



RWANDA FOOD AND DRUGS AUTHORITY ANNUALREPORT FY 2025-2026

September, 2026

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LIST OF ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	Full Meaning
ACES	Africa Centre of Excellence for Sustainable Cooling and Cold Chain
ADR	Adverse Drug Reaction
AEFI	Adverse Events Following Immunization
AESI	Adverse Events of Special Interest
AFYAWAVE	AFYAWAVE Clinical Trial
AI	Artificial Intelligence
AKIISA	African Knowledge Institute for Innovation and Scientific Advancement
BAG-CPAP	BAG-CPAP Clinical Trial
BoD	Board of Directors
CAPA	Corrective and Preventive Actions
CB Link	CB Link
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CHCR	Cosmetics and Household Chemicals Registration
CHW	Community Health Worker
CoA / CoAs	Certificate(s) of Analysis
CoK	City of Kigali
CFO	Chief Finance Officer
DG	Director General
DDG	Deputy Director General
EAC	East African Community
EAC-MRP	East African Community – Mutual Recognition Procedure
EOHS	Environmental, Occupational Health and Safety
FDA	Food and Drug Administration
FSMIL	Food Safety Monitoring, Inspection and Licensing
FY	Financial Year
GCP	Good Clinical Practice
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practice(s)
GSDP	Good Storage and Distribution Practices
HODs	Heads of Departments
HMDR	Human Medicines and Devices Registration
HPLC	High-Performance Liquid Chromatography
HTN	HTN Clinical Trial
ICSRs	Individual Case Safety Reports
IREMBO	IREMBO
iRIMS	Integrated Regulatory Information Management System
ISoP	International Society of Pharmacovigilance
ISO	International Organization for Standardization
ISO 9001:2015	ISO Standard for Quality Management Systems
ISO/IEC 17025:2017	International Standard for Competence of Testing and Calibration Laboratories
IT	Information Technology
IVDs	In Vitro Diagnostic Devices
KALUMA	KALUMA Clinical Trial
LSD	Laboratory Services Department
MINALOC	Ministry of Local Government
MINICOM	Ministry of Trade and Industry
ML3	Maturity Level 3

ML4	Maturity Level 4
MMVCT	MMVCT Clinical Trial
MoH	Ministry of Health
MoU / MoUs	Memorandum/Memoranda of Understanding
NCD	Non-Communicable Disease
NIFDC	National Institutes for Food and Drug Control
NISS	National Intelligence and Security Service
NPC	National Product Catalogue
OAG	Office of the Auditor General
OPTIPRO	OPTIPRO Clinical Trial
PANGEA	PANGEA Operation
PBRER	Periodic Benefit-Risk Evaluation Report
PENGUIN	PENGUIN Clinical Trial
PMS	Post-Market Surveillance
PoEs	Points of Entry
PSUR	Periodic Safety Update Report
PT	Proficiency Testing
PTB	Physikalisch-Technische Bundesanstalt
Q1	Quarter 1
Q2	Quarter 2
Q3	Quarter 3
Q4	Quarter 4
QMS	Quality Management System
QR	Quick Response
RAB	Rwanda Agriculture and Animal Resources Development Board
RDB	Rwanda Development Board
REMA	Rwanda Environment Management Authority
RES	Regulatory Ecosystem Strategy
RICA	Rwanda Inspectorate, Competition and Consumer Protection Authority
RNP	Rwanda National Police
RISA	Rwanda Information Society Authority
RIB	Rwanda Investigation Bureau
RMS	Rwanda Medical Supply Ltd
RSB	Rwanda Standards Board
RWF	Rwandan Francs
SEWI	Single Electronic Window
SKCP	Smart Kigali Command Post
SLA / SLAs	Service Level Agreement(s)
SOP / SOPs	Standard Operating Procedure(s)
STEP-Mag	STEP-Mag Clinical Trial
TACT	TACT Clinical Trial
UMC	Uppsala Monitoring Centre
UK	United Kingdom
UMUCYO	UMUCYO Government Procurement System
UR-STH	University of Rwanda – School of Traditional Health
USALAMA XI	USALAMA XI Operation
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VigiFlow	VigiFlow
VigiMobile	Vaccine and Medicine Safety Mobile Reporting System
VMDR	Veterinary Medicines and Devices Registration
WHO	World Health Organization

FOREWORD

On behalf of the Rwanda Food and Drugs Authority (Rwanda FDA), I am pleased to present the Annual Report for the Fiscal Year 2025/2026. This report reflects the Authority's continued commitment to fulfilling its mandate of protecting public health through effective regulation of medicines, vaccines, medical devices, food, cosmetics, household chemicals and other regulated products. It also provides an account of the collective efforts undertaken during the year to strengthen Rwanda's regulatory system and respond to the evolving needs of the country.

The reporting year was marked by continued efforts to strengthen the effectiveness, quality and responsiveness of regulatory services. Rwanda FDA remained focused on improving regulatory processes, strengthening institutional systems, developing staff competencies and enhancing collaboration with stakeholders. The Authority also continued to build on its regulatory maturity and quality management foundations, while embracing digital transformation and other approaches aimed at improving the efficiency and reliability of its operations.

The progress made during the year was made possible by the commitment of Rwanda FDA staff and the continued engagement of stakeholders across the health and regulatory ecosystem. Our collaboration with the Government of Rwanda, the Board of Directors, development and technical partners, regulated industries, health professionals and other stakeholders remained essential to advancing the Authority's work. The support provided through national and international partnerships also contributed to strengthening institutional capacity and promoting continuous improvement in regulatory functions.

The year was not without challenges. The changing regulatory environment, increasing demands on regulatory services, system limitations and the need for specialised technical capacity continued to require adaptability and sustained institutional effort. Rwanda FDA remained committed to addressing these challenges through continuous improvement, stronger coordination, capacity development and responsible use of available resources.

I take this opportunity to express my sincere appreciation to the Government of Rwanda for its continued support and guidance, and to the Rwanda FDA Board of Directors for its oversight and strategic direction. I am equally grateful to our national and international partners for their valuable contribution to the Authority's mandate. Most importantly, I commend the management and staff of Rwanda FDA for their dedication, professionalism and resilience throughout the reporting period.

As we enter the next phase of our institutional journey, Rwanda FDA remains committed to strengthening a credible, effective and responsive regulatory system that supports public health and contributes to Rwanda's development priorities. We will continue to work closely with our stakeholders and partners to consolidate the progress made, address remaining gaps and uphold the highest standards of regulatory practice.

Sincerely,

George NTAGANDA
Chief Budget Manager
CFO/PLA/REP/A/FDA/01/2026



Digitally signed by
Rwanda FDA(Chief
Finance Officer)
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EXECUTIVE SUMMARY

Rwanda FDA, established under Law N°003/2018 of 09/02/2018, continued during FY 2025/2026 to fulfil its mandate of regulating health products and related activities to protect public health and ensure the quality, safety and efficacy of regulated products in Rwanda. The year was characterised by sustained regulatory implementation across product registration and authorization, establishment licensing and inspection, post-market surveillance, pharmacovigilance, import and export control, laboratory testing, clinical trial oversight, quality management, digital transformation and institutional capacity strengthening. The Authority maintained its WHO Global Benchmarking Tool Maturity Level 3 and continued preparations towards higher regulatory maturity and international quality standards.

Regulatory performance remained substantial across the major product categories. The Authority registered 238 human medicinal products, 75 veterinary medicinal products, 73 cosmetics and household chemical products, and 634 food products during the financial year. In establishment regulation, 1,031 pharmaceutical establishment licences were approved and issued, supported by 1,975 pharmaceutical premises-related regulatory inspection and oversight activities. Food regulatory oversight included 717 licensing inspections and 24 GMP inspections, while broader follow-up, enforcement, re-inspection, risk-based and disposal-related inspections strengthened compliance monitoring. Market surveillance and safety oversight were also maintained through 1,200 individual case safety reports, 200 post-market surveillance samples, and 30 reported product recall actions or batches, demonstrating continued use of regulatory interventions to address safety, quality and compliance concerns.

The Authority also maintained regulatory control over the movement of regulated products. A total of 10,787 import licences were approved and issued, with 6,173 consignments inspected at points of entry and 1,470 consignments inspected at importers' or clients' premises. For food products, 5,124 import licences were approved and issued, complemented by inspection of 3,334 consignments at points of entry and 4,778 consignments released under seal for further inspection. Laboratory Services supported regulatory decision-making through the testing and reporting of 1,432 samples during the year. Clinical trial oversight also continued, including the review of new trial applications, amendments, renewals and safety reports.

Institutional strengthening remained an important feature of FY 2025/2026. The Authority advanced quality management and regulatory system strengthening through continued focus on WHO GBT Maturity Level 3, preparedness for Maturity Level 4, ISO 9001:2015 certification and ISO/IEC 17025:2017 accreditation. Staff and stakeholder capacity was strengthened through technical training and professional development across regulatory assessment, pharmacovigilance, food safety, laboratory testing, quality management and other specialized areas. Digital transformation also progressed through the continued use and development of iRIMS, IREMBO, Smart Admin and the electronic Quality Management System, supporting improved regulatory processing, information management, traceability and service delivery.

Despite these achievements, the Authority continued to experience challenges related to digital system functionality, specialized staffing, technical capacity and resource requirements. In particular, limitations in iRIMS affected some aspects of regulatory processing, document management and client-portal functionality, while staffing gaps in specialized functions increased

operational pressure. Overall, FY 2025/2026 demonstrates continued implementation of Rwanda FDA's regulatory mandate and progressive strengthening of the systems, competencies and regulatory controls required to protect public health and ensure effective oversight of regulated products and activities in Rwanda.

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 recognized 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 2025-2026

This section presents the achievements realized by Rwanda FDA during the 2025–2026 fiscal year in implementing its regulatory mandate. The results are organized according to the Authority's core functions and highlight progress made in delivering regulatory services, strengthening compliance, and protecting public health

3.1. Registration of regulated products

3.1.1. Human Medicines and Devices Registration

During the FY 2025/2026, the Human Medicines and Devices Registration function continued to implement its mandate of assessing and registering human medicinal products in accordance with established regulatory requirements. During the year, the function received 518 new applications and managed a total of 695 applications across the four quarters, of which 625 applications were assessed and processed. The function registered 238 human medicinal products during the financial year, representing an overall registration rate of 34% based on the total applications managed during the reporting period. Quarterly registration rates were 41.6% in Q1, 36% in Q2, 34% in Q3, and

27% in Q4. Overall, the performance demonstrates the continued efforts of the Human Medicines Assessment and Registration function to process applications and facilitate regulatory decisions for human medicinal products throughout the financial year

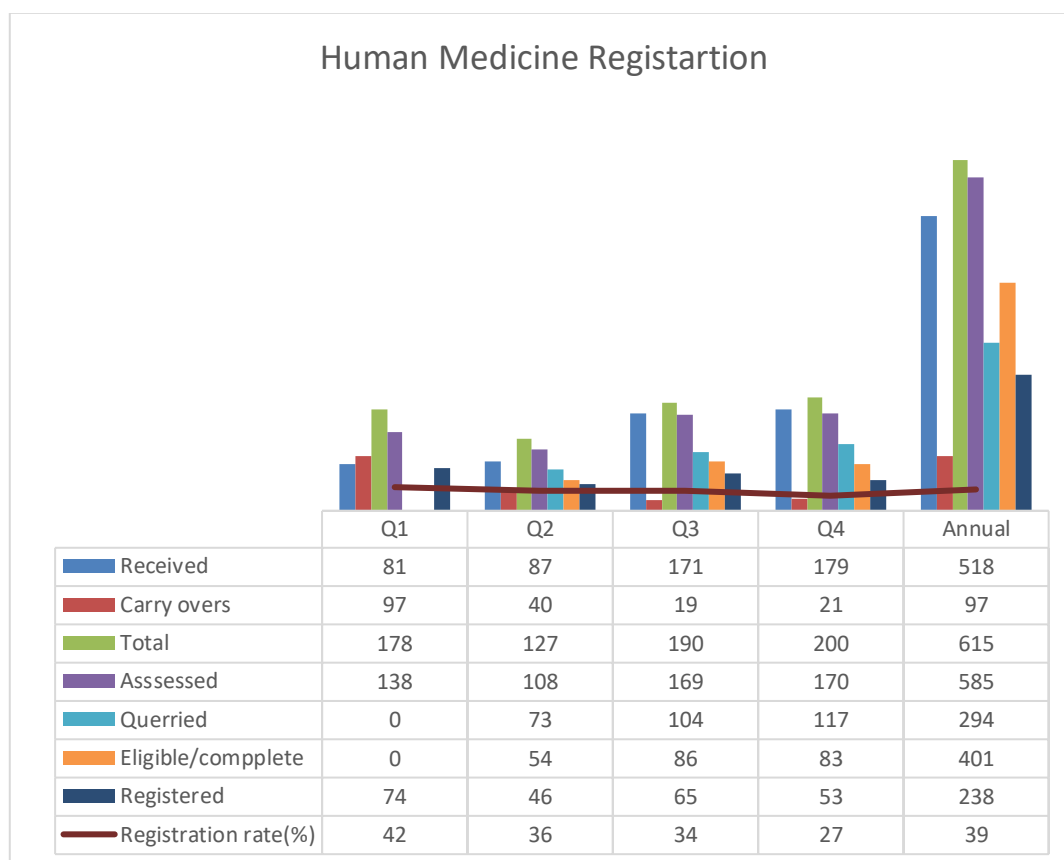


Figure 1: Human Medicines and Devices Registration details FY 2025-2026

a. National and International Obligations for Controlled Substances

During FY 2025/2026, Rwanda FDA fulfilled its national and international obligations for the control of narcotic drugs, psychotropic substances and precursors through the compilation and submission of required annual statistical and estimation reports. The reports covered production, manufacture, consumption, stocks, seizures, medical and scientific requirements, and substances used in the illicit manufacture of controlled drugs. The Authority also submitted estimates of national requirements for narcotic drugs, synthetic drug manufacture and other substances subject to international control.

