Rwanda Food and Drug Authority Business Plan for Financial Sustainability 2021–2025

Republic of Rwanda

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STATEMENT BY THE CHAIRMAN OF THE BOARD OF DIRECTORS

The Rwanda Food and Drugs Authority (FDA) Business Plan for Financial Sustainability 2021–2025 comes at the height of both global and national financial turmoil and is an important document guiding Rwanda FDA into a new direction regarding resource mobilization for institutional capacity building, growth, and sustainability. Its development has seen participation from key stakeholders, including our own members of staff who have enormously contributed to Business Plan's development.

The business plan provides an opportunity to Rwanda FDA as one of the world's youngest national medicines and food regulatory agency, established in 2018, not to start from zero but learn from others to optimize and improve efficiency of the available resources, automate most regulatory processes, and minimize redundances to improve service delivery.

The plan builds on other existing government strategies and policies and is not only limited to the national strategic framework of vision 2035, whose intention is to elevate the country from the current state to a middle-income country and which goes hand in hand with the urge to strengthen institutions to catalyze positive change that is needed.

As the chair of board of directors, I'm particularly very pleased with the approach used to develop this document, that saw the involvement of our major stakeholders—mainly our business clients and developments partners—taking a big role in shaping and guiding the process, including the validation process as part of the approval process before actual implementation.

In this respect, I wish to request the management of Rwanda FDA, that during the implementation, they should have a plan to have regular meetings with all the stakeholders including our development partners to take stock of the status and level of implementation, table the progress being made and obstacles or challenges to the implementation and together, seek solution on addressing the challenges and any outstanding issues.

The Board wishes to reaffirm its continued commitment and support to the management of Rwanda FDA and the partners towards the implementation of the 2021—2025 business plan and creating further advocacy. In this regard, I encourage the management and the staff of Rwanda FDA to closely follow the implementation of the entire business plan for the success and betterment of the institution and the health sector in general.

The Board of Directors take this early opportunity to congratulate management of Rwanda FDA for the successful development of this comprehensive business plan and for engaging USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program that provided the needed support.

I wish the Rwanda FDA management and staff successful implementation of this five-year business plan (2021–2025).
Endorsed at Kigali, Rwanda, on this…… day of April Two Thousand and Twenty-Two.

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

STATEMENT BY THE DIRECTOR GENERAL

The Rwanda FDA Business Plan 2021–2025 comes as one of the key documents at the current infancy stage of Rwanda FDA as a national medicines' regulatory agency. The five-year business plan intends to help Rwanda FDA to identify and consolidate its traditional sources of financing but to also identify new sources of funds and resources to support implementation of its 2021—2024 strategic plan to achieve the set objectives.

The overall purpose of the business plan is to financially empower Rwanda FDA with the required financial resources towards implementation of the institution's overall plan and transform it into a high performing, result-oriented and customer-focused institution that will lead to high quality service delivery.

I have no doubt that the focus of Rwanda FDA during the implementation of this business plan remains on ensuring availability of safe, efficacious, affordable, and high-quality medical products and safe pre-packed food staff on the Rwandan market, as per Authority's mission provided under Law N° 003/2018 of 09/02/2018.

As the Rwanda FDA enters the phase of implementation of this business plan, it will continue building more partnerships, collaborations, synergies, and ties with the existing and new national and international partners to establish a conducive regulatory environment that will support availability of safe, quality, and efficacious medical products on the market and thriving of pharmaceutical products manufacturing plants in the country as its top priority.

Public, customer, and partner engagement will remain at the center of implementation of the business plan, which will be an avenue to create more awareness and advocacy of the work done by Rwanda FDA, resulting in more informed public and improved public and customers' confidence in the regulated products circulating on the market.

Successful implementation of the business plan remains Rwanda FDA management and staff's priority and we request all its stakeholders and partners to be on board and provide technical and financial support as they can so as to realize the mission of our organization.

I wish to take this opportunity to express my gratitude towards the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) program towards the financial and technical support provided during the entire process of developing this business plan. I'm also grateful to all our stakeholders who have been involved in one or another way, during the development and validation process.

Last and not the least, I wish to request that we continue working with you all side by side as Rwanda FDA embarks on the implementation of this key document to the advantage of the people of Rwanda.

Dr. Emile Bienvenu
Director General
Rwanda Food and Drugs Authority

ACRONYMS AND ABBREVIATIONS

BK	Bank of Kigali
CESP	Common European Submission Portal
CHLS	Central Health Laboratory Services
DARRTS	Document Archiving, Reporting, and Regulatory Tracking System
DCPs	Decentralized Procedures
EAC	East African Community
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
ESG	Electronic Submissions Gateway
EU	European Union
FAMHP	Federal Agency for Medicines and Health Products (Belgian)
FDA	Food and Drug Authority
FTE	Full-time Employee
FY	Financial Year
GBT	Global Benchmarking Tool
HAS	Health Sciences Authority (Singapore)
HPRG	Health Products Regulation Group
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostic Devices
MEB	Medicines Evaluation Board Agency
MINECOFIN	Ministry of Finance and Economic Planning
MoH	Ministry of Health
MOHCDGE	Ministry of Health, Community Development, Gender, Elderly and Children
MTaPS	Medicines, Technologies, and Pharmaceutical Services
NCAs	National Competent Authorities
QA	Quality Assurance
QM	Quality Management
QMS	Quality Management System
RDB	Rwanda Development Board
RICA	Rwanda Institute for Conservation of Agriculture
RRA	Rwanda Revenue Authority
RSB	Rwanda Standards Board
SOPs	Standardized Operating Procedures

TGA	Therapeutic Goods Administration (Australia)
TMDA	Tanzania Medicines and Medical Devices Authority ()
USA	United States of America
USAID	US Agency for International Development
USP	US Pharmacopeia
WHO	World Health Organization

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EXECUTIVE SUMMARY

The recently established Rwanda Food and Drug Authority (FDA) is developing a business plan for financial sustainability to complement and operationalize its 2021 to 2026 Strategic Plan with the support of the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) program. The main objective of the business plan is to outline how the Rwanda FDA can become a financially sustainable, world class regulatory Authority.

The plan covers client needs and satisfaction, the Rwanda FDA's organizational structure, governance, management, quality management system, IT and equipment, costs, and revenue structure, as well as an overview of regulation. The results of the analysis show that the Rwanda FDA will become financially sustainable in the next five years, arriving at a minimum subsidy in financial year (FY) 2025–2026 of 312 million RWF, mostly as a financial backup (Rwanda FDA registering a net surplus that year). A benchmarking exercise, however, shows that none of the reviewed agencies in countries such as Ghana, Tanzania, USA, Netherlands, Australia, Mauritius, and Europe are 100% financially sustainable —– each receives some funding from the central government to at least cover staff salaries.

The financial projections are based on the following five-year (2021–2026) strategy for Rwanda FDA:

1. **Develop an organization that aligns with its ambitions**
    - Create Support Functions Department with a separate ICT Unit, Legal Unit, Communication Unit and Industrial market and Pharmaceutical Pricing Unit
    - Increase the staff of Quality Control Laboratory to make it a fully-fledged laboratory
    - Hire staff for vaccine regulation
    - Resolve conflict of interest issues with the Board
    - Develop a regular training plan for staff and make sure it is enforced

2. **Digitize services and operations**
    - Ensure all the services are accessible online from start to finish of the entire process, including online payment and document submission, for domestic and foreign applicants
    - Recruit an ICT director and two more software developers
    - Increase awareness about the online system among the clients
    - Ensure that the website is properly and neatly organized and up to date
    - Pay subscription fees to continue accessing global best practices standards

3. **Increase revenue to maintain financial sustainability**
    - Conduct an awareness campaign to increase the market coverage for the current services, especially in the food sector
    - Add new services, such as laboratory testing services for other regulatory authorities, paid training services for healthcare professionals, industry, consumers, and academia, scientific advice, and technical support for other laboratories
    - Develop a new revenue stream by restructuring the current fee's structure and introducing pre-application screening fees and separate registration and laboratory fees

4. **Improve the quality management system**
    - Establish a well-equipped and staffed Quality Management Division with sufficient permanent staff to cover all QMS responsibilities
    - Hire one documents management specialist
    - Hire one audits and complaints management specialist
    - Prioritize addressing the non-conformities identified in the recent internal audit

- Secure ISO 9001 certification for the whole organization and ISO 17025 accreditation for the laboratory
- Improve support function guidance and SOPs, especially for finance (monitoring the revenues, etc.) and tariffs/fees and charges payment procedures

5. **Introduce customer-oriented culture**
    - Improve client communication and care through trainings
    - Make sure clients have a 'relationship manager' or a specific contact(s) at the Rwanda FDA
    - Hire a client service specialist
    - Create infographics or lighter versions of the main guidelines on regulation
    - Organize regulatory conferences and make sure Rwanda FDA appears occasionally on radio/TV shows

The plan comes with additional costs, especially concerning the training of staff (approximately 1 billion RWF per year), as well as IT costs (10% of all operational costs, and laboratory costs for testing consumables (reference standards), accessing regulatory standards, such as US Pharmacopeia (USP) and the European Directorate for the Quality of Medicines (EDQM) and for the ISO certification.

In the last projected year (FY 2025–2026), Rwanda FDA will also be able to develop some additional services for new services, such as laboratory testing services, scientific advice, training services and technical support for other labs, but this will not generate substantial revenue in the short term (but should be able to generate revenue in the long term).

The financial projections show that the Rwanda FDA will reach a level of sustainability over the years covered. The generated revenue (without government subsidies) is expected to increase from 6.7 billion RWF in the first year to 9.7 billion RWF in FY 2025—2026. In FY 2025—2026, the Authority will be sustainable with a surplus of 2 billion RWF with a limited subsidy of 312 million RWF, which means a net surplus (without subsidy) of 1.7 billion RWF generated from collecting revenues.

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1 OVERVIEW

1.1 BACKGROUND

The Rwanda FDA was established by the Law N° 003/2018 of 09/02/2018, with a mission to protect public by regulating human and veterinary medicines, vaccines, and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials. In February 2021, the Rwanda FDA's Strategic Plan for 2021/2024 was developed with the support of the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) program.

Together with the MTaPS team, the Rwanda FDA issued a call for proposals for a business plan, which would complement and operationalize its Strategic Plan. The business plan development will include key Rwanda FDA functions such as the regulatory framework, organizational structure, financial management (pricing and/or costing of services), quality management systems and client services.

1.2 OBJECTIVES

The overall objective is to develop an actionable business plan for the Rwanda FDA. The business plan for financial sustainability for the period covering 2021 to 2026 should strengthen the financial management, enhance accountability, and ensure financial sustainability of the regulatory Authority. The long-term objective for the Rwanda FDA is to reduce its dependency on government and donor funding and attain financial autonomy.

1.3 METHODOLOGY

A market-based approach was applied in developing the business plan. This approach entitled a gap analysis and a comparison of Rwanda FDA's current key regulatory functions with selected similar and more established regulatory authorities i.e., Singapore HSA; Mauritius FDA; USA FDA; Australia TGA, Tanzania MDA, Ghana FDA, European Medicine Agency (EMA), Belgium Federal Agency for Medicines and Health Products (AFMPS), Netherlands Medicines Evaluation Board (MEB). The key Rwanda FDA functions evaluated included the regulatory framework, organizational structure, financial management (pricing and/or costing of services), quality management systems and client services. A combination of data collection, desk research, document analysis and review, and stakeholder interviews were performed on the related information from Rwanda FDA, stakeholders, and benchmarked regulatory authorities. The identified gaps from the analysis were assessed and recommendations and opportunities for improvement were proposed based on global best practices.

1.3.1 EVALUATION OF THE CURRENT REGULATORY FRAMEWORK AND ORGANIZATION

- The current regulatory functions, organizational and governance structure, and management systems of Rwanda FDAs departments and divisions were evaluated and compared to selected model regulatory authorities.
- Gaps and areas of improvement were identified and recommendations for improvements were provided based on global best practices and standards, considering technology, staffing, and training programs to deliver sustainability and profitability of regulatory functions.

1.3.2 Evaluation of the Current Financial Management and Organization

- Financial management data from the office of the Chief Finance was collected and an analysis was conducted on how the Rwanda FDA currently manages its resources in terms of sources of funding, revenue, expenses, assets, liabilities, and overall fee structure. Additionally, the current Rwanda FDA fee practices and structure were compared with selected model regulatory authorities.
- Gaps in the financial management system based on the cost and revenue analysis of regulatory functions and fee structure were evaluated and proposed strategies for improvements were based on gap analysis.
    - These strategies considered recommendations for revenue generation and enhancement by restructuring or adjusting current fee structure, while considering the realistic situation on the ground, benchmarks and what the regulated sector can handle. The projections and assumptions for financial strategy considered the existing Rwanda Manual of Public Financial Management (PFM) Policies and Procedures and adopted PFM standards for budget preparation and execution, revenue and expenditure management, asset and liability management, procurement, public investment, accounting, and reporting as well as oversight.
- Rwanda FDA's current organizational structure was compared to global best practices and analyzed through the lenses of the future expansion of Rwanda FDA services and (oversight of pharmaceutical pricing, vaccine regulation) as well as service delivery (digitization) and modifications were suggested.

1.3.3 Verification of the Current Quality Management System

- Rwanda FDA's implementation of a Quality Management System (QMS) was evaluated to ensure that it focuses on improving quality of products and services to its clients. The current QMS was evaluated to ensure it informs long-term service expansion plans for client care related functions (i.e., feedback procedures, service requirements and general satisfaction), provides for an internal quality assurance mechanism for introduction, monitoring and improvement of personnel, operations and outsourcing services, financing activities offered by the regulatory authority.
- Recommendations for improvements across these functional areas were provided based on the gaps identified and industry best practices.

1.3.4 Analysis of Client Needs and Satisfaction

- An analysis of client's satisfaction and needs in terms of delivery of Rwanda FDA services, especially in terms of scope of services, quality of the services delivered, timelines of the services delivered, and delivery channels was evaluated through a client survey, staff interviews, and stakeholders' interviews. The current service expansion/improvement processes and mechanisms were analyzed and recommendations for improvements across these functional areas were proposed based on the outcomes of the interviews and survey. In this business plan when we refer to "clients", we mean those entities that pay for Rwanda's FDA services as written in the regulations and when we refer to "stakeholders", we mean those entities who partner with Rwanda FDA such as PSM, MTaPS, MINICOM, MINECOFIN.

1.3.5 Stakeholder Consultative workshop

- A consultative workshop with Rwanda FDA and key stakeholders on the draft business plan was held. The resulting comments were addressed, and the final business plan was approved by Rwanda.

2 ORGANIZATION OVERVIEW

2.1 BACKGROUND

The Rwanda FDA was established in 2018 to contribute to the achievement of the country's socio-economic goals and protection of public health.

Rwanda FDA works closely with sister institutions under the Ministry of Health, local government, Rwanda National Police, Rwanda Investigation Bureau, and international organizations to coordinate the enforcement of and compliance with regulations to ensure maximum impact for the public welfare. The Authority also develops partnerships, where appropriate, with the private sector, including regulated industries, academic institutions, trade organizations, advocacy groups, and nongovernmental organizations.

Rwanda FDA's mandate[1] is to:

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

[1] LAW N°003/2018 of 09/02/2018

- Regulate the use of unregistered products regulated under this law for clinical trial purposes or compassionate use.
- Disseminate information on quality and safety of products regulated under this law to health professionals and other concerned persons.
- Conduct operational research and studies on food and pharmaceutical products and publish the findings to contribute to the investment promotion.
- Build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions.
- Advise the government on all matters regarding the products regulated under this law.

2.2 MISSION, VISION, VALUES[2]

The vision of the Rwanda FDA is to become a world class regulatory authority effectively protecting and promoting public health.

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

The five core values of the Rwanda FDA are:

1. **Professionalism**: serving with professionalism for excellent service delivery
2. **Integrity:** continuously work with integrity
3. **Accountability:** promoting accountability at all times
4. **Teamwork:** nurturing teamwork to achieve common objectives
5. **Innovation:** striving for innovation to create value for our stakeholder and other interested parties

2.3 STATUTORY FRAMEWORK

The Rwanda Food and Drugs Authority is an autonomous entity established under Law N°003/2018 of 09/02/2018. The law sets out its mission, organization, and function, and mandates the Authority to protect public health by regulating human and veterinary medicines, vaccines, and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials.

Other laws that aide the Rwanda FDA in accomplishing its mandate include the laws on organization, function, and competence of the council of pharmacists; the law relating to the control of tobacco; the law on governing substances and narcotic drugs, psychotropic precursors in Rwanda; the law on determining offences and penalties in general; and the law relating to the regulation and inspection of food and pharmaceutical products. Additionally, the Authority relies on prime ministerial and Ministerial orders for the interpretation and implementation of laws. The orders provide more specificity and detail than the original legislation.

The Authority's mandate aligns with critical national framework policy documents, including the Rwanda VISION 2050, the MOH Health Sector Strategic Plan (HSSP) IV (2015), the National Food and Nutrition

[2] Rwanda FDA website https://www.rwandafda.gov.rw/home and Rwanda FDA Strategy https://www.rwandafda.gov.rw/fileadmin/user_upload/RwandaFDA/Publications/RWANDAFDA_DOCUMENTS/Strategic_Plans/Rwanda_Food_and_Drugs_Authority_Strategic_Plan_2021-2024.pdf

Policy (2014), the National Pharmaceutical Products Pricing and Containment Policy (2020), the Policy of traditional complementary alternative medicine (2019), the National Pharmacy Policy (NPP) (2016), the National Health Sector Policy (2015), the National Strategy for Transformation 1 (NST1) 2017–2024, National Pharmaceuticals Pricing Containment Policy (2020), and Health Financing Strategic Plan (HFSP) 2018-2024. These policies govern how the Authority interprets and implements regulations.

The Rwanda FDA has various regulations that govern its responsibilities as mandated in the law. These regulations offer the Rwanda FDA clients a legal framework of how the Rwanda FDA will effectively and efficiently regulate its mandated responsibilities. These regulations specifically address how the laws and orders will be implemented and how they will be enforced. The Rwanda FDA has 16 regulations currently published on its website which is a remarkable increase from the seven (7) regulations mentioned in the 2019/2020 Annual Report.

Guidance and guidelines are intended to provide clarifying procedural considerations to clients who intend to engage with the Rwanda FDA. The Rwanda FDA has eight (8) guidance documents and 38 guidelines currently published on its website, which is an increase from the seven (7) regulations and 19 guidelines mentioned in the 2019/2020 Annual Report.

2.4 ORGANIZATION, GOVERNANCE AND MANAGEMENT

Rwanda FDA has been in existence for three years and its organizational structure is not yet fully established. A new organizational structure with 194 staff has been suggested in the Strategic Plan and confirmed by the Prime Minister's Order No 162/03 of 21/12/2020, but not all the positions have been filled yet. The remaining 20 positions were expected to be filled by September 2021.

Under the new organizational structure, Rwanda FDA's operations are organized into two main technical departments: the Department of Food and Drugs Assessment and Registration, with four (4) divisions, and the Department of Food and Drugs Inspection and Safety Monitoring with three (3) divisions. There is also a standalone Quality Control Laboratory Division with four (4) units, which is not yet fully operational. The support functions are organized under the Office of the Director General (legal, communications, public relations, market, regulation, compliance, quality) and under the office of the CFO (finance, IT, HR, planning, administration, and procurement). The Rwanda FDA also has an internal audit team attached to the Board of Directors.

The Board of Directors is composed of seven (7) members. The Board has two (2) subcommittees, one for finance and another one for regulatory affairs. Rwanda FDA is also in the process of establishing Advisory Committees.

The Rwanda FDA reports to the Ministry of Health.

2.5 CLIENT SEGMENTS

Rwanda FDA's foremost client is the Rwandan public, who benefit from its vision and mission as end users of the outcomes of its regulatory mandate that calls to protect and promote public health. However, given its different roles and responsibilities, the Rwanda FDA also engages with a large pool of direct clients, who fall into the following categories:

- Pharmaceutical industry
    - Pharmaceutical manufacturers - domestic
    - Pharmaceutical manufacturers - foreign
    - Pharmaceutical distributors

    - Medical devices & IVDs manufacturers
    - Medical devices distributors
    - Contract manufacturing organizations
    - Rwanda Medical Supply Ltd
- Laboratories
    - Pharmaceutical laboratories
    - Clinical laboratories
- Research institutions
    - Clinical trial facilities
    - Contract research organizations
    - Research centers/ universities
- Pharmacies
    - Retail pharmacies
    - Wholesale pharmacies
- Food industries and outlets
    - Food manufacturers - domestic
    - Food manufacturers - foreign
    - Food processing facilities
    - Food distributors
    - Food retailers
    - Food laboratories
- Veterinary industries and outlets
    - Veterinary medicines manufacturers - domestic
    - Veterinary medicines manufacturers - foreign
    - Veterinary medicines distributors
    - Veterinary medicines retailers
- Household chemicals industries and outlets
    - Household chemical manufacturers - domestic
    - Household chemical manufacturers - foreign
    - Household chemical distributors
    - Household chemical retailers
- Medicated cosmetics industries and outlets
    - Medicated cosmetics companies
- Tobacco industries
    - Tobacco & tobacco products manufacturers - domestic
    - Tobacco & tobacco products manufacturers - foreign
    - Tobacco & tobacco products distributors
    - Tobacco & tobacco products retailers

2.6 SERVICE OFFERINGS [3]

The Rwanda FDA provides more than 200 individual services, which can be grouped into the following categories based of the how they are "billed".

