB) monitoring committees, COMESA SPS meetings, and AfCFTA implementation committees. The Authority provided regulatory guidance to facilitate market access, harmonize standards, and revise regulatory service fees for greater transparency. Through these interventions, Rwanda FDA improved

regulatory efficiency, reduced non-tariff barriers, and supported the smooth flow of quality medicines and health products across regional and international markets

### 3.4. Quality Management System and Institutional Development

During FY 2024-2025, Rwanda FDA made substantial progress in strengthening regulatory systems and institutional capacity. WHO conducted a follow-up assessment on the implementation of Institutional Development Plans for marketing authorization and regulatory inspection functions, confirming satisfactory progress. Building on these efforts, Rwanda FDA officially attained WHO Maturity Level III, marking a significant milestone in regulatory excellence.

#### 3.4.1. Regulatory Documentation and Compliance

During the reporting year, Rwanda FDA made significant strides in strengthening its regulatory documentation and compliance framework under the Quality Management System (QMS). Achievements spanned across multiple regulatory fields, reflecting a comprehensive approach to improving regulatory oversight and service delivery.

In the area of **Human Medicines**, regulatory documentation was enhanced through the revision and updating of key guidelines, Standard Operating Procedures (SOPs), and templates. These updates supported product assessment, marketing authorization, registration processes, and ongoing compliance monitoring, ensuring that regulatory practices are aligned with international standards and best practices.

For **Veterinary Medicines**, the Authority revised and standardized essential regulatory documents, strengthening oversight of veterinary products and ensuring adherence to established quality standards. This effort improved efficiency in dossier assessment, regulatory decision-making, and compliance enforcement for veterinary products.

In **Food Products**, regulatory documentation was strengthened through the development and revision of guidelines and SOPs. These documents aimed to enhance the registration process, streamline assessment of food supplements, and promote compliance with food safety regulations.

**Laboratory Services** also saw substantial improvements, with the development/review and implementation of 88 Standard Testing Procedures (STPs). These procedures improved the consistency, reliability, and standardization of laboratory operations, supporting evidence-based regulatory decisions across all product categories.

Across the institution, a total of 12 guidelines and 15 SOPs were revised to align with evolving regulatory needs, while 42 templates for licenses, certificates, and cross-cutting forms were harmonized to promote consistency and efficiency in service delivery. Additionally, Rwanda FDA developed new regulatory and organizational documents, notably the Environmental, Occupational Health, and Safety guidelines and a draft Talent Acquisition and Retention Strategy. These initiatives further reinforced regulatory compliance and institutional capacity, underpinning the Authority's commitment to quality, efficiency, and continuous improvement.

### **3.4.2. ISO Certification and Internal Audits**

Preparations for ISO certification progressed, focusing on ISO 9001:2015, ISO 27001:2013, and ISO/IEC 17025:2017 standards. Internal quality audits covered all 27 processes, including import/export controls, clinical trials oversight, post-marketing surveillance, pharmacovigilance, marketing authorization, ICT and HR management, and inspection of regulated premises. Non-conformities were identified, communicated, and corrective actions implemented. Additionally, all staff were trained on principles of QMS based on ISO9001:2015 and risk management. The deployment of the Smart Admin platform enhanced QMS documentation and workflow management.

### **3.4.3. Competency Framework and Talent Development**

The competency framework and talent management systems were strengthened to support institutional growth, with staff numbers increasing from 194 to 312. Analysis revealed 69% meta and functional skills and 31% role-specific competencies. A revised competency framework and a draft Talent Acquisition and Retention Strategy were developed to ensure a skilled, motivated, and sustainable workforce.

### **3.4.4. Environmental, Occupational Health and Safety (EOHS) Compliance**

EHS compliance was reinforced through the development of guidelines, SOPs, and inspection checklists. Pilot inspections at headquarters identified gaps, and staff awareness sessions were planned to ensure adherence to EHS standards, promoting a safe and compliant work environment.

### **3.4.5. Customer Complaints Management**

Customer complaints were actively monitored and addressed, with 21 complaints resolved in Q2 and follow-ups conducted on outstanding cases. This improved responsiveness and enhanced stakeholder satisfaction, reflecting Rwanda FDA's commitment to client-centric service delivery.

## **4. BUDGET EXECUTION**

By the end of FY 2024-2025, 83% of the total budget of RWF 9,887,381,590 was executed. Financial support from development partners, totaling RWF 207,710,756, recorded an execution rate of 52%, reflecting partial utilization of allocated donor funds during the fiscal year

## 5. INSTITUTIONAL CHALLENGES, AND WAY FORWARD STRATEGIES

### 5.1. Challenges.

As Rwanda FDA continues to uphold its mandate to protect public health, key operational challenges have been identified that require strategic action. These include inefficiencies in digital systems, low compliance in pharmaceutical establishments, limited laboratory capacity, and delays in the product registration process. Addressing these issues is essential to improving regulatory effectiveness and public trust.