The implementation of these obligations strengthened national monitoring and control of controlled substances and supported Rwanda's compliance with applicable international conventions and reporting requirements.

b. Regional Regulatory Collaboration

Rwanda FDA maintained active participation in regional regulatory harmonization initiatives, particularly through the East African Community (EAC). The Authority participated in joint dossier assessment activities, including assessment of seven dossiers during Q3, followed by virtual and plenary discussions for collective review and regulatory decision-making.

Participation in EAC joint assessments provided opportunities to strengthen regulatory

collaboration, promote harmonization of regulatory practices, and leverage shared technical expertise among participating regulatory authorities.

3.1.2. Veterinary Medicines Assessment and Registration Performance

During FY 2025/2026, the Veterinary Medicines Assessment and Registration function continued to implement its mandate of assessing and registering veterinary medicinal products in accordance with established regulatory requirements. During the year, the function received 26 new applications and assessed and processed 81 applications across the four quarters. Based on the assessment outcomes, 81 applications were eligible for registration, resulting in the registration of 75 veterinary medicinal products and an overall registration rate of 88%. Quarterly performance recorded registration rates of 0% in Q1, 61% in Q2, 47% in Q3, and 50% in Q4, reflecting variations in the number and status of applications processed during each quarter. Overall, the function maintained continuous regulatory assessment and registration activities throughout the financial year, contributing to the effective implementation of the Rwanda FDA mandate for the regulation of veterinary medicinal products

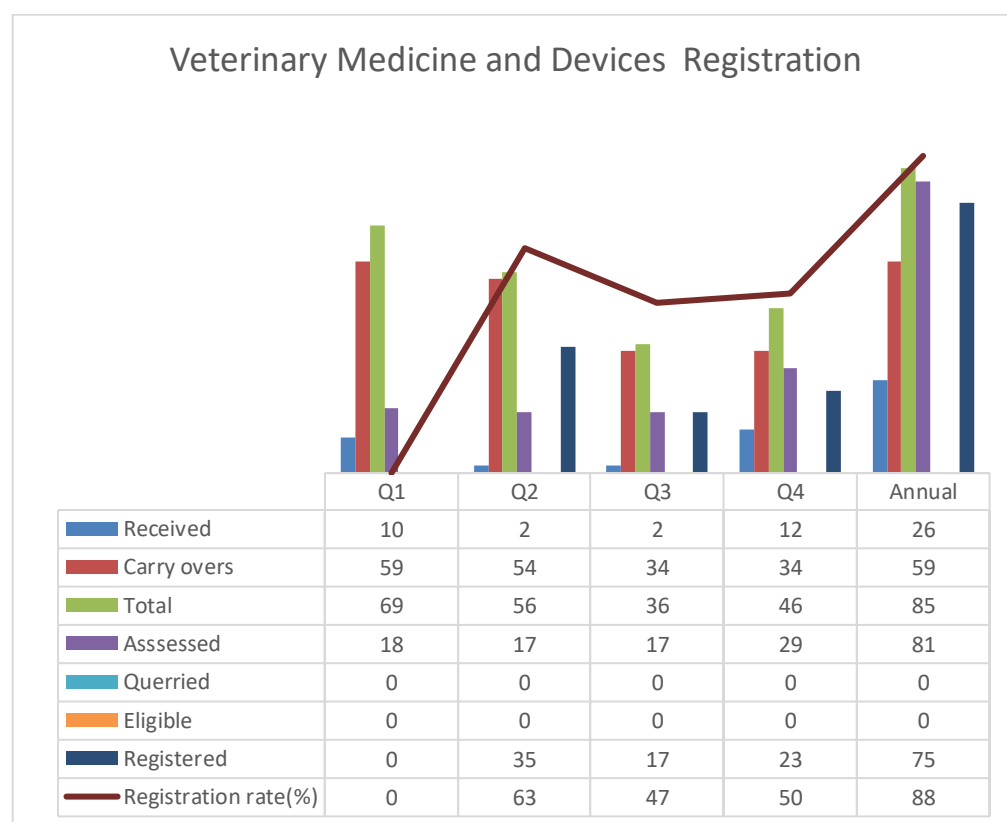


Figure 2: Veterinary Medicines and Devices Registration Details FY 2025-2026

a. Regional and International Regulatory Harmonization and Cooperation

During FY 2025/2026, the Authority strengthened regional and international regulatory cooperation through participation in EAC harmonization initiatives and international technical forums on veterinary medicines regulation. The Authority contributed to EAC-MRP technical working groups and regional meetings addressing product registration, regulatory reliance, GMP

inspection, vaccines and veterinary ectoparasiticides, including the review, finalization and validation of the Harmonized EAC Veterinary Medicines Regulatory Reliance Guidelines.

At the international level, the Authority participated in the 18th VICH Forum Meeting and specialized pharmacovigilance training with the UK Veterinary Medicines Directorate, strengthening technical knowledge and exposure to international regulatory practices.

Overall, these engagements strengthened the Authority's contribution to regional regulatory harmonization, technical capacity and alignment with regional and international veterinary medicines regulatory practices.

3.1.3. Cosmetics and Household Chemicals

During FY 2025/2026, the Cosmetics and Household Chemicals Registration function continued to implement its mandate of assessing and registering cosmetics and household chemical products in accordance with established regulatory requirements. During the year, the function received 136 new applications and assessed and processed 305 applications across the four quarters. A total of 73 products were registered during the financial year, representing an overall registration rate of 61% based on the total applications managed during the reporting period. Quarterly registration performance varied, with registration rates of 24% in Q1, 72.4% in Q2, 54.1% in Q3, and 27.3% in Q4. The variation in quarterly performance reflects differences in the volume and status of applications handled during each quarter. Overall, the function sustained regulatory assessment and registration activities throughout the financial year, contributing to the effective regulation and authorization of cosmetics and household chemical products for the Rwandan market.

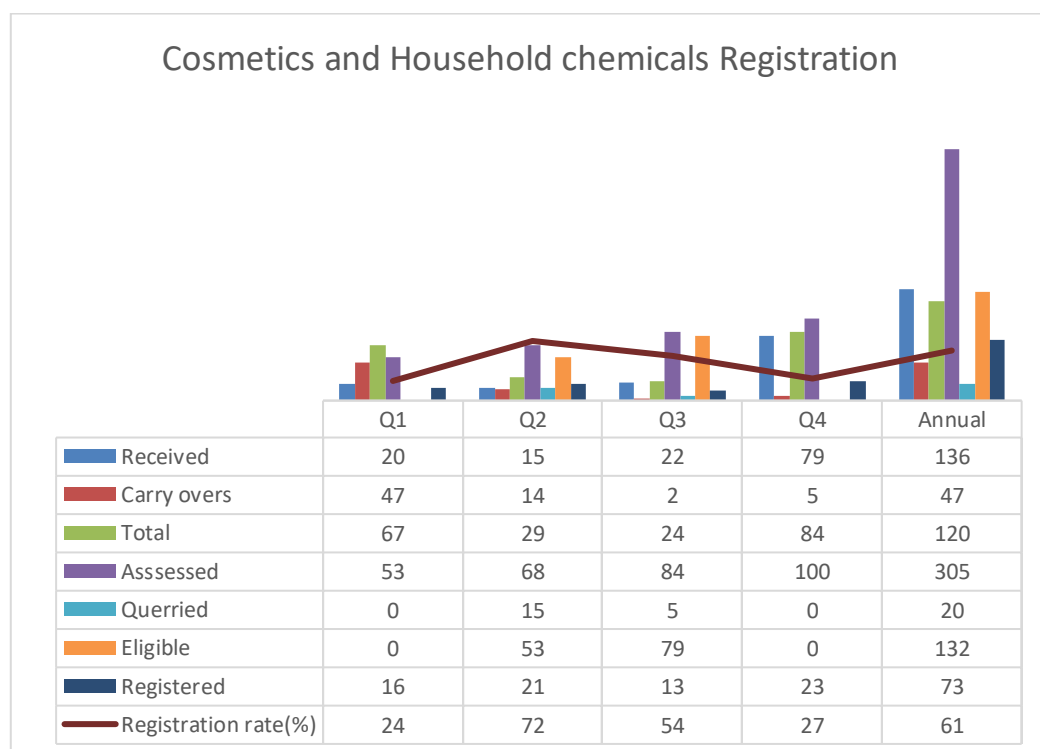


Figure 3: Cosmetics and Household Chemicals Registration Details FY 2025-2026

a. Stakeholder Awareness and Regulatory Compliance

Stakeholder awareness and engagement remained an important component of CHCR regulatory

activities during the financial year. The Division conducted awareness and training activities aimed at improving stakeholders' understanding of registration requirements, promoting compliance, and encouraging the registration of cosmetics and household chemical products before they are placed on the market.

During Q1, awareness campaigns and training for local stakeholders were conducted in Bugesera, Ngoma and Kirehe Districts in Eastern Province. The engagements focused on cosmetics and household chemicals regulatory requirements, registration procedures, and compliance with applicable regulatory documents.

In Q3, the Division conducted further awareness and training activities in Nyabihu, Ngororero and Rutsiro Districts in Western Province. The engagements emphasized the importance of product registration, the potential acute and chronic adverse effects associated with substandard cosmetics and household chemicals, and the contribution of other Rwanda FDA regulatory functions, including inspection and licensing, import and export control, and GMP, to ensuring product quality, safety and efficacy.

The Division continued this engagement in Q4 through an awareness and training activity conducted in Rwamagana District. The activity reinforced knowledge of registration requirements, regulatory procedures, product safety, and the roles of other relevant regulatory functions. Stakeholders demonstrated improved understanding of the regulatory requirements and expressed willingness to initiate or strengthen registration of their products. Overall, the stakeholder engagements conducted during the year contributed to strengthening awareness of regulatory requirements and promoting compliance among cosmetics and household chemicals stakeholders.

3.1.4. Food Products registration

During FY 2025/2026, the Food Products Registration function continued to implement its regulatory mandate of assessing and registering food products in accordance with established regulatory requirements. During the year, the function received 529 new applications and managed a total of 762 applications, of which 1,341 applications were assessed and processed across the four quarters. A total of 634 food products were registered, representing an overall registration rate of 57.3%. Quarterly performance showed a positive improvement toward the end of the financial year, with registration rates of 32.4% in Q1, 47.6% in Q2, 41.7% in Q3, and 91.8% in Q4. The strong performance recorded in Q4 contributed significantly to the overall annual results and reflects continued efforts by the Food Products Registration function to advance applications through the regulatory assessment and registration process.