1. Registration of human and veterinary medicine (domestic and foreign)

[3] Regulation CBD/TRG/004 Rev 2: REGULATIONS RELATED TO THE REGULATORY SERVICE TARIFF/FEES AND FINES

2. Registration of medical devices (domestic and foreign)
3. Registration of in-vitro diagnostic devices (domestic and foreign)
4. Registration of medicated cosmetics and household chemicals (domestic and foreign)
5. Registration of laboratory chemicals, poisons, and pesticides (domestic and foreign)
6. Registration of food products (domestic and foreign)
7. Registration of tobacco and tobacco products
8. Clinical trials authorization
9. Retention/renewal of registered products
10. GMP inspections of regulated food and drugs facilities
11. Operational License/Permit/Certificate
12. Approval of variations to registered products
13. Issuance of import/export permits
14. Evaluation and approval of promotional materials
15. Issuance of Laboratory Results for Samples of Rwanda FDA regulated products
16. Response to Adverse Drug Reaction reports
17. Issue administrative fines for importation, sale, and distribution of unapproved substandard and counterfeit products.
18. Regulating pricies by putting in place mark up on pharmaceuticals

These services correspond to the Rwanda FDA's mission as defined by the law.

2.7 BENCHMARK COMPARISON

The goal of the Rwanda FDA is to become a world class regulatory authority effectively protecting and promoting public health. As part of the business plan development, Rwanda FDA was benchmarked against select, well-established, regional, and global regulatory authorities. The outcome of the benchmarking activity should facilitate recommendations and implementation of best practices across the Authority.

The regulatory authorities used as benchmarks were:

- Ghana Food and Drug Authority (FDA)
- Tanzania Medicines and Medical Devices Authority (TMDA)
- US Food and Drug Administration (US FDA)
- Singapore Health Sciences Authority (HSA)
- Belgian Federal Agency for Medicines and Health Products (FAMHP)
- Netherlands Medicines Evaluation Board Agency (MEB)
- Australia Therapeutic Goods Administration (TGA)
- Mauritius Ministry of Health and Wellness
- European Medicines Agency (EMA)

The benchmark areas include sources of income for delivery of regulatory services and client satisfaction, scope of regulated drug and food products, organizational characteristics (structure and operations) and quality management. The overall outcomes of the global benchmarking comparisons are summarized in the Table 1 below.

The Rwanda FDA service offerings are most comparable to Ghana FDA and US FDA, since they all regulate food and drugs within one authority. Netherlands MEB food regulation is unique in that it has a limited scope and only focuses on the registration of botanicals and novel foods. For other benchmarked authorities, food regulatory activities are carried out by different entities or agencies within their government operations. The regulation of human tissue materials and blood management is not consistent

across the benchmarked authority, with about half of them regulating these products; therefore, a point of consideration for the Rwanda FDA.

Rwanda FDA and Ghana FDA are the only two authorities that regulate both cosmetics and household chemicals, while Tanzania MDA and US FDA only regulate cosmetics and not household chemicals. Rwanda FDA, like the US FDA, Mauritius Pharmacy Board and Belgium FAMHP, offers registration of laboratory chemicals, poisons, and pesticides. Rwanda FDA also offers registration serviced for tobacco and tobacco products like Ghana FDA, US FDA, and Singapore HSA.

Otherwise, the overall regulatory services such as registration of vaccines, regulation of clinical trials issuing operational license, permit, certificate, conducting facility inspections, issuing import/export permits, monitoring ADR reporting, control and evaluation of promotional and advertising materials, laboratory services and training offered by the Rwanda FDA in both the food and drug areas are comparable to the services of the benchmarked authorities.

Specific key takeaways from the benchmark activities include:

- The international authority (Ghana, Tanzania, USA, Netherlands, Australia, Mauritius, and EU) still receives subsidies from their respective governments to, at a minimum, cover salaries. Therefore, the Rwanda FDA falls within best practices of other regulatory authorities in receiving some budgetary support.
- The Rwanda FDA services that call for tariffs/fees and charges are comparable to regional benchmark authority such as Ghana FDA, Tanzania TMDA, and Mauritius MOHW. The Pricing Benchmark (see section 3.5.2) conducted shows that the Rwanda FDA pricing structure is adequate and no further pricing increases or decreases are recommended at this time.
- Benchmarked authorities, such as the US FDA[4], and EMA[5], have detailed procedures on how to calculate fees, make payments and refund requests readily available on their website. Therefore, a point of improvement for the Rwanda FDA would be the implementation of said best practices.
- The Rwanda FDA charges a lump sum registration fee, which includes laboratory services. Separating the laboratory fees from registration fees, as is done in some of the benchmarked markets, (e.g., Ghana FDA and Singapore HSA) would allow the laboratory more flexibility in outsourcing its services to stakeholders and other regulatory authorities that do not have laboratory capacity, and therefore generate more income for the Authority.
    - e.g. Singapore HSA – 45% of its operating income in 2019 was from laboratory analysis fees compared to 12% from licensing fees.
- A special fee structure should be considered for medicines that are essential but have low market presence, such as orphan drugs, or those that are needed to fulfill a market shortage. This is in line with the WHO GBT sub-indicator RS07.03 which allows for the reduction or exemption of dues, taxes, tariffs, or fees in defined situations for public health interest and is practiced by benchmarked countries, such as Tanzania, and US FDA.
- A properly staffed IT department is crucial, if the Rwanda FDA aims to be a world class institution, like the authorities in the US, Belgium, and Singapore. Digitization of the Rwanda FDA's regulatory processes and services, especially those that interface with clients, should be prioritized. Therefore, ensuring client satisfaction is in line with the outlined best practices.

[4] Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry

[5] Explanatory note on general fees payable to the EMA July 2021

- International benchmarking confirms that the establishment of advisory boards is critical for regulatory authorities to obtain independent external expert advice on scientific and technical matters from experts in the pharmaceutical industry, academia, and scientific associations.
- The Rwanda FDA should consider separating the food and drug functions of the Authority into different departments. This level of specialization will streamline duties and allow for effective delivery of services to contribute to the overall mission of the Authority. This model replicates the organizational structure of other well-established regulatory authorities.
- A comprehensive training program is paramount for developing and retaining quality staff, as demonstrated by international benchmarking for instance Singapore HSA has a series of Professional Educational Programs, while US FDA has two learning management systems (LMS) ComplianceWire LMS (online-based learning) and the Pathlore LMS (classroom-based training) for its employees [6]. Training programs and continuous professional development should be part of the Rwanda FDA's organization operations and key performance indicators (KPIs) for staff.
- The current Quality Management staffing levels within the Authority structure are not sufficient. The Rwanda FDA needs to create a Quality Management division that will implement QMS principles and ensure global best practices are met and maintained. This is in line with the benchmarked authorities and WHO GBT - RS05.04.

Overall, the regulatory services offered by the Rwanda FDA in both the food and drug area are comparable to the benchmarked regulatory authorities. However, opportunities for improvement were identified in all areas related to regulated products, financial management, and organizational characteristics (structure and operations). These are addressed in more detail in the following sections of the business plan.

[6] https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/fda-employees

Table 1: Global Benchmarking Comparisons										
Country	**Rwanda**	**Ghana**	**Tanzania**	**USA**	**Singapore**	**Belgium**	**Netherlands**	**Australia**	**Mauritius**	**Europe**
Authority or Agency	**Rwanda FDA**	**Ghana FDA**	**Tanzania MDA**	**US FDA**	**Singapore HSA**	**Belgium FAMHP**	**Netherlands MEB**	**Australia TGA**	**Mauritius Pharmacy Board**	**EMA**
Government allocation	Yes	Yes	Yes	Yes	Yes	Yes (Taxes)	Yes	Yes	Yes (part of MOH)	NA
Food Regulation within the same Authority or Agency	Yes	Yes	No	Yes	No	No	Yes, botanicals and novel foods	No	No	No
Services										
Registration of human medicine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Registration of veterinary medicine	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Registration of Vaccines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Registration of medical devices	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Registration of cosmetics and household chemicals	Yes	Yes	Yes (cosmetics)	Yes (cosmetics)	No	Yes (cosmetics)	No	No	No	No
Registration of laboratory chemicals, poisons, and pesticides	Yes	No	No	Yes	No	Yes	No	No	Yes	No
Registration of food products	Yes	Yes	No	Yes	No	No	Yes (botanicals and novel foods	No	No	No
Registration of tobacco and tobacco products	Yes	Yes	No	Yes	Yes	No	No	No	?	No
Clinical trials	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Operational license, permit, certificate	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Inspections	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Laboratory services	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Import/export permits	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ADR reports	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Promotional and advertising materials control and evaluation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 1: Global Benchmarking Comparisons										
Country	**Rwanda**	**Ghana**	**Tanzania**	**USA**	**Singapore**	**Belgium**	**Netherlands**	**Australia**	**Mauritius**	**Europe**
Human tissue material	No	No	No	Yes	Yes	Yes	No	Yes	NA	Yes
Blood management	No	Yes	No	Yes	Yes	No	No	Yes	NA	Yes
Training	Yes	Yes	Yes	Yes		Yes	Yes	Yes	NA	Yes
Organization										
Quality (ISO - QMS and Lab Certification)	Non-Yet	ISO/ML3	ISO/ ML3	Yes	Yes	Yes	Yes	Yes	NA	Yes
ICT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes

NA – Not available (not publicly available on the website).

3 GAPS ANALYSIS AND FINDINGS

3.1 REGULATIONS ON TARIFFS/FEES AND CHARGES

3.1.1 OVERVIEW OF REGULATION ON TARIFFS/FEES AND CHARGES

A review of the regulations on tariff/fees and charges was conducted to ensure that the regulatory mandate for collection is supported by laws, ministerial order, regulations, guidelines, and guidance for the clients to understand and execute their regulatory obligation to the Rwanda FDA. While conducting this analysis the following observations were made:

1. Rwanda FDA laws, orders (PO, PM), regulations, and guidelines for the registration of human medicine confirm that the regulatory framework for fees and tariffs has been established, with just one gap identified:
    - There is no guidance on the Rwanda FDA website that provides the clients clear step-by-step procedures regarding payment of tariffs/fees and charges when engaging the Rwanda FDA for its services. There should be a publicly available guidance that links the Regulation CBD/TRG/004 Rev 2 and the more division level guideline Doc. No.: DHT/GDL/001.
    - Benchmarked authorities, such as the US FDA[7], and EMA[8], have detailed procedures on how to calculate fees, make payments and refund requests readily available on their website.
2. The quality of key regulatory documents needs to be improved in line with QMS documentation principles as errors and omissions were identified:
    - On page two (2) of the regulation there is an error in listing the law under Article 5: Tariffs/fees and services - Listed as - Rwanda FDA Law 003/2018 of 09/02/2019 but should be - Rwanda FDA Law 003/2018 of 09/02/2018.
    - This regulation should also reference the Law No 47/2012 and Ministerial Order No 022/17/10/TC, as they directly relate to the regulatory framework for fees/tariffs and charges.
    - The document number states it is on revision number two; however, there is no "document revision history" table showing the changes to the document.
    - Additionally, the document does not have an "effective date" like other Rwanda FDA technical regulations. However, it was adopted, issued, and signed by the DG

The relevant documents and observations are listed in Table 2 below:

[7] Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry

[8] Explanatory note on general fees payable to the EMA July 2021

Table 2: Overview of Regulation on Tariffs/Fees and Charges		
#	**Regulatory Document**	**Observation**
1	LAW N°003/2018 of 09/02/2018 ESTABLISHING RWANDA FOOD AND DRUGS AUTHORITY AND DETERMINING ITS MISSION, ORGANIZATION AND FUNCTIONING	This law not only establishes Rwanda FDA but also lays out its mandate. Article 9.4 relates to establishing tariffs related to services offered by Rwanda FDA. This law is supported by Law No 47/2012 and Ministerial Order No 022/17/10/TC, Regulation CBD/TRG/004 Rev 2.
2	No 47/2012 of 14/01/2013 LAW RELATING TO THE REGULATION AND INSPECTION OF FOOD AND PHARMACEUTICAL PRODUCTS	This law relates to the registration of activities and Premises. Article 26 relates to the requirements for registration of pharmaceutical products and medical devices. It states that a Ministerial order shall determine fees for registration of pharmaceutical products and medical devices. This law is supported by a Ministerial Order No 022/17/10/TC, Regulation CBD/TRG/004 Rev 2.
3	MINISTERIAL ORDER Nº 002/17/10/TC OF 27/10/2017 DETERMINING THE FEES FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES AND OTHER RELATED SERVICES	This order determines fees for registration of pharmaceutical products, medical devices, and other related services. Article 3 relates to the registration fees for pharmaceutical products and medical devices which are listed in the Annex. This ministerial order is supported by Regulation CBD/TRG/004 Rev 2.
4	Regulation CBD/TRG/004 Rev 2 REGULATIONS RELATED TO THE REGULATORY SERVICE TARIFF/FEES AND FINES	The purpose of this regulation is to establish tariffs, fees and charges for regulatory services rendered by Rwanda FDA. This regulation should be supported by a guidance document, but it cannot be found.
5	Guideline Document: Doc. No.: DHT/GDL/001 Guidelines on submission of documentation for registration of human medicinal products	Section 1.3.e Payment of fees shall be made in accordance with regulations No. CBD/TRG/004 related to regulatory services tariffs/ fees and charges. The fees are for each respective product registration excluding transfer and other charges. This guideline document supports the regulations and law that a fee should be paid for registration of human medicine products. However, there is no procedural document stating how to go about paying the fee to Rwanda FDA.

Table 2: Overview of Regulation on Tariffs/Fees and Charges		
#	**Regulatory Document**	**Observation**
6	Form Ref. Doc.: DAR/GDL/001 ANNEX II: PRODUCT REGISTRATION APPLICATION FORM	This form in section 2.0 DECLARATION BY AN APPLICANT, state "It is hereby confirmed that fees have been paid according to the Rwanda FDA regulations and a proof of payment is enclosed in the dossier." This allows for confirmation/verification of payments for services related to registration of human medicine products. This document supports the guideline document Doc. No.: DHT/GDL/001

3.1.2 Assessment of Regulation on Tariffs/Fees and Charges

The appropriateness of the tariff/fees and charges was also assessed and compared to benchmarks. Rwanda FDA services that call for tariffs/fees and charges are comparable to regional benchmark countries such as Ghana FDA, Tanzania TMDA, and Mauritius. The current fees are appropriate and in line with relevant services offered. However, in the medium term it, is recommended to restructure some of the fees allowing more flexibility when registering products. For example, pre-application screening fees could be introduced, as a percentage of the application fee that is credited to the registration fees if an application is accepted for assessment and lost if the application is rejected during the pre-application step.

The Rwanda FDA could also aim to separate the laboratory fees from the lump sum registration fees, as is done in some of the benchmarked markets, e.g., Ghana FDA and Singapore HSA. In the case of Singapore HSA, 45% of its operating income in 2019 was from laboratory analysis fees compared to 12% from licensing fees. This would allow the laboratory more flexibility in outsourcing some of its services to stakeholders and other regulatory authorities that do not have laboratory capacity.

The prices of the current fees are, however, judged to be adequate and should not be increased or reduced. A special fee structure should be considered for medicines that are essential but have low market presence, such as orphan drugs, or those that are needed to fulfill a market shortage. This is in line with the WHO GBT Sub indicator RS07.03 which allows for the reduction or exemption of dues, taxes, tariffs, or fees in defined situations for public health interest and is practiced by benchmarked countries such as Tanzania.

Table 3: Assessment of Regulation on Tariffs/Fees and Charges		
#	**Observation**	**Implication**
1	Rwanda FDA is a relatively new organization. Therefore, the regulations, guidelines, and guidance, have validity dates as recent as August 2021.	There are still more regulations and guidelines to be drafted as Rwanda FDA becomes more experienced in its process and mandate. This will offer an opportunity for document streamlining and creation of new documents because of new processes and scientific thinking.
2	Review of Regulation CBD/TRG/004 Rev 2, REGULATION GOVERNING SERVICE FEES TARIFF AND FINES found inconsistencies and errors.	The document creation and formatting system is inadequate in ensuring generation of high-quality documents, therefore lacking in QMS principles.

Table 3: Assessment of Regulation on Tariffs/Fees and Charges		
#	Observation	Implication
3	There is no guidance that provides clear step-by-step procedures regarding fee/tariffs and charges payments.	This creates a gap for clients who intend to engage with Rwanda FDA for its services. They know they must pay fees for services offered; however, how, and what they need to pay is unclear.

3.2 Organization, Management and Governance

3.2.1 Overview of Organization, Management and Governance

The Rwanda FDA senior management comprises the Director General, the Head of Food and Drugs Inspection and Safety Monitoring Department, the Head of Food and Drugs Assessment and Registration Department, the CFO and all the Division Managers: Division Manager of Food and Drugs Import & Export Control, Division Manager of Food and Drugs Inspection and Compliance, Division Manager of Human Medicine and Devices Assessment and Registration, Division Manager of Quality Control Laboratory, Division Manager of Pharmacovigilance and Food Safety Monitoring, Division Manager of Cosmetics & Household Chemicals Assessment and Registration, Division Manager of Veterinary Medicine Devices Assessment and Registration and Division Manager of Food Assessment and Registration. The senior management gathers in a monthly meeting, to which middle management can be invited depending on the topic being discussed. The senior management meets more often if there are any urgent matters to discuss.

Currently, the biggest division (43 employees) is the one issuing import and export permits, which also seems to bring in the biggest revenue for the Rwanda FDA (although this is hard to judge, as Rwanda FDA does not track the revenue from the different services). The laboratory division is currently not yet offering its services to outside clients. Although it is one of the most expensive divisions to run, with the second biggest overhead (29 employees, although not all the positions are yet filled), it does not generate any revenue. The registration of different categories of products (drugs, food, tobacco, chemicals, etc.) is also one of the main Rwanda FDA missions and the corresponding department counts 44 employees in total.

3.2.2 Assessment of Organization, Management and Governance

Detailed observations about organization and governance at Rwanda FDA are presented in Table 4 below.

Table 4: Assessment of Organization, Management and Governance		
#	Observation	Implication
1	Rwanda FDA has not yet filled in all the positions from the suggested organizational structure. The remaining employees were supposed to be recruited by the end of September 2021.	Rwanda FDA is still not fully staffed, especially the lab. Other divisions are also short staffed, making it harder to clear the backlog of applications for human medicine and devices.
2	Rwanda FDA is supposed to oversee and coordinate the implementation of the National Pharmaceutical Product Pricing and Containment Policy.	Rwanda FDA should create a Pharmaceutical Pricing Unit.

Table 4: Assessment of Organization, Management and Governance		
#	**Observation**	**Implication**
3	Many key people have been recruited recently, with a large group starting in June 2021.	Integrating a high number of new employees will be a challenge, even for a new institution with many new staff like the Rwanda FDA. However, it also means that the institutional knowledge at Rwanda FDA is very limited and concentrated with a handful of employees.
4	The admin and support roles at Rwanda FDA are scattered between the Office of the DG and the Office of the CFO.	The separation of admin staff in different offices might decrease their efficiency and make communication and collaboration more difficult. The staff is also more likely to have competing priorities.
5	Rwanda FDA does not have a proper IT Department and a CTO, but only four IT positions at the same level under the CFO.	Rwanda FDA lacks the IT staff necessary to make operations more efficient. In the future, when the number of applications increases, this is going to be a serious issue. Having a properly staffed IT department is crucial if Rwanda FDA aims to be a world class institution, as shown by the benchmark from US FDA, Belgium, Singapore, and others. Moreover, not having an IT manager in charge of the team can lead to inefficient decision making, lack of direction and slow call to action.
6	Many IT responsibilities (security, software development and others) are outsourced to either RISA or NCSA.	Outsourcing IT responsibilities makes it easier to access expertise (RISA and NCSA certainly has it) and is less costly, but it can increase projects' timelines because of slow responses, and it decreases Rwanda FDA's agility and control.
7	Rwanda FDA only has one software developer.	Internal capacity cannot keep up with Rwanda FDA's changing IT demands and needs, therefore Rwanda FDA often must source external solutions that are not necessarily the best fit.
8	Rwanda FDA cannot increase or decrease salaries and allowances (housing, transport) at its discretion, because they are set by the Public Service Statute law from 08/10/2021 and by the relevant Prime Minister's Order.	As a public entity, Rwanda FDA needs to comply with the Service Statute law for the employee's salary and benefits, which makes it very difficult to have agility in retribution and motivating staff. It can also make it harder to retain quality staff and increase the staff turnover. Typically, other authorities (such as the US FDA) must respect public statute laws for the basic salary but can have some flexibility to act on the benefits package, for example a retention bonus for a certain job description.
9	The Rwanda FDA salaries, as defined by the Public Service Statute law from 08/10/2021 and by the relevant Prime Minister's Order, are lower compared to salaries in the private sector.	This could further contribute to staff turnover and dissatisfaction. It is likely that quality staff will stay at Rwanda FDA for the time necessary to gain expertise and exposure, and then switch to the private sector after.

Table 4: Assessment of Organization, Management and Governance		
#	**Observation**	**Implication**
10	Rwanda FDA does not currently do any systematic training of staff. There was, however, an induction training for the new staff who joined in June 2021.	Given that Rwanda FDA cannot act on the salaries and benefits, training is the only tool that the Authority should retain quality staff. If proper professional training is not implemented, it can further contribute to employee turnover and dissatisfaction.
11	It appears that the Chairman of the Board has a clinical research site in Kigali which is being regulated (and currently inspected) by Rwanda FDA.	The Chairman has a clear conflict of interest which is not acceptable for a world class regulatory Authority.
12	Rwanda FDA has so far not established any internal or external advisory boards involving external subject matter experts. To date, internal scientific committees have been gathering informally e.g., the pharmacovigilance committee.	International benchmark suggests that establishing advisory boards is critical for regulatory authorities to get independent external advice on scientific and technical matters from experts in the pharmaceutical industry, academia, and scientific associations
13	Rwanda has not conducted any employee satisfaction survey so far.	This means that Rwanda FDA management has very sparse information about their employees' satisfaction. Having a proper survey will provide insight on the work environment and culture of Rwanda FDA and a way to assess immediate supervisors on various management qualities.

3.3 SERVICE ANALYSIS AND CLIENT NEEDS

3.3.1 MARKET

3.3.1.1 THE PHARMACEUTICAL MARKET

According to Fitch Solutions[9] Rwanda's pharmaceutical market is underdeveloped compared to international and regional standards. Pharmaceutical sales stood at 155.5 billion RWF (165.2 million USD) in 2020, which is comparatively lower than the much bigger Ugandan market which totaled 410.3 million USD, the Tanzanian market (536.4 million USD), or the Kenyan market (1.1. billion USD). Fitch Solutions expects the Rwanda market to grow at a compound annual growth rate (CAGR) of 11.4% by 2025 to reach 266.8 billion RWF (265.7 million USD).

