



Implementing a Computerized Medicine Registration System in Mozambique



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OVERVIEW

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program worked with Mozambique to strengthen its pharmaceutical system by developing well-defined and documented regulatory procedures and evaluation criteria. SIAPS helped the country's Ministry of Health implement Pharmadex, a computerized information system, to manage its national medicine registration process.

ENVIRONMENT

In 2012, the Government of Mozambique began a national accelerated response to HIV and AIDS. As a result, better awareness, funding, and deployment of proven interventions have significantly improved HIV prevention, treatment, and care support. This includes the rapid scaling up of antiretroviral therapy. With significant support from the US President's Emergency Plan for AIDS Relief, coverage of eligible adults rose from 47% in 2012 to 72% by the end of 2013 (PEPFAR Mozambique Country Operational Plan, FY14).

However, there is a shortage of quality essential medicines in the country, exacerbated by the time it takes for medicine importers and distributors to get authorization for importing and selling medicines. The longest wait times are for antiretroviral, antimalarial, and new molecule medicines that require more complex documentation, such as World Health Organization (WHO) prequalification. To help close these gaps, Mozambique engaged SIAPS to strengthen the pharmaceutical sector's institutional and individual capacity.

Photo: Staff from SIAPS in Mozambique and from the Registration Sector of the Ministry of Health's Pharmacy Department.

INTERVENTION: AUTOMATING MOZAMBIQUE'S PHARMACEUTICAL REGULATION PROCESS

SIAPS focused on supporting the sector by strengthening medicine registration and pharmacovigilance. Medicine regulation comprises premarketing evaluation, marketing authorization, and postmarket surveillance to ensure compliance with established standards. The medicine registration process should be efficient and should ensure that products approved for sale meet the country's criteria for efficacy, safety, and quality.

To improve and expedite that process, SIAPS helped the Ministry of Health's Pharmaceutical Department (PD) define and document medicine approval procedures and evaluation criteria. It also helped the PD implement Pharmadex, an automated registration management system designed to improve the registration process and reduce the average number of days needed for registration.

With Pharmadex, users can process all information needed for national medicine registration through one online database. The database is a checklist of requirements per registration type and enables comparisons among suppliers and products. It tracks product applications as well as information on cost, product use, and safety. Pharmadex provides a comprehensive picture of a product's safety profile and approval history, and it requires users to comply with good registration practices.

STRATEGIC APPROACH: STRENGTHENING HEALTH SYSTEMS THROUGH CAPACITY BUILDING

Effective pharmaceutical information systems and other health technologies as well as good governance practices can help maintain and improve medicine quality and access. For this intervention, MSH's Pharmaceuticals and Health Technologies Group applied its general approach to strengthening health systems. This approach is a five-step process that includes performing an options analysis; designing a specific, tailored intervention; implementing and managing that intervention; monitoring performance; and measuring outcomes. Capacity building is fundamental to the approach, which involves local stakeholders in every project phase. That means ensuring that stakeholders are building skills at each stage of a new process and that solutions are locally relevant and sustainable.



Figure 1. Strategic approach

STEP ONE: OPTIONS ANALYSIS

Previously, the Ministry's PD used the SIAMED system, supported by WHO, for managing product registration applications and information. However, the system has not been functional for several years due to limited technical support. In its place, the PD's registration unit used an Excel database to capture basic information about applications and registered products. However, the database was programmed to capture only limited information, and Excel has relatively few functions, so the PD's registration unit had difficulty monitoring and evaluating the processes for medicine product applications and maintaining lists of approved products. It was challenging to archive hard copies of approval dossiers and to retrieve data.

SIAPS worked with the PD to review the current information system and related technical needs for product registration, licensing and inspection, pharmacovigilance, and quality assurance. SIAPS also performed a system analysis to define data elements and identify an appropriate tool that would be compatible with local technology and capacity.