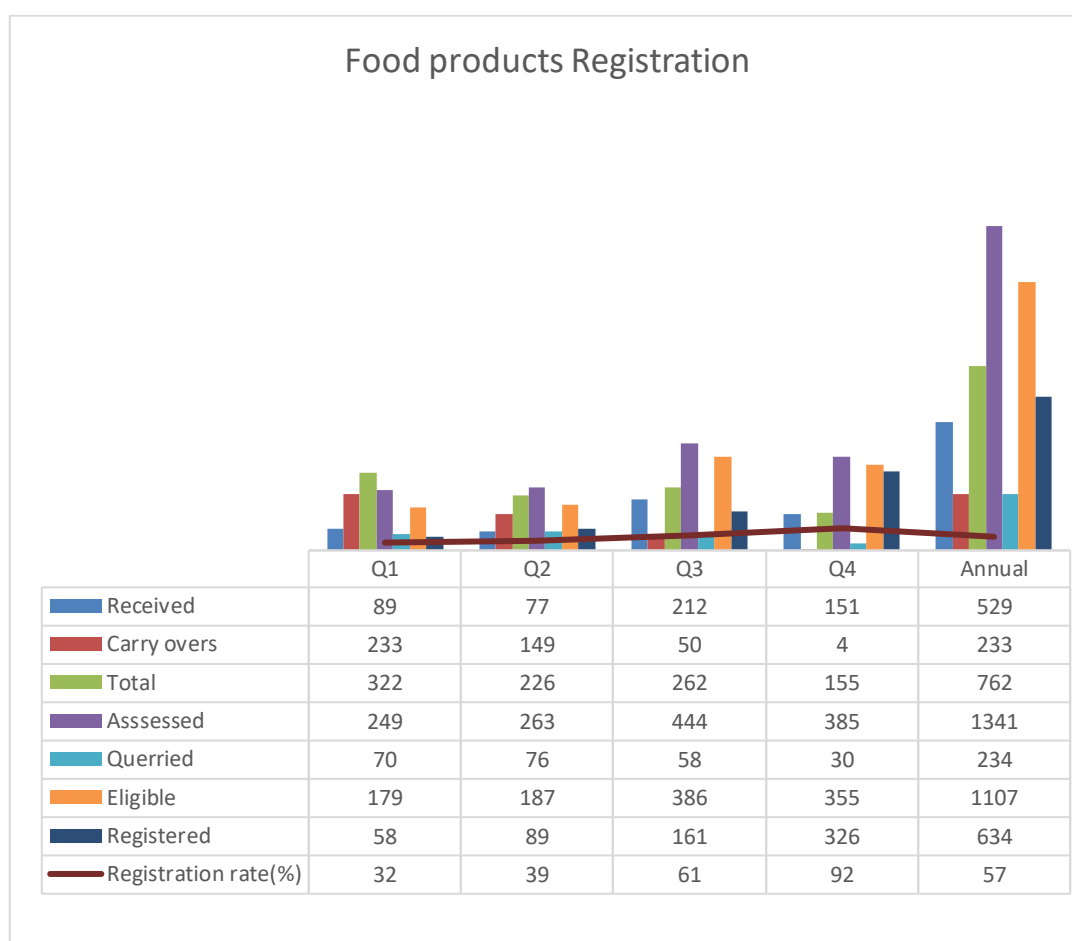


Figure 4: Food Products Registration Details FY 2025-2026

a. Information Control Related Applications

During FY 2025/2026, the Authority received 32 applications for authorization to promote and advertise food products. Of these, 20 applications were approved, 5 required revision and resubmission, 3 required additional information, and 4 were rejected. The applications were assessed against applicable regulatory requirements governing the promotion and advertisement of food products.

The processing of these applications strengthened regulatory oversight of food-related promotional and advertising information and supported the dissemination of compliant and accurate information to consumers.

b. Inspections on Food Promotion and Advertisement

During FY 2025/2026, the Authority conducted inspections and market-surveillance activities to assess compliance with requirements governing the promotion and advertisement of food products. A total of 69 food establishments and 2 radio stations were inspected during the year. The inspections covered Gicumbi, Gakenke, Rulindo, Musanze, Burera, Kigali City, Kayanza, Rubavu, Kamonyi, Muhanga, Ruhango, Nyanza and Huye Districts.

The inspections increasingly focused on food supplements and included 12 food supplement shops and pharmacies in Q4, in addition to food establishments and other operators covered during the year. The activities assessed compliance with registration and advertising requirements and identified unauthorized, misleading or unsupported promotional practices. The inspections and

market-surveillance activities strengthened oversight of food promotion and advertisement and supported improved compliance and responsible marketing practices among food business operators.

c. Market Survey on Food Supplements

During FY 2025/2026, the Authority conducted a market survey on food supplements in 39 food supplement shops across Kicukiro, Gasabo, Nyarugenge, Kayanza, Musanze and Rubavu Districts. The survey assessed the registration status and availability of food supplements on the market and generated information to support product traceability, compliance monitoring and future regulatory and enforcement actions.

The survey also assessed compliance challenges and provided an opportunity to raise awareness among operators on requirements governing food promotion, advertisement and marketing. Operators generally demonstrated willingness to comply with the applicable regulatory requirements and to communicate the requirements to their suppliers. The survey strengthened market intelligence on food supplements and supported improved regulatory oversight and consumer protection.

d. Enforcement of Unauthorized Promotion and Advertisement

During FY 2025/2026, the Authority strengthened enforcement against unauthorized promotion and advertisement of food products. A total of 14 warning letters and one administrative sanction letter were issued to companies found to have disseminated non-approved advertisements through different channels.

The enforcement actions required non-compliant operators to take corrective measures and reinforced compliance with applicable requirements governing the promotion and advertisement of food products. They complemented inspection, market-surveillance and stakeholder awareness activities aimed at preventing misleading and unauthorized information from reaching consumers.

e. Information Management and Reporting

During FY 2025/2026, the Authority maintained reporting templates and updated registers to capture and consolidate information on promotional authorization applications, inspections, market surveillance and enforcement activities. However, reliance on manual data management continued to affect the efficiency and accuracy of information consolidation and reporting.

Further digitization and strengthening of information management systems will be important to improve the accuracy, timeliness and reliability of regulatory information and support more effective monitoring of compliance trends in food promotion and advertisement.

3.2. Facility Inspections and Licensing

3.2.1. Pharmaceutical Establishment Licensing

During FY 2025/2026, Rwanda FDA continued to strengthen pharmaceutical regulatory oversight through licensing, inspections, compliance and enforcement, Good Storage and Distribution Practices (GSDP), Good Manufacturing Practices (GMP), safe disposal and Good Clinical Practice (GCP) regulatory activities. The performance of these regulatory functions is presented in the sections below.

a. Applications Received and Pharmaceutical Establishment Inspections

During FY 2025/2026, the Authority received 1,182 applications for pharmaceutical establishment licensing, covering new licenses, renewals and variations. The applications were processed through the established regulatory procedures, including premises inspections and compliance verification. A total of 1,975 pharmaceutical premises-related regulatory inspection and oversight activities were conducted during the financial year. These comprised 831 premises licensing and compliance inspections, 102 GSDP inspections, 108 safe-disposal supervision activities and 934 enforcement inspections. The inspection and oversight workload comprised 814 activities in Q1, 382 in Q2, 491 in Q3 and 288 in Q4.

The proportion of pharmaceutical establishments operating with valid licenses increased from 72.7% in Q1 to 78.8% in Q2 and 90% in Q4, reflecting the continued regulatory monitoring of pharmaceutical establishments. In Q4, all 50 premises licensing applications under the monitoring exercise were inspected. Of these, 46 were completed within 30 working days, while four were delayed by one to three days. The maximum reported delay decreased from 330 days to three days following implementation of a monitoring tool for tracking applications through the regulatory process.

b. Licenses Approved and Issued

Following the processing of pharmaceutical establishment licensing applications, including the required regulatory inspections and compliance verification, the Authority approved and issued 1,031 licenses during FY 2025/2026 out of the 1,182 applications received, representing an overall performance rate of 87.2%. The quarterly performance was as follows:

Quarter	Applications Received	Regulatory Inspections and Oversight Activities	Licences Approved/Issued	Queried/Delayed	Licensing Performance
Q1	349	814	301	48	86.2%
Q2	328	382	295	33	89.9%
Q3	213	491	186	27	87.3%
Q4	292	288	249	43	85.2%
Annual Total	1,182	1,975	1,031	151	87.2%

Table 1: Table showing applications and License approvals for pharmaceutical establishments FY 2025-2026

The Authority maintained a licensing performance rate above 85% in all four quarters, with the highest quarterly performance recorded in Q2 at 89.9%. Of the 1,182 applications received, 1,031 licenses were approved/issued, while 151 applications were queried or delayed during the reporting period.

Overall, the Authority processed pharmaceutical establishment licensing applications alongside premises inspections, compliance monitoring and other regulatory oversight activities. The annual regulatory workload included 1,975 pharmaceutical premises-related inspection and oversight activities, while 1,031 pharmaceutical establishment licenses were approved/issued during FY 2025/2026.

c. *Pharmaceutical Compliance, Enforcement and Safe Disposal*

The Authority's inspection programme identified and addressed non-compliance across pharmaceutical establishments through routine inspections, enforcement activities, regulatory directives and follow-up inspections.

A total of 934 enforcement inspections were conducted during FY 2025/2026. The principal areas of non-compliance identified included poor storage conditions, inappropriate handling of controlled medicines, expired or recalled pharmaceutical products, dispensing of prescription-only medicines without prescriptions, operation without authorized pharmacists, operation without valid premises licenses and cold-chain deficiencies. Q4 enforcement findings included 28 findings related to poor storage conditions and 21 findings related to controlled-medicine handling among reported retail pharmacy findings. Other observations included expired or recalled medicines, dispensing of prescription-only medicines without prescriptions, absence of authorized pharmacists and licensing-related breaches.

The Authority also conducted 108 safe-disposal supervision activities during the year. These activities covered the appropriate management and disposal of pharmaceutical products and addressed risks associated with inappropriate disposal.

d. *Good Storage and Distribution Practices (GSDP)*

During FY 2025/2026, the Authority conducted 102 GSDP inspections of pharmaceutical wholesalers and other relevant establishments. The inspections assessed compliance in areas including documentation, quality management systems, premises and equipment, operations, personnel and implementation of written procedures.

In Q4, 28 GSDP inspections identified 78 deficiencies, comprising 48 minor, 29 major and one critical deficiency. Documentation and Quality Management Systems recorded the highest number of findings, followed by premises and equipment and operational controls.

e. *Good Manufacturing Practices (GMP)*

GMP regulatory oversight remained a major component of pharmaceutical regulation during FY 2025/2026. The Authority received 412 GMP applications and conducted 127 GMP inspection and assessment activities. These included physical inspections, reliance-based desk assessments, domestic inspections, joint inspections and triggered inspections. A total of 138 GMP certificates were reported as issued during the four quarters. GMP assessments identified 398 reported deficiencies during the year, predominantly major and minor deficiencies, with critical deficiencies reported in some quarters. Common areas of deficiencies included qualification and validation, equipment, materials management, production, quality control, documentation, HVAC systems, hygiene and sanitation, premises and pharmaceutical quality systems.

The reliance mechanism was applied in the assessment of foreign manufacturers. In Q4, 29 of the 50 GMP applications received were considered eligible for reliance-based desk assessment, while 21 were scheduled for physical inspection. During the quarter, 36 GMP inspection and assessment activities were reported, comprising 32 foreign activities, one joint inspection, one triggered inspection and two domestic manufacturing facility inspections. The Authority also conducted GMP inspector competence development activities through training, mentorship and technical learning opportunities, supporting technical capacity in GMP assessment and inspection.

f. Good Clinical Practice (GCP)

During FY 2025/2026, the Authority continued regulatory oversight of clinical trial sites through risk-based GCP inspections, including routine, follow-up, joint and triggered inspections. A total of 17 GCP inspection activities were reported during the year.

Across Q2–Q4, 98 inspection findings were reported, with the majority classified as major. The findings related to study conduct, participant protection, data integrity, documentation, investigator responsibilities and regulatory compliance. The Authority addressed identified deficiencies through CAPA assessment, regulatory correspondence, warning letters and enforcement follow-up.