[9] Fitch Solutions, Rwanda's Pharmaceutical & Healthcare Markets to Post Modest Growth over Medium Term, 24 May 2021

There are only a few established manufacturers in the country—the Rwanda FDA only counts six (6) in their client database—and most pharmaceuticals are imported, mainly from India, Belgium, and Kenya[10].

3.3.1.2 THE FOOD SECTOR[11]

The Rwanda food industry has been growing organically for the past years and is still largely unregulated. In the mapping of Rwanda food processing industries and importers, which was conducted in 2020 through Voice for Change Partnership Project, 474 food industries were mapped during the first phase using a questionnaire and geographical coordinates mapping using ArcGis technology, while the second phase of mapping involved 448 food industries. At the end of the mapping exercise, 37% of the mapped industries fulfilled the requirements for premise suitability and qualified for premise license, 30% received notice to rectify defects while operating, 5% received a suspension notice to rectify defects and 29% receives a closure notice for the sake of public health protection, and 32% were not scored because they were not operating at the time of visit. 80% of food industries did not hold a standardization mark (S-Mark, the product certification attesting that attributes, characteristics, quality, or status of goods is in accordance with established standards) as required by Law N° 47/2012. Regarding food quality and safety, repeated cases of poor-quality agriculture and animal-based products were reported by both inspectors and consumers, as were counterfeit products, poor packaging, and storage conditions, forcing various food products to be recalled from the markets.

3.3.2 CLIENT NEEDS AND SATISFACTION

To identify clients' needs and satisfaction, an online survey targeting Rwanda FDA clients was designed and administered over Google forms. The survey was sent to 201 clients from the pharmaceutical, tobacco, food, veterinary and cosmetics industries. Unfortunately, the survey response rate was relatively lower (25%) than expected. Overall, only 50 clients responded, from the following industries[12]:

The low response could be attributed to various reasons, i.e., delays in getting clients' email addresses which shortened the response time due to the tight project deadlines, or accuracy of the client emails; over 13% of the email addresses can back as invalid thus resulting in fewer clients receiving the survey. Additionally, many clients do not have email addresses, for example, 32% of the human retail pharmacies, 58% of the human wholesale pharmacies, and over 90% of the veterinary pharmacies have no email addresses. Accordingly, in the next survey, consideration should be given to various ways (paper or telephone) of survey delivery for clients with no email addresses. Consequently, we propose that the client database is updated with correct client contact information including email addresses where possible. Our recommendation for the next survey is that it is administered directly by Rwanda FDA to its clients, with ample response time thus increasing the probability of a higher response rate.

[10] Fitch Solutions, Rwanda's Pharmaceutical & Healthcare Markets to Post Modest Growth over Medium Term, 24 May 2021

[11] This section of the business plan is taken from the Rwanda FDA 2021-2024 Strategic Plan and Rwanda FDA Mapping of the Food Processing Industries and Importers in Rwanda ODG/REP/0/FDA/02/2021

[12] The total is 58 because some of the clients have multiple roles, e.g., retail pharmacy and pharmaceutical distributor.

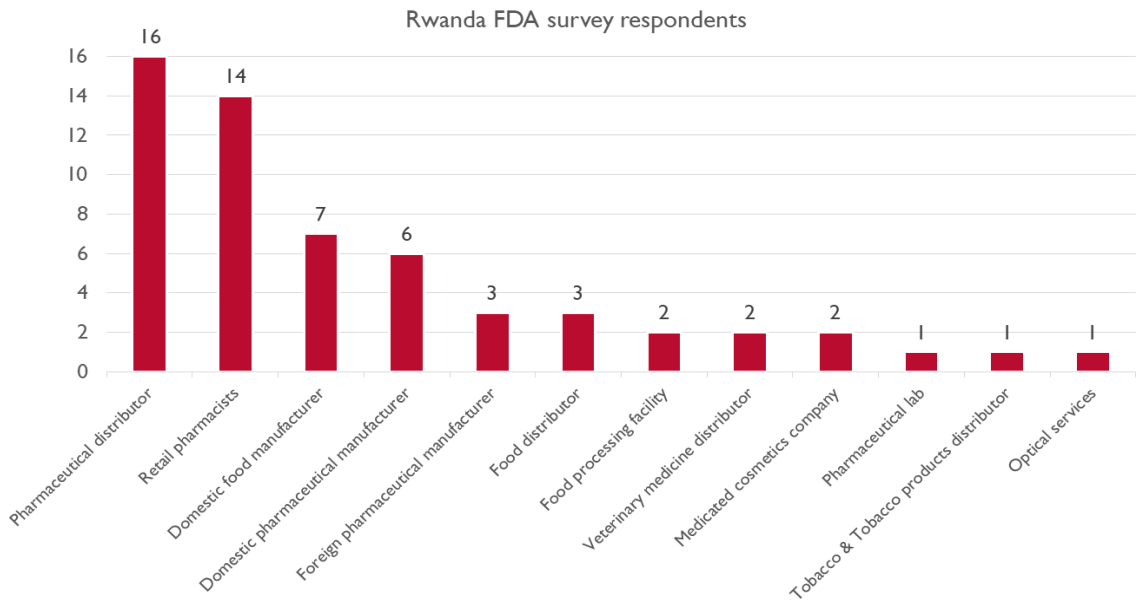


Chart 1: Rwanda FDA client satisfaction survey number of respondents

Nineteen (19) of the respondents (38%) declared contacting the FDA only once per year, but 16 contact Rwanda FDA monthly, five (5) of them several times a month, six (6) daily, and the others on a per demand basis.

The respondents contacted Rwanda FDA for the following services:

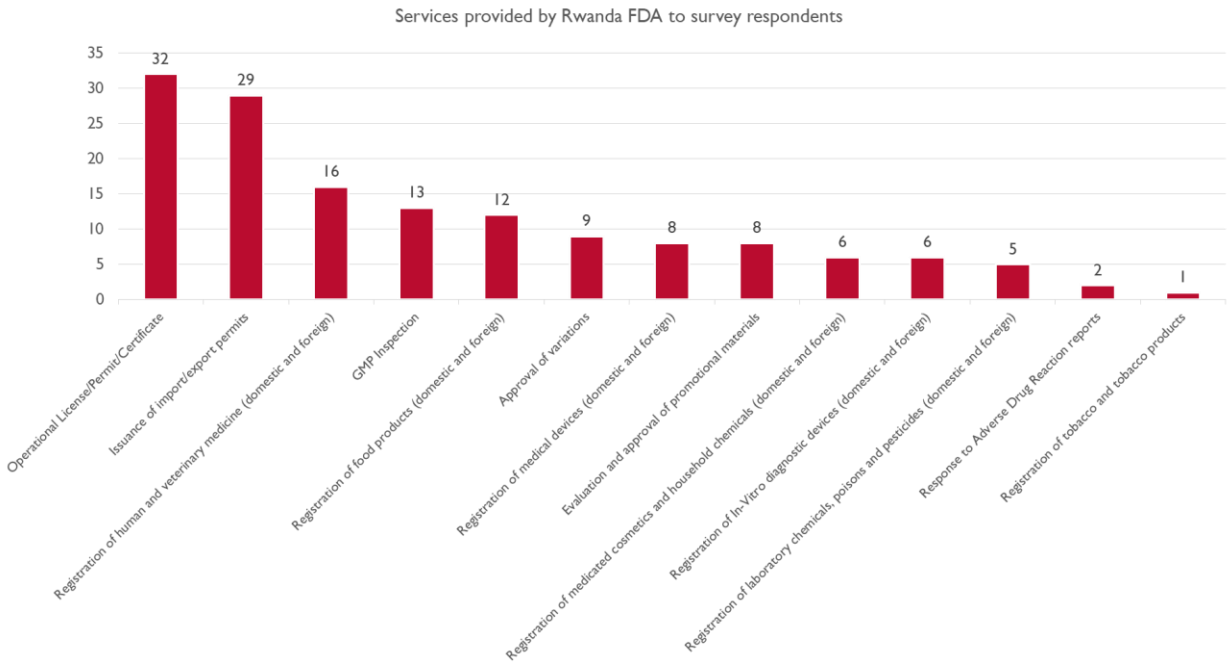


Chart 2: Rwanda FDA services used by clients

The respondents were then asked a series of questions about their satisfaction with Rwanda FDA services, on a scale from one to five, where one was bad and five was good.

PRODUCT REGISTRATION PROCESS

The first question was about the speed of the product registration process. As we can see from the Chart 3 below, 18 respondents (36%) are not happy with the speed (answering "1" or "2" on the scale), whereas 11 are (answering "5" or "6" on the scale), and 15 appear to be neutral (response "3" on the scale).

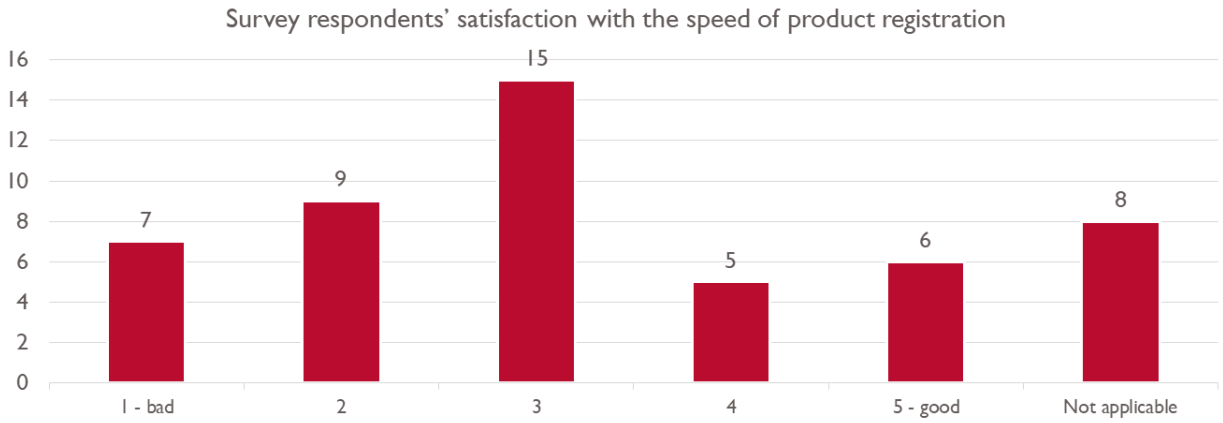


Chart 3: Client satisfaction with the speed of product registration

The second question was about the price of the product registration process. As we can see from the Chart 4 below, 20 respondents (40%) are not satisfied with the price (answering "1" or "2" on the scale), only 14 (28%) are, while nine (9) appear to be neutral (response "3" on the scale) and another seven (7) are not concerned ("NA" response).

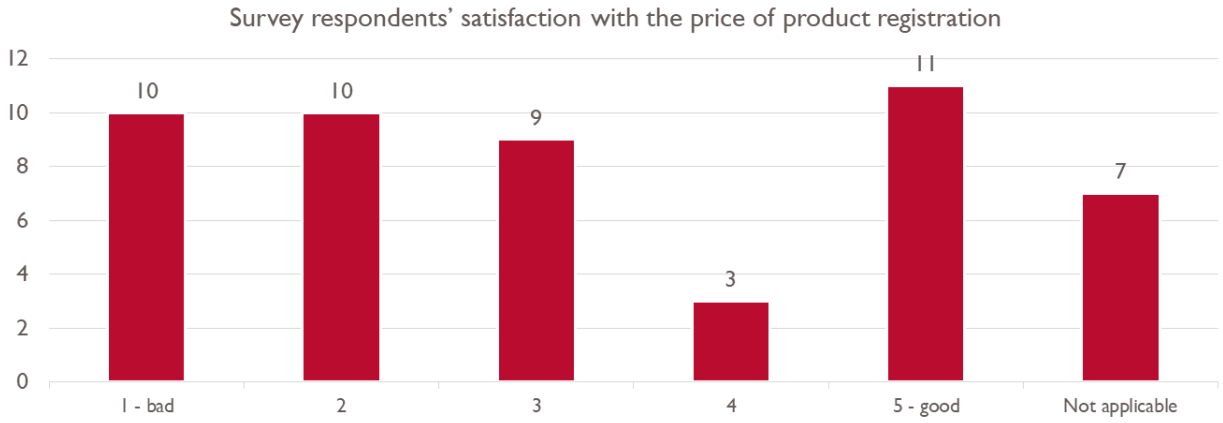


Chart 4: Client satisfaction with the cost of product registration

The third question was about the quality of the product registration process. Most of the respondents appear to not have an opinion on this matter, as 19 answered "3" on the scale and 16 (32%) consider the quality to be good. Only six (6) respondents (12%) think it is bad.

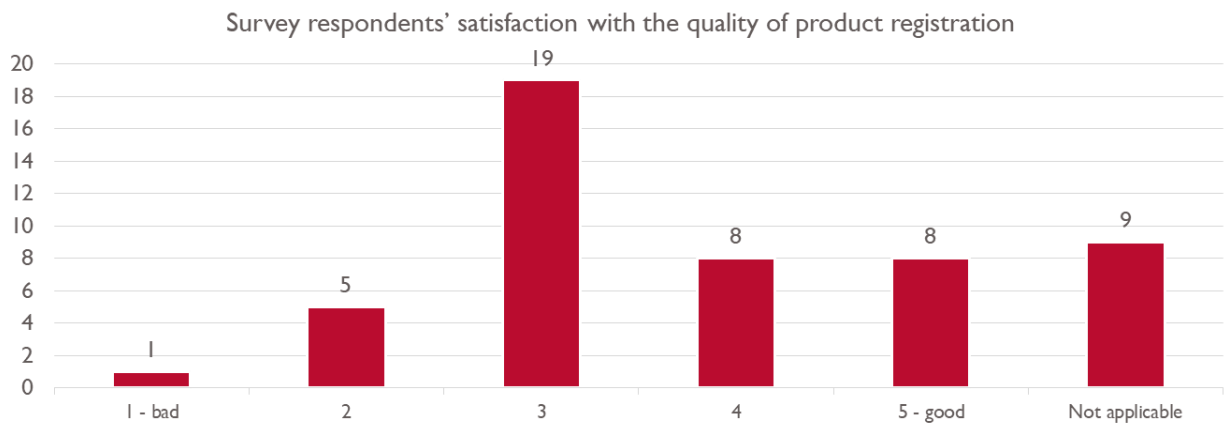


Chart 5: Client satisfaction with the quality of product registration process

ISSUANCE AND RENEWAL OF LICENSES

Another set of questions concerned the process of issuing and renewing licenses.

The effectiveness of the process of issuing and renewing licenses is considered mostly good by the survey respondents: 28 respondents (56%) answered "4" or "5" on the scale and only six (6) respondents consider the effectiveness of the process to be bad.

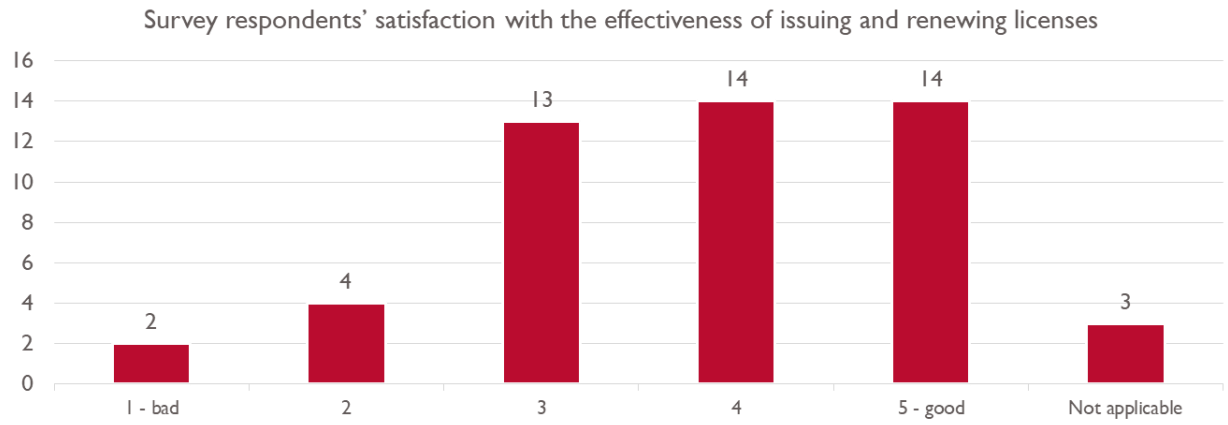


Chart 6: Client satisfaction with the effectiveness of issuing and renewing licenses

The process of issuing and renewing licenses also appears to be found user-friendly by the survey respondents: 29 respondents (58%) answered "4" or "5" on the scale and only nine (9) respondents considered the ease of the process inadequate.

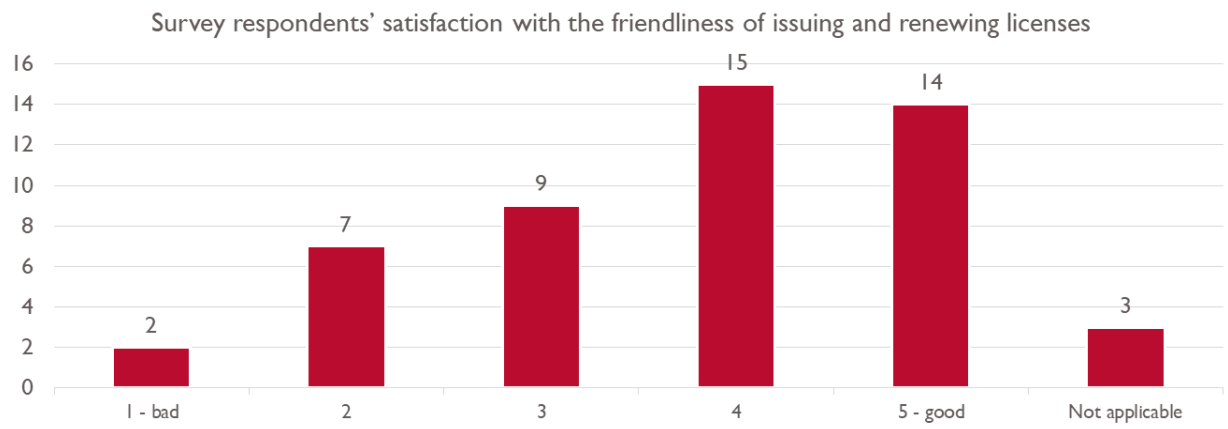


Chart 7: Client satisfaction with process of issuing and renewing licenses

GMP Inspection

Another set of questions was targeted at the GMP inspection.

For those who are concerned by this service (only 35 respondents or 70% out of the 50), the transparency of the GMP inspection appears to be good: 23 respondents answered "4" or "5" on the scale, and only seven (7) answered "1" or "2" ("bad" on the scale).

Chart 8: Client satisfaction with the transparency of GMP inspection

The price of the GMP inspection appears to divide the respondents: 18 of them answered "4" or "5" on the scale, which means they consider it being adequate, while another 16 consider the price to be too high (answering "1" or "2" on the scale).

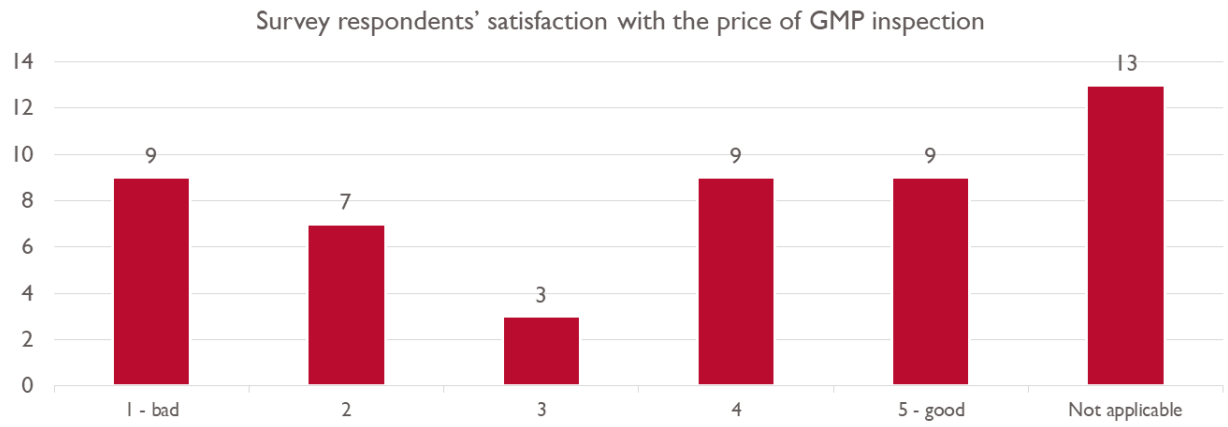


Chart 9: Client satisfaction with the price of GMP inspection

The feedback is also quite even considering the speed of the GMP inspection: 16 respondents consider it to be adequate ("4" or "5" responses on the scale) while another 16 respondents judge it bad ("1" and "2" responses on the scale).