STEP TWO: INTERVENTION DESIGN

The SIAPS headquarters team customized Pharmadex to meet the specific requirements of Mozambique's registration process. In addition, to help ensure the quality of imported medicines, SIAPS helped the PD develop requirements for medicine marketing authorization.

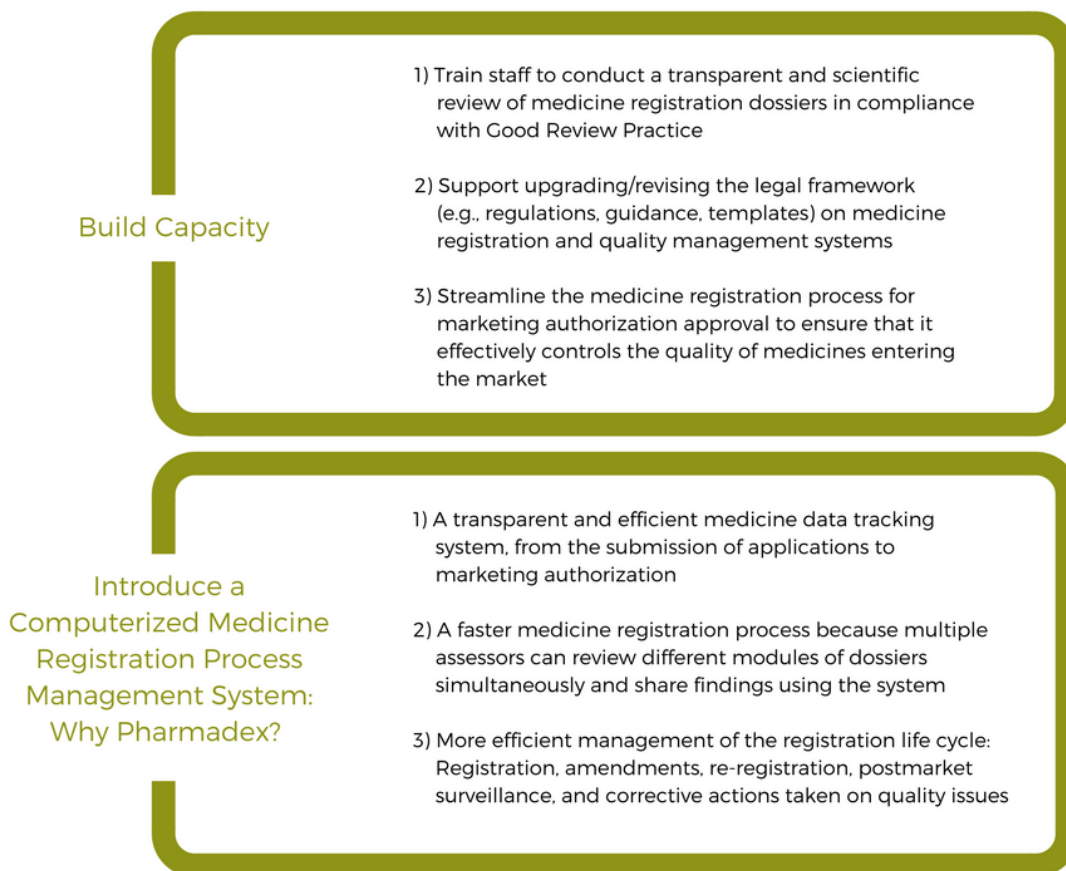


Figure 2. Strategy for strengthening the medicine registration process

STEP THREE: IMPLEMENTATION

In July 2014, the SIAPS team trained PD staff in the necessary skills, knowledge, and technical support to effectively use and maintain Pharmadex. The main objectives were to adapt the tool, procure required hardware and/or software, identify local IT resources for support, and prepare for system launch. A second training in September 2015 explained the concept of a common technical document and data requirements for medicine registration, international standard practices for global medicine, and regulatory harmonization efforts.