3.3. Food establishment inspections and licensing

During FY 2025/2026, the Food Safety Monitoring, Inspection and Licensing (FSMIL) Division strengthened oversight of food business operators through inspection and licensing, GMP certification, post-market surveillance, food safety monitoring and enforcement activities. The Division also advanced the harmonization and digitalization of food regulatory processes to improve compliance and regulatory service delivery.

The annual performance focused on strengthening compliance across food manufacturing facilities, food supplement shops, wholesalers, retailers and other food businesses, while enhancing market surveillance and enforcement of food safety and quality requirements. Detailed performance under each regulatory function is presented in the subsequent sections of this report.

a. Food Establishment Applications Received and Inspection Eligibility

During FY 2025/2026, a total of 1,870 food establishment application dossiers were received and processed. The applications covered food manufacturing facilities, food supplement shops, wholesalers and other categories requiring regulatory consideration. Of the applications received, 768 applications were eligible for physical inspection, while 1,102 applications did not require physical inspection. Applications that did not require physical inspection included notification letters, applications with missing documentation, complaints, cases related to resignation of responsible technicians, and Corrective and Preventive Action (CAPA) submissions.

The applications requiring inspection included new applications, renewals, re-inspections, additional line applications and other applications requiring physical verification of premises. The eligible applications represented approximately 41.1% of all applications received, while approximately 58.9% were handled without physical inspection.

b. Food Establishment Licensing Inspections

During the financial year, 717 licensing inspections were conducted against the 768 applications eligible for inspection, resulting in an overall inspection coverage of approximately 93.4%.

The inspections covered food manufacturing facilities, food supplement shops, wholesalers and outlets. The annual inspection workload also included inspections undertaken as part of follow-up and enforcement activities, re-inspections, risk-based inspections, joint inspections, sample collection and disposal of unfit products.

In total, the quarterly detailed inspection records indicate 1,355 licensing, follow-up, enforcement, re-inspection, risk-based and disposal-related inspections conducted during the year. The inspection workload increased as the Division expanded risk-based surveillance and enforcement activities alongside routine licensing inspections. The inspection activities supported verification of premises suitability, compliance with food safety requirements, implementation of corrective actions and adherence to applicable regulatory requirements before and after authorization.

c. Licensing and Regulatory Authorizations Issued

During FY 2025/2026, the Authority issued 848 food premises licenses, compliance notification letters and Food Business Operational Licenses across the different stages of the revised food regulatory framework. The licensing framework evolved during the year following the integration of premises suitability and Good Manufacturing Practices (GMP) requirements into a harmonized food regulatory process. During Q1, under the existing framework, 133 premises licenses were issued, comprising 44 new licenses and 89 renewed licenses, representing 83.1% of the applications assessed for licensing. Following implementation of the revised framework, the regulatory process increasingly relied on completion responses, compliance notification letters and Food Business Operational Licenses.

In Q2, 128 applications received successful completion responses and clearance to proceed with product registration, while 100 applications received corrective action requests before final approval. In Q3, 126 compliance notification letters were issued for premises licensing and GMP requirements integrated into a single licensing requirement, while 54 Food Business Operational Licenses were issued following successful product registration. In Q4, the Authority issued 221 Food Business Operational Licenses and compliance notification letters, comprising 154 for food manufacturers, 62 for food product wholesalers and 5 for food supplement shops. In addition, 90 Food Business Operational Licenses for food manufacturers were issued following the issuance of product registration certificates.

d. Feedback and Compliance Communication

The Authority issued feedback and compliance communication to applicants throughout the financial year to facilitate correction of identified gaps and progression of applications. At least 829 general feedback letters were reported across Q1, Q3 and Q4, comprising 154 in Q1, 363 in Q3 and 312 in Q4. In addition, 16 GMP-related feedback letters were issued in Q1, while 4 GMP compliance notification letters were communicated to applicants during Q2. The feedback process supported applicants in addressing deficiencies and completing the requirements for premises authorization, GMP compliance and related regulatory processes.

3.3.1. Food GMP Inspection and Certification

During FY 2025/2026, the Authority continued to strengthen oversight of food manufacturing establishments through Good Manufacturing Practices (GMP) inspection and certification. A total of 22 GMP-related applications were received during the financial year, while 24 GMP inspections were conducted, including inspections of foreign food manufacturing facilities. The inspections were undertaken to assess compliance with applicable GMP requirements and to inform regulatory

decisions relating to food manufacturing operations.

During the year, 26 GMP certificates were issued or reported through the quarterly performance records. The reported certificates included certificates finalized from applications submitted in previous quarters and therefore represent certificates reported during the financial year rather than necessarily unique applications received during the same period. Overall, GMP inspection and certification activities supported the Authority's regulatory oversight of food manufacturing establishments and the verification of compliance with established food safety and quality requirements.

3.3.2. Inspection and Integration of Major Food Outlets

During FY 2025/2026, the Authority continued to identify, inspect and integrate major food outlets into the formal food regulatory framework. A total of 128 major food outlet inspections were conducted during the year, comprising 36 in Q1, 21 in Q2, 23 in Q3 and 48 in Q4. The inspections focused on identifying major food outlets, raising awareness of regulatory requirements, assessing compliance and supporting operators to obtain the required regulatory authorization.

The inspection programme was complemented by mapping and follow-up regulatory activities. In Q1, five major food outlets obtained licenses following awareness and inspection activities. In Q4, a further 53 major food outlets were mapped, of which 48 were inspected. These activities expanded the Authority's identification and regulatory coverage of major food businesses and supported their integration into the formal food safety and regulatory system.

3.3.3. Post-Market Surveillance and Food Safety Monitoring

During FY 2025/2026, the Authority conducted nationwide food safety post-market surveillance through inspections of commercial centres and food establishments. A total of 468 commercial centres were inspected across the financial year, comprising 128 centres in Q1, 117 in Q2, 110 in Q3 and 113 in Q4. The surveillance programme covered 29 districts during Q1, Q2 and Q3 and 22 districts in Q4, and resulted in the assessment and documentation of 3,938 food establishments in the Food Safety Post-Market Surveillance database. The surveillance activities identified food safety and quality non-compliances and provided a basis for regulatory follow-up of establishments and products found not to meet applicable requirements.

The quarterly performance records explicitly documented 1,008 non-compliance cases during the year. The most frequently reported concerns were poor storage practices and expired food products. In Q1, 182 non-compliance cases were identified, including 69 cases involving expired food products (38%) and 59 cases of poor storage practices (32.4%). In Q3, 364 cases were identified, of which 183 (50.3%) involved poor storage practices and 154 (42.3%) involved expired food products. In Q4, 462 cases were identified, including 221 (47.8%) related to poor storage practices and 176 (38.1%) involving expired food products. Storage-related deficiencies included inadequate temperature control for dairy products such as yoghurt and fermented milk and inadequate storage arrangements for dry products, including the absence of pallets for maize flour.

Other food safety and quality concerns identified through surveillance included unauthorized or

illegal manufacturing of alcoholic beverages and other products, counterfeit and tampered products, inadequate or misleading labelling, and substandard or off-specification food products. The surveillance records also documented establishments where no specific food safety or quality non-compliance was identified, including 89 establishments in Q1, 796 in Q3 and 845 in Q4.

The food safety surveillance programme therefore combined commercial-centre coverage, establishment-level inspection, documentation of compliance status and identification of food safety and quality concerns across the reporting period. The annual coverage of 468 commercial centres and 3,938 documented food establishments demonstrate the scale of the Authority's post-market surveillance activities during FY 2025/2026.

a. Enforcement and Joint Inspection Activities

Enforcement activities were implemented throughout the financial year to address illegal operations, unsafe food practices and non-compliant products. During Q2, the Division conducted 336 joint inspections nationwide under the USALAMA XI operations and other coordinated enforcement activities. The operations involved collaboration with institutions including RIB, RNP, MINICOM, RSB, REMA, NISS, SKCP, Local Authorities, RDB, CoK, RICA and MoH.

The operations resulted in the closure of 64 alcoholic beverage manufacturing facilities, disposal of 211,901 litres of substandard products, including 33,732 litres of non-alcoholic products and 178,169 litres of alcoholic products, and the arrest of 54 individuals involved in illegal activities. Administrative sanctions included 30 fines and temporary closures and 34 license revocations. In Q3, 59 joint enforcement inspections were conducted across different districts, covering food manufacturers, distributors and wholesalers, retailers, transport vehicles and hospitality establishments.

In Q4, a further 25 joint enforcement inspections were conducted across different districts. These inspections covered manufacturers, distributors and wholesalers, retailers, food supplement outlets, transporters and hospitality establishments. The activities targeted poor-quality, substandard and falsified products and other food safety violations. The enforcement activities were supported by joint and service monitoring with other institutions, including inspections conducted during national and international events to strengthen food safety controls.

b. Regulatory Framework and Process Harmonization

During FY 2025/2026, the Authority strengthened the regulatory framework governing food business operators through harmonization of regulatory processes.

A single regulation for processed food was established, integrating premises licensing, GMP inspections, product registration and import/export control. Combined formats for premises and GMP suitability and Food Business Operational Licenses were adopted. The validity period of the relevant authorization was also extended from two years to five years, reducing the frequency of renewal while maintaining regulatory oversight through risk-based inspection and post-licensing monitoring.

The Authority also developed and commenced implementation of the Risk-Based Inspection Plan 2025–2030. Under the plan, inspection frequency is determined according to the risk classification of facilities, with low-risk facilities scheduled for one inspection during the third year after licensing, medium-risk facilities scheduled for two inspections during the second and fourth years, and high-risk facilities scheduled for four inspections during the first, second, fourth and fifth years after licensing.

c. Food Safety Awareness and Stakeholder Engagement

The Authority conducted food safety awareness and stakeholder engagement activities to improve understanding of regulatory requirements among food business operators and the public. Food safety awareness was conducted through the YouthConnekt 2025 programme, including radio and television engagement and awareness activities at Nkumba National Ubutore Development Center. The activities addressed Rwanda FDA requirements, food safety regulatory challenges and harmonized services involving relevant regulatory institutions.

The Authority also participated in the “Waramutse Rwanda” Radio Rwanda programme on 11 June 2026, where food safety inspection, imported food control and regulatory requirements for food manufacturing establishments were discussed. In collaboration with RDB, the Authority conducted hotel inspections associated with seven major events, strengthening food safety monitoring in hospitality establishments during high-profile national and international events. A Memorandum of Understanding with MINALOC was also signed to strengthen collaboration between the Authority and local governments, particularly in enforcement activities.

3.4. Pharmacovigilance, Post-Market Surveillance and Medicine Safety

During FY 2025/2026, the Rwanda Food and Drugs Authority strengthened pharmacovigilance, post-market surveillance and medicine safety activities to support the continuous monitoring of the safety, quality and appropriate use of medical products. The activities covered collection and assessment of individual case safety reports, investigation of serious adverse events, supportive supervision and capacity building, review of periodic safety reports, medicine safety communication, oversight of promotion and advertising, post-market surveillance, product recalls and recall audits.

The annual activities strengthened the national safety surveillance system through active reporting, facility-level supervision, investigation of suspected safety and quality concerns, regulatory action against non-compliant products and continued engagement with healthcare professionals and other stakeholders.

3.4.1. Pharmacovigilance Safety Reporting

The Authority received 1,200 individual case safety reports (ICSRs) during FY 2025/2026. The reports comprised adverse drug reactions (ADRs), adverse events following immunization (AEFIs) and other individual safety reports received through spontaneous reporting, healthcare facilities, marketing authorization holders and supportive supervision activities. The reports were validated, analysed and submitted to the UMC/WHO through the applicable pharmacovigilance reporting

systems. Of the reported cases, 1,098 were recorded as ADRs and 93 as AEFIs based on the reported annual case classifications.

Pharmacovigilance activities also included assessment and follow-up of serious cases, causality assessment, communication of findings to reporters and referral of vaccine-related serious cases to the National AEFI Committee where required. The reporting system continued to capture safety information from both routine spontaneous reporting and active case identification through supportive supervision. This contributed to strengthening the completeness of national safety data and the sharing of Rwanda's safety information with the global pharmacovigilance system.

a. Investigation of Serious AEFI Cases

Serious AEFI investigations were conducted as part of routine vaccine safety surveillance. During the year, five serious AEFI cases were investigated, with investigation reports completed for most cases. Cases requiring additional evidence remained subject to further follow-up and causality assessment by the National AEFI Committee.