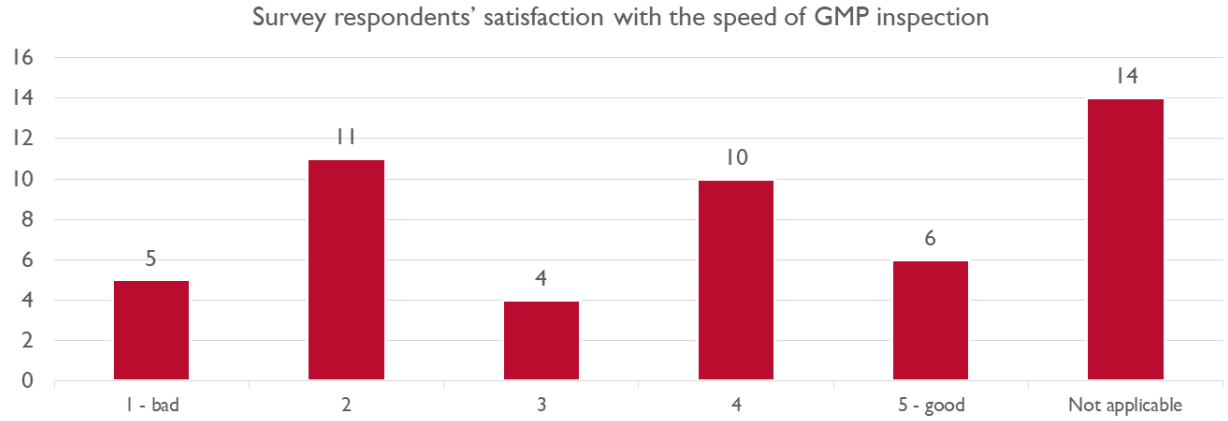


Chart 10: Client satisfaction with the speed of GMP inspection

OVERALL SATISFACTION WITH RWANDA FDA

The Rwanda FDA's overall communication and accessibility is judged good by 60% (30) of respondents, while only nine (9) respondents consider it inadequate (responses "1" and "2" on the scale).

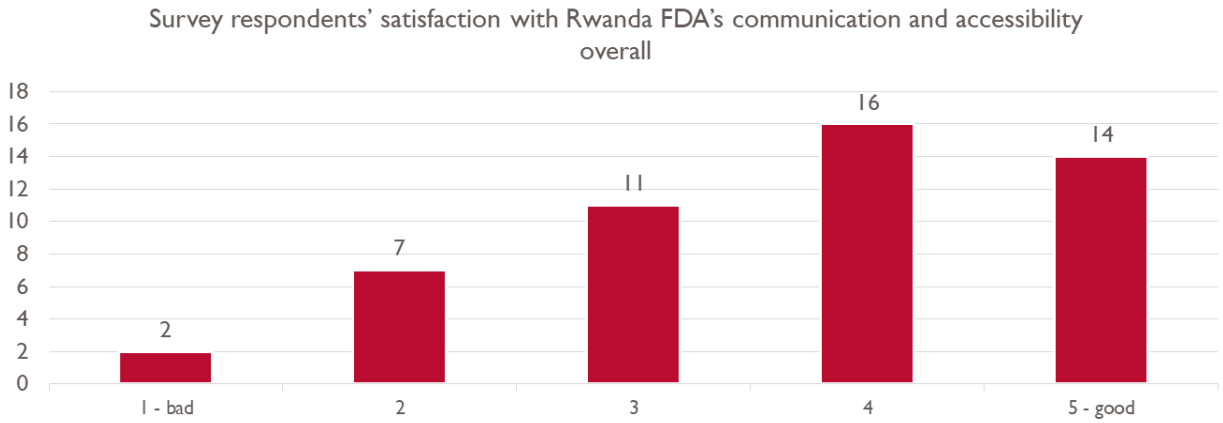


Chart 11: Client satisfaction with Rwanda FDA's communication and accessibility

When asked about missing services, the respondents responded broadly by evoking their desire for effective communication and customer care (7 responses), stating that they would appreciate having a number for Rwanda FDA or employees' email addresses with clear instructions on whom to call/write with different issues. They also complained about missing training and awareness on Rwanda FDA services (5 responses), and they would like to have better laboratory services (4) and online services in a 'one-stop center' portal (3). Some also raised the issue of regulating traditional healers (2).

When asked about what they would improve at the Rwanda FDA, the responses were similar. The respondents once again mentioned communication, which seems to be a consistent issue (11 respondents), with some respondents also suggesting setting up a call center and an overall wish for the Rwanda FDA to improve the speed of their responses to clients. The respondents would also appreciate regular and more structured feedback from Rwanda FDA. Eleven respondents said that they would like the processes (mostly product registration and licensing) to be faster. Three (3) respondents expressed the need for online services, and five (5) spoke again about the need for training, both on the Rwanda FDA services and on the use of PRIMS. Only five (5) respondents suggested that the fees for Rwanda FDA services should be reduced. Some respondents suggested that a license should be given for more than a year, possibly three (3) years. Lastly, some respondents spoke about specific issues, such as the need to allow the multiple use of one import visa since they have deliveries from one proforma invoice. Another advocated for export permits for food to be revoked if one follows the regular customs procedures and EAC regulations.

Thirty-one respondents (62%) have reported experiencing delayed response from Rwanda FDA, while 11 (22%) have had issues contacting Rwanda FDA customer care in the past, and another 11 (22%) spoke about extensive communication back and forth about a single issue, illustrating the communication problem mentioned earlier. 15 respondents (30%) consider that the Rwanda FDA website is not working efficiently or is not up to date. 13 respondents (26%) were confronted with registration timelines which were longer than initially announced by Rwanda FDA, but more importantly, nine (9) respondents (18%) complained about inconsistent or unprofessional advice and eight (8) even reported that Rwanda FDA had lost the document they had previously sent or that they were forced to send one document repeatedly. Eight (8) respondents (16%) complained about the lack of guidelines documentation regarding regulatory procedure, which suggests that the guidelines published on the website might not be enough or are not easily accessible.

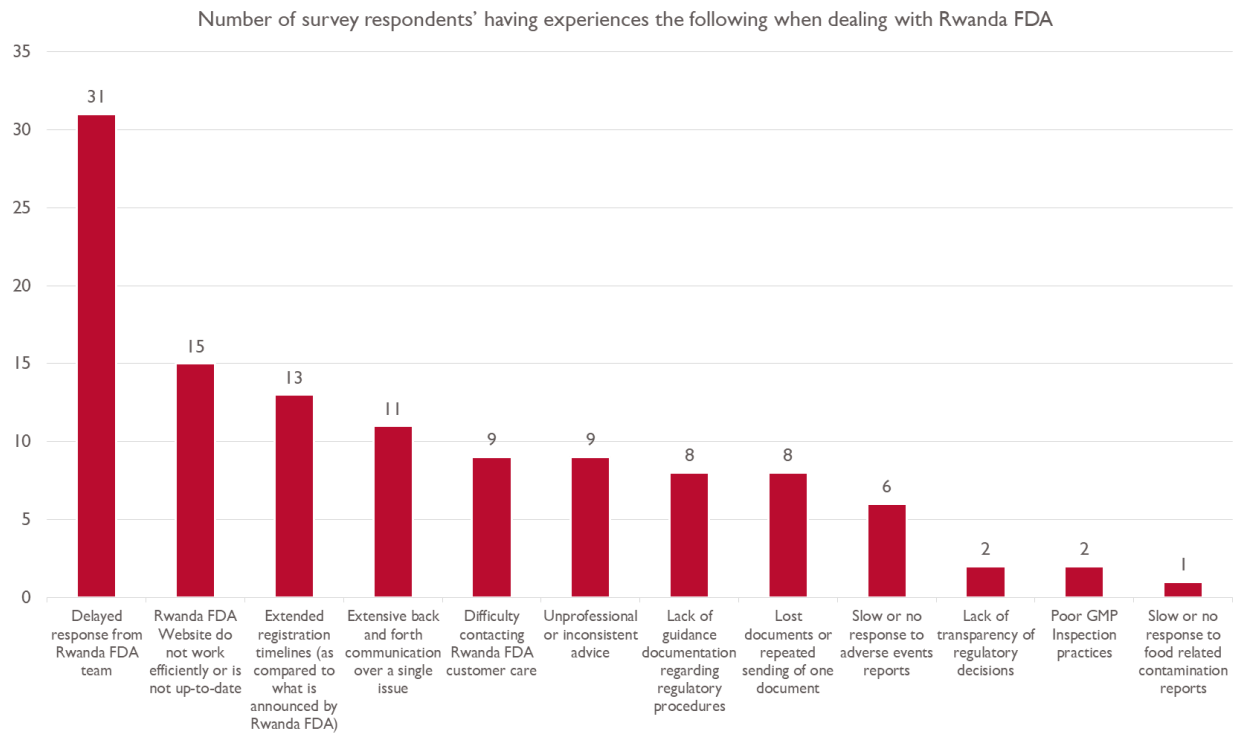


Chart 12: Client defined issues when dealing with Rwanda FDA

3.3.3 Assessment of Client Needs and Satisfaction

From these client survey results (although not statistically representative due to low response rate), it appears that Rwanda FDA is appreciated for the quality of its services, which cover most of its clients' needs, but not for its customer approach and communication. This is likely because most Rwanda FDA employees are subject matter experts in their field (related to pharmaceuticals, food, veterinary medicine, etc.) with little to no training in communication and client service relations.

In Table 5 below there are some detailed observations about services and client facing processes at the Rwanda FDA.

Table 5: Assessment of Client Needs and Satisfaction

#	Observation	Implication
1	Rwanda FDA currently has no client feedback mechanism. Clients can only reach out to Rwanda FDA via a generic email and a toll-free line available 24/7 to leave their feedback.	There is insufficient connection between Rwanda FDA and its clients, and the absence of feedback mechanism makes it very hard to know if clients are satisfied with Rwanda FDA services. It is also likely that the feedback received through email will be overly negative as people rarely make the effort to reach out to give positive feedback. From the analysis of the client survey, it seems that the clients would appreciate being able to give feedback to Rwanda FDA.

Table 5: Assessment of Client Needs and Satisfaction		
#	**Observation**	**Implication**
2	When asked for things to improve, most Rwanda FDA customers complained about unsatisfactory communication.	It appears that despite its Client Service Charter, Rwanda FDA is not applying the basics of client communication. This adds to clients' dissatisfaction, but also increases the workload for Rwanda FDA, whose employees must follow up with dissatisfied clients, and discourages new clients from coming to Rwanda.
3	The public lacks awareness of and training on the new regulations, especially in the food sector.	Rwanda FDA is currently not collecting all the revenue that they should from product registration (the estimation is that only 20% of the current market is covered). It also means that the market is today to a large extent unsafe and unattractive to new players from abroad.
4	Almost a third (26%) of clients' report that they have experienced extended registration timelines.	Extended timelines are probably due to the backlog of applications that Rwanda FDA is still trying to clear as a new institution, which can be understood by clients. However, it appears that communication about timelines is not properly done, and clients are having unrealistic expectations which leads to deception and dissatisfaction.
5	A lot of applications received by Rwanda FDA are incomplete (especially in the food sector). Some applications come in without payments, some lack important documents. Rwanda FDA needs to follow up repeatedly with the clients to provide a complete set of documentation and payment.	Having to follow up on incomplete applications makes it harder to meet the deadlines defined by the SOP. It is also a time consuming and inefficient use of resources. Rwanda FDA should consider having a pre-application screening procedure where poor applications can be rejected prior to being received by the Authority. There should be a fee for this process.
6	Most clients are satisfied with Rwanda FDA's prices, but the Authority sometimes should give them a grace period for payment.	While it appears from the client survey that most of the clients are satisfied with the prices, small clients and clients in the food sector do not always have cash to pay for the Rwanda FDA's services upfront. This brings additional complexity to Rwanda FDA and with the current lack of follow up on revenues and adds to the revenue collection gaps.

3.4 TECHNOLOGY AND EQUIPMENT

3.4.1 ASSESSMENT OF TECHNOLOGY AND EQUIPMENT

The Rwanda FDA lacks digitization and technology equipment, compared to world-class agencies such as the US FDA, Singapore's HSA and Australia's TGA. Most of the services are not accessible online, payment cannot be done online, documents need to be handed in as physical copies, the PRIMS software is used only by a fraction of clients, the website is not appreciated by the clients, and employees do not have the proper equipment to work.

Below are some detailed observations about Technology and Equipment at Rwanda FDA.

Table 6: Assessment of Technology and Equipment		
#	**Observation**	**Implication**
1	IT literacy is low within Rwanda FDA, and some staff reach out to the IT team with minor IT problems.	IT literacy is crucial if Rwanda FDA wants to be a world class institution. Having to handle minor IT issues raised by staff also takes up the IT team's time.
2	Some of the divisions, including staff under the DG office, lack IT equipment, and staff have been using their own computers.	This poses a security risk and can create data protection issues, especially as Rwanda FDA handles sensitive client data.
3	The pandemic has helped Rwanda FDA to digitize some of its processes and document handling, but a lot of things are still done on paper.	While there is certainly a need for physical documentation for the different services Rwanda FDA provides, international benchmarks suggest that digitization of processes, especially the ones including clients, is key; for instance, US FDA, EMA, and others use software such as Extedo, Lorenz, GlobalSubmit™ eCTD for regulatory submissions. Additionally, various commercially available regulatory information and document management systems are commonly used by other regulatory authorities.
4	The PRIMS software has not been fully implemented as of today (the main module working is the import/export).	This creates a lot of parallel manual processes prone to errors and miscommunications. IT makes it especially difficult to extract any meaningful information from the system, such as revenue categorization, full list of registered products or complete client list.
5	The PRIMS software is in English and there is no Kinyarwanda version.	This can pose issues, especially on the client side. Applicants not proficient in English (especially in the food sector) will likely keep on using emails to apply instead of migrating to the PRIMS system.
6	Currently, a lot of clients, especially in the food sector, continue to apply via emails.	This makes it very difficult to track and follow up on the applications. The staff has created a parallel database which is updated every day. This basically doubles the workload. It is also hard for the manager to have an overview of all applications, assign them to staff and check on progress.
7	Currently, the system does not enable payment within the system. The applicant needs to deposit money on the Rwanda FDA account in the bank.	This makes it hard to know how much revenue is coming in for which type of service, rendering any revenue analysis impossible. It is also time consuming as the revenue accountant needs to spend time daily on reconciling the payments on the account with the payments due.

Table 6: Assessment of Technology and Equipment		
#	**Observation**	**Implication**
8	The system is currently being updated. However, even after the update, application and payment will not be integrated. Applicants will still have to pay at the bank and then the bank will automatically inform PRIMS. However, this will only work with Bank of Kigali (BK).	It is unclear if this will help Rwanda FDA to track different revenue categories. Moreover, having to physically pay in a bank is not user friendly, especially for international players, which Rwanda FDA is trying to attract.
9	The Rwanda FDA website is overflowing with documents and the orientation is difficult. Some of the links are not working; some links are in Kinyarwanda and others in English; and not all the website sections are populated (e.g., laboratory).	The Rwanda FDA website does not provide a good client experience, and this is confirmed by the client survey where respondents mentioned that they would appreciate a rehaul.
10	The Rwanda FDA lab is not fully equipped yet and cannot perform all the tests necessary. Some of the tests are currently being sent abroad.	This increases the timelines and makes it harder to respect the timelines specified in SOPs and increases the cost.

3.5 Cost and Revenue Structure

3.5.1 Overview of Cost and Revenue Structure

Rwanda FDA is still a new organization, established as an independent Authority only in mid-2018; therefore, there are only three (3) years of historical finances. As per the declaration of the Director of the Finance Unit at Rwanda FDA, during the first fiscal year, the Authority was fully financed by the government, and for the subsequent years, the expenditures were partially financed by the fees for the Rwanda FDA services. In the financial year 2019/2020, Rwanda FDA generated revenue to cover 38% of costs. In the current financial year (2020/2021), only the salaries are subsidized by the government, while the rest of the expenses are covered by the Rwanda FDA.

MINECOFIN has started to phase out the subsidies, and the Rwanda FDA is expected to be fully sustainable within a few years. Based on the historical financials, it appears that the Rwanda FDA may already be sustainable, but it is difficult to predict its revenue from one fiscal year to another, especially as the revenue collection is not automatic. At present, government subsidies thus remain necessary to cover this cash flow variability. When actual revenue collections exceed projections, the Authority cannot spend the surplus in the given financial year because it is not approved by the finance law. However, the remaining balance is taken as the Authority's opening balance in the next financial year and considered for the following year's budget. It can be expected that as the Authority gets better at predicting its revenues, the need for government subsidies will decrease.

It is worth noting that all the agencies studied in the international benchmark still receive subsidies from the government, at a minimum, to cover salaries. Therefore, Rwanda FDA falls within best practices of other regulatory authorities in receiving some budgetary support.

3.5.2 Pricing Benchmark

Table 7: Registration Fee (RWF) Domestic

Authority or Agency	Rwanda FDA	Ghana FDA	Tanzania MDA	US FDA	Mauritius Pharmacy Board
Government Allocations	Yes	Yes	Yes	Yes	Yes (part of MOH)
Human medicines	300,000	110,990	504,500	269,190,101	590,265
Veterinary medicines	200,000	33,633	504,500	444,410,014	NA
Medical devices (Class D)	220,000	208,527	252,250	368,947,913	NA
Medicated Cosmetics	150,000	55,495	43,387	NA	NA
Clinical Trial Authorization (PI)	500,000	8,408,333	NA	1,412,600,000	NA

Table 8: Registration Fee (RWF) Foreign

Authority or Agency	Rwanda FDA	Ghana FDA	Tanzania MDA	US FDA	Australian TGA
Government allocation	Yes	Yes	Yes	Yes	Yes
Human medicines	1,261,250	1,210,800	2,018,000	236,138,288	71,978,024
Biologics	NA	504,500	3,531,500	119,048,883	5,592,483
Veterinary medicines	605,400	605,400	2,018,000	498,342,073	NA
Herbal medicines	252,250	1,210,800	NA	2,969,451,685	NA
Medical devices (Class D)	2,522,500	807,200	2,522,500	368,947,913	60,934,923
Medicated Cosmetics	252,250	252,250	100,900	NA	NA
Clinical Trial Authorization (PI)	4,036,000	25,225,000	3,027,000	6,659,400,000	16,799,850

Table 9: Registration Fee (RWF) Foreign

Authority or Agency	Mauritius Pharmacy Board	Singapore HSA	Belgium FAMHP	Netherlands MEB	EMA
Government allocation	Yes (part of MOH)	Yes	Yes (Taxes)	Yes	NA
Human medicines	590,265	10,861,885	33,778,293	33,972,021	355,516,105
Biologics	NA	11,870,885	NA	NA	NA

Veterinary medicines	NA	NA	34,575,403	NA	177,938,159
Herbal medicines	NA	NA	NA	5,162,044	NA
Medical devices (Class D)	NA	NA	NA	17,608,059	NA
Medicated Cosmetics	NA	NA	NA	NA	NA
Clinical Trial Authorization (PI)	NA	NA	19,293,089	NA	NA

Table 10: GMP for Pharmaceutical or medical devices (Foreign) - Fee (RWF)					
	Rwanda FDA	**Ghana FDA**	**Tanzania MDA**	**Singapore HSA**	**Australian TGA**
Government allocation	Yes	Yes	Yes	Yes	Yes
					/hr/inspector
East Africa	3,027,000	4,036,000	4,036,000	24,216,000	1,067,724
Rest of Africa	4,036,000	4,036,000	5,045,000	24,216,000	1,067,724
Asia	5,045,000	7,567,500	6,054,000	18,363,800	1,067,724
Europe	6,054,000	7,567,500	7,063,000	24,216,000	1,067,724
America	7,063,000	7,567,500	8,072,000	24,216,000	1,067,724
Australia and New Zealand	6,054,000	7,567,500	NA	24,216,000	761,593
GMP Licensing per year	200,000	8,408,333	252,250	2,078,540	3,598,901

Table 11: GMP Inspection Foods (Foreign) - FEE (RWF)			
	Rwanda FDA	**Ghana FDA**	**US FDA**
Government allocation	Yes	Yes	Yes
			/hr/inspector
East Africa	3,027,000	4,036,000	312,790
Rest of Africa	4,036,000	4,036,000	312,790
Asia	5,045,000	7,567,500	312,790

Europe	6,054,000	7,567,500	312,790
America	7,063,000	7,567,500	312,790
Australia and New Zealand	6,054,000	7,567,500	312,790

Table 12: Operational License/Permit/Certificate - FEE (RWF)				
	Rwanda FDA	**Ghana FDA**	**Tanzania MDA**	**Singapore HSA**
Government Allocation	Yes	Yes	Yes	Yes
Foreign Medical representative	302,700	NA	1,009,000	NA
Pharmaceutical Manufacturers	300,000	133,188	302,700	2,078,540
Retail Pharmacy	200,000	NA	NA	519,635
Renewal Retail Pharmacy	100,000	NA	NA	519,635
Permit for Food importation	0.5%	0.8%	NA	NA
Permit for medical device importation (human)	2.0%	1.3%	2.0%	NA
Permit for importation of Tobacco and tobacco products	2.0%	NA	NA	NA
Permit for importation Human medicines (FPP)	2.0%	1.8%	2.0%	NA
Permit for importation Veterinary medicines (FPP)	1.0%	1.3%	NA	NA

Table 13: REGISTRATION Food and Tobacco Products - FEE (RWF)			
	Rwanda FDA	**Ghana FDA**	**Tanzania MDA**
Government allocation	Yes	Yes	Yes
Domestic			
Food Supplements	249,223	20,180	655,850
Tobacco and tobacco products	1,000,000	15,135,000	NA
Foreign			
Food Products (Liquors)	1,513,500	2,522,500	201,800
Food Supplements	706,300	302,700	807,200

3.5.3 Assessment of Cost and Revenue Structure

Below are some detailed observations about Rwanda FDA's costs and revenues.