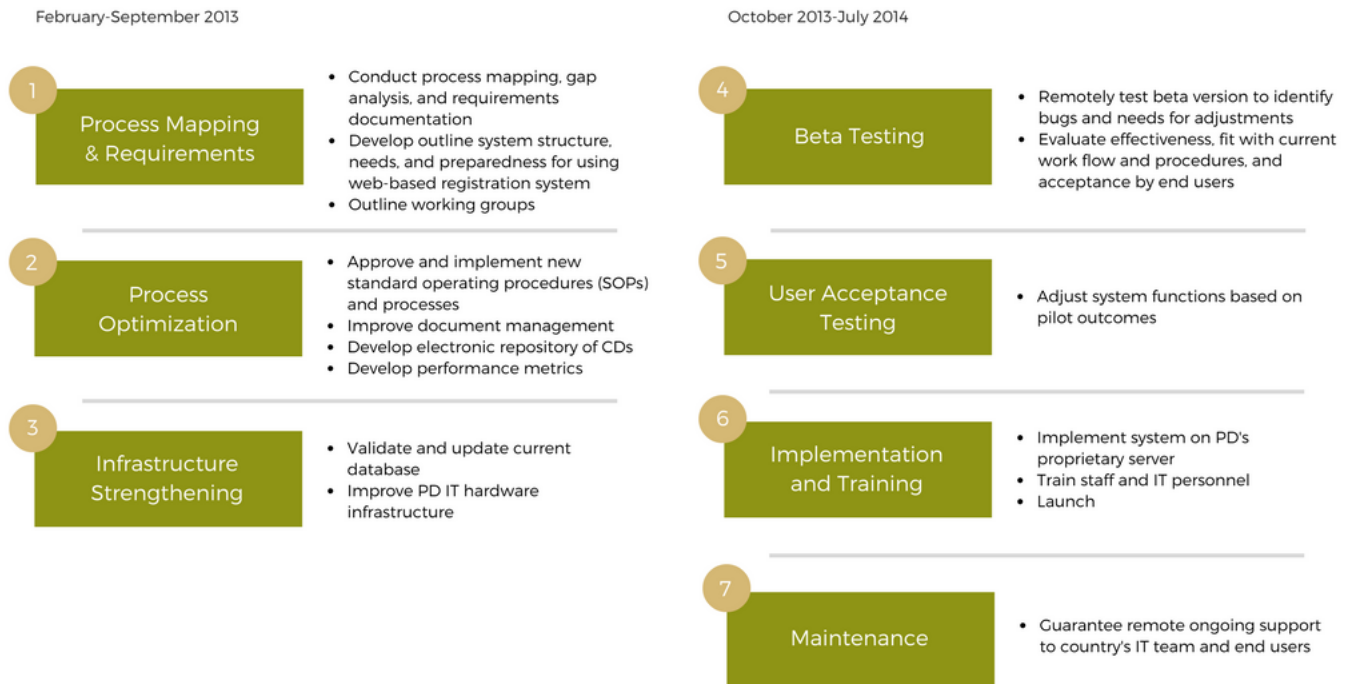


Figure 3. The Pharmadex implementation roadmap

On October 1, 2015, Pharmadex went live on a new PD local server and users began entering data from applications under review. Unlike with the Excel database, users were able to enter more comprehensive data, including detailed information on active ingredients, excipients and their functions, proposed indications, manufacturing facilities and inspection records, and foreign registration status.

STEP FOUR: PERFORMANCE MONITORING

The SIAPS monitoring and evaluation team adopted the following indicators for Pharmadex from the SIAPS Global Indicators:

- Average number of days to evaluate and reach a final decision on applications for pharmaceutical product registration
- Number of pharmaceutical management guidelines, lists, and SOPs developed or updated and submitted for adoption

- Percentage of items on the country’s Essential Medicines List that are registered
- Percentage of imported pharmaceutical products that are registered (devised specifically for this project)

STEP FIVE: MEASURING OUTCOMES

Following the January 2016 workshop noted below, SIAPS conducted a data quality assessment using USAID’s systematic approach to assess measures of data quality, including accuracy, reliability, precision, and completeness.