The investigations involved Rwanda FDA, the immunization programme, district teams and the National AEFI Committee and focused on establishing the circumstances surrounding reported events, assessing potential causal relationships and identifying information required for regulatory decision-making.

b. Stakeholder Engagement

The Authority conducted targeted stakeholder engagements to strengthen awareness and reporting of adverse events. Two stakeholder meetings brought together 66 healthcare providers, including 34 medical doctors from public district hospitals and selected private hospitals and 32 responsible pharmacists from retail pharmacies in Kigali. The engagements promoted the use of VigiMobile, VigiFlow and other reporting channels and strengthened collaboration between healthcare institutions and Rwanda FDA.

c. Periodic Safety Update Reports and Benefit-Risk Monitoring

The Pharmacovigilance Division received and screened 70 PSURs/PBRERs and other aggregate safety reports during the reporting year based on the reported submissions. The reports were screened for completeness, recorded in the PSUR database and assessed as part of continuous monitoring of the safety profile and benefit-risk balance of medicinal products. Six PSURs were fully assessed, with the assessments confirming a continued favourable benefit-risk balance for the respective products. In the fourth quarter, 24 aggregate safety reports were screened and recorded, with no new safety issues identified from the reviewed reports.

3.4.2. Medicine Safety Information and Risk Communication

The Authority continued to develop and communicate medicine safety information to healthcare professionals, patients and other relevant stakeholders. During FY 2025/2026, a total of 17 medicine safety information materials and updates were developed and communicated, addressing identified or potential medicine-related risks and promoting rational use and risk-minimization measures.

Key safety topics covered included the risk of severe itching following discontinuation of long-

term use of Cetirizine and Levocetirizine, the risk of fever associated with Mebendazole, rational use of Paidoterin decongestant liquid, Diclofenac, Artemether-Lumefantrine, Chlorpheniramine and Metronidazole, as well as fixed drug eruptions associated with Carbamazepine (Tegretol) and sexual dysfunction associated with Dolutegravir. These communication activities strengthened the dissemination of medicine safety information and promoted awareness of potential risks, rational medicine use and appropriate risk-minimisation measures.

a. Control of Promotion, Advertising and Marketing of Regulated Products

The Authority continued regulatory oversight of the promotion and advertising of regulated medical products to ensure compliance with applicable requirements and to minimize misleading or inappropriate promotional information.

During the year, 15 promotional material applications were received through iRIMS. Four applications were approved, while 11 were rejected due to incomplete documentation, requiring applicants to provide additional information to meet regulatory requirements. In addition, the Authority conducted on-site awareness and compliance activities. 42 facilities were visited to sensitise operators on requirements governing promotion and advertising of regulated products. The Authority also conducted vetting of non-approved promotional advertisements as part of enforcement activities.

3.4.3. Post-Market Surveillance of Medical Products

Post-market surveillance activities were implemented through routine inspections, investigation of suspected poor-quality products, field screening, product sampling, laboratory testing and regulatory action. During FY 2025/2026, the Authority conducted routine PMS inspections across pharmaceutical establishments and investigated reports of suspected poor-quality medical products. The surveillance programme included both complaint-based investigations and proactive field surveillance, including participation in the countrywide PANGEA XVIII operation.

A total of 200 samples were reported as collected during the year, comprising samples of human medicines, veterinary medicines, cosmetics, medical devices and consumables. In Q4 alone, 112 samples were collected, including 78 human medicine samples, 9 veterinary medicine samples, 17 cosmetic samples and 17 medical device and consumable samples. Laboratory testing was complemented by field screening and visual inspection. In Q3, 72 medical products were visually inspected and field-screened, with six identified as suspected poor-quality products and subjected to further investigation. The laboratory also issued 18 certificates of analysis for previously submitted samples during the same period.

The surveillance programme also included awareness activities targeting pharmaceutical establishments. In Q4, 141 healthcare professionals from 76 pharmaceutical establishments were trained on early detection of suspected poor-quality products and appropriate reporting channels.

3.4.4. Product Recalls and Recall Audits

Product recalls constituted an important regulatory response to identified safety, quality and compliance concerns. During FY 2025/2026, the Authority implemented 30 reported recall actions/products or batches across the reporting periods and conducted recall audits to verify the effectiveness of recall implementation.

The annual recall actions included medicines, veterinary products and medical devices. In Q1, seven product recalls were conducted, comprising three drugs, one veterinary product and three medical

devices. Five recall actions were audited, including four drugs and one medical device. In Q2, four products were recalled through voluntary and statutory recall mechanisms across different batches. No recall audit was conducted during the quarter, with the audit activity scheduled for subsequent surveillance activities.

a. Products Specifically Identified in Recall Actions

During Q3, four medical products were officially recalled from the market on 5 February 2026 following investigations that confirmed the products were unauthorized, substandard or falsified for the Rwandan market. The products specifically identified in the quarterly report were:

Imodium® (Loperamide hydrochloride) 2 mg capsules – manufactured by ASPIN Pharma Pvt Ltd, Pakistan; all batches recalled.

Nexium® (Esomeprazole) 20 mg and 40 mg tablets – labelled in Turkish and claimed to be manufactured by AstraZeneca; all batches recalled.

Flagentyl® (Secnidazole) 500 mg tablets – labelled in Turkish with no legitimate manufacturer indicated; all batches recalled.

The Q3 recall programme also included one recall audit session to verify recall effectiveness for four medical products, including a batch of rosuvastatin, IV catheters G24 (all batches), Povimax (all batches), and adhesive perforated plasters from a specific manufacturer.

b. Akerol Recall

In Q4, 15 batches of Akerol 2.5 mg/5 ml syrup were recalled from the market following confirmation of leakage of the syrup from the bottle caps. One recall audit session was subsequently conducted to verify the effectiveness of recall implementation. The recall activities demonstrate the Authority's use of market surveillance, investigation and enforcement measures to remove products presenting confirmed quality or regulatory concerns from the market and to verify the effectiveness of corrective actions.

3.4.5. Regional Professional Development and Technical Engagement

The Pharmacovigilance and Clinical Trial Division strengthened technical capacity through participation in regional pharmacovigilance and vaccine safety activities. Pharmacovigilance staff participated in the International Society of Pharmacovigilance (ISoP) Africa Chapter Conference held in Namibia from 19–20 May 2026 under the theme “*Patient Safety First*”. Staff also participated in Adverse Events of Special Interest (AESI) training organised by Africa CDC, in collaboration with CEPI, from 21–22 May 2026. The engagements strengthened knowledge of emerging safety issues and supported continued professional and regulatory capacity development.

3.4.6. Clinical Trial Oversight

During FY 2025/2026, the Authority continued to strengthen regulatory oversight of clinical trials to ensure compliance with regulatory requirements, Good Clinical Practice (GCP) standards, and the protection of participants involved in clinical research. The Authority reviewed and processed clinical trial applications covering new trials, ongoing applications requiring additional information, pre-submission consultations and clinical trial qualifications, amendments, and annual renewals. Across the reporting year, 12 new clinical trial applications were received/reviewed, of which 8 were approved. In addition, the Authority conducted 6 pre-submission reviews and clinical trial qualification activities, supported sponsors and Principal Investigators through regulatory queries,

and facilitated the progression of eligible applications to regulatory decisions.

The Authority also reviewed clinical trial protocol amendments throughout the year. A total of 15 amendment applications were processed, with 9 amendments approved and additional applications subjected to regulatory queries and requests for clarification. Annual oversight of approved trials was further maintained through the review of 8 applications for renewal or extension of clinical trial approval, resulting in 3 renewal approvals, while other applications were queried pending submission of additional information from sponsors or Principal Investigators.

a. Clinical Trial Safety Monitoring

The Authority maintained active safety monitoring of ongoing clinical trials through the review, recording and causality assessment of safety reports submitted by authorized clinical trial sponsors. During the year, 41 clinical trial safety reports were received and reviewed. These reports originated from several authorized studies, including HTN, BREATHE, PENGUIN, Malaria-GVGH, HOPE II, and OPTIPRO. The safety reports were subjected to appropriate regulatory and causality assessment processes, with follow-up actions undertaken where applicable to support continued monitoring of participant safety.

b. Compliance and Study Progress Monitoring

The Authority continued to monitor the conduct and progress of authorized clinical trials through the review of periodic progress reports and site close-out reports. During FY 2025/2026, 27 progress and site close-out reports were reviewed and recorded, supporting continuous oversight of trial implementation and compliance with approved requirements. The Authority also participated in internal Clinical Trial Technical Committee meetings to review regulatory and inspection findings and support regulatory decision-making. A total of 14 internal technical committee meetings were conducted during the reporting year, including review and grading of GCP inspection findings from clinical trials such as KALUMA, TACT, BAG-CPAP, Baby Buddy, MARLIN and PENGUIN.

c. Processed Clinical Trial Applications

During the year, the Authority processed and progressed several clinical trial applications through regulatory review, query, additional data submission and approval. Key applications processed during the reporting period included mHealth-CHW Tool, AEFIX, SurgPASS, UR-STH Trial, STEP-Mag Trial, CASCADE Trial, MMVCT and AFYAWAVE. These regulatory processes involved assessment of submitted information, issuance and review of additional information from sponsors, and issuance of regulatory decisions where the required requirements were fulfilled.

3.5. Drugs Import and Export Control

During FY 2025/2026, Rwanda FDA, through the Drugs Import and Export Control Division, continued to regulate the importation and exportation of medical products and other regulated products through the Integrated Regulatory Information Management System (iRIMS) and the Single Electronic Window (SEWI). Regulatory control covered the processing of import license applications and inspection of consignments at points of entry and, where applicable, at importers' or clients' premises following conditional release under seal.

a. Import Licenses Issued

During the financial year, the Authority received a total of 12,431 applications for import licenses, of which 10,787 were approved, representing an overall annual approval rate of 86.8%. The quarterly volumes were 3,085 applications in Q1, 3,112 in Q2, 2,882 in Q3 and 3,352 in Q4, with 2,721, 2,721, 2,616 and 2,729 approvals respectively. The approved import licenses covered a range of regulated products. In Q1 alone, the approved applications included 1,283 human medicines, 51 veterinary medicines, 1,093 human medical devices and IVDs, 20 veterinary medical devices, 368 cosmetics, 219 public health chemicals, 20 tobacco products and 31 controlled substances.

b. Consignment Inspection

The Authority conducted inspection of imported consignments at various points of entry and at importers' or clients' premises throughout the year. A total of 6,173 consignments were inspected at points of entry, while 1,470 consignments were inspected at importers'/clients' premises following release under seal.

The quarterly inspections at points of entry were 1,571 in Q1, 2,176 in Q2, 1,218 in Q3 and 1,208 in Q4. Inspections conducted at importers' or clients' premises following conditional release under seal were 433 in Q1, 351 in Q2, 328 in Q3 and 358 in Q4. In addition, Q1 recorded 1,570 consignments cleared for intra-regional transport.

c. Regulatory Compliance

Rwanda FDA continued to address non-compliance with importation requirements, including incomplete documentation and failure to follow established regulatory procedures. Awareness and engagement activities were maintained to improve importers' understanding of regulatory requirements and strengthen compliance with importation procedures.

3.6. Food Import and Export Control

During FY 2025/2026, Rwanda FDA, through the Food Import and Export Control Division, continued to regulate the importation and exportation of food products, food supplements, animal feeds, packaging materials and other regulated food-related products through the iRIMS platform and inspection activities at Points of Entry (PoEs) and importers' premises.

a. Import License Application Processing and Issuance

During the financial year, the Authority received and processed a total of 5,456 applications for food import licenses, of which 5,124 licenses were approved and issued, representing an overall approval rate of 94.0%. The quarterly volumes were 1,362 applications in Q1, 1,195 in Q2, 1,434 in Q3 and 1,465 in Q4, reflecting sustained demand for regulatory clearance of imported food and related products.

b. Export License Processing

The Authority also processed export license applications for food products, food supplements and animal feeds. In Q1, 13 export license applications were processed, of which 6 licenses were granted and 7 applications rejected due to non-compliance with regulatory requirements.

c. Food Consignment Inspection and Clearance

Food import controls were strengthened through inspection of consignments at Points of Entry and follow-up inspection of consignments released under seal. During the year, 3,334 consignments were inspected at Points of Entry, including high-risk and low-risk food consignments, while 4,778 consignments were released under seal for further inspection at owners' or importers' premises. In addition, 169 processed-food consignments were inspected at exit points for export in Q1, all of which were approved for export.