Table 14: Assessment of Technology and Equipment		
#	**Observation**	**Implication**
1	The money collected for Rwanda FDA services is deposited to the Rwanda FDA account with the Central Bank. Rwanda FDA, however, cannot access the money without having an approved budget by MINECOFIN.	This means that Rwanda FDA does not have any financial autonomy. Moreover, having to create and approve a budget makes it very difficult to adjust for realities on the ground, as Rwanda FDA cannot know in advance how many inspections they will have to do, how many import and export permits they will have to issue, or how many employees will be tied up in clearing the backlog for human medicine division. Rwanda FDA has so far always underestimated their revenues, which leads to inefficient use of money and overestimating the need for resources (ex. in the 2020-2021 financial year, Rwanda FDA has not exhausted their budget, although that might also be the result of the coronavirus pandemic).
2	There is no system for tracking the categories of revenues at Rwanda FDA.	This makes it impossible to know how much money has been collected for the different services (e.g., food products versus drug products, registration vs. import/export permits) and makes it even more difficult to do any meaningful revenue analysis and projections for the budget.
3	Rwanda FDA financial statements have been done on a cash-based recording up to now (Rwanda FDA is currently switching to accrual-based system).	This type of recording financials makes it easier to show how the money from MINECOFIN has been spent, but it makes it almost impossible to assess if Rwanda FDA is currently financially sustainable or not. Financially, the agency is currently managed as an entity of MoH, not as an independent public operator.
4	Rwanda FDA already has a partnership with Tanzania Medicine & Medical Devices Authority and is in the process of signing a partnership with Ghana Food and Drugs Authority.	These partnerships enable Rwanda FDA to exchange expertise, knowledge, and technology, which makes the operations more efficient and, therefore, less costly.
5	Rwanda FDA is planning on regulating prices of drugs on the market in the future.	This activity can help Rwanda FDA bring in some small revenue, especially through the fines.
6	All the benchmarked agencies (US, Australia, Netherlands, Belgium, Singapore, Mauritius, Tanzania) still receive subsidies from the government.	This seems to suggest that to become a world class agency, with digitized services, a proper training program, and a fully equipped laboratory, Rwanda FDA will need to keep on receiving subsidies from the government in the years to come.

Table 14: Assessment of Technology and Equipment		
7	From the benchmark conducted, it appears that Rwanda FDA pricing structure is adequate, which is also confirmed by the client survey.	There is no need for Rwanda FDA to reduce the prices of its services. The current pricing structure is comparable to or lower than those of neighboring countries, so it does create an incentive for pharmaceutical companies to come to Rwanda.

3.6 QUALITY MANAGEMENT SYSTEM

3.6.1 OVERVIEW OF QUALITY MANAGEMENT SYSTEM

The Rwanda FDA is in the process of implementing a Quality Management System (QMS) that focuses on improving quality of products and services while protecting and promoting public health. Since the Authority is a relatively new organization, with a high percentage of employees that have been at the Authority for four months or less, there should be an expectation of a learning curve that must be overcome. The quality management system framework being implemented is governed by the Authority's Quality policy, Quality manuals, customer charter and process SOPs. However, the structural organization and functionality of the quality assurance (QA) analyst and internal audit personnel is not clear. A recent assisted QMS internal audit by an outside consultant identified various key findings that align with observations made by the business plan development team in this respect.

The Rwanda FDA has projected plans to obtain ISO certification; however, no concrete plans were shared at the time of interviewing different responsible persons. Rwanda FDA's quality policy statement states that "is committed to providing the highest quality of regulatory services that meet customer requirements by implementing a QMS that complies with the requirements of ISO 9001:2015." Therefore, Rwanda FDA should focus on attaining globally recognized ISO 9001:2015, ISO 17025:2017, WHO WHO-GPPQCL (Good Practices for Pharmaceutical Quality Control Laboratory) accreditations/certification as potential enablers to successful WHO Global Benchmarking Tool (GBT) assessment.

3.6.2 ASSESSMENT OF QUALITY MANAGEMENT SYSTEM

As the Rwanda FDA continues to grow and establish itself while striving to achieve its goal of becoming a world class regulatory Authority; its collection of regulatory documents governing its mandated activities will increase relative to the services offered. Therefore, the Authority should consider investing in a state-of-the-art document management system that allows for easy navigation and document management internally.

Currently, accessing the relevant regulatory documents on the Rwanda FDA's website is tedious and confusing because the documents are not classified by function or department. For example, guidelines and guidance for foods, drugs, tobacco, medical devices, and clinical trials (just to name a few) are all listed together in one tab. The accessibility of the documents on the Rwanda FDA website should be in a client friendly format where documents are organized by department and topic.

Below are some detailed observations about the Quality Management System at Rwanda FDA.

Table 15: Assessment of Technology and Equipment		
#	**Observation**	**Implication**
1	The Quality management system at Rwanda FDA is led and coordinated by one full-time person (QA analyst) and a system of QA focal points in each (8) division.	This makes it impossible to implement and maintain a quality management system that matches the status of a world class regulatory authority that Rwanda FDA is striving to achieve.
2	Rwanda FDA has no records that it has conducted any client survey related to the Authority's service offering. This function is under the job responsibility of the QA analyst. Currently, there are no means to collect, monitor and analyze client feedback.	This presents a gap since Rwanda FDA cannot gauge or score itself on how it delivers the services mandated by its mission, vision, and values. Although this task is under the QA analyst responsibilities, it requires collaboration with other divisions (e.g., website developers, communication team and client database manager).
3	Organization QMS: Rwanda FDA does not have globally recognized certifications; however, it is implementing a Quality management system in line with global standards.	The Authority's Quality Manual and Policy are based on ISO 9001:2015 Quality management system requirements. In parallel, the Authority is preparing for WHO Global Benchmarking Tool (GBT) assessment. Rwanda FDA projects it will attain ISO certification within two (2) years (2023).
4	Laboratory QMS: Rwanda FDA laboratory does not have globally recognized laboratory accreditations/certifications. The laboratory has a Quality manual and several QMS-related laboratory SOPs.	It is not clear how the implementation of QMS in the laboratory is handled since there is no designated full-time employee (FTE) (QA specialists) dedicated to the laboratory. The lab has not conducted any internal audits; however, it was part of the consultant supervised internal audit. Projections to attain ISO 17025:2017 certification in 3–4 years (2024/2025) have been expressed by the QA employee.
5	No independent internal audit or external audit has been conducted on Rwanda FDA's processes.	This may be indicative of the short time of existence of Rwanda FDA or the lack of adequate staff to conduct these types of audit activities. SOP: Conduct of Internal Quality Audits - QMS/SOP/048 with an effective date June 1, 2021, shows that the QA functions of the Authority are in the process of implementing QMS required documentation and processes.
6	A recent (June/July 2021) assisted internal audit was conducted by a consultant with Rwanda FDA employees as observers and auditees. There were nine (9) major non-conformities and three (3) minor non-conformities.	Rwanda FDA has more work to do on ensuring that its quality management system meets the global standards. This is reflected by the 15 recommendations highlighted by the auditor.
7	The current onboarding of newly hired staff involves induction training, but minimal further formal training program related to the job function is available. It is unclear if any training records are maintained by either HR or the QA analyst.	Hiring qualified employees and retaining a competent workforce is a key priority of Rwanda FDA. Having a continuing professional development program will ensure that they are motivated and able to achieve the goals of Rwanda FDA. Benchmarked authorities have well defined training programs for their employees as part of their QMS.
8	Regulations CBD/TRG/010 Rev_1, April 2020 and CBD/TRG/012 Rev_ 1, April 2020: These	Rwanda FDA employees responsible for web publishing should ensure that the information

Table 15: Assessment of Technology and Equipment		
#	**Observation**	**Implication**
	two published regulations are outdated and should be archived. One guideline document is published in the regulation section and should be moved to the guideline section of the website.	available on the website for clients is up to date and in the right location, therefore improving the client experience.
9	The regulatory documentation should be uniform in format. Documents do not have the "Regulation Development History" and/or "Document Revision History", while others are noted as "Rev. No 1" but do not contain a "Document Revision History" table.	There is a gap in the document creation process and document uniformity. Those in the quality unit should continuously align the format of documentation to ensure uniformity and clarity of document history.
10	Rwanda FDA quality documents, such as SOPs, appear to be available in an excel spreadsheet.	This is a manual system and thus makes it difficult to have any control of documents. Therefore, a document management system software would be suitable to streamline and track this function.

4 RECOMMENDATIONS AND OPPORTUNITIES FOR IMPROVEMENT

The following recommendations have been developed based on the operational, regulatory, quality management system and financial system gap analysis of the Rwanda FDA, as well as an international benchmarking exercise. The recommendations also aligned with all strategic priority areas and many strategic objectives that are outlined in Rwanda FDA's Strategic Plan for years 2021-2024, see Annex 8.1 for more details. The recommendations are predicated on the Rwanda FDA's ambition to become a financially sustainable, world class authority capable of regulating medicines and other health products within scope.

4.1 DEVELOP AN ORGANIZATION THAT ALIGNS WITH ITS AMBITIONS

4.1.1 STRATEGIC ACTIONS

Rwanda FDA needs to reorganize its support staff to make it more efficient in its operations. This means creating a proper Support Functions Department and reorganizing the support staff in newly created units, such as an ICT Unit, Legal Unit and Communication Unit. This type of organization replicates the organizational structure in some of the more established FDAs benchmarked. In the future, consideration should also be given to separating the Foods and Drug functions of the Authority into different departments. The level of specialization will streamline duties and allow for effective delivery of services to contribute to the overall mission of the Authority.

Also, as per the recently adopted National Pharmaceutical Product Pricing and Cost Containment Policy, Rwanda should create a Pricing unit, to be able to regulate pharmaceutical pricing. The unit should be created under the new Support Functions Department and should have the Market and Pricing Analyst, as well as the two Industrial Market Specialists. Moreover, given the importance of implementing a national harmonized pricing, it is important to recruit a director for this unit.

To become a world class laboratory, the Rwanda FDA also needs to increase the scope of the Quality Control Laboratory to make it a fully-fledged laboratory. This has been observed through the client survey results and is also in line with the international standards. Therefore, within the next five (5) years, the Lab needs to increase its staff, especially in the Medicine and Cosmetics Testing Unit and in the Food Testing Unit. The Lab also needs to hire laboratory chemicals store manager, a laboratory quality management specialist, and an administrative assistant. In the proposed organizational chart, the Laboratory counts 42 employees and could become a department instead of a division. The laboratory should also designate funds for testing consumables (reference standards) and accessing regulatory standards such as US Pharmacopeia (USP) and the European Directorate for the Quality of Medicines (EDQM).

As Rwanda is preparing to start manufacturing vaccines, the Rwanda FDA needs to be ready to regulate this new field. To this goal, the Authority should bring in additional experts, such as a Vaccine Inspection and Compliance Analyst, Clinical/ Toxicologist Specialist, Vaccines and Biosimilar Registration Analyst/Specialist and Vaccine Testing Officer.

This sizeable recruitment will need to be part of an overall recruitment strategy developed by the HR Unit and Rwanda FDA will have to allocate budget specifically for recruitment costs - these can range between one month of salary for a regular recruiting and two months if the position is senior and a headhunter needs to be used. These costs have been provisioned for in the financial plan.

This review discovered that the Chairman of the Board has a conflict of interest because he is a director at a clinical research organization that is regulated by the Rwanda FDA. This is not acceptable in a world class regulatory Authority and should be checked and avoided across the whole organization. Enforcement of

the conflict-of-interest policy (especially anything related to employees and stakeholders having their own business, ownerships in a regulated company, third party relationships, etc.) should be standard across the Rwanda FDA, both on paper and in practice.

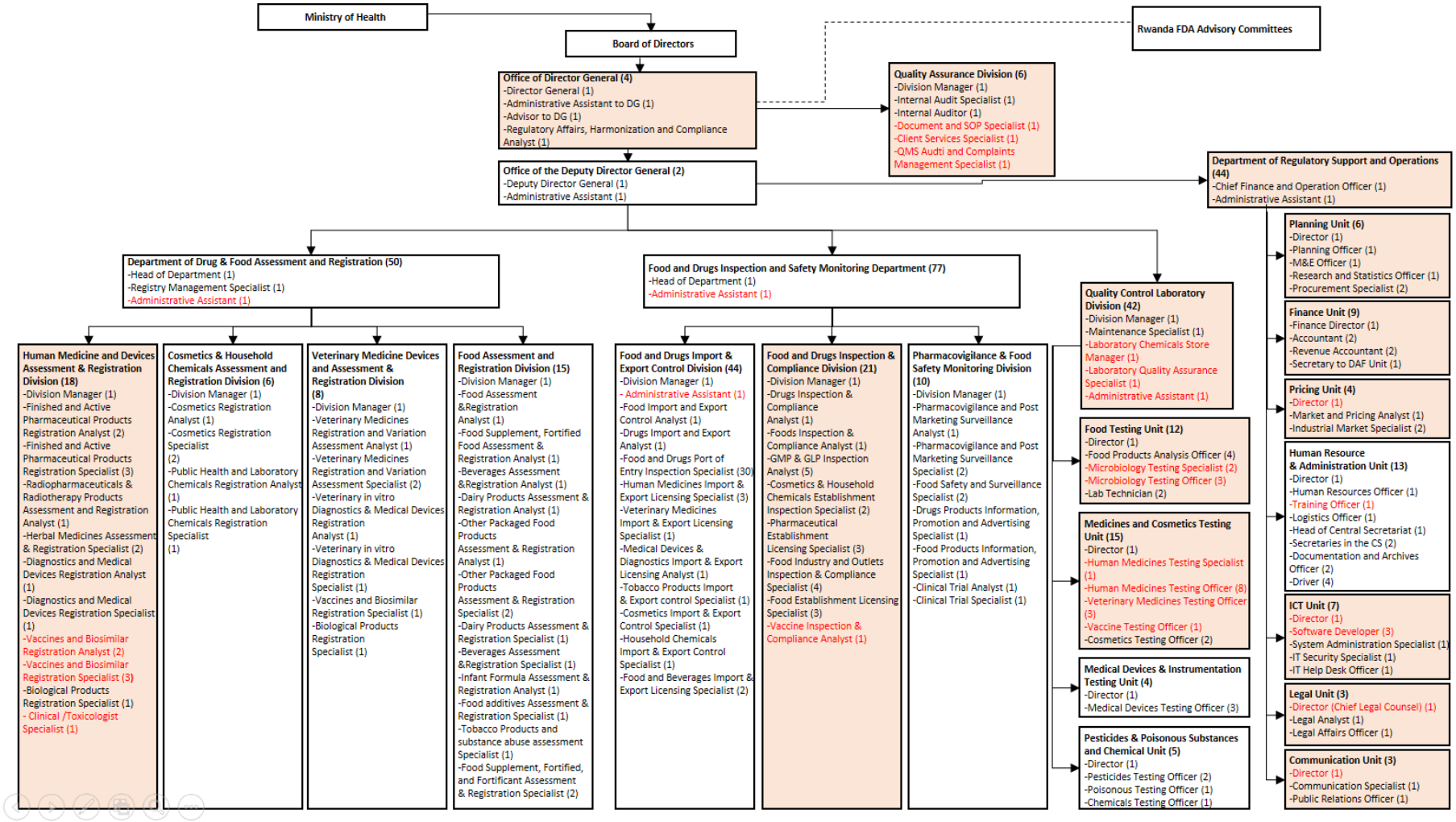
Unfortunately, unlike for example the US FDA, the Rwanda FDA cannot change the remuneration and the bonuses of its employees, which are set by the Prime Minister's order on public statute. This makes it particularly difficult to retain staff. Therefore, the Rwanda FDA needs to use other means to avoid staff turnover and to create an organization that is adequately aligned with the Authority's ambition. The main means to do that is to create a proper training program for staff, comprising not only training on Rwanda FDA's different fields of expertise, but also on quality management and client management. Additionally, the training program should allow for continuous learning, encourage career development and at the same time promote a work-life balance. The comprehensive training program is key for developing and retaining quality staff, as demonstrated by international benchmarking, for instance Singapore HSA has a series of Professional Educational Programs, while US FDA has two learning management systems (LMS) ComplianceWire LMS (online-based learning) and the Pathlore LMS (classroom-based training) for its employees [13]. Rwanda FDA should be doing regular training needs assessment and update the training program accordingly. Also, training record management should be part of the QMS procedures of Rwanda FDA Quality Management Division.

However, in the long run, Rwanda FDA should consider changing its status to be able to increase salaries, as these are substantially lower as compared to the private sector.

[13] https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/fda-employees

4.1.2 PROPOSED ORGANIZATIONAL STRUCTURE

The proposed organizational structure comprises 224 employees, which add 30 people to the current structure. (Pink boxes are divisions/departments/units with changes and the additional employees are marked in red.)



4.1.3 Implementation Actions and Timelines

Table 16: Organization: Implementation Actions and Timelines				
#	**Action**	**Impact**	**Responsible**	**Timing**
1	Implement the new organization	High	HR Director, CFO, DG	FY 2022-2023
2	Hire the ICT unit director, the Chief Legal Counsel (Legal unit director) and the Communication Unit director	High	HR Director, CFO	FY 2022-2023
3	Hire two department Administrative Assistants (for Inspection and Safety department and (Assessment and Registration department)	Medium	HR Director, Head of Departments	FY 2022-2023
4	Hire two Human Medicine Testing Officers	High	HR Director, Lab Director	FY 2022-2023
5	Create a Pricing Unit and hire its director	High	HR Director, CFO	FY 2022-2023
6	Create a Quality Management Division under a Quality Management (QM) Manager	High	HR Director, QM Division Manager	FY 2022-2023
7	Hire one Document Management Specialist	High	HR Director, QM Division Manager	FY 2022-2023
8	Hire one Audits and Complaints Managements Specialist	Medium	HR Director, QM Division Manager	FY 2022-2023
9	Hire the Laboratory Administrative Assistant, Laboratory Chemical Store Manager and Laboratory Quality Management Specialist	High	HR Director, Lab Director	FY 2022-2023
10	Hire one Training Officer	High	HR Director	FY 2022-2023
11	Design and implement a training program	High	HR Director	FY 2022-2023
12	Implement a proper conflict of interest policy	High	HR Director	FY 2022-2023
13	Hire one Administrative Assistant for the Imports and Exports Division	Medium	HR Director, Division Manager	FY 2023-2024
14	Hire one Clinical/Toxicologist Specialist who will deal with new drugs and clinical issues (preferably an MD)	High	HR Director, Division Manager	FY 2023-2024
15	Hire three Human Medicine Testing Officers	High	HR Director, Lab Director	FY 2023-2024
16	Hire one Human Medicine Testing Specialist	Medium	HR Director, Lab Director	FY 2024-2025

Table 16: Organization: Implementation Actions and Timelines				
#	Action	Impact	Responsible	Timing
17	Hire one Microbiology Testing Specialist	Medium	HR Director, Lab Director	FY 2024-2025
18	Hire one Vaccine Registration Specialist, one Vaccine Registration Analyst and one Vaccine Inspection Analyst	High	HR Director, Division Managers	FY 2025-2026
19	Hire one Vaccine Testing Officer	Medium	HR Director, Division Managers	FY 2025-2026
20	Hire one Microbiology Testing Officer	Medium	HR Director, Lab Director	FY 2025-2026
21	Hire one Veterinary Medicine Testing Officer	Medium	HR Director, Lab Director	FY 2025-2026

4.2 DIGITIZE REGULATORY/SUPPORT SERVICES AND OPERATIONS

4.2.1 STRATEGIC ACTIONS

One of the main observations of both the client survey and the operational assessment is that the Rwanda FDA is lagging behind world class authorities in terms of the digitization of its services. The Authority needs to make all its services accessible online from start to finish, including online payment and document submission for both domestic and foreign applicants. Different solutions exist which can connect to or complement the PRIMS system (or any other system used by Rwanda FDA in the future): such as Extedo, GlobalSubmit™ eCTD, Document Archiving, Reporting, and Regulatory Tracking System (DARRTS), Electronic Submissions Gateway (ESG), Common European Submission Portal (CESP) that are used by EMA, South Africa, and the US FDA. These IT solutions will help the Authority and its clients manage processes such as Product Registration Planning & Tracking, Submission Publishing & Lifecycle Management, Pharmacovigilance Management. The overall digitalization needs to be informed by a business process re-engineering to make automation effective and optimal. This is especially important to attract newcomers to the market and differentiate the Rwanda FDA from competition in the neighboring countries. Rwanda has a reputation as the African country with the most ease of doing business, where a company can be registered online within a few minutes. Therefore, Rwanda FDA should capitalize on best practices and lessons learnt by RDB, RRA and other stakeholders.

As the Rwanda FDA digitizes its operations, document management system and client services, it is also important that the authority has a proper ICT team with an ICT director who can set strategic direction, decide on competing priorities, and design the overall ICT strategy for the Rwanda FDA. The Rwanda FDA should also hire two more software developers who will be responsible for the digitization. This is not to say that Rwanda FDA should stop working with RISA and NCSA, but it should have a bigger internal team to gain control, speed, and flexibility.

A further necessary step is to increase client awareness of the Rwanda FDA's digital services, and especially the current PRIMS system (or the new system that Rwanda FDA will have in the future). The assessment revealed that many clients, especially in the food sector, continue to apply via email, which makes it very difficult to follow up on applications and revenue collection. The process needs to be more efficient as the

number of applications increases - every application needs to be recorded in PRIMS or another submission software and the manager needs to have a dashboard telling them who is handling which application, in which state is the application, what are the deadlines, delays, etc. As for the clients, it is useful and normal to have a transition period during which the clients will be able to use both an email and the online system, but this period should not go for more than a year. During the year, training on how to use the online system should be organized for clients so that they know how to use it (this was also mentioned in the client survey). The Rwanda FDA should also make sure that the online system has a Kinyarwanda version, as many applicants, especially from the food sector, do not speak fluent English.

Lastly, the Rwanda FDA should overhaul its website (a project is already ongoing) and make sure it is properly organized and kept up to date. Various clients have complained in the client survey that they do not know where to find guidelines on regulations and Rwanda FDA procedures, which suggests that the current website organization is not ideal or that the documentation provided is incomplete. We recommend organizing the website according to the client's journey, e.g., make all documents needed for product registration, operational license, or clinical trial, accessible under one click in one place. The documents should be available both in English and Kinyarwanda and they should be up to date (at present, there are cases where more than one version of some document exists, and it is unclear which version is the most current). The website should also be mobile friendly.

The Rwanda FDA should also make sure that it keeps on paying subscriptions to access global best practice standards, such as the US Pharmacopeia, and the European Directorate for the Quality of Medicines (EDQM), which are currently being subsidized by USP - PQM+.

