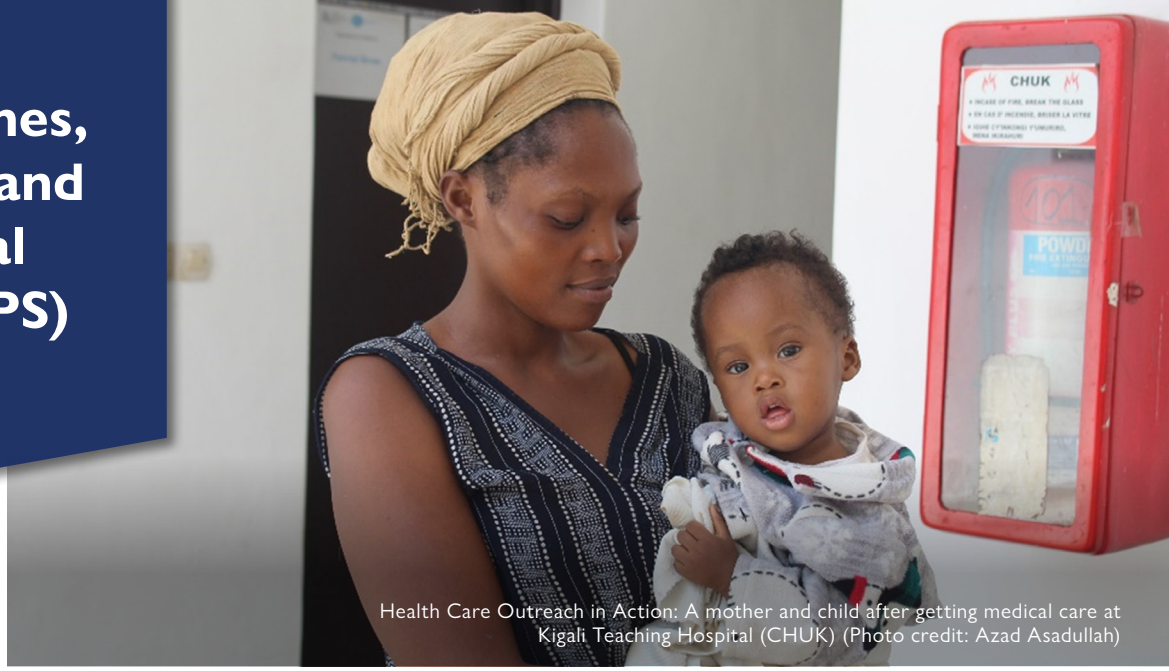
USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Improved Access.
Improved Services.
Better Health Outcomes.



Health Care Outreach in Action: A mother and child after getting medical care at Kigali Teaching Hospital (CHUK) (Photo credit: Azad Asadullah)

MTaPS COUNTRY SUMMARY REPORT
RWANDA (2018–2024)

About USAID MTaPS

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) enables low- and middle-income countries to strengthen their pharmaceutical systems, which are essential to establishing higher-performing health systems and achieving better health outcomes. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

Learn more at
https://www.mtapsprogram.org/

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FROM THE AMERICAN PEOPLE

INTRODUCTION

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which are critical for ensuring access to and appropriate use of safe, effective, quality-assured, affordable medicines, vaccines, health technologies and products, and related pharmaceutical services to improve health. MTaPS' objectives are to (1) strengthen pharmaceutical-sector governance; (2) increase institutional and human resource capacity for pharmaceutical management and services, including regulation of medical products; (3) increase availability and use of pharmaceutical information for decision making and advance the global learning agenda; (4) optimize pharmaceutical-sector financing, including resource allocation and use; and (5) improve pharmaceutical services, including product availability and patient-centered care, to achieve desired health outcomes.