For consignments inspected at owners' premises following release under seal, 1,346 consignments were confirmed compliant and approved for release based on the reported Q2–Q4 follow-up inspection results. The control system therefore supported risk-based clearance while ensuring that consignments requiring additional verification were subjected to further regulatory inspection before market release.

3.7. Laboratory Services

During FY 2025/2026, the Laboratory Services Department (LSD) continued to provide quality control testing for regulated products, including processed foods, human and veterinary medicines, cosmetics, biologicals, herbal medicines and medical devices. Laboratory testing supported pre-market, post-shipment and post-market regulatory activities and provided evidence for regulatory decision-making and compliance with applicable quality standards.

3.7.1. Laboratory Testing Services

During the financial year, the Laboratory Services Department received a total of 1,659 samples for testing across food, medicines, medical devices, vaccines and biologics, and cosmetics. These comprised 376 samples in Q1, 498 in Q2, 388 in Q3 and 397 in Q4. Across the four quarters, 1,432 samples were tested and reported, while 140 samples remained in progress, 78 were untested or carried forward, and 9 samples were subcontracted.

Food testing constituted the largest component of the laboratory workload, with 1,286 food samples received during the financial year. Of these, 1,211 samples were tested and reported, while 75 remained untested or were carried forward from the reporting periods. Food testing included samples received through Food Registration and Information Control, Food Import and Export Control, Food Safety Monitoring, Inspection and Licensing, and proficiency testing. The quarterly food testing workload included 259 samples received in Q1, 354 in Q2, 339 in Q3 and 334 in Q4.

Drug testing also remained an important laboratory function. A total of 287 drug samples were received during the year, of which 155 were tested and reported. The remaining samples were either in progress or carried forward for testing. Drug testing included samples associated with post-marketing surveillance, controlled and high-risk products, and proficiency testing activities. The Department also received 76 medical device samples, of which 65 were tested and reported, with 11 samples remaining in progress. A total of 9 vaccine and biologics samples were received during the year and were handled through subcontracting arrangements. In addition, 1 cosmetic sample was received and tested during Q4.

3.7.2. Laboratory Testing Outcomes

The laboratory received 1,659 samples during FY 2025/2026, of which 1,432 were tested and resulted in Certificates of Analysis (CoAs). A further 140 samples were in progress, 78 remained untested, and 9 were handled through subcontracting arrangements. Of the 1,432 CoAs issued, 888

samples passed, 349 failed, and 199 were reported without a conformity statement or regulatory decision.

Food Testing accounted for the largest volume of laboratory activity, with 1,286 samples received and 1,211 tested, while 75 samples remained untested. A total of 1,211 CoAs were issued, comprising 708 passed, 311 failed, and 196 reported without a conformity statement or regulatory decision. The samples covered Food Registration and Information Control, Food Import and Export Control, FSMIL and proficiency testing (PT) activities.

Drug Testing received 287 samples, of which 155 were tested, 129 were in progress, and 3 remained untested. The laboratory issued 155 CoAs, comprising 152 passed, no failed samples, and 3 reported without a conformity statement or regulatory decision. The samples included those related to post-market surveillance (PMS), controlled/high-risk products and proficiency testing (PT).

Devices and Instrumentation Testing received 76 samples, of which 65 were tested and 11 were in progress. All 65 tested samples resulted in CoAs, comprising 27 passed and 38 failed, with no results reported without a conformity statement or decision. These included medical device samples received and tested through Import and Export Control.

Vaccines and Biologics Testing received 9 samples, all of which were handled through subcontracting arrangements. No samples were tested directly by the laboratory and no CoAs were issued under this category.

Cosmetics Testing received and tested 1 sample, resulting in 1 CoA, which indicated a passed result. No samples remained in progress or untested under this category.

Unit	Received samples/Division/Unit	Samples Tested	Samples in Progress	Untested Samples	Samples Subcontracted	CoAs Issued	CoAs – Samples Passed	CoAs – Samples Failed	CoAs with No Conformity Statement/No Decision	Comments
Food Testing Unit	1,286	1,211	0	75	0	1,211	708	311	196	Includes Food Registration & Information Control, Food Import & Export Control, FSMIL and PT samples.

Devices & Instrumentation Testing Unit	76	65	11	0	0	65	27	38	0	Medical device samples received and tested through Import & Export Control.
Vaccines & Biologicals Testing	9	0	0	0	9	0	0	0	0	Samples handled through subcontracting arrangements.
Drug Testing	287	155	129	3	0	155	152	0	3	Includes PMS, controlled/high-risk products and PT samples.
Cosmetics	1	1	0	0	0	1	1	0	0	Sample received and tested in Q4.
TOTAL	1,659	1,432	140	78	9	1,432	888	349	199	Consolidated FY 2025/2026 figures from Q1–Q4 reports.

Table 2: Consolidated Annual Laboratory Testing Table FY 2025-2026

a) Food and Drug Samples Received versus Tested, FY 2025/2026

The comparison shows that food testing accounted for substantially more samples received and tested than drug testing during the financial year. Food testing recorded 1,286 samples received and 1,211 tested, while drug testing recorded 287 samples received and 155 tested.

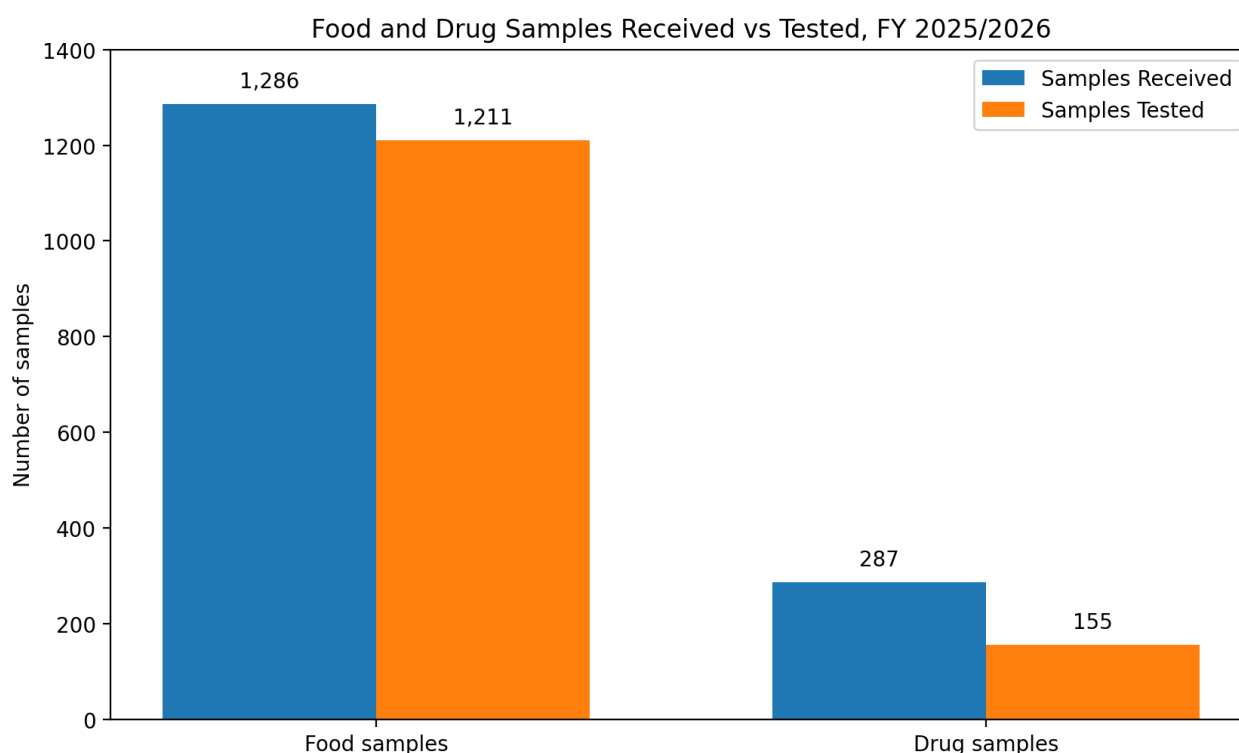


Figure 5: Food and Drugs Samples Received and Tested

3.7.3. Turnaround Time and Laboratory Backlog

The Department continued to monitor testing performance against established turnaround times. In Q1, 20 drug samples and 253 food samples were tested and reported within the 21-working-day timeline. In Q2, 83.5% of samples were reported as tested within the set timeline, while delays were mainly associated with technical challenges affecting the HPLC testing system.

By Q4, 93% of samples were tested and reported within the set timeline. The remaining samples were mainly attributable to samples carried forward from the previous quarter, newly received samples still within the testing timeline, and vaccine samples undergoing subcontracted testing.

3.7.4. Proficiency Testing and Subcontracting of Testing Services

The Department continued to participate in proficiency testing schemes to strengthen the reliability and competence of laboratory testing. In Q3, 12 proficiency testing samples were tested and reported, while in Q4, 4 PT samples were processed and submitted to the respective PT arrangements. Subscription and registration with PT providers were also undertaken in collaboration with RMS. Subcontracting arrangements were also advanced for specialized testing. During Q3, arrangements were initiated for testing of the biological product Basiliximab at NIFDC and for four vaccine samples. In Q4, the vaccine testing subcontracting process continued, including follow-up on tendering, determination of costs and engagement with King Faisal Hospital on payment modalities.

3.7.5. Laboratory Equipment Maintenance, Calibration and Technical Support

Laboratory equipment maintenance and calibration were undertaken to sustain operational capacity and reliability of testing services. In Q3, 178 pieces of equipment underwent maintenance, including 102 preventive maintenance activities, while 203 calibration parameters were externally calibrated

by RSB. In Q4, an additional 50 pieces of equipment underwent maintenance, including 40 planned preventive maintenance activities, and time and temperature parameters were calibrated for 30 main laboratory equipment. Across the reported Q3 and Q4 activities, maintenance services covered 228 pieces of laboratory equipment, including 142 planned preventive maintenance activities. The Department also provided 128 technical support interventions to equipment users in Q3 to maintain the functionality of laboratory instruments.

3.7.6. Preparation for ISO/IEC 17025 Accreditation

Preparations for ISO/IEC 17025 accreditation continued throughout the year through quality-system strengthening and engagement with relevant technical partners. Activities included review and alignment of the Laboratory Quality Manual, review of accreditation requirements, assessment of the proposed accreditation scope, engagement with PTB, registration with proficiency testing providers, and preparation for peer and mock assessment processes.

3.8. Regulatory Ecosystem Strategy (RES)

During FY 2025/2026, Rwanda FDA continued to play a central role in advancing its strategic mandate through strategic partnerships, regulatory innovation, industrial support, policy development, pricing reforms, pharmaceutical supply chain strengthening, and digital transformation.

Throughout the financial year, the Authority focused on strengthening collaboration with national, regional, and international stakeholders; supporting the implementation of strategic Memoranda of Understanding (MoUs); Through the RES division, a regulatory strategies to support local pharmaceutical production and a resilient pharmaceutical supply chain were drafted; advancing the implementation of the National Pharmaceutical Product Pricing and Cost Containment Policy; and strengthening national pharmaceutical traceability systems.

The Authority also coordinated engagements with government institutions and development partners to address regulatory and operational priorities, including collaboration with the Rwanda Development Board (RDB) One Stop Centre to support the clearance of Rwanda FDA-related backlogs and compliance with applicable Service Level Agreements (SLAs).

3.8.1. Strategic Collaboration and Partnerships

During FY 2025/2026, Rwanda FDA strengthened strategic collaboration with national and international institutions to enhance regulatory capacity, promote innovation, and support sustainable development of the regulated health products sector. A number of strategic partnership frameworks were advanced during the year. These included collaboration with Zenysis Technologies, the African Knowledge Institute for Innovation and Scientific Advancement (AKIISA), and the Africa Centre of Excellence for Sustainable Cooling and Cold Chain (ACES).

The roadmap and implementation work plan for the MoU with Zenysis Technologies were reviewed and awaiting for it's approval for implementation. The partnership is expected to strengthen regulatory intelligence, data analytics, evidence-based decision-making, and the use of data for regulatory planning and oversight. Rwanda FDA also initiated a partnership with AKIISA to promote collaboration in scientific research, training, innovation, and knowledge development. The draft MoU was finalized and validated, paving the way for its formalization and implementation.