4.2.2 Implementation Actions and Timelines

Table 17: Digitization: Implementation Actions and Timelines

#	Action	Impact	Responsible	Timing
1	Finalize the implementation of all PRIMS modules	High	ICT Director, CFO/CEO	FY 2022–2023
2	Design and run an awareness campaign about Rwanda FDA online services and the use of PRIMS	High	HR Director, Communication unit director, ICT Director	FY 2022–2023
3	Finalize the remaking of the website	High	ICT Director, Communication unit director, client services specialist	FY 2022–2023
4	Implement regular updating of the website	High	ICT Director	FY 2023–2024
5	Hire one software developer	Medium	HR Director, ICT Director	FY 2023–2024
6	Digitize Rwanda FDA services	High	ICT Director, CFO/CEO, DG	FY 2023–2024
7	Ensure continuous subscription to regulatory standards such as US Pharmacopeia (USP) and the European Directorate for the Quality of Medicines (EDQM)	Medium	ICT Director, Heads of departments	FY 2023–2024 and following

4.3 INCREASE REVENUE TO MAINTAIN FINANCIAL SUSTAINABILITY

4.3.1 STRATEGIC ACTIONS

As the Rwanda FDA is aware, it currently does not control the totality of the market, meaning that there are still some clients who do not register their products or premises, especially in the food sector. To cover the entire sector, the Rwanda FDA should invest in a comprehensive awareness campaign, as well as specific training on its services. This will enable the Rwanda FDA to substantially increase its revenue.

Once the Rwanda FDA laboratory is ISO certified and WHO prequalified, it should work on adding new services to its portfolio such as:

1. Laboratory testing services for other government stakeholders (such as RSB), regulatory partners (such as EAC country partners) and the network of WHO PQ laboratories. This may require investing in testing capabilities that are not widely available in the region, e.g., vaccine testing and biologics testing.
2. Providing technical support to local manufacturers by assisting in building capacity for their laboratory employees, setting up of the laboratories, and offering training on quality control testing of regulated products through on-site and off-site training.

The Rwanda FDA should also offer paid training services, for instance for stakeholders who would like to learn about laboratory testing. The Rwanda FDA can also start offering scientific advice related to the pharmaceutical and food sectors and academia. This is consistent with what other regulatory agencies, such as Ghana, EMA, US, or the Netherlands, have been doing.

Current fees are judged to be priced appropriately and should be neither increased nor reduced. However, as it grows and the market matures, Rwanda FDA should consider periodically restructuring its fees. It is recommended that a costing exercise be considered in future projections to effectively determine the cost of delivery of the regulatory services and identify how to re-structure the fees to meet the cost of operations. Current recommendations for restructuring include:

- Introduction of pre-application screening fees, which could be a percentage of the application fee that is credited to the registration fees if an application is accepted for assessment and lost if the application is rejected during the pre-application step.
- Introduction of separate registration and laboratory fees would allow the laboratory more flexibility in outsourcing its services to stakeholders and other regulatory authorities that do not have laboratory capacity, and therefore generate more income for the Authority.
- Introduction of special fees structures for medicines that are essential and have low market presences (e.g., orphan drugs) or that are needed to fulfill a market shortage. in line with the WHO GBT sub-indicator RS07.03.

The present recommendations are in line with Rwanda's Public Financial Management (PFM) Policies and Procedures.

4.3.2 IMPLEMENTATION ACTIONS AND TIMELINES

Table 18: Finances: Implementation Actions and Timelines				
#	Action	Impact	Responsible	Timing
1	Design and run an awareness campaign about Rwanda FDA online services and the use of PRIMS	High	HR Director, Communication unit director, ICT Director	FY 2022–2023
2	Introduce new laboratory testing services	High	Lab Director, client services specialist	FY 2025–2026
3	Introduce paid training services	High	HR Director, training officer, client services specialist, DG	FY 2025–2026
4	Introduce technical support for other laboratories	Medium	Lab Director, client services specialist	FY 2025–2026
5	Introduce paid scientific advice to pharmaceutical sector and academia	High	Heads of department, HR Director, client services specialist, DG	FY 2025–2026
6	Restructure current fees into pre-application screening fees, application fees and laboratory fees	High	Lab Director, Heads of department, DG	FY 2025–2026
7	Start regulating vaccine manufacturing	High	Lab Director, Heads of department, DG	FY 2025–2026

4.4 IMPROVE QUALITY MANAGEMENT SYSTEMS

4.4.1 STRATEGIC ACTIONS

The current state of the Rwanda FDA Quality Management System (QMS) needs to improve for it to consistently provide services that meet client needs and applicable regulatory requirements. The QMS system should aid in enhancing client satisfaction through the effective application of QMS principles. This includes having processes for the continual improvement of the Authority's functions related to its mandate, as well as ensuring consistent alignment to client needs and applicable regulatory requirements.

The current quality management staffing levels within the Authority structure are not sufficient. This presents challenges in achieving the level of compliance set out in the objectives of the quality policy and quality manual. Therefore, Rwanda FDA needs to create a Quality Management (QM) division staffed with employees that will implement QMS principles and ensure that it meets all the requirements per global best practices. This is in line with the benchmarked authorities and WHO GBT - RS05.04.

To mitigate these shortcomings, the Rwanda FDA should prioritize addressing the non-conformities identified in the recent assisted internal audit and follow through on the recommendations provided. The Rwanda FDA should focus on attaining globally recognized ISO 9001:2015, ISO 17025:2017, WHO WHO-GPPQCL (Good Practices for Pharmaceutical Quality Control Laboratory) accreditations/certification as a potential enabler to successful WHO Global Benchmarking Tool (GBT) assessment.

The Rwanda FDA should reexamine, streamline, organize and improve support function documents such as guidance documents, guidelines, and SOPs. These documents include those related to Finance services such as monitoring the revenues procedures which result in an improvement in the reporting of financials.

Documents related to payment procedures for tariffs/fees and charges also need to be created which will improve client awareness and ensure that the payment for regulatory services is smooth and timely.

4.4.2 Implementation Actions and Timelines

Table 19: Quality Management System: Implementation Actions and Timelines				
#	**Action**	**Impact**	**Responsible**	**Timing**
1	Create a Quality Management Division	High	HR Director, Quality Management (QM) Division Manager	FY 2022–2023
2	Hire one Document Management Specialist and one QMS Audits and Complaints Management Specialist	High	HR Director, QM Division Manager	FY 2022–2023
3	Prioritize addressing the non-conformities identified in the recent assisted internal audit	High	QM Division manager, Senior Management, Heads of department, Division managers	FY 2022 – 2023
4	Improve support function guidelines and SOPs, especially for Finance (monitoring the revenues, etc.) and tariffs/fees and charges payment procedures.	High	QM Division manager, Heads of department, Division managers	FY 2022–2023
5	Get the ISO certification for the Authority and accreditation for the QC laboratory	High	Lab Director, QM Division manager, DG	FY 2022-2023 for QMS FY 2025–2026 for QC Laboratory

4.5 Introduce Customer Oriented Culture

4.5.1 Strategic Actions

The main emerging message through the client survey was that most Rwanda FDA clients are not satisfied with the Rwanda FDA's client communication and customer care. This is common in public institutions, but should be improved, particularly as the Rwanda FDA is trying to attract manufacturers and other stakeholders into the market. The Rwanda FDA should therefore make sure that all its client-facing staff is trained on client relationship management and client communication.

Moreover, the Rwanda FDA should consider working on an improved client communication procedure and putting in place a proper relationship manager or at least a list of Rwanda FDA contact(s) for clients. The survey respondents complained that they do not have a direct contact for the Rwanda FDA but must go through a generic email address and a toll-free line, where they are not sure if their requests will be attended to.

The Rwanda FDA should also hire a Client Service Specialist who would be responsible for managing the info@ email address, creating, and running client surveys, and directing relevant complaints and questions to the Heads of departments and Division managers.

There are many recently published guidelines on various procedures (such product registration, licensing etc.) on the Rwanda FDA website. However, due to the complexity of some of the procedures, the Authority should consider adding infographics or flow charts that are more user friendly for its clients, published in both English and Kinyarwanda. Currently, some of the clients are lost and find the guidelines hard to digest. This will have a positive impact on reducing the number of incomplete or poorly organized applications.

The Rwanda FDA should also think about organizing regular regulatory conferences to familiarize stakeholders and clients on specific regulatory mandates and future plans of the agency. It could also help to have an occasional show on radio or TV to communicate on Rwanda FDA's mandate, services, and achievements.

4.5.2 Implementation Actions and Timelines

Table 20: Client Communication: Implementation Actions and Timelines

#	Action	Impact	Responsible	Timing
1	Hire a Client Services Specialist within the Quality Management Division	High	HR Director, QM Division manager	FY 2022–2023
2	Implement client communication and care training to all client facing staff	High	HR Director, training officer, Communication unit director, client services specialist	FY 2022–2023
3	Put in place a system of relationship managers or publish a list of relevant client contacts	High	HR Director, Communication unit director, client services specialist	FY 2022–2023
4	Organize regular regulatory conferences	Medium	Heads of department, Division managers, Communication unit director	FY 2022–2023
5	Ensure to be invited occasionally invited on radio/TV shows	Low	Communication unit director	FY 2022-2023
6	Translate the main regulatory guidelines into info graphics	High	ICT Director, Heads of department, Division managers	FY 2023–2024

The financial projections are based on the following summary of the five-year (2021–2026) strategy for Rwanda FDA:

1. **Develop an organization that aligns with its ambitions**
    - Create Support Functions Department with a separate ICT Unit, Legal Unit, Communication Unit and Pharmaceutical Pricing Unit
    - Increase the staff of Quality Control Laboratory to make it a fully-fledged laboratory
    - Hire staff for vaccine regulation
    - Resolve conflict of interest issues with the Board
    - Develop and a regular training plan for staff and make sure it is enforced

2. **Digitize services and operations**
    - Ensure all the services are accessible online from start to finish of the entire process, including online payment and document submission, for domestic and foreign applicants
    - Recruit an ICT director and two more software developers
    - Increase awareness about the online system among the clients
    - Ensure that the website is properly and neatly organized and up to date
    - Keep on paying subscription fees to access global best practices standards

3. **Increase revenue to maintain financial sustainability**
    - Conduct an awareness campaign to increase the market coverage for the current services, especially in the food sector
    - Add new services, such as laboratory testing services for other regulatory authorities, paid training services for healthcare professionals, industry, consumers, and academia, scientific advice, and technical support for other laboratories
    - Develop a new revenue stream by restructuring the current fee's structure and introducing pre-application screening fees and separate registration and laboratory fees

4. **Improve the quality management system**
    - Establish a well-equipped and staffed Quality Management Division with sufficient permanent staff to cover all QMS responsibilities
    - Hire one Documents Management Specialist
    - Hire one Audits and complaints managements specialist
    - Prioritize addressing the non-conformities identified in the recent internal audit
    - Secure ISO 9001 certification for the whole organization and ISO 17025 accreditation for the laboratory
    - Improve support function guidance and SOPs, especially for finance (monitoring the revenues, etc.) and tariffs/fees and charges payment procedures

5. **Introduce customer-oriented culture**
    - Improve client communication and care through trainings
    - Make sure clients have a 'relationship manager' or a specific contact(s) at the Rwanda FDA
    - Hire a Client Service Specialist
    - Create infographics or lighter versions of the main guidelines on regulation
    - Organize regulatory conferences and make sure Rwanda FDA appears occasionally on radio/TV shows

5 FINANCIAL PROJECTIONS

5.1 OVERVIEW

Rwanda FDA's financial projections were approached from a conservative point of view based on the existing data available within the institution. The 2020/2021 financials were taken as the baseline for the projections for the costs and revenues, and the action plans provided by the Rwanda FDA were considered. Given that current revenue collection is still low (only approximately 20% of the expected revenues), there is room for revenue growth in the coming years. This trend will keep on for some years ahead, since Rwanda FDA has several initiatives (awareness campaigns, technology upgrade, automation of payments and registration, integration with RRA, etc.) that will lead to an increased market share. While maintaining a conservative view on the growth potential, we anticipate that the Rwanda FDA's annual revenues will steadily increase by 10% every year for at least the next 3 years, that is from 2021/2022 to 2023/2024. By that time, as the institution matures, we assume that the growth will start increasing at a decreasing rate whereby it will be 8% in the fourth year and 6% the fifth year. In FY 2025–2026, it was assumed that Rwanda FDA will have additional revenues from laboratory testing services, scientific advice, vaccine regulation, paid training services and technical support for other labs. These additional revenues could amount to 343 million RWF in FY 2025–2026. The total revenues in FY 2025–2026 are projected to be 9.7 million RWF without government subsidies.

The operating expenses were based on the last financial year's report (2020/2021); and increased at the inflation rate. Additional costs were assumed, specifically for staff training program (approximately 1 billion RWF every year), IT costs (10% of operating expenses and costs for reference standards), laboratory costs (10 million RWF in FY 2023-2024 for chemical reference standards and 40 million RWF In FY 2025-2026 for ISO certification), and costs of organizing trainings, awareness campaigns and regulatory conferences (11.5 million RWF in FY 2022–2023 and FY 2023–2024 and 6.1 million RWF in the following years).

Even with these costs, Rwanda FDA can retain a positive EBITDA and net surplus over the years without government subsidies. That said, the government subsidies can be significantly decreased at a rate of 35% every year to reach a minimum value of 312 million RWF in FY 2025/2026, mostly as a financial backup.

5.2 KEY ASSUMPTIONS

5.2.1 GENERAL COST ASSUMPTIONS

- In general, the costs will increase by an inflation rate of 3%. This is a standard practice to avoid understating projected expenses, which would lead to overstatement of net income. As a reference, we referred to the inflation rate of the last three years. Based on data from National Institute of Statistics, the average inflation rate for the last three years stood at 2.4% in December 2019[14], 7.7% in December 2020[15] and 0.8% in December 2021[16]. The average is 3.4%, and we used a round figure of 3% to approximate the potential future change in operating expenses. This allows us to be more conservative in our projections.
- The fixed assets will be depreciated at the rate provided by the Rwandan law and applied by Rwanda Revenue Authority (RRA). The computers and accessories are depreciated at 50% and all other assets are depreciated at 25% every year.

[14] https://www.statistics.gov.rw/publication/consumer-price-index-cpi-december-2019
[15] https://www.statistics.gov.rw/publication/consumer-price-index-cpi-december-2020
[16] https://www.statistics.gov.rw/publication/consumer-price-index-cpi-december-2021

- We assumed that Rwanda FDA will neither pay income tax nor dividends.
- The staff costs are based on the salary structure provided by Rwanda FDA and will be increased to adjust for inflation of 3% every year.
- Employees benefit from a training program where they can attend one international conference every other year and two local/regional conferences every year. The cost of international training per person is estimated at two (2) million RWF (all included), and the cost of local training at 800,000 RWF (all included).
- Once the USP - PQM+ program stops subsiding costs for the US Pharmacopeia and the EDQM (European Directorate for the Quality of Medicines), the Rwanda FDA will keep on assuming the costs directly, starting from FY 2023–2024.
- Given the implementation of online services, the IT costs will rise to 10% of operational expenses. This is consistent with the numbers observed during the benchmarking exercise.
- The laboratory will buy chemical reference standards at an approximate cost of 10 million RWF in FY 2023–2024.
- The Rwanda FDA will organize two regulatory conferences per year, at an approximate cost of one million RWF per year.
- The Rwanda FDA will spend an additional 1.5 million RWF on an awareness campaign.
- In the FY 2022–2023 and FY 2023–2024, the Rwanda FDA will organize 30 workshops and awareness training sessions at a total cost of nine (9) million RWF. In the FY 2024–2025 and FY 2025–2026, the Rwanda FDA will organize 12 workshops at a total cost of 3.6 million RWF.

5.2.2 Specific Cost Assumptions for Human Resources

FY 2022–2023

- Hiring of 15 new staff:
    - 2 Human Medicine Testing Officers
    - 1 Document Management Specialist
    - 1 Audits and Complaints Managements Specialist
    - 1 Pharmaceutical Pricing Unit Director
    - 1 ICT Unit Director
    - 1 Chief Legal Counsel (Legal Unit Director)
    - 1 Communication Unit Director
    - 1 Client Services Specialist
    - 1 Department (Inspection and Safety) Administrative Assistant
    - 1 Department (Assessment and Registration) Administrative Assistant
    - 1 Laboratory Administrative Assistant
    - 1 Laboratory Chemical Store Manager
    - 1 Laboratory Quality Management Specialist
    - 1 Training Officer

FY 2023–2024

- Hiring of six new staff:
    - 3 Human Medicine Testing Officers
    - 1 Clinical /Toxicologist Specialist
    - 1 Division (Imports and export) Administrative Assistant
    - 1 Software Developer

FY 2024–2025

- Hiring of three new staff:
    - 1 Human Medicine Testing Specialist
    - 1 Microbiology Testing Specialist
    - 1 Software Developer

FY 2025–2026

- Hiring of six new staff:
    - 1 Vaccine Registration Analyst
    - 1 Vaccine Registration Specialist
    - 1 Vaccine Inspection Analyst
    - 1 Vaccine Testing Officer
    - 1 Microbiology Testing Officer
    - 1 Veterinary Medicine Testing Officer
- The overall cost of this recruitment strategy is 28.6 million RWF over 4 years: 14.4 million RWF in FY 2022-2023, 4.4 million RWF in FY 2023-2024, 3.1 million RWF in FY 2024-2025 and 6.8 million RWF in FY 2025-2026.

5.2.3 General Revenue Assumptions

- The revenue growth is projected at 10% per year in the first three years, at eight percent in FY 2024–2025, and at six percent in the last year.
- Government subsidies are considered as revenues and will decrease by 35% every year from 1.7 billion RWF in the first year of projections to reach the amount of 312 million RWF in FY 2025–2026.
- In FY 2025–2026, the Rwanda FDA will start offering laboratory testing services to other regulatory laboratories. The number of samples is estimated at 300 per year, with 100 for drug tests, 100 for microbiology tests, and 100 for food chemistry tests. Based on Ghana's pricing, the price is estimated at 200,000 RWF for drug tests, 300,000 RWF for microbiology tests, and 100,000 RWF for food chemistry tests. This will bring in revenue of 60 million RWF in FY 2025–2026.
- In FY 2025–2026, the Rwanda FDA will start offering paid scientific advice. The number of paid scientific advice given is estimated at 10 per year, with a price of 261,496 RWF for advice on human medicine and 131,345 RWF for veterinary medicine. These prices are estimated based on EMA’s prices and adjusted for Rwanda price levels. This service will bring in an additional revenue of 3.9 million RWF in FY 2025–2026.
- In FY 2025–2026, the Rwanda FDA will also start offering paid training services for market players who would like to get trained on laboratory testing, for instance. The assumption is to organize one training per month with five participants. The price of these training sessions is estimated at 100,000 RWF, based on Kenya’s benchmark. This service will bring in an additional revenue of 6 million RWF in FY 2025–2026.
- In FY 2025–2026, the Rwanda FDA will also start offering technical support for other laboratories. The assumption is to have 15 clients per year for this service, at a price of 300,000 RWF. This service will bring in an additional revenue of 4.5 million RWF in FY 2025–2026.
- In FY 2025–2026, Rwanda FDA will earn an additional 268 million RWF from vaccine regulation. This supposes the revenue for the registration of one foreign vaccine and three domestic vaccines.

5.2.4 ASSUMPTIONS ON EQUITY

- For the sake of complete financials, it is assumed that the existing assets could be considered as the initial equity. From the asset register, the calculated net value of 3,743,879,690 RWF was taken as the owner's equity.
- The other part of initial equity (first year) is composed of retained earnings of 7,751,423,433 RWF taken from the Rwanda FDA Financial Report of 2020–2021.