MTaPS employs a pharmaceutical system-strengthening (PSS) approach to identify and implement strategies and actions that achieve coordinated and sustainable improvements of a pharmaceutical system to make it more responsive and resilient for achieving better health outcomes. The MTaPS approach emphasizes locally led development, country ownership, and self-reliance to support countries on the pathway to sustainability.

At the country level, the MTaPS approach is adapted to the specific context, national health system-strengthening strategies, and USAID's vision and support. In Rwanda, from 2018 to 2024, MTaPS provided technical assistance to the Ministry of Health (MOH) to strengthen pharmaceutical systems and services in these areas: regulatory systems, including their governance, management information systems, marketing authorization of medical products, pharmacovigilance (PV), quality management system (QMS), and oversight of clinical trials; antimicrobial stewardship, infection prevention and control (IPC), and Ebola virus disease (EVD) preparedness and response; COVID-19 vaccination, focusing on vaccination safety; maternal, newborn, and child health (MNCH); and HIV/AIDS.

CHALLENGES

- Limited capacity and lack of a functional regulatory framework for Rwanda FDA
- Gaps in key regulatory functions; outdated and slow product registration processes
- Underutilized PV system; need for enhanced patient safety monitoring
- Gaps in IPC and PV highlighted by COVID-19 and EVD challenges in the region

PARTNERS

MTaPS collaborated with a diverse range of local and international partners in Rwanda to strengthen its health care system, including:

- Food and Agriculture Organization
- MOH
- National Pharmacy Council
- Palladium (implementer of the USAID Rwanda Integrated Health Systems Activity)
- Rwanda Biomedical Center (RBC)
- Rwanda Development Board
- Rwanda FDA
- Rwanda Information Society Authority
- Rwanda Pharmaceutical Students Association
- USAID Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM)
- US Pharmacopoeia—Promoting the Quality of Medicines Plus
- WHO

COUNTRY CONTEXT

Rwanda has progressed in strengthening its pharmaceutical sector in recent years. In 2018, Rwanda Food and Drugs Authority (FDA) was established to protect public health by regulating human and veterinary medicines, vaccines, and medical devices. The 2018 assessment using the World Health Organization's (WHO) Global Benchmarking Tool (GBT) indicated that Rwanda FDA was operating at the lowest maturity level (ML), with several critical areas needing improvement, including incomplete regulatory frameworks, significant inefficiencies in medical product registration, and an inadequate national PV system. The National Pharmaceutical Sector Strategic Plan 2018–2024 called for improved governance and enhancement of institutional and human resource capacity to effectively carry out pharmaceutical management and regulatory functions.

EVD outbreaks in the Democratic Republic of the Congo and Uganda, with high mortality rates, highlighted the need for improved IPC in health facilities to reduce cross-border risks. Rising antimicrobial resistance (AMR) in Rwanda[1] led to a national plan and strategies to combat antibiotic misuse. In preparing for a mass COVID-19 vaccination campaign, Rwanda encountered challenges, including weak regulation preventing rapid vaccine authorization, outdated adverse event monitoring guidelines, and a lack of training for health workers in vaccine safety. To reduce child and maternal mortality, Rwanda prioritized enhancing MNCH services by promoting appropriate use of quality essential MNCH medicines (like oxytocin and oxygen), strengthening pharmaceutical management, case management for children under the age of 5, and improving youth access to family planning to lower teen pregnancies.

STRATEGIC APPROACH

MTaPS is dedicated to supporting Rwanda's goal of promoting equitable access to quality-assured essential medicines and health technologies at an affordable cost. This effort is aligned with the USAID/Rwanda strategic objective of strengthening the pharmaceutical system for sustained improvements in health outcomes to control the HIV epidemic, combat infectious disease threats, and expand MNCH services. MTaPS customized its technical guidance for Rwanda by adopting international evidence-based guidelines, such as the WHO GBT,[2] the safety surveillance manual for COVID-19 vaccines,[3] and WHO's Access, Watch, and Reserve (AWaRe) classification,[4] to address the above challenges. MTaPS' core strategy focused on reinforcing the existing health system in Rwanda to leverage established infrastructure and expertise. MTaPS assistance was aligned with national and institutional plans, such as the Rwanda FDA strategy for 2021–2024, was driven by local data, and was characterized by synergistic collaboration and coordination among Rwanda's ministries, agencies, multinational partners, and experts from both the public and private sectors. MTaPS' approach included capacity building tailored to the needs of local partners and facilities and innovation and digital alization of health systems. Institutionalization and sustainability were key aspects of the approach, as well as continuous monitoring and evaluation (M&E) of performance to ensure progress toward program goals and objectives.

