

SIAPS
TECHNICAL HIGHLIGHT

Strengthening Capacity for Monitoring and Evaluating Mozambique’s Regulatory System

May 2017

The US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, helps countries build stronger and more resilient pharmaceutical systems.

In Mozambique, SIAPS has been working with the Ministry of Health’s (MOH) pharmaceutical department (PD), which functions as the country’s regulatory authority, to strengthen its capacity at the national level. The PD’s main function is to ensure access to safe, effective, and quality pharmaceuticals through the public and private sectors that contribute to the best possible health outcomes.



BACKGROUND

Prior to 2013, the PD did not have a formal, comprehensive system to measure its performance in essential medicine regulatory functions, including marketing authorization; medicine quality control; pharmacovigilance; licensing of health professionals and establishments (pharmacies, wholesalers, and manufacturers); inspection of pharmaceutical establishments; and clinical trials. One of the PD’s priorities has been to develop a monitoring and evaluation (M&E) system to assess department performance; improve transparency and ensure accountability; help guide the planning, coordination, and implementation of regulatory activities; and foster a culture of evidence-based decision making (figure 1).



Figure 1. Theory of change

INTERVENTION

Between 2013 and 2016, SIAPS worked with the PD to help the department create, implement, and institutionalize a comprehensive M&E system (figure 2).



Figure 2. Steps to implementing an M&E system in Mozambique

Assess Existing Regulatory System

In 2012, SIAPS began working with the PD to establish an M&E system. A series of assessments took place to evaluate the regulatory system in Mozambique and facilitate the selection of a core set of regulatory system performance metrics for the PD. Required actions were defined to further build the PD's capacity to collect, analyze, report, and use data for decision making.

Establish M&E Sub-unit and Build its Capacity

From October 2015 to May 2016, an M&E technical working group, comprising a team of SIAPS technical advisors and two PD staff selected as M&E focal points, assisted in the development of new M&E tools, including a performance indicator reference sheet, worksheets for data collection, a performance monitoring plan, and a data quality assessment tool. SIAPS then trained the two PD M&E staff in the use of the tools.

The M&E staff were also trained in how to perform a data quality assessment (DQA) to:

- Verify the quality of reported data for key indicators
- Assess the capacity of data management systems to collect, manage, and report quality data
- Implement corrective measures through action plans to strengthen the PD's data management and reporting system and improve data quality

In May 2016, SIAPS supported the PD in organizing a stakeholder workshop for about 30 participants to reach consensus, build capacity, and chart a clear path on how to foster evidence-based decision making at all levels in the department. Attendees included two PD staff selected as M&E focal points and six representatives from the PD's main units, including registration, inspection, pharmacovigilance, administration, judiciary, and the quality control laboratory. In collaboration with the head of the PD, roles and responsibilities for the two PD M&E focal points and six PD unit representatives were defined.

Conduct Pilot Test and Validate Tools

In January 2016, equipped with knowledge of basic concepts and tools, the M&E staff performed the first baseline data collection for 13 pilot indicators. These indicators were selected for their relevance, methodological reliability, source reliability, comparability, and alignment with other National Medicines Regulatory Authorities that SIAPS supports and that had more mature regulatory systems. The staff reported the results to PD unit representatives for review and analysis. After consensus on information quality and accuracy, the final version of the report was submitted to the head of the PD and discussed at an April 2016 PD board meeting. Based on the results, the heads of each sector and related areas defined strategies to improve the performance of their respective units and future data collection.

Develop Results Framework and Define Additional Performance Indicators

Based on its assessments and reviews of quarterly reports, the M&E team identified the need for a results framework with clear strategies to achieve PD goals. The team developed a framework based on the six strategic objectives of the PDⁱ as stated in the *Strategic Plan of the Health Sector 2013–2017 (Levantamento Estratégico para o Plano Estratégico do Sector da Saúde (PESS) 2013-2017)*):

- Pharmaceutical governance strengthened
- Compliance with good manufacturing and marketing practices
- Financial and asset management capacity strengthened
- Assurance that medicines circulating in the country are efficient, safe, and of good quality
- Enhanced institutional capacity
- Use of information for decision making

Based on these objectives, the PD identified 49 additional indicators for a total of 62. These included the 13 pilot indicators and other indicators per WHO guidelinesⁱⁱ.

Institutionalize Indicators within MOH Results Framework

The final step was to decide which indicators would be part of the MOH's overall results framework and how often results should be reported to the MOH. This action promotes transparency and accountability between the PD and the MOH Directorate of Planning and Cooperation (DPC). The two departments are working to incorporate nine PD indicators into the MOH results framework.

Adopting and using appropriate indicators helps health organizations obtain data for decision making and operate more efficiently. These measures in turn help ensure the efficiency of pharmaceutical services; increase people's access to quality, safe, and cost-effective medicines; and promote rational medicine use.

Indicators to be Incorporated into the MOH Results Framework

1. Number of regulatory actions taken in the previous year as a result of national pharmacovigilance activities
2. Average number of days for granting registration
3. Percent of medicine samples analyzed out of the total number of existing medicines
4. Percent of quality medicines in the total number of samples analyzed
5. Percent of imported pharmaceutical products that are registered
6. Percent of essential medicines list products that are registered
7. Number of notifications of suspected adverse drug events (ADRs) reported by provinces
8. Percent of ADRs reviewed
9. Number of health professionals trained in pharmacovigilance

PROGRESS

The development team used UNAIDS criteria, which describe the 12 main components of a functional M&E systemⁱⁱⁱ, to assess the progress of Mozambique's M&E system.