5.3 STATEMENT OF COMPREHENSIVE INCOME

Table 21: Statement of Comprehensive Income (RWF)					
	2021/2022	**2022/2023**	**2023/2024**	**2024/2025**	**2025/2026**
Generated Revenues	6 746 564 446	7 421 220 890	8 163 342 979	8 816 410 417	9 688 467 018
Government Subsidies	1 748 043 731	1 136 228 425	738 548 476	480 056 510	312 036 731
Cost of Sales	-	-	-	-	-
Gross Profit	6 746 564 446	7 421 220 890	8 163 342 979	8 816 410 417	9 688 467 018
Operating Expenses	(4 016 816 798)	(5 519 586 693)	(5 697 481 379)	(5 849 787 445)	(6 105 030 837)
Employee Benefits	(3 013 063 671)	(3 212 845 660)	(3 323 575 583)	(3 427 618 722)	(3 580 130 977)
Other Operating Expenses	(1 003 753 127)	(2 321 172 457)	(2 378 261 379)	(2 425 313 247)	(2 531 649 194)
EBITDA (Net Op. Profit)	**4 477 791 378**	**3 023 431 198**	**3 200 054 494**	**3 443 534 958**	**3 888 723 578**
Depreciation	(1 179 463 578)	(1 830 621 757)	(2 339 752 206)	(2 196 879 865)	(1 929 015 066)
EBIT	**3 298 327 800**	**1 192 809 441**	**860 302 287**	**1 246 655 094**	**1 959 708 512**
Interest payment	-	-	-	-	-
EBT	**3 298 327 800**	**1 192 809 441**	**860 302 287**	**1 246 655 094**	**1 959 708 512**
Tax	-	-	-	-	-
Net Profit After Tax	**3 298 327 800**	**1 192 809 441**	**860 302 287**	**1 246 655 094**	**1 959 708 512**
Dividend Declared	-	-	-	-	-
Retained Earnings for the Period	3 298 327 800	1 192 809 441	860 302 287	1 246 655 094	1 959 708 512

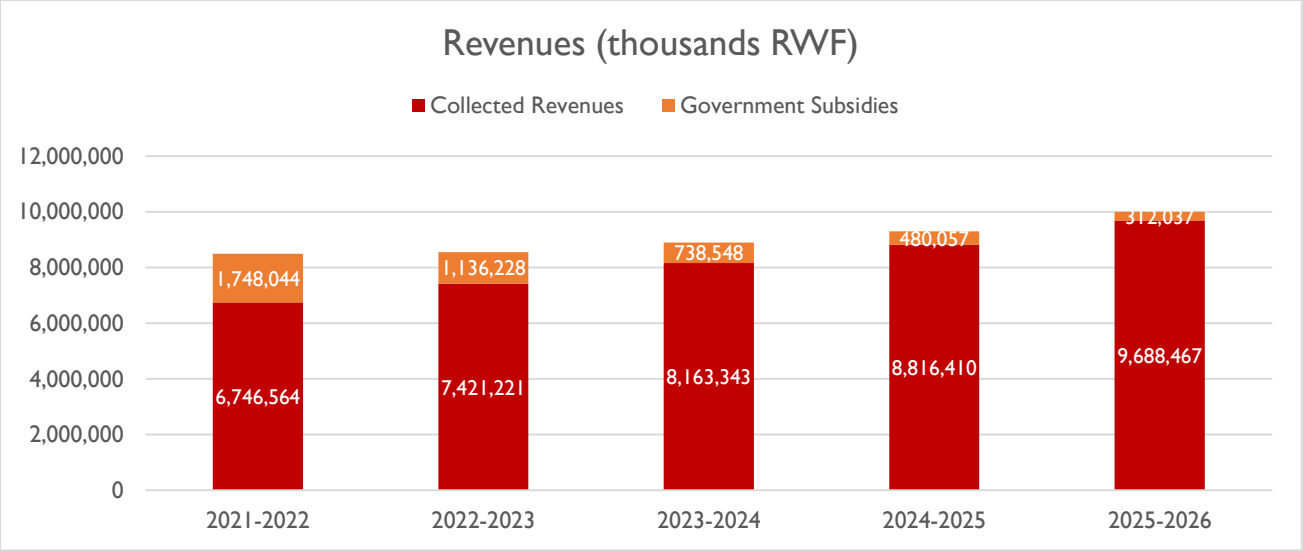


Chart 13: Revenue

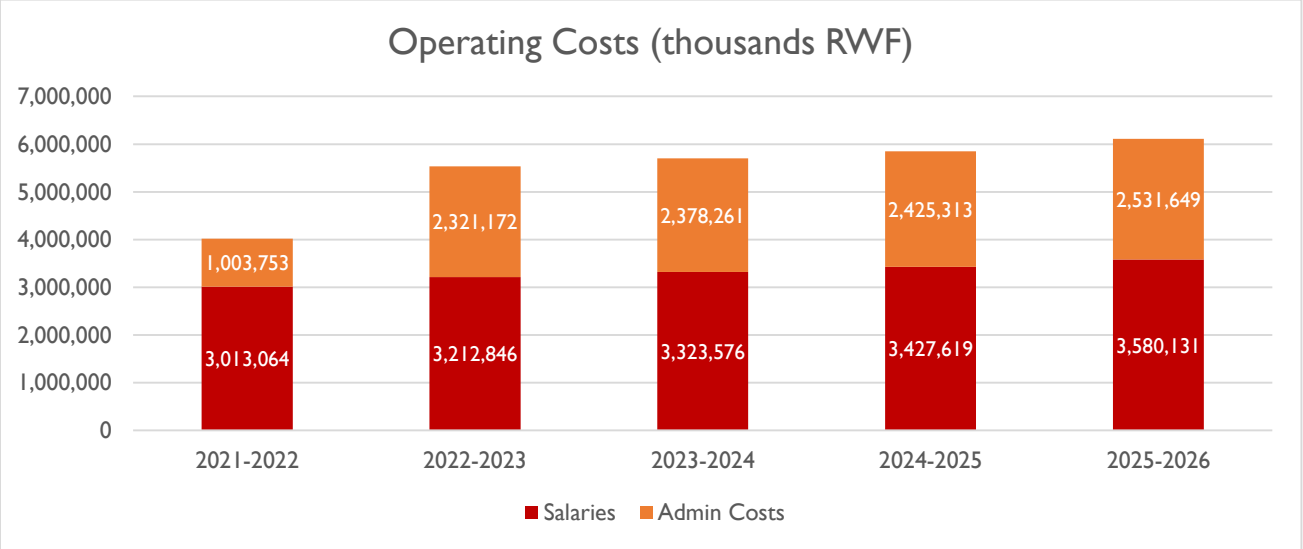


Chart 14: Operating costs

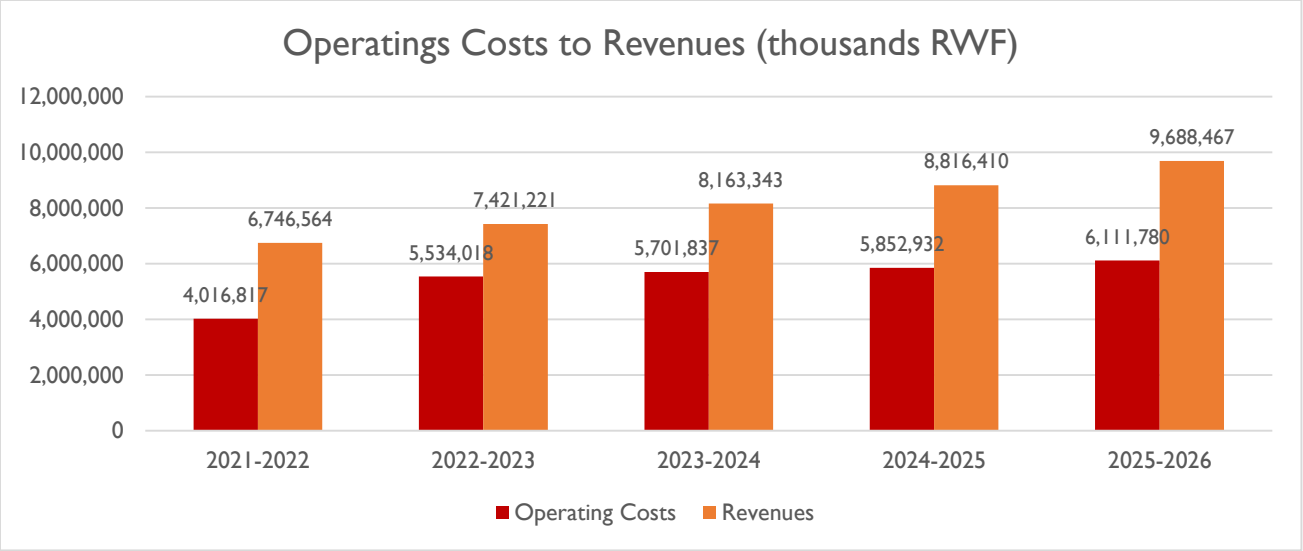


Chart 15: Operating costs to revenue

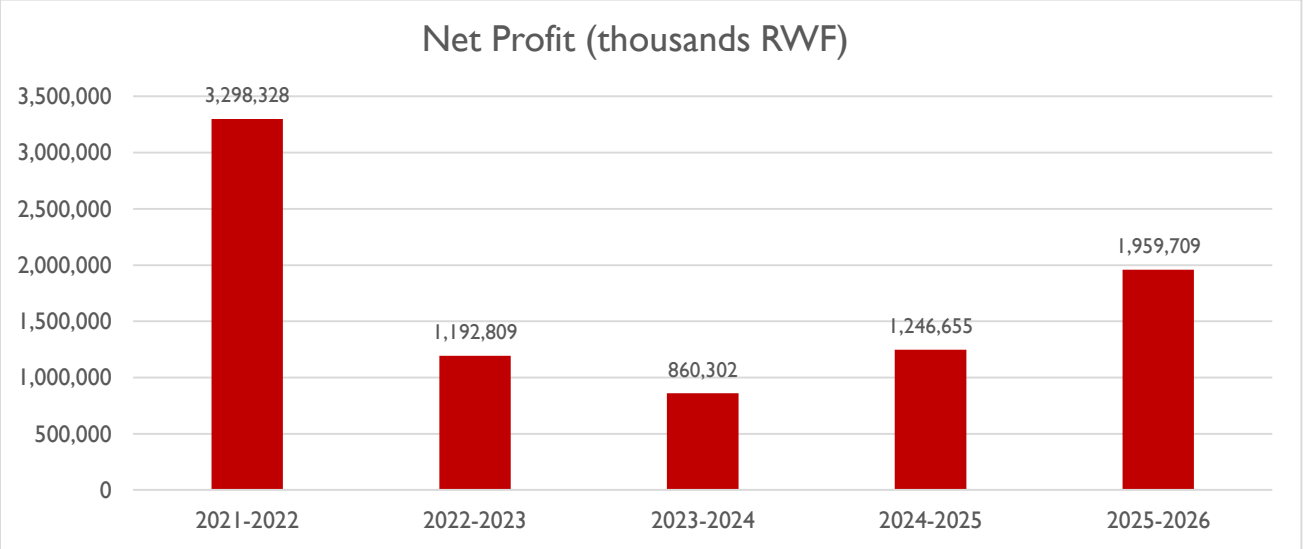


Chart 16: Net profit

5.4 STATEMENT OF FINANCIAL POSITION

Table 22: Balance Sheet (RWF)					
	2021-2022	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**
Current Assets	10 282 780 027	10 871 912 703	11 790 160 527	13 426 810 034	15 607 238 808
Cash	10 097 942 645	10 668 591 583	11 566 507 294	13 185 264 544	15 351 200 587
Trade Receivables	184 837 382	203 321 120	223 653 232	241 545 491	256 038 220
Property, Plant and Equipment	4 841 000 222	5 569 378 466	5 525 226 260	5 147 650 613	4 948 205 547
Total Assets	**15 123 780 249**	**16 441 291 169**	**17 315 386 786**	**18 574 460 648**	**20 555 444 354**
Current Liabilities	330 149 326	454 850 804	468 644 134	481 062 902	502 338 096
Payables	330 149 326	454 850 804	468 644 134	481 062 902	502 338 096
Equity	14 793 630 924	15 986 440 365	16 846 742 652	18 093 397 746	20 053 106 258
Owner Capital	3 743 879 690	3 743 879 690	3 743 879 690	3 743 879 690	3 743 879 690
Retained Earnings	11 049 751 233	12 242 560 675	13 102 862 962	14 349 518 056	16 309 226 568
Total Equity and Liabilities	**15 123 780 249**	**16 441 291 169**	**17 315 386 786**	**18 574 460 648**	**20 555 444 354**

5.5 STATEMENT OF CASH FLOWS

Table 23: Cash Flow Statement (RWF)					
	2021-2022	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**
Cash flow from operating activities	5 573 418 849	3 129 648 938	3 193 515 711	3 438 061 467	3 895 506 044
Net profits after taxes	3 298 327 800	1 192 809 441	860 302 287	1 246 655 094	1 959 708 512
Depreciation	1 179 463 578	1 830 621 757	2 339 752 206	2 196 879 865	1 929 015 066
Change in accounts receivable	765 508 645	(18 483 738)	(20 332 112)	(17 892 259)	(14 492 729)
Change in accounts payable	330 118 826	124 701 478	13 793 330	12 418 768	21 275 195
Cash flow from investment activities	(2 276 584 110)	(2 559 000 000)	(2 295 600 000)	(1 819 304 218)	(1 729 570 000)
-New purchase of Fixed assets	(2 276 584 110)	(2 559 000 000)	(2 295 600 000)	(1 819 304 218)	(1 729 570 000)
Cash flow from financing activities	-	-	-	-	-
Net Proceeds from Borrowings	-	-	-	-	-
Net Proceeds from Owners	-	-	-	-	-
Net change in cash current period	3 296 834 739	570 648 938	897 915 711	1 618 757 249	2 165 936 044
Starting bank balance	6 801 107 906	10 097 942 645	10 668 591 583	11 566 507 294	13 185 264 544
Ending Bank balance	10 097 942 645	10 668 591 583	11 566 507 294	13 185 264 544	15 351 200 587

5.6 SUMMARY OF FINANCIAL ANALYSIS

Table 24: Key Indicators (RWF, %)					
	2021-2022	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**
Revenue	8 494 608 177	8 557 449 315	8 901 891 455	9 296 466 927	9 657 431 774
Gross Profit	6 746 564 446	7 421 220 890	8 163 342 979	8 816 410 417	9 688 467 018
EBITDA	4 477 791 378	3 023 431 198	3 200 054 494	3 443 534 958	3 888 723 578
EBIT	3 298 327 800	1 192 809 441	860 302 287	1 246 655 094	1 959 708 512
Net Earnings	3 298 327 800	1 192 809 441	860 302 287	1 246 655 094	1 959 708 512
Net Cash from Operating Activities	5 573 418 849	3 129 648 938	3 193 515 711	3 438 061 467	3 895 506 044
Capital Expenditures	2 276 584 110	2 559 000 000	2 295 600 000	1 819 304 218	1 729 570 000
Cash	10 097 942 645	10 668 591 583	11 566 507 294	13 185 264 544	15 351 200 587
Total Equity	14 793 630 924	15 986 440 365	16 846 742 652	18 093 397 746	20 053 106 258
Liquidity Ratios					
Current Ratio	31,15x	23,90x	25,16x	27,91x	31,07x
Quick Ratio	31,15x	23,90x	25,16x	27,91x	31,07x
Cash Ratio	30,59x	23,46x	24,68x	27,41x	30,56x
Profitability Ratios					
Gross profit margin	100,0%	100,0%	100,0%	100,0%	103,7%
Operating profit margin	48,9%	16,1%	10,5%	14,1%	21,0%
Net profit margin	48,9%	16,1%	10,5%	14,1%	21,0%
ROA	21,8%	7,3%	5,0%	6,7%	9,5%
ROE	22,3%	7,5%	5,1%	6,9%	9,8%
Break-even Sales	5 196 280 376	7 364 639 874	8 041 589 168	8 049 811 833	7 756 067 891

6 CONCLUSION

With this five-year business plan, the Rwanda FDA will be able to strengthen financial management, enhance accountability, and ensure financial sustainability of the Regulatory Authority, while reducing its dependency on government and donor funding and attain financial autonomy.

The five strategic recommendations have been developed based on the operational, regulatory, quality management system and finance assessment of the Rwanda FDA and on the international benchmark conducted.

The financial projections are based on the following five-year (2021-2026) strategy for Rwanda FDA:

1. **Develop an organization that aligns with its ambitions**
    - Create Support Functions Department with a separate ICT Unit, Legal Unit, Communication Unit and Pharmaceutical Pricing Unit
    - Increase the staff of Quality Control Laboratory to make it a fully-fledged laboratory
    - Hire staff for vaccine regulation
    - Resolve conflict of interest issues with the Board
    - Develop a regular training plan for staff and make sure it is enforced

2. **Digitize services and operations**
    - Ensure all the services are accessible online from start to finish of the entire process, including online payment and document submission, for domestic and foreign applicants
    - Recruit an ICT director and two more software developers
    - Increase awareness about the online system among the clients
    - Ensure that the website is properly and neatly organized and up to date
    - Keep on paying subscription fees to access global best practices standards

3. **Increase revenue to maintain financial sustainability**
    - Conduct an awareness campaign to increase the market coverage for the current services, especially in the food sector
    - Add new services, such as laboratory testing services for other regulatory authorities, paid training services for healthcare professionals, industry, consumers, and academia, scientific advice, and technical support for other laboratories
    - Develop a new revenue stream by restructuring the current fee structure and introducing pre-application screening fees and separate registration and laboratory fees

4. **Improve the quality management system**
    - Establish a well-equipped and staffed Quality Management Division with sufficient permanent staff to cover all QMS responsibilities
    - Hire one Documents Management Specialist
    - Hire one Audits and complaints managements specialist
    - Prioritize addressing the non-conformities identified in the recent internal audit
    - Secure ISO 9001 certification for the whole organization and ISO 17025 accreditation for the laboratory
    - Improve support function guidance and SOPs, especially for finance (monitoring the revenues, etc.) and tariffs/fees and charges payment procedures

5. **Introduce customer-oriented culture**
    - Improve client communication and care through trainings
    - Make sure clients have a ‘relationship manager’ or a specific contact(s) at the Rwanda FDA

- Hire a Client Service Specialist
- Create infographics or lighter versions of the main guidelines on regulation
- Organize regulatory conferences and make sure Rwanda FDA appears occasionally on radio/TV shows

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8 ANNEXES

8.1 RWANDA FDA BUSINESS PLAN ALIGNMENT WITH RWANDA FDA STRATEGIC PLAN 2021-2024

The recommendations also aligned with all strategic priority areas and many strategic objectives that are outlined in Rwanda FDA's Strategic Plan for years 2021-2024, see Table below for more details.

Table 25: Assessment of Technology and Equipment

#	Recommendations	Strategic Framework
1	Develop an organization that aligns with its ambitions • Create Support Functions Department with a separate ICT Unit, Legal Unit, Communication Unit and Pharmaceutical Pricing Unit • Increase the staff of Quality Control Laboratory to make it a fully-fledged laboratory • Hire staff for vaccine regulation • Resolve conflict of interest issues with the Board • Develop and a regular training plan for staff and make sure it is enforced	Strategic Priority Area 1, Strategic Objective 5, points i. ii., and iii. Strategic Priority Area 3, Strategic Objective 1, point iii. Strategic Priority Area 3, Strategic Objective 2, points ix., and x.
2	Digitize services and operations • Ensure all the services are accessible online from start to finish of the entire process, including online payment and document submission, for domestic and foreign applicants • Recruit an ICT director and two more software developers • Increase awareness about the online system among the clients • Ensure that the website is properly and neatly organized and up to date • Keep on paying subscription fees to access global best practices standards	Strategic Priority Area 3, Strategic Objective 3, points ii., and iii.
3	Increase revenue to maintain financial sustainability • Conduct an awareness campaign to increase the market coverage for the current services, especially in the food sector • Add new services, such as laboratory testing services for other regulatory authorities, paid training services for healthcare professionals, industry, consumers, and academia, scientific advice, and technical support for other laboratories • Develop a new revenue stream by restructuring the current fee's structure and introducing pre-application screening fees and separate registration and laboratory fees	Strategic Priority Area 3, Strategic Objective 2, points i., ii., and iv.
4	Improve the quality management system	Strategic Priority Area 1, Strategic Objective 1, points i., and ii.

Table 25: Assessment of Technology and Equipment		
#	**Recommendations**	**Strategic Framework**
	• Establish a well-equipped and staffed Quality Management Division with sufficient permanent staff to cover all QMS responsibilities • Hire one Documents Management Specialist • Hire one Audits and complaints managements specialist • Prioritize addressing the non-conformities identified in the recent internal audit • Secure ISO 9001 certification for the whole organization and ISO 17025 accreditation for the laboratory • Improve support function guidance and SOPs, especially for finance (monitoring the revenues, etc.) and tariffs/fees and charges payment procedures	Strategic Priority Area 1, Strategic Objective 5, points ii. Strategic Priority Area 3, Strategic Objective 1, points i., and iv.
5	Introduce customer-oriented culture • Improve client communication and care through trainings • Make sure clients have a 'relationship manager' or a specific contact(s) at the Rwanda FDA • Hire a Client Service Specialist • Create infographics or lighter versions of the main guidelines on regulation • Organize regulatory conferences and make sure Rwanda FDA appears occasionally on radio/TV shows	Strategic Priority Area 2, Strategic Objective 1, points i., ii., iii., and iv.

8.2 BENCHMARKING EXERCISE

8.2.1 GHANA[17]

The Food and Drugs Authority (FDA) was established in August 1997 under the Food and Drugs Law, 1992 (PNDCL 305B). The FDA is the national regulatory body in Ghana mandated by Parts 6 (Tobacco Control Measures), 7 (Food and Drugs) and 8 (Clinical trials) of the Public Health Act, 2012 (Act 851) to assure the safety, quality and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant local and international standards to protect public health of the people in Ghana.

The FDA is an Agency under the Ministry of Health with an eleven-member governing board inclusive of the Chief Executive Officer, who is responsible for the day-to-day administration of the FDA. The office of the Chief Executive consists of the internal audit, human resource, communications and public education, project, research and management information systems, finance, administration, import and export control, laboratory services departments and regional offices. Under the Chief Executive are five specialized divisions: 1) Food Evaluation and Registration, 2) Drug Registration & Inspection, 3) Safety Monitoring & Clinical Trials, 4) Medical Devices, Cosmetics and Household Chemical Substance and 5) Monitoring & Evaluation.

The Ghana FDA's Technical Advisory Committees (TAC) for Safety were formed to act as a forum to advise the FDA on matters relating to the post-approval safety, quality, efficacy, and effectiveness of products granted marketing authorization by the Authority. The TAC provides expertise to assist the FDA Ghana in making appropriate risk management decisions, however, the decision-making responsibility remains with the FDA Ghana.

The Ghana FDA through its fees, charges and administrative fines collects revenues to aid in running its operations. Per the 2019 annual report[18], a revenue of 61,835,392 GHS (10 billion RWF) was collected. The FDA's expenditure was 54,245,793 GHS (9 billion RWF) which is 81% of the revenue collected. 52% of the total expenditure was on goods and services, 25% on compensation and 23% on assets (CAPEX). However, Ghana FDA receives 50% of the internally generated funds 49,835,392 GHS (8 billion RWF) from the Ministry of Finance for its operations, while the other 50% is retained by the Ministry. Of note, the 50% is insufficient to cover the costs of operations. It is not clear whether Ghana FDA receives funding allocation from the government to cover the remaining operational costs.

Ghana FDA has both the ISO/IEC 17025:2017 certification for its laboratory and ISO 9001:2015 certification for its head office. The Laboratory has a Quality Assurance Unit that develops and implements the QMS in accordance with ISO/IEC 17025:2017 and WHO-GPPQCL (Good Practices for Pharmaceutical Quality Control Laboratory). Implementation of ISO has also commenced for the regional offices.

8.2.2 TANZANIA[19]

The Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGE). The TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment by the Parliament of the Tanzania Food, Drugs and Cosmetics Act, Cap 219. This Act was later

[17] Ghana Food and Drug Authority Website: http://www.fdaghana.gov.gh/
[18] Ghana FDA 2019 Annual Reports: http://www.fdaghana.gov.gh/img/annualrep/2019%20Annual%20Report.pdf
[19] Tanzania Medicines and Medical Devices Authority Website https://www.tmda.go.tz/

amended in 2019 to Tanzania Medicines and Medical Devices Act, Cap 219 and the TFDA shifted the responsibilities of regulating food and cosmetics to Tanzania Bureau of Standards (TBS).