KEY MILESTONES

2019
- 233 institutional development plans (IDPs) developed following the 2018 WHO GBT assessment
- Active safety monitoring of new HIV treatments introduced to health care providers

2020
- Rwanda FDA strategic plan (2021–2024) developed to guide strengthening of regulatory system
- Pharmacovigilance Monitoring System (PViMS) piloted at Rwanda FDA for safe introduction of EVD vaccine and HIV regimens (https://pvims.rwandafda.gov.rw/)

2021
- WHO AWaRe antibiotic classification integrated into revised National Essential Medicines List
- PViMS implemented to capture adverse events following immunization (AEFIs) and ensure safe COVID-19 vaccine introduction

2022
- Simulation exercises conducted in high-risk zones for EVD outbreak preparedness
- Medicines and therapeutics committee (MTC) manual and medicine use evaluation tool launched to revitalize MTCs in hospitals

2023
- Launch of fully operational Integrated Regulatory Information and Management System (IRIMS) (https://www.irims.rwandafda.gov.rw/portal/)
- PViMS enhanced for medicine and vaccine safety monitoring and made interoperable with WHO VigiFlow

2024
- Rwanda FDA is close to achieving ML3; 9 IDPs related to 4 subindicators pending

KEY RESULTS

Working in collaboration with the MOH and other stakeholders, MTaPS supported Rwanda in achieving the following key results:

Pharmaceutical-sector governance

- Strategic plan (2021–2024), costed business plan (2021–2026), 20 regulations, and other regulatory documents developed for Rwanda FDA, contributing to achieving ML3, indicative of a functional, stable national regulatory authority.
- The number of nonimplemented subindicators reduced, from 233 in 2018 to 4 in 2024, signifying an improved overarching regulatory framework and regulatory functions.
- MTC operational manual, tools, and standard operating procedures (SOPs) developed and 313 health care providers from 47 hospitals oriented for improved pharmaceutical management at health facilities.

Institutional and human resource capacity for pharmaceutical-sector management

- Health care workers, including Rwanda FDA regulatory personnel trained in various aspects of pharmaceutical management and regulatory systems, including medicine evaluation and registration, Good Manufacturing Practices (GMP), Good Review Practices, Good Reliance Practices, PV, QMS, and medicine management, thereby strengthening the pharmaceutical management capacity of health care providers.
- Two eLearning courses on medicine evaluation and registration and PV embedded within Rwanda FDA to facilitate longer-term health care worker capacity building.

Availability and use of information

- Average registration process for medicines and products reduced from 9 months to 3 months due to IRIMS increasing efficiency of Rwanda FDA's regulatory functions.
- Increased government revenue collection ($304,908 in 2023) and improvement in efficiency of intragovernmental transactions, due to IRIMS integration with iRembo, an online platform that facilitates access to regulatory and other government services for citizens.
- Fully operational PViMS compatible with WHO VigiFlow for reporting adverse events (including active safety monitoring and spontaneous reporting of AEFIs for EVD and COVID-19 vaccines) and for providing regulatory feedback to clients, patients, and health facilities.
  - 1,881 AEFIs (including 946 serious AEs) reported through PViMS from June 2021 to December 2023.