In addition, discussions with ACES progressed with the objective of strengthening collaboration in cold-chain systems and sustainable cooling solutions. The initial validation of Rwanda FDA's

feedback on the draft MoU was completed on 29 May 2026.

3.8.2. Coordination with Rwanda Development Board One Stop Centre

The RES Division coordinated Rwanda FDA activities related to the clearance of regulatory backlogs through the RDB One Stop Centre. The intervention focused on ensuring that Rwanda FDA services remained aligned with the Service Level Agreements (SLAs) established under the RDB Service Charter.

The coordination contributed to improved follow-up of pending regulatory processes and supported efforts to reduce backlogs and improve the timeliness and predictability of regulatory services provided through the One Stop Centre.

The initiative also strengthened inter-institutional coordination between Rwanda FDA and RDB and provided a mechanism for identifying and addressing bottlenecks affecting the delivery of regulatory services to applicants and other stakeholders.

3.8.3. Implementation of the National Pharmaceutical Product Pricing and Cost Containment Policy

Significant progress was made during FY 2025/2026 in implementing the National Pharmaceutical Product Pricing and Cost Containment Policy, particularly through the development of a Rwanda Pharmaceutical Pricing Database.

Consultative engagements were conducted with CB Link, with technical support from the World Health Organization (WHO), to guide the development of the pharmaceutical pricing database. An inception report was prepared and subsequently reviewed with the Rwanda Information Society Authority (RISA) and the Rwanda FDA Information Technology team. The inception report was approved, providing a foundation for further development and operationalization of the pricing database.

The database is expected to strengthen the availability and management of pharmaceutical pricing information, improve transparency in medicine pricing, support evidence-based regulatory decisions, and contribute to cost-containment measures within the pharmaceutical sector.

The Authority also engaged Rwanda Medical Supply Ltd (RMS Ltd) regarding its request for revision of the existing mark-up. Following discussions, it was agreed that a detailed analysis of the data submitted by RMS Ltd would be undertaken to determine an appropriate revised mark-up level. These interventions represent important steps toward establishing a more transparent, evidence-based, and sustainable pharmaceutical pricing system in Rwanda.

3.8.4. Industrial Support and Revision of the Regulation Governing Service Fees

During FY 2025/2026, Rwanda FDA revised the regulation governing service fees to improve clarity, consistency, transparency, and alignment with national fiscal reforms.

The revision resulted in several important improvements, including:

- Clear categorization of GMP inspection fees for renewals and non-registration purposes;
- Harmonization of service classifications covering product registration, licensing, inspections, and importation services;
- Consolidation of previous amendments into one coherent regulatory framework;

- Improved clarity of applicable fees and payment procedures; and
- Enhanced predictability and transparency for regulated stakeholders.

The revised service-fee framework is expected to improve stakeholder understanding of regulatory costs, support compliance, reduce ambiguity in the application of fees, and contribute to more efficient regulatory service delivery.

3.8.5. Implementation of Pharmaceutical Traceability Activities

Progress was also made in strengthening Rwanda's pharmaceutical traceability framework. A draft SOP for Product Code Creation and Updating of the Rwanda National Product Catalogue (NPC) was developed to standardize master-data management, product-code creation, updating procedures, and the use of unique product identifiers.

The SOP is intended to establish consistent procedures for maintaining accurate pharmaceutical product information and supporting the development of a reliable national traceability system. By the end of the financial year, the SOP had undergone division-level validation and was progressing toward Quality Management System (QMS) submission and final approval.

The development of the SOP represents an important milestone toward strengthening pharmaceutical traceability, improving supply-chain visibility, supporting product authentication, and enhancing the ability of Rwanda FDA and other relevant stakeholders to monitor pharmaceutical products throughout the supply chain.

3.9. Quality Management Systems and Institutional Quality Assurance

During FY 2025/2026, Rwanda FDA continued to strengthen its institutional Quality Management System (QMS), regulatory performance and alignment with international standards. Key areas of focus included maintaining WHO Global Benchmarking Tool (GBT) Maturity Level 3 (ML3), advancing preparedness for Maturity Level 4 (ML4), progressing towards ISO 9001:2015 certification and ISO/IEC 17025:2017 accreditation, strengthening internal quality assurance, improving regulatory documentation and document control, enhancing staff competencies, and promoting workplace health, safety and wellness.

The Authority also advanced digitalization of QMS processes through Smart Admin and development of an electronic QMS (e-QMS), strengthened institutional complaints monitoring and customer feedback mechanisms, and reinforced continuous improvement through internal audits, management reviews, corrective actions and competency development.

3.9.1. WHO GBT ML3 Maintenance and ML4 Preparedness

Throughout FY 2025/2026, Rwanda FDA sustained efforts to maintain WHO GBT Maturity Level 3 and strengthen preparedness for Maturity Level 4. The Authority coordinated benchmarking follow-up activities, particularly for the Regulatory Systems function, while supporting other regulatory functions in implementing recommendations and maintaining readiness for future benchmarking.

A structured self-assessment programme covering the regulatory functions was implemented, and operational KPIs were refined into regulatory performance indicators. Rwanda FDA also participated in WHO workshops on regulatory performance indicators and piloting of the computerized global competency framework. By the end of the fiscal year, self-assessments

covering all nine regulatory functions across Maturity Levels 1–4 had been completed, strengthening the Authority's ability to identify regulatory gaps, monitor improvement and prepare for future WHO benchmarking.

3.9.2. ISO Certification and Accreditation

Significant progress was made towards ISO 9001:2015 certification and ISO/IEC 17025:2017 accreditation. The Authority advanced the procurement and preparatory processes for both standards, including Board approval of the related tenders, submission of approved Terms of Reference, publication of tenders through the UMUCYO government procurement system, and evaluation of bids for consultancy and certification services.

Preparations for external quality assessments were also advanced. By Q4, preparations for the ISO/IEC 17025 pre-assessment scheduled for 7–10 July 2026 had been finalized. These activities represent important progress in strengthening the Authority's institutional quality systems and laboratory quality assurance in line with internationally recognized standards.

3.9.3. Regulatory Documentation and Document Control

Rwanda FDA strengthened its regulatory framework through the development, review, updating and harmonization of regulatory documents throughout the year. In Q1, 22 regulatory documents were reviewed, updated or developed, followed by 28 regulatory documents reviewed and updated in Q2. Further regulations, guidelines, SOPs, manuals, templates and other controlled documents were developed or revised during Q3 and Q4.

The areas covered included processed food products, pharmaceutical supply and distribution, pharmacovigilance, medical devices, lot release, clinical trials, GMP, cannabis and cannabis-related products, scientific review committees, food and food supplement registration, records management, non-conformities, CAPA, deviations, confidentiality, appeals and complaints, and institutional performance monitoring. These interventions strengthened regulatory consistency, document harmonization, traceability and compliance with QMS requirements.

3.9.4. Internal Quality Audits and Continuous Improvement

Rwanda FDA strengthened internal quality assurance through implementation of the approved institutional audit programme and systematic follow-up of previous audit findings. Internal audits focused on compliance with ISO 9001:2015 requirements, documentation and operational controls, as well as regulatory and corporate processes.

Audited areas included import and export control of regulated pharmaceutical products and medical devices, including in-vitro diagnostics, environmental and occupational health and safety, food information and advertising, communication and customer service, and legal compliance. By Q4, 11 institutional processes had been audited, while two additional processes were scheduled for completion based on auditee availability. Identified non-conformities and opportunities for improvement were communicated to process owners, with root cause analysis and corrective action mechanisms strengthened to support continual improvement and prevent recurrence.

3.9.5. Management Review and Governance

Rwanda FDA continued to strengthen institutional governance through systematic follow-up of resolutions arising from Management Reviews. Of the 38 recommendations arising from the FY 2024/2025 Management Review, 17 (45%) had been fully implemented, 8 (21%) were under continuous implementation, and 13 (34%) were progressing satisfactorily by the end of FY

2025/2026.

The continued monitoring of these recommendations strengthened institutional accountability and ensured that identified gaps and improvement actions were systematically tracked and addressed.

3.9.6. Environmental, Occupational Health, Safety and Workplace Wellness

Rwanda FDA strengthened Environmental, Occupational Health and Safety (EOHS) and workplace wellness initiatives during the year. EOHS inspections were conducted at Authority premises, including the Laboratory Services Department premises in Kicukiro and headquarters in Nyarutarama. An external inspection was also conducted in collaboration with the City of Kigali, Rwanda National Police and Rwanda Energy Group, focusing on fire prevention and security compliance.

Fire safety awareness activities were conducted at Rwanda FDA premises, combining theoretical and practical sessions with support from the Rwanda National Police. Workplace wellness was further promoted through NCD risk-factor awareness and screening activities. A five-day workplace NCD screening programme screened 138 staff members, comprising 56 women and 82 men, followed by sensitization on healthier lifestyles and early risk management.

3.9.7. Complaints Management and Customer Satisfaction

Rwanda FDA continued to strengthen complaints management and client-centred service delivery through monitoring and follow-up of complaints received through the institutional customer support system.

During Q2, 77 complaints were received, comprising 44 service-related and 33 product-related complaints. Of these, 59 (77%) were resolved, while 3 were under review and 15 remained pending. In Q3, 24 complaints were received, of which 4 were resolved, 4 were in progress, 7 were pending and 3 were rejected. In Q4, 40 complaints were monitored, with 17 (42.5%) resolved, 4 (10%) under active processing and 19 (47.5%) pending. To further strengthen client feedback, Rwanda FDA launched a QR code-based customer satisfaction survey, providing a mechanism for clients to provide real-time feedback on services and supporting the identification of areas for service improvement.

3.10. Regulatory Quality Assurance and Audit Recommendations

During FY 2025/2026, Rwanda FDA strengthened the implementation and monitoring of recommendations arising from internal and external audits across key regulatory functions. These included ISO 9001:2015 quality audits, Office of the Auditor General (OAG) performance audits, WHO GBT self-assessments and internal QMS audits. Corrective and preventive actions focused on strengthening regulatory controls, improving traceability and compliance, addressing identified quality gaps, and improving the timeliness and effectiveness of regulatory services.

For Human Medicines and Medical Devices, implementation of previous ISO 9001:2015 recommendations reached 98–99%. Key improvements included strengthened temperature monitoring for product samples, improved traceability of Marketing Authorization certificates through inclusion of dossier reference numbers, and enhanced compliance with procedures for updating the product register. The Authority also continued addressing OAG recommendations related to unregistered medicinal products and medical devices, risk-based regulation and delays in service delivery through strengthened regulatory tools, improved application tracking and timeline monitoring in iRIMS, and enhanced engagement with manufacturers, importers, wholesalers and

other stakeholders.

For Veterinary Medicines and Devices, Rwanda FDA continued implementing audit recommendations related to unregistered veterinary medicinal products, veterinary medical devices and IVDs, as well as delays in regulatory service delivery. The Authority strengthened stakeholder engagement to increase registration and notification of regulated products and developed and validated Guidelines for Notification of Veterinary Medical Devices and In Vitro Diagnostic Devices on 27 February 2026, introducing a risk-based classification framework. Measures to address service-delivery delays included improved use of iRIMS, organisational restructuring and recruitment of two additional staff. An internal QMS audit of marketing authorization management found 73% compliance, 18% minor non-conformities and 9% opportunities for improvement, with follow-up of the identified findings continuing during the year.

For Cosmetics and Household Chemicals Registration, an internal QMS audit identified 70% compliance, 20% opportunities for improvement and 10% major non-conformity. In response, the Authority strengthened the regulatory framework through revision of existing guidelines and development of guidelines for variation applications covering registered cosmetics, vector control products and public health laboratory chemical products. The revised and new guidelines were approved on 2 May 2026 and placed under implementation. The function also participated in an OAG performance audit, which highlighted the need for clearer assessment and registration timelines to improve transparency and documentation of causes of delays. In addition, the Authority advanced the development and external validation of regulations and guidelines for Ethyl Alcohol (Ethanol) Control in Rwanda, which were under approval at the end of the financial year.

3.11. Monitoring of Board of Directors' Resolutions and Management Decisions

Throughout FY 2025/2026, the regulatory functions continued to monitor and implement relevant resolutions of the Board of Directors and management decisions, with emphasis on strengthening regulatory efficiency, accountability, oversight and performance monitoring. The functions maintained follow-up mechanisms to track actions arising from Board and management decisions and to support timely implementation.

