USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTAPS) PROGRAM

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Medicines in a Rwandan pharmacy. Photo credit: Todd Shapera

Business Plan Development for Rwanda Food and Drugs Authority

Technical Brief | April 2022 | RWANDA

This brief provides an overview of MTaPS' support to the Rwanda Food and Drugs Authority's business plan development, the lessons learned from the activity, and recommendations for future implementation.

Background

The Rwanda Food and Drugs Authority (FDA) was established in 2018 by Law N° 003/2018 of 09/02/2018[1] with a mission to protect the 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. The Rwanda FDA was established by the government to contribute to the achievement of the country's socio-economic goals and the protection of public health.[2] The Rwanda FDA works closely with local government agencies and international organizations to coordinate the enforcement of and compliance with regulations to ensure maximum impact on public welfare.

In November 2018, the Rwanda FDA's regulatory system was assessed using the World Health Organization (WHO) Global Benchmarking Tool (GBT) and found to be at maturity level I (some elements of a regulatory system exist).[3] The Authority aims to reach maturity level 3 (a stable, well-functioning, and integrated regulatory system) by December 2022.

[1] https://www.rwandafda.gov.rw/fileadmin/user_upload/RwandaFDA/Publications/GENERAL_DOCUMENTS/Laws/LAW_003_RWANDA_FDA.pdf
[2] https://www.rwandafda.gov.rw/home
[3] https://www.who.int/tools/global-benchmarking-tools

The Rwanda FDA has the necessary foundation to effectively protect and promote public health. To meet WHO GBT maturity level 3 or 4, the Rwanda FDA needs to strengthen its regulatory framework by implementing regulatory best practices and strengthening service delivery across the whole organization, including its financial strategies, to enabling it to attain financial sustainability. To fulfill its mission, the Rwanda FDA gets funding from the government, grants, donations, fees levied on applications for licenses and registration of regulated products, administrative fines, and fees for rendered services.

The current business plan defines the Rwanda FDA's objectives and how it intends to achieve them, acting as a written roadmap for financial and operational issues as well as detailing strategic action items.[4]

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and its partner Pharmaceutical Systems Africa (PSA) worked with the Rwanda FDA to develop a business plan that complements its 2021–2024 strategic plan. Development was initiated on May 25, 2021, and ended in May 2022.

Strategic approach

Working within the current regulatory framework, MTaPS and PSA supported the Rwanda FDA in developing its business plan. The overall objective was to develop an actionable business plan for the Rwanda FDA to strengthen financial management, enhance accountability, and ensure the financial sustainability of the national regulatory authority. The long-term objective was for the Rwanda FDA to reduce its dependency on government and donor funding and attain financial autonomy.

Secondary research and document analysis

A desk review of current laws, Rwanda FDA regulations, guidelines, strategic plans, policies, operational manuals, organizational charts and staffing, annual financial reports and statements, manuals, and the client service charter, in addition to other literature such as the Ministry of Health (MOH) strategic plan and the Rwanda health sector performance report FY 2019–2020, was undertaken to understand the context in which the Rwanda FDA is operating and its internal functions. The process included reviewing current funding sources and expenditures to determine the financial situation of the Authority and identifying options for increasing funding to limit dependency on government funding sources. A cost and revenue analysis, including a review of the regulation on fees, was performed to determine the optimal price for the Authority to render regulatory services and to develop recommendations for adjustments based on the cost and revenue study findings.

The analysis covered the Rwanda FDA's organizational structure, governance, management, financial management (pricing and/or costing of services), quality management system, IT and equipment, costs and revenue structure, client needs and satisfaction, client services, and an overview of regulations.

A market-based approach was applied in developing the business plan that was based on benchmarking the Rwanda FDA's key regulatory functions against similar and well-established national and regional regulatory authorities, including:

- Singapore Health Sciences Authority
- Mauritius Food and Drugs Authority (FDA)[5]
- US Food and Drug Administration (US FDA)
- Australia Therapeutic Goods Administration
- Tanzania Medicines and Medical Devices Authority (TMDA)
- Ghana Food and Drugs Authority (FDA)
- Netherlands Medicines Evaluation Board
- Belgium Federal Agency for Medicines and Health Products
- European Medicines Agency (EMA)

This approach provided useful information from other regulatory authorities in more developed markets that could be translated into insights for the Rwanda FDA. The regulatory processes and requirements were analyzed by comparing the existing regulations and guidelines to international best practices as outlined by the WHO GBT and regulatory practices of the benchmarked regulatory authorities. However, the benchmarking exercise showed that the authorities in

[4] Adam Hayes, Investopedia.com. What Is a Business Plan? Updated May 04, 2022. Available at: https://www.investopedia.com/terms/b/business-plan.asp

[5] Competition Commission. June 2021. Market Study of the Pharmaceutical Sector in Mauritius, MS/004: Report of the Executive Director. Available at: https://competitioncommission.mu/wp-content/uploads/2021/06/MS004-FullReport-080621.pdf

Rwanda FDA staff and stakeholders at the Rwanda FDA business plan validation meeting

Ghana, Tanzania, the US, the Netherlands, Australia, Mauritius, and Europe are not 100% financially sustainable since each receives some funding from the central government, at least to cover staff salaries.

Primary research: Management and stakeholder interviews and client survey

The business plan development team conducted interviews with the Rwanda FDA management; chair of board of directors; outgoing director general; three heads of departments; eight division managers; regulatory affairs, harmonization, and compliance analyst; quality assurance analyst; director of the finance unit; human resource director; procurement specialist; software developer; and IT security specialist. Interviews focused on existing operations and objectives, goals for the Rwanda FDA, the strategic vision, and strategic opportunities.