- The iRIMS system is not yet fully functional.
- Compliance levels among pharmaceutical establishments remain low, with expired licenses may be posing potential challenges for enforcement and risks to public health.
- Limited progress has been made in implementing the project aimed at strengthening Rwanda FDA's testing capacity.
- Several dossiers remain pending for extended periods due to delays either in receiving requested additional information or responses from applicants.

### 5.2. Way Forward Strategies

#### 5.2.1. Accelerate iRIMS Upgrade and Full Implementation

To enhance the overall efficiency of regulatory operations, it is recommended to expedite the upgrade and full implementation of the iRIMS. A fully operational system will significantly improve the processing of applications and strengthen communication between Rwanda FDA and its stakeholders.

#### 5.2.2. Strengthen Compliance Monitoring and Enforcement

Low compliance among pharmaceutical establishments, particularly concerning expired licenses, continues to pose a significant regulatory challenge. To address this, Rwanda FDA will:

- Increase the frequency and coverage of routine inspections to ensure comprehensive oversight;
- Minimize delays in providing feedback to clients in order to enhance responsiveness and compliance;
- Develop and implement a digital tracking system for timely identification of non-compliance and expired licenses.

These measures aim to strengthen regulatory enforcement and promote adherence to licensing requirements across the sector.

### 5.2.3. Assess and Enhance Laboratory Testing Capacity

A comprehensive assessment of Rwanda FDA's laboratory testing capacity is essential to ensure the Authority is fully prepared to meet regulatory demands. The assessment should identify existing capacity gaps and recommend:

- Mitigation strategies to address shortcomings;
- Required resources and infrastructure to support operations;
- Investment priorities aligned with Rwanda FDA's long-term regulatory objectives.

This approach will guide strategic planning and strengthen the Authority's ability to deliver quality regulatory services.

### 5.2.4. Revisit and Enforce Registration Guidelines

The current registration process requires improvement to enhance efficiency and clarity. It is recommended that Rwanda FDA:

- Review existing registration guidelines and ensure their consistent implementation;
- Establish clear timelines and deadlines for dossier evaluation and finalization;
- Introduce a policy to archive or close dossiers that remain inactive beyond the stipulated response period, with applicants advised to initiate a new application, if necessary.

These measures will contribute to improved service delivery, reduce backlog, and enhance regulatory accountability.

## 6. CONCLUSION

During the fiscal year 2024–2025, Rwanda FDA demonstrated a sustained commitment to strengthening regulatory systems, enhancing institutional capacity, and safeguarding public health. The Authority made significant progress in implementing its strategic and operational plans, ensuring that regulatory functions across human and veterinary medicines, vaccines, medical devices, and food products were effectively executed. Key achievements included the attainment of WHO Maturity Level 3, marking a major milestone in regulatory maturity, and substantial enhancements in the Quality Management System (QMS), including internal audits, staff training, ISO preparedness, and the development of institutional talent acquisition and retention strategies.

The year was characterized by strong engagement in regulatory partnerships and collaborations at both regional and international levels. Rwanda FDA successfully formalized several Memoranda of Understanding with regulatory authorities, including SAHPRA, CEPI, ANPP (Algeria), EDA (Egypt), BOMRA (Botswana), and ABMed (Benin), among others. These partnerships facilitated joint technical working activities, regulatory reliance initiatives, capacity building, and harmonization of regulatory practices, thereby reinforcing Rwanda FDA's leadership in regional regulatory cooperation.

Additionally, efforts to implement the National Pharmaceutical Pricing and Cost Containment Policy, together with initiatives to strengthen traceability and supply chain oversight, contributed to improving access to affordable, safe, and quality medical products.

The Authority's laboratory and quality systems capacity was significantly enhanced through preventive and corrective maintenance, calibration of instruments, environmental monitoring, and the preparation for ISO/IEC 17025 accreditation. Staff skills were strengthened through a range of training programs, study visits, workshops, and knowledge-sharing sessions, resulting in increased operational efficiency, harmonized procedures, and improved service delivery across regulatory functions.

Financially, Rwanda FDA maintained disciplined budget execution, utilizing 83% of its total budget of RWF 9,887,381,590, while development partner contributions of RWF 207,710,756 were partially executed at a rate of **52%**, reflecting careful alignment of resources to priority activities.

Looking forward, Rwanda FDA is well-positioned to consolidate its achievements, continue capacity-building initiatives, expand regulatory reliance mechanisms, and drive digital transformation across its functions. The Authority remains committed to delivering high-quality, timely, and transparent regulatory services, further strengthening public trust, regional collaboration, and the safety and efficacy of medicines, vaccines, and other regulated products in Rwanda and the broader African region.