Over **500** health workers, including Rwanda FDA **regulatory personnel,** trained in various aspects of pharmaceutical management and regulatory processes, including medicine evaluation and registration, GMP, **Good Review Practices, Good Reliance Practices,** PV, and QMS

$304,908 in **government revenue** collected from IRIMS integration with iRembo

Pharmaceutical services

- Developed and implemented the pharmaceutical service accreditation standards across health facilities, thereby enhancing overall quality of care.
- Comprehensive PV strategy that provides a framework guiding PV planning, implementation, monitoring and evaluation, and stakeholder coordination entrenched PV into Rwanda's health system to enhance patient safety in use of medical products.
- Rwanda FDA alerted to a number of suspected substandard pharmaceutical products by health care providers through Rwanda FDA's PV reporting system, leading to investigation, implementation of quality control measures, and issuance of public safety communications to health care providers and patients.
    - o 261 suspected substandard pharmaceutical product reports received as of December 2023, resulting in relevant regulatory actions by Rwanda FDA, such as suspension of 4 products due to quality issues and recall of 73 batches.

Global Health Security Agenda/AMR

Use of Antimicrobial Medicines Optimized

- The MOH adopted the AWaRe categorization of antibiotics as per WHO recommendations and updated the National Essential Medicines List to guide prescribers in appropriate antibiotic use.
- Standardized therapeutic guidance also updated with AWaRe categorization to promote the accurate prescription of antibiotics for both treatment and prophylaxis and further advance AMR containment.

IPC

- National IPC policy and IPC strategic plan for 2020–2024 updated.

COVID-19 vaccination and safety

- National PV guidelines and SOPs updated to include COVID-19 vaccines; PViMS updated to incorporate COVID-19 AEFI reporting, thereby enhancing safety surveillance for COVID-19 vaccines.
- 23 regulators and 159 health workers trained in COVID-19 vaccine PV, resulting in 1,708 COVID-19 vaccine AEFI reports submitted to national PV reporting system from June 2021 to December 2023, with MTaPS support, to help ensure safety, timely regulatory response, and trust in the vaccination program.
- Rwanda FDA competency to assure quality of clinical trials was enhanced when 2 inspectors received training and mentorship in Good Clinical Practices and conducted the inspections of 10 clinical trial sites, including 1 administering COVID-19 vaccines to adolescents and adults.

EVD

- Ebola IPC guidelines, compliance monitoring tool, and 12 SOPs developed for increased safety and effective preparedness and response.
- 1,150 health workers trained in Ebola IPC, including IPC guidelines, tools, and SOPs. Simulation exercises conducted for better EVD and hemorrhagic fever virus preparedness.
- Increased compliance with Ebola IPC requirements (70 to 100%) in most categories, signifying improved safety.

HIV/AIDS

- To conduct active surveillance of dolutegravir-based antiretroviral therapy regimens to determine their safety, MTaPS assisted the Rwanda Biomedical Center (RBC) and Rwanda FDA in the development of a study protocol that was implemented in 20 health facilities with 1,440 enrolled patients.

3,676
adverse drug event (ADE) reports, including
1,708
COVID-19 vaccine AEFI reports,
submitted via national PV reporting system **to Rwanda FDA** from 2021–2023

1,150
health workers trained in **Ebola IPC**

> *The system that we have in FDA with the help of MTaPS is not only helping our clients, but also our staff. Initially we used to work during the weekends to process applications, we had a big workload, but now we can go home at 5:00 pm and we don't have to work on the weekends."*
>
> *Dr. Joseph Habiyaremye*
> *medical devices and diagnostics import and export licensing analyst, Rwanda FDA*

- The program also equipped Rwanda FDA with a customized electronic PV monitoring system (PViMS) for safety monitoring of dolutegravir-based regimens for HIV patients, ensuring patient safety.

- RBC situational analysis of antiretroviral multimonth dispensing (MMD) and optimal pack sizes resulted in the adoption of 6-month MMD with 90-unit packs. The situational analysis also endorsed a shift to bimonthly antiretroviral dispensing for certain clients, confirming MMD's feasibility and client satisfaction.