RESULTS

With the implementation of Pharmadex, the average number of days for a single medicine registration process (from submission to final decision) decreased from 400 to 176, exceeding the project goal. The Pharmadex implementation process was an important contributing factor to that time reduction, along with other PD efforts.

However, user uptake was slow for the first three months after Pharmadex was launched, and the time staff dedicated to using the system was less than 10% of the time estimated for use. SIAPS conducted a situational analysis to monitor system usage, and in January 2016 it convened a workshop to review those results, identify obstacles, and develop solutions.

In response to identified bugs and other system issues, SIAPS hired a new information technology team that included one technical advisor with regulatory experience and two IT specialists, one local and one based in Ukraine. They also brought in a consultant to work closely with PD users to help ensure they were inputting files, reviewing applications, and reporting system errors correctly. This helped restart the application entry process, and records submissions have increased.

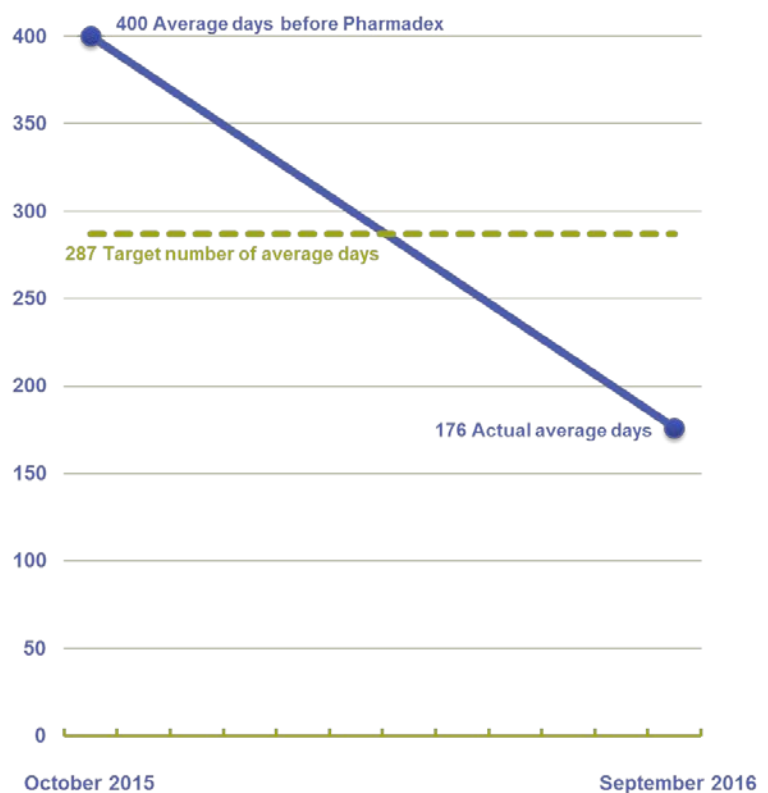


Figure 4. Pharmadex implementation helped decrease the time required to register and approve new medicines products