The TMDA is now responsible for regulating quality, safety and effectiveness of medicines, medical devices, diagnostics, biocidals and tobacco products. TMDA is managed as an Executive Agency in accordance with the Executive Agencies Act, Cap. 245 which was also amended in 2009.

The TMDA is organized under the Minister of Health with a Ministerial Advisory Board and a Permanent secretary as direct reports. The Office of the Director General who reports to the Permanent secretary has seven (7) direct reporting administrative units: Internal Audit Unit, Finance and Accounts Unit, Legal Service Unit, Quality Control and Risk Management Unit, Communication and Public Education Unit, Procurement Management Unit. In addition, there are zone offices, which are directly responsible to the Director General through the Zone Managers who oversee service delivery at zone offices.

TMDA functions are executed through three (3) Directorates and Zones, namely Medical Products Control, Laboratory Services and Business Support. There are nine (9) sections under these three (3) Directorates.

The Authority in financial year 2019/2020[20] planned to collect a total of 38,984,602,395 TZS (16 billion RWF) from various sources, where 33,564,363,698 TZS (14 billion RWF) is from local sources, 5,137,926,697 TZS (2 billion RWF) is a donation of Government for Salaries, and 282,312,000 TZS (12 million RWF) are funds from Development partners (EDCTP). The Authority in the period 2019/2020 spent a total of 37,771,486,655 TZS (16 billion RWF) which is equivalent to 97% of collections from all sources, for carrying out its various responsibilities.

The TMDA has continued to provide its services for customers effectively using ICT and implementing best practices of performance (Quality Management System) to international ISO standard 9001:2015 in service delivery. In addition, the Authority in this period has continued to improve service delivery standards for customers by implementing the Service Agreement for Customer Service (CSC) revived in 2020 to meet customer needs and expectations.

The TMDA has continued to enforce ISO/IEC standard requirements 17025:2017 for investigation of therapeutic materials and reagents, as well as World Health Organization Guidelines (WHO) Recognition of Laboratory (WHO Prequalification) in terms of pharmacological examination.

8.2.3 USA[21]

The US Food and Drug Administration has a similar scope to the one of Rwanda FDA. It is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of the nation's food supply, cosmetics, and products that emit radiation.

The FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

[20] TMDA Annual Report 2019/20 https://www.tmda.go.tz/uploads/publications/en1615542346-Annual%20Report%20(3).pdf
[21] U.S. Food and Drug Administration website https://www.fda.gov/

The FDA is responsible for advancing public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

In general, the FDA regulates the following:

1. Foods, including dietary supplements, bottled water, food additives, infant formulas, and other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)
2. Drugs, including prescription drugs (both brand-name and generic) and non-prescription (over the counter) drugs
3. Biologics, including vaccines for humans, blood and blood products, cellular and gene therapy products, tissue, and tissue products and allergenics
4. Medical Devices, including simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices and surgical implants and prosthetics
5. Electronic Products that give off radiation, including microwave ovens, x-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps and sunlamps
6. Cosmetics, including color additives found in makeup and other personal care products, skin moisturizers and cleansers, nail polish and perfume
7. Veterinary Products, including livestock feeds, pet foods, veterinary drugs, and devices
8. Tobacco Products, including cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco

The FDA is an agency within the U.S. Department of Health and Human Services. Previously, the FDA was organized in four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations. Since the reorganization in March 2019, the FDA is organized into the Office of the Commissioner, seven (7) Centers and nine (9) Offices.

The seven (7) Centers are: Center for Biologics Evaluation and Research; Center for Devices and Radiological Health; Center for Drug Evaluation and Research; Center for Food Safety and Applied Nutrition; Center for Tobacco Products; Center for Veterinary Medicine; and Oncology Center of Excellence. The nine (9) Offices are: Office of Regulatory Affairs; Office of Clinical Policy and Programs; Office of External Affairs; Office of Food Policy and Response; Office of Minority Health and Health Equity; Office of Operations; Office of Policy, Legislation, and International Affairs; Office of the Chief Scientist; and Office of Women's Health. The Centers and Offices are themselves organized in different Offices.

In the FY 2018, the US FDA employed in total 17,023 full time equivalents (FTE) and the estimates for the following years were counting on an increase of almost another 1,000 by 2020. The biggest headcount was in the Center for drug evaluation and research (5,203 FTE) and Office of regulatory affairs (4,787 FTE). On the contrary, the Center for food safety and applied nutrition only had 1,105 employees.

The FDA FY 2020 budget was 5.9 billion USD (5.9 trillion RWF). About 55%, or 3.2 billion USD (3.2 trillion RWF), of FDA's budget is provided by federal budget authorization. The remaining 45%, or 2.7 billion USD (2.7 trillion RWF), is paid for by industry user fees. Human Drugs regulatory activities account for 33% of FDA's budget; and 65% of these activities are paid for by industry user fees, the rest being provided by the federal budget. Food regulatory activities account for 19% of FDA's budget; but only 1% of these activities are paid for by industry user fees, so almost totality of these costs is assumed by the federal government. Devices and radiological health regulatory activities account for 10% of the FDA's

budget, biologics regulatory activities account for 7% and animal drugs and feeds regulatory activities account for another 4%.

For the 2022 budget, the FDA requests a total of 6.5 billion USD (6.5 trillion RWF), an overall increase of 477 million USD (478 billion RWF) compared to the FY 2021. This includes an increase of 343 million USD (345 billion RWF) in budget Authority.

8.2.4 SINGAPORE [22]

The Singapore Health Sciences Authority (HSA) has an entirely different scope from Rwanda FDA. The HSA mission is to regulate health products, serve the administration of justice, secure the nation's blood supply, and safeguard public health. The Authority was established as a statutory board under the Ministry of Health in 2001 with the integration of five of its former national agencies: Centre for Drug Evaluation, Institute of Science and Forensic Medicine, National Pharmaceutical Administration, Product Regulation Department and Singapore Blood Transfusion Service.

The HSA went through different reorganizations since 2001 and is currently organized in four (4) different groups:

1. Health product regulation group: This group is responsible for regulating medical devices, therapeutic products (including vaccines), health supplements, Chinese proprietary medicine, traditional medicine, cosmetic products, and tobacco products. The group deals with everything from product registration, premise licensing, variations, clinical trials to adverse effects, advertisements, classification, etc.
2. Applied sciences group: This group serves the administration of justice through forensic medicine, forensic science and analytical chemistry testing of toxicology, chemical metrology, tobacco compliance, cosmetics, drugs, and pharmaceutics.
3. Blood services group: This group is responsible for securing the nation's blood supply by ensuring a safe and adequate blood supply for public and private hospitals.
4. Corporate services group: This group entails the HSA support functions, such as communication, facilities management, finance, HR, IT, legal, risk management, safety and quality, strategy, and compliance.

The HSA also has a group of internal auditors. The HSA also used to regulate food products, but the Food Safety Division was transferred to the Singapore Food Agency in April 2019.

Approximately 67 million SGD (50 billion RWF)[23], which is almost half (45% in financial year 2018/2019 and 44% in financial year 2019/2020) of the HSA revenues, come from laboratory analysis fees. Another 31%, or 47 million SGD (35 billion RWF) come from blood processing and patient laboratory testing fees. License fees account for only 12% of the revenues, or 18 million SGD (13 billion RWF).

The total revenue earned from the HSA services amounted to 152 million SGD (113 billion RWF) in FY 2019/2020, a 2% increase from FY 2018/2019. However, the revenues were not sufficient to cover the expenses. In terms of operating expenses, the biggest costs are salaries and staff costs, which represent more than a half of the total costs. To cover the shortfall, in FY 2019/2020, the HSA received 102 million SGD (76 billion RWF) of government grants, an increase from FY 2018/2019, when they received 87 million

[22] Singapore Health Sciences Authority Website: https://www.hsa.gov.sg/
[23] HSA Annual report 201920 https://www.hsa.gov.sg/about-us/annual-reports

SGD (65 billion RWF). This enables the HSA to achieve an overall surplus of 35 million SGD (25 billion RWF) in FY 2019/2020.

The HSA has several advisory committees: Medicines advisory committee, medical devices advisory committee, Complementary health products advisory committee, Product vigilance advisory committee, Panel of advisors for the HSA proficiency testing program in chemical testing, and Panel of advisors for the HSA external quality assessment program in clinical chemistry.

The Corporate services group, Information management department, corporate headquarters, Tobacco regulation branch, Vigilance and compliance branch, Enforcement branch and Audit & licensing division are all ISO 9001:2015 certified. The laboratory has been ISO 17025 accredited since 1997.

The HSA is very intentional about developing and retaining their staff and has a whole curriculum grouped under the Professional Education Program with different modules such as Leadership module, and other activities such as the Sciences and Innovation Day.

The HSA has also digitized all its services - all the applications for product regulation can be done online, including for foreign based applicants. The applicants can also pay online for the services.

8.2.5 BELGIUM[24]

The Belgian Federal Agency for Medicines and Health Products (FAMHP) was established by the law of 20 July 2006. The scope of its mission doesn't quite match the scope of Rwanda FDA - unlike Rwanda FDA, the Belgian FAMHP does not regulate food or tobacco products.

Its mission is the following:

"Ensuring, from development to use, the quality, safety and efficacy:

1. of medicines for human and veterinary use, including homeopathic medicines and herbal medicines, pharmacy made and officinal preparations.
2. of health products, including medical devices and accessories, and raw materials for the preparation and production of medicines.

Ensuring, from collection to use, the quality, safety and efficacy of all operations involving blood, cells and tissues, which are also defined as health products".

In 2019, the FAMHP had closed 3,452 applications (including applications for amendments) to clinical tests, 8,097 applications for marketing authorizations for medicines, 10,364 adverse drug reaction reports and conducted 2,281 inspections and investigations.

The Authority is organized into three Directorates General:

1. Directorate General PRE authorization for all the activities prior to the first marketing authorization for a medicine or health product. This directorate has four (4) divisions: Research and Development Division (for human use), Marketing Authorization Division (for human use), Medicines for Veterinary Use Division and Assessors Division.
2. Directorate General POST authorization for all the activities after the first marketing authorization for a medicine or a health product. This directorate has five (5) divisions: Marketing Authorization

[24] Belgian Federal Agency for Medicines and Health Products (FAMHP) Website: https://www.famhp.be/en

Division, Vigilance Division, Human Body Material Unit, Health Products Division and Proper Use Division.

3. Directorate General Inspection for all inspection and control activities. This directorate has five (5) divisions under a Special Investigation Unit: Industry Division, Distribution Division, Dispensing Division, Authorizations Division and Medical Devices Division.

The FAMHP also has a spearhead unit dealing with vaccines and oncology.

The support functions at FAMHP are organized into seven units or divisions: Budget and Management control division, Communication division, Legislation and litigation division, Personnel and organization division, Quality division, Facility unit (front office and back office) and International Relations Unit.

Unlike Rwanda FDA, the FAMHP also has a PPMO (projection and portfolio management office) and ICT strategy coordinator, who is overseeing an ICT division and a Project and portfolio management office coordination.

The FAMHP has established three committees: Transparency Committee, Consultative Committee and Scientific Committee. The Consultative Committee met three times during 2019, whereas the Transparency Committee met eight (8) times.

In 2019, the FAMHP had 484 statutory employees. The number of employees has been steadily increasing since 2015, when there were only 350 employees.

The FAMHP[25] is financed through a combination of direct fees perceived for their services (for registration, clinical trials, European Medical Agency fees, Period safety update report fees, and others) and additional variable taxes collected from the clients (medical device tax, contribution 15, 30 and 50 cents, etc.). The law from 11 March 2018 regarding the financing of the FAMHP extends the variable taxes collected by the FAMHP from two to five taxes. In 2019, this combined revenue amounted to 60 million EUR (71 billion RWF). The expenditure was 87 million EUR (103 billion RWF; a decrease compared to the initial 95 million EUR budget), out of which almost half was spent on salaries and contributions. The second biggest cost was ICT expenses (approximately nine (9) million EUR or 10 billion RWF). As the expenditure was bigger than the revenues, the FAMHP received a subsidy of almost 30 million EUR (35 billion RWF), which represents close to 30% of the budget. In theory, the FAMHP is supposed to repay some of the taxes perceived back to the state (and to the taxpayers), but this has proved to be difficult as the fees for the services alone do not cover the expenses. The situation appears to have been similar in 2018.

8.2.6 NETHERLANDS [26]

The Medicines Evaluation Board Agency (MEB) falls under the Ministry of Health, Welfare and Sport (VWS). The MEB is responsible for assessing and monitoring the risk of medicines for human use, and for promoting the proper use of medicines, which makes its scope quite different from Rwanda FDA's scope. The Board has a maximum of 17 members, including the chair. They are leading experts in the medicine or pharmaceutical field who fulfil their role of Board member alongside their day jobs.

The Board is supported by the Agency, which covers the primary process, support units and various programs. The units involved in the primary process are responsible for assessing and monitoring medicines, each based on its own expertise. All medicines, except for veterinary medicines, botanicals, and

[25] FAMHP Annual Report 2019 https://www.famhp.be/en/Publications/Annual_Reports
[26] Medicines Evaluation Board Agency (MEB) Website: https://english.cbg-meb.nl/

novel foods, are assessed by four (4) pharmacotherapeutic groups (PT groups) which are organized according to medical condition. The Regulatory Information Centre (RIC), the Quality Unit, the Pharmacology, Toxicology and Pharmacokinetics Unit, and the Pharmacovigilance Unit are all part of the primary process and report to the executive director. The primary process is backed up by the support units and programs.

The MEB Agency collected 3.4 million EUR (4 billion RWF) in revenues in 2019. This was due to 1.5 million EUR (1 billion RWF) higher revenues than budgeted. The higher revenues concern a large number of non-recurring items, including the realization of the residual value of the MEB's inventory and additional financing that the MEB received from the Ministry of VWS for various projects and for processing a higher number of notifications of medicine shortages. The Agency also recorded 1.9 million EUR (2 billion RWF) lower costs than budgeted. The lower costs observed were due to the revenues from applications for new marketing authorizations being lower than budgeted.

The MEB[27] ultimately closed in 2020 with a loss of 0.7 million EUR (839 million RWF). This was due to 3.5 million EUR (4 billion RWF) higher revenue and 4.2 million EUR (5 billion RWF) higher expenses than budgeted. The higher revenue came from an increase in revenue of 2.3 million EUR (2.7 billion RWF) for procedures through the EMA, 0.4 million EUR (479 million RWF) for National applications and 0.6 million EUR (719 million RWF) for annual fees. Revenue from decentralized procedure (DCPs) was 1.1 million EUR (1.3 billion RWF) lower than budgeted. Subsidy income was also 0.4 million EUR (479 million RWF) higher due to the implementation of several additional projects.

8.2.7 AUSTRALIA [28]

The Therapeutic Goods Act 1989 sets out the legal requirements for the import, export, manufacture, and supply of therapeutic goods in Australia. The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood, and blood products. Therapeutic goods are regulated to ensure that medicinal products and medical devices in Australia meet standards of safety, quality, and efficacy at least equal to that of comparable countries.

The TGA is part of the Health Products Regulation Group (HPRG) in the Australian Government Department of Health. HPRG includes the following divisions: Regulatory Legal Services Branch, Medicines Regulation Division, Medical Devices and Product Quality Division, Regulatory Practice and Support Division.

The TGA recovers the cost of all activities undertaken within the scope of the Therapeutic Goods Act 1989 from industry through fees and charges.[29] TGA receives payment for evaluation services in advance of service delivery, which can extend across financial years. In 2019, TGA Revenues sources include own-source revenue of 159 million AUD (119 billion RWF) from sale of goods and rendering of services and revenue of 2.2 million AUD (1.6 billion RWF) from government. The total expenses in 2019 were 160,141,000 AUD (120 billion RWF) with the highest percentage going to employee benefits (58%) and corporate service (23%).

[27] MEB Annual Report 2019 ad 2020 MEB Annual Report (cbgjaarverslag.nl)
[28] Therapeutic Goods Administration (TGA) Website: https://www.tga.gov.au/
[29] Department of Health Annual Report 2019–20 https://www.health.gov.au/resources/publications/department-of-health-annual-report-2019-20

The TGA has statutory advisory committees that were established under the Therapeutic Goods Regulations 1990. There are currently seven (7) statutory advisory committees that provide independent expert advice on specific scientific and technical matters.

The TGA uses these standards as assessment criteria and TGA officers participate in their development. Australia is a member of the ISO and maintains ISO certification for its laboratory.

8.2.8 MAURITIUS[30]

The pharmaceutical industry in Mauritius is highly regulated under the Ministry of Health and Wellness. The principal legislations are the Pharmacy Act 198312 (the "Pharmacy Act"[31]), the Pharmacy Council Act 201513 (the "Pharmacy Council Act"), the Consumer Protection (Price and Supplies Control) Act 199814 (the "Consumer Protection (Price and Supplies Control) Act") and various regulations made by the responsible Minister through those Acts. The different services offered by the Ministry fall under the Dangerous Chemicals Control Board, a National Pharmacovigilance Committee, Pharmacy Board, and the Central Health Laboratory Services (CHLS).

The "Pharmacy Act" provided for the main framework for regulating the manufacturing, importation, distribution, and sale of pharmaceutical products in Mauritius, led by the Pharmacy Board (the "Board"). The Board consists of Chief Medical Officer (the 'Director General Health Services'), who is also the Chairman of the Board; the Chief Government Pharmacist (the 'Director of Pharmaceutical Services'); five (5) pharmacists appointed by the Minister; and a law officer designated by the Attorney General.

The Pharmacy Board is responsible for pharmaceutical registration but the guidelines on the registration process are not publicly available. However, there is a Pharmacy Act that lists fees for Registration of Pharmaceutical Products - Government Notice No. 47 of 2016. Although it has a limited scope it was used to benchmark the registration fees. The Food Act No. 64 of 13 June 1998 does not list any food registration or premise licensing fee; it does list laboratory fees for testing of food products.

There is no publicly available annual report for the Ministry, therefore financials are not discussed. There is no specifically allocated budget to drug regulation comparable to Rwanda FDA scope. It is therefore not possible to compare Mauritius to Rwanda and this benchmark does not appear to be useful.

8.2.9 EUROPE [32]

The European Medicines Agency (EMA) is a decentralized agency of the European Union (EU) responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU. The EMA is the EU body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision, and pharmacovigilance of medicinal products. The Agency provides the Member States and the EU institutions with the best possible advice on any questions relating to the evaluation of the quality, safety, and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The EMA is governed by an independent Management Board. Its day-to-day operations are carried out by the EMA staff, overseen by EMA's Executive Director.

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[30] Market Study Mauritius 004-FullReport-080621 https://competitioncommission.mu/wp-content/uploads/2021/06/MS004-FullReport-080621.pdf

[31] Pharmacy Act https://health.govmu.org/Documents/Legislations/Documents/Pharmacy%20Act%202015.pdf

[32] European Medicines Agency Website: https://www.ema.europa.eu/en

1. The Management Board consists of 36 members, appointed to act in the public interest, who do not represent any government, organization, or sector. The Board sets the Agency's budget, approves the annual work program and is responsible for ensuring that the Agency works effectively and co-operates successfully with partner organizations across the EU and beyond.
2. The advisory functions of the EMA provide support services to the Executive Director and the Agency on a range of operational, policy and scientific issues in their various fields of expertise. The advisory functions report directly to the Executive Director.
    - Human Medicines Division oversees human medicines throughout their lifecycle. This includes the provision of guidance and advice during medicine development, the marketing authorization process, and the safety monitoring of medicines on the market. It also works to facilitate access to and the optimal use of medicines, for the benefit of patients in the European Union.
    - Veterinary Medicines Division oversees veterinary medicines throughout their lifecycle. This includes the provision of guidance and advice during medicine development, the marketing authorization process and the safety monitoring of medicines on the market. It also works to facilitate access to and the optimal use of veterinary medicines, for the benefit of animal welfare, animal health and public health in the European Union.
    - Stakeholders and Communication Division is responsible for ensuring that the Agency has a coherent, coordinated, and consistent approach to stakeholder and partner relations management and communication.
    - Information Management Division enables the Agency, its staff, members of its committees, working parties and advisory groups, and other stakeholders, to make efficient and effective use of information technology to achieve its organizational and policy objectives.
    - Administration and Corporate Management Division is responsible for strategic planning, budgeting, human resource management, monitoring activities, recruiting, managing, and administering staff and seconded personnel, managing revenue, expenditure and accounts, quality and risk management, internal communication, and providing and running the necessary infrastructure and meeting services for the effective functioning of the Agency.
3. The EMA has four mission-critical task forces (Digital Business Transformation, Data Analytics and Methods, Regulatory Science and Innovation, Clinical Studies and Manufacturing) which support its human and veterinary medicines divisions, bringing together expertise to drive transformational change in high-priority areas of the Agency's work.

The EMA has seven scientific committees that evaluate medicines along their lifecycle from early stages of development, through marketing authorization to safety monitoring once they are on the market. In addition, the Agency has several working parties and related groups, which the committees can consult on scientific issues relating to their field of expertise. These bodies are composed of European experts made available by national competent authorities of the EU Member States, which work closely with the EMA in the European medicines regulatory network.

In 2019, the Agency's total revenue was 339.9 million EUR (405 billion RWF) compared to 317.1 million EUR (317 billion RWF) in 2018[33]. The revised Financial Regulation, which came into effect on 1 July 2019, introduced two (2) new fund sources for handling assigned revenue: R0 for external assigned revenue (inducements related to the EMA building in Amsterdam) and CL for internal assigned revenue (rent and building charges received from the Agency's subtenant in London). In 2019, assigned revenue received amounted to approximately 10.2 million EUR (12 billion RWF). National Competent Authorities (NCAs)

[33] EMA Annual Report 2019 https://www.ema.europa.eu/en/documents/annual-report/2019-annual-report-european-medicines-agency_en.pdf

in the EU Member States receive part of the fee revenue for the assessments they carry out on behalf of the Agency. In 2019, EMA paid a total of 121.6 million EUR (145 billion RWF) to the national competent authorities, compared to 114.1 million EUR (136 billion RWF) in 2018.