MNCH

- To improve quality of care for MNCH, guidelines on regulating medical gases and job aids for medical oxygen administration in hospitals were developed to ensure the availability and appropriate use of quality medical oxygen for the management of hypoxic newborns and children, as well as COVID-19 cases.
- An implementation manual, SOPs, and job aids developed and disseminated to guide health workers on procedures for correct cold storage and management of oxytocin to ensure its quality to the point of administration.
- Rwanda has prioritized increased access to curative care for children under five at the community level through integrated community case management. Skills and competence of community health workers to appropriately manage medicines and consumables used in the community were improved through development of a set of minilessons to be used by health center staff for monthly refresher trainings.
- Due to the high number of teen pregnancies in Rwanda, MTaPS assisted the MOH to identify challenges in access to family planning products by youths and recommended appropriate interventions for the MOH and their partners to consider implementing to improve youths' access to family planning services.

Transforming Rwanda FDA: Empowering Regulation with a Cutting-Edge Information Management System

The integration of MTaPS-supported IRIMS with iRembo, Rwanda's national payment gateway, has significantly streamlined Rwanda FDA's application processes and improved revenue collection. From May 2023 to January 2024, a total of 14,630 applications were processed digitally through IRIMS across various regulatory functions. The most notable application load was seen in Rwanda FDA's Import and Export regulatory function, where there were over 12,000 applications, followed by the Premises and Product Registration regulatory functions. This digital transformation increased operational efficiency and transparency in regulatory proceedings of Rwanda FDA. In terms of financial impact, IRIMS has proven to be a game-changer. The system has facilitated a substantial increase in revenue collection, securing over 454 million Rwandan francs (USD 304,000), with significant contributions from GMP, pharmaceutical license, and product registration fees.

This reflects a leap forward in digital governance, illustrating the transformative power of technology in enhancing regulatory efficacy and fiscal sustainability within the public health systems.

The launch ceremony of the Rwanda FDA IRIMS, May 2023. Photo credit: Paul Bwathondi.

FEATURED RESOURCES

- Technical Brief: Strengthening Pharmacovigilance in Rwanda: Introducing PViMS for Spontaneous Reporting of Adverse Drug Effects (2023)
- Technical Brief: Business Plan Development for Rwanda Food and Drugs Authority (2022)
- Technical Brief: AWaRe Categorization for Antibiotics in Rwanda (2022)
- Rwanda Foods and Drug Authority Strategic Plan 2021–2024
- Mapping of Registration of MNCH Medical Products: Rwanda (2020)
- Action-Oriented Quality Assurance Framework for Oxygen

Rwanda Food and Drug Authority Strategic Plan 2021–2024

PATHWAY TO SUSTAINABILITY

MTaPS provides technical guidance and supports countries in establishing strategic direction and development of critical capacities on a pathway to sustainable and resilient pharmaceutical systems. Through its activities in country, MTaPS strengthened the capacity of the local government and local organizations (public and private) for improved, locally led, and more sustainable pharmaceutical service delivery, as highlighted below:

- IRIMS was made operational within government and data systems for ongoing implementation through a successful partnership with Rwanda FDA, MOH, and WHO.
- Evidence of Rwanda FDA's commitment to enhancing regulatory services includes updated policies, effective IDP implementation, and attaining a higher WHO GBT ML, with only four remaining subindicators to be addressed.
- Rwanda FDA's four-year business plan focuses on improving financial management and accountability to achieve autonomy by decreasing dependency on external funding.
- Establishment of eLearning programs for medicine registration and PV ensures that Rwanda FDA staff and health care professionals have access to continuing professional development.
- Ongoing integration of PViMS with Rwanda FDA's IRIMS will improve PV decision making sustainably to ensure long-term safety oversight of medical products.
- Adopting AWaRe classification improves sustainable antibiotic stewardship and patient safety in management of common infectious diseases and will guide the MOH in locally appropriate, central-level antibiotic procurement and distribution.
- Rwanda FDA's M&E system promotes sustainable practices by utilizing the WHO GBT for continual self-improvement and comprehensive benchmarking across eight regulatory functions.
- Creation of an expert cadre specializing in medicine registration, clinical trial oversight, and PV across all levels of the health system promotes long-term regulatory excellence.