Human Medicines and Devices Registration implemented measures aimed at sustaining gains from backlog clearance and improving regulatory performance, including the continued use of risk-based and reliance approaches, digital regulatory systems, performance monitoring, capacity development and stakeholder engagement. The function also strengthened the presentation of registration performance information to improve the transparency and completeness of reporting to management and the Board.

Veterinary Medicines and Devices Registration continued monitoring actions arising from Board and management decisions, including resolutions from the Board meeting held on 23 December 2025. The function maintained Excel-based tracking tools to monitor the status of product dossiers and support follow-up of regulatory processes. Although formal guidelines for defining and managing the VMDR backlog were not developed during the year, monthly dossier tracking supported continued monitoring of outstanding applications.

Cosmetics and Household Chemicals implemented and monitored management decisions related to the Action Plan, budget execution and regulatory performance. Key actions included stakeholder awareness and training, stakeholder mapping, staff capacity development, and strengthening regulatory performance reporting. The function also compiled comprehensive information on application status, including applications received, carried forward, assessed, registered, rejected and pending, as well as dossiers submitted for peer review, thereby improving the availability of

information for management oversight and decision-making.

3.12. Development, Review, Validation and Implementation of Regulatory Strategies and Tools

During FY 2025/2026, the Authority continued to strengthen its regulatory framework through the development, review, validation and implementation of guidelines, regulations, application forms, assessment tools and SOPs across human medicines and medical devices, veterinary products, cosmetics and household chemicals, and food products.

For Human Medicines and Medical Devices Registration (HMDR), regulatory tools were developed and reviewed to strengthen the regulation of medical devices, IVDs, herbal medicines and tobacco products. Key initiatives included guidelines on submission requirements, changes to registered devices, software as a medical device, radiopharmaceuticals and notification of low-risk devices and IVDs, as well as continued development of tobacco product registration guidelines and tools for variations of registered pharmaceutical products. Risk-based regulatory approaches, including considerations for AI-enabled medical devices, were also advanced.

For Veterinary Medicines and Devices Registration (VMDR), six regulatory documents were developed and reviewed, covering abbreviated registration procedures, notification of veterinary medical devices and IVDs, assessment of quality, safety and efficacy, renewal and variation of marketing authorizations, and handling of product samples for laboratory testing. The notification guidelines for veterinary medical devices and IVDs were validated with stakeholders, and approved regulatory documents and tools were disseminated through a workshop to strengthen stakeholder understanding and compliance.

For Household Chemicals and Cosmetics Registration (CHCR), key regulatory documents progressed from review and internal validation through external validation, approval and implementation. The revised and newly developed guidelines covering registration and variation of cosmetics, vector control products, public health antiseptics and disinfectants, and public health laboratory chemicals were approved and placed under implementation. The Division also advanced the Regulation and Guidelines for Ethyl Alcohol (Ethanol) Control in Rwanda through external validation and approval processes.

For Food Regulation, the regulatory framework was strengthened through the review, validation and approval of regulations governing processed food products and food fortification, while the draft Regulations Governing the Marketing of Breastmilk Substitutes was published for stakeholder consultation. Additional operational tools included the draft Alcoholic Beverages Regulations, guidelines and inspection tools for safe home-brewing and preparation of traditional beverages, and six SOPs covering inspection, database management, enforcement, post-market surveillance and post-licensing activities.

3.13. Staff, Assessor and Stakeholder Capacity Strengthening

During FY 2025/2026, the Authority continued to strengthen the technical capacity and competencies of staff, assessors, healthcare professionals, food business operators and other regulatory stakeholders through targeted training, professional development, supportive supervision and technical collaboration. Capacity-building activities covered regulatory assessment, pharmacovigilance, quality management, laboratory testing, food safety, veterinary medicines, cosmetics and household chemicals, medical devices, risk management and emerging regulatory issues.

For Human Medicines and Medical Devices Registration (HMDR), staff and assessors participated in 10

training and workshop activities, covering areas including vaccine and biological product assessment, pharmacovigilance, GxPs, bioequivalence, impurity assessment, specifications assessment and regulatory competencies. These activities strengthened technical knowledge and supported consistent, scientifically sound regulatory decision-making.

For Veterinary Medicines and Devices Registration (VMDR), staff participated in regional and international capacity-building activities covering veterinary medicinal products, vaccines, ectoparasiticides, pharmacovigilance, regulatory reliance and aquatic animal medicines. The Division also identified priority areas for continued assessor development, including dossier assessment, quality assessment, stability, analytical methods, biological products, veterinary pesticides, post-approval changes, VICH guidelines and reliance approaches.

For Cosmetics and Household Chemicals Registration (CHCR), capacity development was advanced through collaboration with the Egyptian Drug Authority to strengthen staff competencies in the assessment of cosmetics and household chemicals. Staff also participated in specialized training on emerging genetic biocontrol technologies and QMS sessions, broadening technical knowledge and strengthening application of regulatory and quality management principles.

For Food regulatory functions, the Authority conducted stakeholder awareness and training activities on food regulatory requirements, including food product controls, promotion, advertising and marketing requirements. Capacity support was further strengthened through collaboration with RAB, under which 16 professional interns were recruited, trained and deployed to food industries to provide technical assistance on food safety and regulatory compliance. In addition, training of Rwanda Revenue Authority personnel strengthened capacity for food consignment screening, inspection, classification, licensing and referral at points of entry.

For Post-Market Surveillance and pharmacovigilance, supportive supervision reached 323 health facilities and identified 613 previously unreported adverse events from facility records and patient information. The activities also trained 790 healthcare professionals in adverse event detection and reporting, including the use of VigiMobile and VigiFlow, signal detection and routine pharmacovigilance practices.

For Laboratory Services, technical capacity was strengthened through specialized training in food allergen management, food ingredients, quality management systems, risk management and emerging analytical technologies. Laboratory infrastructure and testing capacity were also supported through the acquisition of equipment, reagents, reference standards and other testing materials. In Q4, 10 laboratory equipment items were received, while 23 regulatory and technical documents were developed, reviewed or validated to support laboratory operations and regulatory testing.

For Quality Management Systems (QMS), institutional competencies were strengthened through training in internal quality auditing, root cause analysis and CAPA, ISO/IEC 17025, ISO 19011, ISO 31000 risk management, cybersecurity and other QMS-related areas. A PTB-supported programme strengthened the competencies of six internal auditors, while a three-year institutional Training Plan aligned with the Strategic Plan was developed. By the end of Q4, implementation of the FY 2025/2026 Institutional Training Plan had reached 37%, with long-term capacity-building programmes accounting for 30% of implemented training activities.

3.14. Digital Transformation and Service-Delivery Improvement

During FY 2025/2026, the Authority continued to advance digital transformation initiatives aimed at improving regulatory efficiency, service delivery, information management, transparency and

traceability. Digital systems were increasingly used to support application processing, regulatory monitoring, quality management, data-driven decision-making and pharmaceutical supply-chain oversight.

For Human Medicines and Medical Devices Registration (HMDR), the Integrated Regulatory Information Management System (iRIMS) supported electronic submission, processing and tracking of applications and regulatory decisions. A timeline monitoring tool was integrated into iRIMS to strengthen monitoring of assessment timelines, while communication with applicants on application status was enhanced to support transparency and timely service delivery.

For Veterinary Medicines and Devices Registration (VMDR), iRIMS continued to support electronic submission and tracking of applications, although system limitations affected some regulatory processes. Challenges included difficulties with uploading and downloading dossiers and assessment reports, file-size limitations, non-migration of existing registrations, and limitations in the client portal for viewing and responding to queries. Some approval, registration and post-approval processes therefore continued through manual or parallel processes. Engagement with system developers remained necessary to address these limitations and support full digitalization of the veterinary regulatory workflow.

For Food regulatory services, the Authority continued to support the digitization and harmonization of regulatory services through IREMBO in collaboration with relevant institutions and IT teams. By the end of the reporting period, the digitization process was approximately 65% complete, with the initiative aimed at improving efficiency, interoperability, information management and service delivery to food business operators.

The Regulatory Ecosystem Strategy (RES) Division advanced digital regulatory innovation through initiatives including collaboration with Zenysis Technologies, development of a pharmaceutical pricing database and advancement of pharmaceutical traceability systems. These initiatives strengthened the use of technology and data in regulatory decision-making, improved access to regulatory information and supported enhanced monitoring and transparency across the pharmaceutical supply chain.

For Quality Management Systems (QMS), digitalization progressed through continued use of the Smart Admin platform for controlled document storage, transmission, review and approval, supported by staff training on e-folder, e-approval and workflow modules. Development of the electronic Quality Management System (e-QMS) also progressed, with functionality planned for document control, audit management, management review, change management, risk management and deviation management.

3.15. BUDGET EXECUTION

By the end of FY 2025-2026, 96% of the total budget of RWF 9,064,732,177 was executed. Financial support from development partners totaling RWF 366,732,356, recorded an execution rate of 76%, reflecting partial utilization of allocated donor funds during the fiscal year

3.16. Key Challenges and Areas Requiring Institutional Support

During FY 2025/2026, the Authority continued to address operational and institutional challenges affecting the effective implementation of regulatory activities. For Veterinary Medicines and Devices Registration (VMDR), persistent limitations in iRIMS functionality and integration affected document management, client-portal functionality and the end-to-end processing of regulatory

applications. The Division also required continued specialized and refresher training for assessors in areas including veterinary biological products, quality assessment, pharmacovigilance, pesticides and ectoparasiticides, variations and regulatory reliance. Additional areas requiring attention included limited availability of aquatic animal medicines, low stakeholder awareness, limited pharmacovigilance systems and the domestication of relevant EAC guidelines. An international training and study visit to FDA Ghana could not be implemented due to the absence of funding for additional logistical costs requested by the host authority.

For Cosmetics and Household Chemicals Registration (CHCR), insufficient staffing, particularly the limited number of technical assessors, remained a major constraint to effective implementation of the Division's regulatory and institutional responsibilities. The staffing gap increased pressure on dossier assessment, regulatory document development, stakeholder engagement and audit follow-up activities. The Division also faced challenges in accessing specialized trainers for quality, safety and efficacy assessment of cosmetics and household chemicals. External technical collaboration, including with the Egyptian Drug Authority, and internal capacity-building initiatives were pursued to mitigate the training gap. Continued recruitment of additional technical staff and establishment of sustainable specialized training arrangements remain important institutional support measures.

At the institutional and strategic level, continued coordination and follow-up are required to operationalize strategic partnerships, finalize regulatory strategies and translate developed frameworks into effective operational systems. Digital initiatives, including the pharmaceutical pricing database and traceability system, require sustained collaboration among Rwanda FDA, RISA, IT teams, development partners and other stakeholders to ensure interoperability, data quality, sustainability and effective implementation. Similarly, implementation of local production and pharmaceutical supply-chain strategies requires continued stakeholder engagement, adequate resourcing and alignment with national industrial and health-sector priorities.

3.17. CONCLUSION

FY 2025/2026 was a year of sustained regulatory implementation and institutional strengthening for Rwanda FDA. The Authority registered 238 human medicinal products, 75 veterinary medicinal products, 73 cosmetics and household chemical products, and 634 food products, while 1,031 pharmaceutical establishment licenses were approved and issued. These results demonstrate continued delivery of the Authority's core regulatory mandate across products and regulated establishments.

The Authority also strengthened market control and public health protection through 30 product recall actions or batches, 1,200 individual case safety reports, and 200 samples collected through post-market surveillance. Regulatory control of product movement was maintained through 10,787 import licenses approved and issued, together with the inspection of 6,173 consignments at points of entry and 1,470 consignments at importers' or clients' premises. For food products, 5,124 import licenses were approved and issued, supported by extensive consignment inspection and clearance activities.

Overall, the FY 2025/2026 results demonstrate continued strengthening of Rwanda FDA as an effective and increasingly modern regulatory institution. Progress in quality management, digital

transformation, regulatory capacity, laboratory services, surveillance and strategic collaboration strengthened the systems supporting regulatory decision-making and service delivery. While challenges relating to digital system functionality, specialized staffing and technical capacity remained, the Authority continued to fulfil its mandate and strengthen its contribution to protecting the quality, safety and efficacy of regulated products in Rwanda.