The team also interviewed external stakeholders to understand the environment in which the Rwanda FDA is working and get more information on the financing of the Rwanda FDA and the support it receives from various ministries and development agencies. Among those interviewed were the MOH, Ministry of Finance and Economic Planning, Medical Technology and Infrastructure of the Rwanda Biomedical Centre, Rwanda Revenue Authority, Rwanda Standards Board, Rwanda Medical Supply Ltd, Rwanda Development Board, and United States Pharmacopeia.

Assessment of the quality management system, information technology, and equipment

Based on the document analysis and management interviews, the team assessed the Rwanda FDA's quality management system by interviewing Rwanda FDA staff and reviewing the Authority's documents related to its quality policy and practices. Additionally, a 2021 internal audit was reviewed to assess the current state of the Rwanda FDA's quality management practices. The team also analyzed the level of digitization at the Rwanda FDA in relation to client needs and international best practices, as well as the general equipment.

Analysis of cost and revenue, organization, management, and governance

From the documents received from the Rwanda FDA and using the international benchmarking, the team analyzed the Rwanda FDA's costs and revenues. This was to determine whether the costs are in line with international best practices and the fees comparable, given the size and the structure of the Rwandan market, or whether they should be changed. The team had also planned to analyze the Authority's revenue to identify the biggest revenue

drivers, but this proved to be impossible given the unavailability of data.

The team also analyzed the Authority's organization, management, and governance through the organizational chart and interviews with Rwanda FDA management and compared the findings to the international benchmarking.

Achievements

The Rwanda FDA Business Plan for Financial Sustainability 2021–2025 was developed, validated in a stakeholder workshop, and revised to incorporate stakeholder feedback. It documents the financial situation, gap analysis, and other findings. A financial strategy for the Rwanda FDA for the next five years was developed based on five strategic recommendations that will help the Rwanda FDA become a world class regulatory authority that is financially sound while relying to a small degree on subsidies from the government and partner support. The recommendations are to develop an organization that aligns with its ambitions, digitalize services and operations, increase revenue to maintain financial sustainability, improve the quality management system, and introduce a customer-oriented culture.

In line with the financial strategy, a financial projections model for the next five years was developed. The financial projections show that if the business plan recommendations are followed, the Rwanda FDA will significantly decrease its financial dependence over the next five years.

The review of regulations on tariffs/fees and charges showed that Rwanda FDA services that call for such tariffs/fees and charges are appropriate and in line with services offered and also are comparable to benchmark regional authorities such as the Ghana FDA, TMDA, and Mauritius FDA. However, it was recommended that in the medium term there be a restructuring of some of the fees to allow more flexibility when registering products and consideration of a special fee structure for essential medicines that have low market presence, such as orphan drugs, or those needed to fulfill a market shortage. Recommendations and opportunities for improvement were proposed based on the gap analysis findings and global best practices.

Lessons Learned and Recommendations

- *Leave ample time for document gathering*

The timeline for the business plan development had to be extended several times, and the project ended up lasting longer than expected due to delays in gathering documents from the Rwanda FDA and stakeholders.

- *Agree on process of engaging external stakeholders*

There are different ways of reaching out to stakeholders. The best, but most time-consuming, one is to contact them formally via a request sent by the Rwanda FDA to make sure that the right people are interviewed. While some members of the team were able to reach out in parallel to different contacts among stakeholders, this was on an informal basis and should be used only as a complementary approach; however, this approach avoids unnecessary delays in data collection and validation.

- *Benchmark against similar authorities*

International benchmarking proved to be a particularly useful exercise as the Rwanda FDA aims to be a world class regulatory authority and play in the same field as other recognized authorities, such as the US FDA, Ghana FDA, and EMA. However, it is important to compare what is comparable and select regulatory authorities that have a similar scope as the Rwanda FDA. This meant including the US FDA and Ghana FDA. Other authorities can be added to the benchmarking, but precautions need to be taken in terms of direct comparisons.

- *Remain flexible*

Business plan development is specific to the regulatory authority for which it is being done. Therefore, it is important to comply with the scope of work and remain flexible when facing the reality on the ground. For example, in the case of the Rwanda FDA, it was impossible to properly analyze the revenue, determine the main revenue drivers, and provide any recommendations on the revenue mix because the Authority lacked information about its current revenue split.

- *Prioritize*

The prioritization of the business plan development should be clearly defined and mapped out with all stakeholders to ensure that timelines and deadlines are met with minimal or no downtime.

Sustainability

The Rwanda FDA has a business plan that details all aspects of the business plan development process, including the methodology; organizational overview; gap analysis and findings; recommendations; and opportunities for improvement, including strategic actions, implementation actions, and timelines for key regulatory functions. Financial projections were availed to the Rwanda FDA in MS Excel. To ensure sustainability of the Rwanda FDA business plan, there is alignment with the current Rwanda FDA strategic plan. Implementation of the business plan recommendations will also fulfill the implementation of the Authority's strategic plan.

Conclusion

The five-year business plan will help the Authority strengthen financial management, enhance accountability, and ensure its financial sustainability while reducing its dependency on government and donor funding. The five strategic recommendations were developed based on the operational, regulatory, quality management system, and financial assessment of the Rwanda FDA and on the international benchmarking conducted.

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About USAID MTaPS:

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.