RECOMMENDATIONS

For the Rwandan government:

- Establish an MOH Pharmacy Unit to steer the pharmaceutical sector.

For Rwanda FDA:

- Collaborate with stakeholders to achieve ML3 and aim for ML4 status, as per the WHO GBT, to be recognized as a WHO-listed authority, and specifically:
  - Increase the number of certified QMS auditors to fulfill QMS across regulatory functions.
  - Formulate a targeted capacity building strategy to manage regulatory workload and specialization.
  - Restructure and equip the Information and Communication Technology (ICT) unit with skilled human resources and tools to support management information systems, including PViMS and IRIMS, and ensure network assessments for optimal accessibility.
- An effective QMS is essential for achieving ML3 according to the WHO GBT. Certifying the Authority under the ISO 9001:2015 standard—proposed by two internal audits—remains a critical step to further bolster the Authority's credibility, streamline processes, and enhance overall performance.

For the MOH and RBC:

- Regularize training and mentorship for rapid response teams on Ebola IPC and hemorrhagic fever virus/EVD case management, including IPC compliance monitoring as part of facility preparedness.
- Coordinate with relevant departments of MOH and RBC to ensure appropriate quality medicines, including medical oxygen, are financed, procured, distributed, and used appropriately in MNCH services at both the facility and community levels.

For USAID:

- Assist Rwanda FDA to achieve ML3 status and advance sustainable regulatory system-strengthening efforts to safeguard the supply chain against the infiltration of substandard and falsified medical products.
- Ensure sustained funding and technical assistance for IRIMS and PV to enhance Rwanda's regulatory capacity, including monitoring drug safety and efficacy.

- Support comprehensive pharmaceutical system strengthening initiatives.
- Support implementation of systems for regular M&E of health facilities' compliance with pandemic preparedness and response standards.
- Support the RBC Maternal, Child, and Community Health (MCCH) division for integrated, quality MNCH product management.
- Assist the RBC in implementing a quality-assured oxygen supply roadmap.
- Foster partnerships for MTC promotion and management within health facilities.
- Catalyze sustainable pandemic preparedness and response financing mechanisms.
- Urge political leadership at the highest levels to prioritize pandemic prevention and preparedness for rapid response during future emergencies.

FUTURE CONSIDERATIONS

- For stronger pandemic preparedness, it is essential to develop robust vaccine regulatory systems, which should include marketing authorization processes to ensure vaccine safety and efficacy, strong PV systems with continuous safety monitoring to detect and assess adverse events, and comprehensive postmarketing surveillance to track vaccine performance under real-world conditions.
- Enhance the memorandum of understanding between Rwanda FDA and the University of Rwanda's ICT department to fully leverage the University's ICT expertise to ensure local long-term support for proper functioning and sustainability of IRIMS and PViMS, regulatory capacity, and data-driven pharmaceutical management.
- Incorporate artificial intelligence to accelerate data analysis, introduce predictive capabilities, and optimize clinical trial and supply chain management, as well as ensure regulatory compliance and safety monitoring, revolutionizing pharmaceutical-sector management.
- Support the development of local production capabilities for essential health products, such as vaccines, IPC supplies, and essential MNCH medicines, to increase Rwanda's health care resilience and self-reliance.
- Cultivate public-private partnerships to significantly improve innovation in regulatory frameworks, PV, electronic data system integration, promotion of better pharmaceutical management, pandemic preparedness, and overall health care resilience.

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