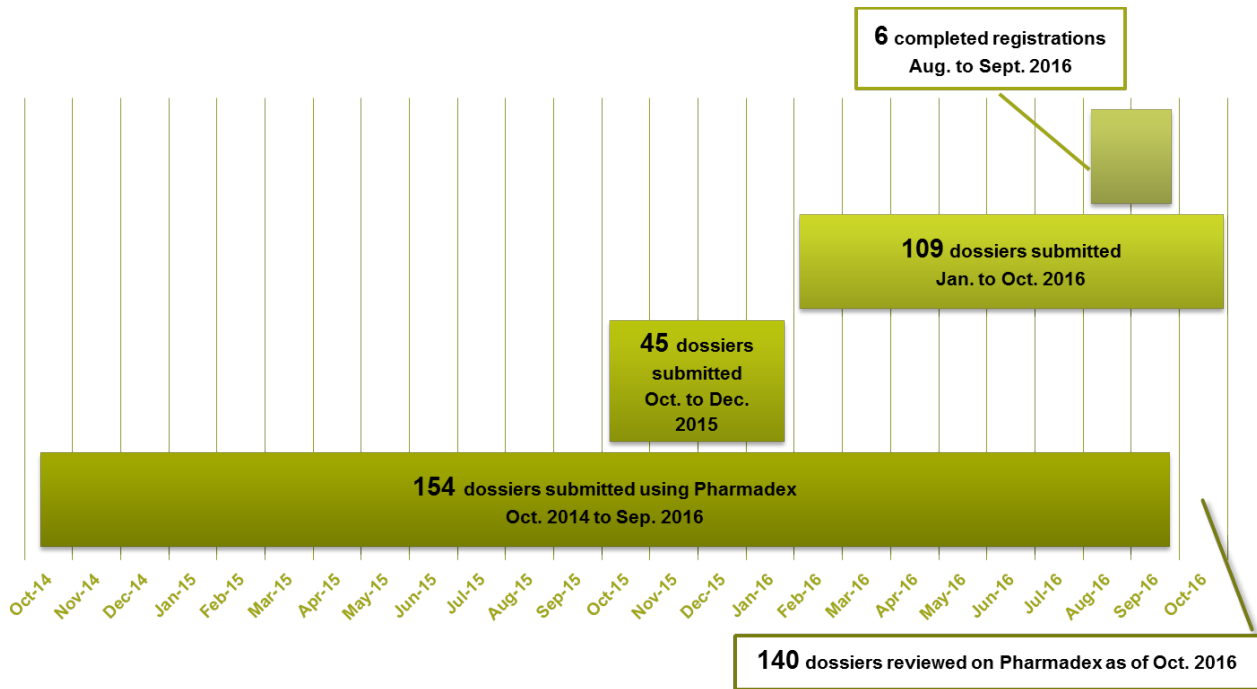


Figure 5. Medicine records handled through Pharmadex from October 2014 to September 2016

SUCCESS FACTORS

The Ministry of Health allocated staff and other resources for a smooth transition to the electronic registration system. Short-term technical assistance staff from SIAPS helped guide informatics and review related legislation. Stakeholders are positive about the process, and Pharmadex users and PD leadership are interested in managing and using the tool and in collaborating to correct system errors and other road blocks.

CHALLENGES AND LESSONS LEARNED

The implementation team did not develop, communicate, or follow a detailed plan or timeline, which might have hindered a smooth process. Monitoring and evaluation indicators were defined late in the process. When Pharmadex was introduced, it was not fully usable due to recurring software bugs, and the PD lacked full-time IT staff to follow up on reported issues and questions. The SIAPS team also lacked sufficient staff to fully monitor software use. Leadership is a critical success factor in changing regulations and processes. However, Mozambique's pharmaceutical sector lacks sufficiently trained staff. SIAPS should have strengthened the PD's registration capacity, accountability, transparency, and leadership prior to introducing Pharmadex. In addition, there are too few regulators, leading to a backlog of files to be entered into the system.

NEXT STEPS

- Due to high staff turnover, there is a constant need for technical training on reviewing dossiers. Everyone involved in the Mozambique Pharmadex program agrees that capacity building will be a critical factor in its success going forward. SIAPS recommends establishing an in-house continuous training and certificate program to improve reviewer qualifications.
- Another significant task is to build the capacity of the country's national quality laboratory. Product test results should be included as a part of the registration review process.
- A permanent IT support team comprising local IT staff and identified super users should be established to troubleshoot bugs and to maintain and update equipment. Toward this end, the SIAPS home office IT team will work with local SIAPS staff to outline human resources, budget, and financing options for maintaining Pharmadex.

FURTHER READING

An, Louis and Utkarsh Srivastava. 2014. Training the Mozambican Pharmacy Department on the Use of Pharmadex. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

EunMi Kim. 2016. Strengthening the Medicine Regulatory System by Implementing an Electronic Medicine Registration Data Management System (Pharmadex) in Mozambique. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health.

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