Component of a functional M&E system	Progress
Organizational structure	M&E functions incorporated into PD administrative unit (October 2015)
Human capacity	With SIAPS support, two PD staff designated to the M&E sub-unit and trained to collect, analyze, and report data
Communication, advocacy, and culture	SIAPS Mozambique held the first M&E workshop with M&E specialists from SIAPS headquarters to consolidate and review results and reports (May 2016). The workshop raised awareness of the importance of an M&E system. Other activities that contributed to a transparent, accountable

Component of a functional M&E system	Progress
	M&E culture included routine data collection and analysis, reports to PD sectors, and reporting and discussion of drafted reports and results at monthly and quarterly data review meetings.
Results framework	Framework developed based on PD strategic objectives
Performance monitoring plan (PMP), including performance indicators reference sheet	PMP with related indicators developed. A performance indicator reference sheet and a DQA tool were developed to guide the M&E staff on frequency of data collection and reporting.
M&E database	Indicators table tracker developed in addition to PMP. The table tracker helps to monitor the progress of each indicator in a quarterly basis.
Planning and budgeting	Conducted by SIAPS; transitioned to PD activities in April 2017
Data dissemination and use	Four quarterly reports produced since January 2016
Routine program monitoring	13 baseline indicators established during the pilot phase
Evaluation and research	Quarterly data review meetings set for PD board; first meeting held in April 2016.
Supportive supervision and data auditing	Provincial supportive supervision in Gaza province in November 2016 identified opportunities for improving data quality and collection. Two PD internal data quality assessments were conducted in May and December 2016.

Once the PD's M&E system was established in December 2015, the PD began monitoring activities toward project objectives. The department now reviews performance data in monthly staff meetings and board meetings.

Soon after adopting the M&E system, managers became more attuned to evidence-based decision making and adjusted strategies and activities accordingly. For example, the PD's registration sector developed measures to monitor the use of Pharmadex, the department's computerized medicine registration system, on a weekly basis. The measurements included the number of dossiers submitted to the system and the evaluations conducted. These methods drew managers' attention to the time required to complete applications and alerted users if an intervention was needed to complete a request. This has helped improve the efficiency of the registration process, including a 36% decrease in the average time taken to evaluate and approve a registration application from March 2012 (429 days) to March 2016 (275 days).

Routine monitoring by PD M&E staff has also helped PD managers track the progress of their own activities and solidify future goals. Overall, the M&E system is contributing to improving the PD's transparency, accountability, and efficiency.

CHALLENGES AND LESSONS LEARNED

Improving information flow was critical to making the M&E system more efficient. For example, the M&E technical working group analyzed provincial data to investigate and revise the information flow for adverse drug reaction reports and found gaps in the coding and data processing that hampered proper tracking of notifications. In response, the PD designed an improved data capture process and is introducing standardized ADR report identification codes in all health facilities.

Early adopters of the M&E system saw its benefits. However, other units felt challenged in adopting it, seeing monitoring as a control rather than a quality measure. Avoiding a blaming culture and focusing on finding the root causes of problems and solving them quickly improved system acceptance.

Defining performance indicators as part of a logical framework with causal relationships among goals, objectives, actions, and intended outcomes and impacts also improved the commitment of PD stakeholders. Advocating with the DPC to institutionalize the indicators helped speed up the process, ensured alignment with MOH objectives, and further promoted country ownership and sustainability.

GOING FORWARD

Ongoing Reviews

SIAPS recommends that:

- The new M&E system undergo internal reviews at least every five years according to the PD strategic review timeframe.
- The PD maintain active communication, participation, and coordination with the South African Development Community on indicators and results to promote a unified approach for the region
- The DPC conduct annual external DQAs to audit the quality of reported data
- The M&E focal points continue to provide monthly progress updates following data review meetings within each PD unit, and the PD issue quarterly progress reports to compare performance against its annual work plan

Scaling Up

Data collection practices have improved existing tools and prompted the adoption of better methods for capturing and recording data. Additional efforts must be made to establish these principles and to standardize archival techniques for all processes in the PD to improve overall data collection efficiency.

Data for Decision Making

Only nine of the 62 PD indicators will be included in the MOH results framework. However, the PD will monitor all indicators as part of its own decision making process. Data from each PD unit should be integrated to allow triangulation and analysis from a system-wide perspective.

Capacity Building

The M&E function should be a separate unit reporting directly to the head of the PD for better time and resource allocation. New staff involved with developing and adopting the M&E system should learn about its purpose and process, as well as how to conduct reviews, to help ensure its sustainability.

ⁱ Ministry of Health's Pharmaceutical Department. 2016. Available at: <http://www.arm.co.mz/wp-content/uploads/2016/10/Result-Framework-PD.pdf>.

ⁱⁱ World Health Organization. 2015. Pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems. Geneva: WHO. Available at: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/EMP_PV_Indicators_web_ready_v2.pdf.

ⁱⁱⁱ UNAIDS. 2009. 12 Components Monitoring & Evaluation System Assessment: Guidelines to Support Preparation, Implementation and Follow-Up Activities. Geneva: UNAIDS. Available at: http://www.unaids.org/sites/default/files/sub_landing/files/1_MERG_Assessment_12_Components_ME_System.pdf.

^{iv} A performance indicator reference sheet is used by USAID to define performance indicators. It helps ensure indicator data quality and consistency.

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 of Health.

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