Mozambique End of Project Report

2018

USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access to Pharmaceuticals and Services

This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

This report may be reproduced if credit is given to SIAPS. Please use the following citation.

SIAPS. 2018. *Mozambique End of Project Report.* 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.

Systems for Improved Access to Pharmaceuticals and Services
Pharmaceuticals and Health Technologies Group
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

CONTENTS

ACRONYMS

ADR	adverse drug reaction
ART	antiretroviral therapy
ARV	antiretroviral
DHP	Department of Hospital Pharmacy
DNAM	National Directorate for Medical Care
DNF	National Pharmacy Directorate
DTC	Drug and Therapeutics Committee
M&E	monitoring and evaluation
MOH	Ministry of Health
MSH	Management Sciences for Health
NEML	national essential medicines list
NFM	National Formulary Manual
PD	Pharmaceutical Department
PV	pharmacovigilance
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
TOR	terms of reference
USAID	US Agency for International Development
WHO	World Health Organization

BACKGROUND

In 2012, the population of Mozambique had limited access to medicines of assured quality, safety, and efficacy and to effective pharmaceutical services. In addition to a weak supply chain system, which limited the availability of products at service delivery points, there were notable deficiencies in the pharmaceutical policies and legislation governing the availability and use of products; the institutional, organizational, and human resource capacity of the pharmaceutical sector to perform its regulatory functions (product registration, inspection, pharmacovigilance (PV) and medicine quality testing); the monitoring of medicine safety and rational use; and, the overall management and delivery of pharmaceutical services at the facility level. These problems stemmed not only from limited financial resources but also from weak governance, insufficient capacity, ineffective pharmaceutical management, inadequate availability and use of strategic information, and limited monitoring and supervision of pharmaceutical services at the facility level.[1]

The same year, the US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services Program (SIAPS) Program, implemented by Management Sciences for Health (MSH), started working with the Ministry of Health (MOH) of Mozambique to strengthen the functionality of the pharmaceutical sector by building institutional and individual capacity. SIAPS conducted a comprehensive assessment of the regulatory system in Mozambique to analyze the challenges of the system. Following the regulatory assessment, SIAPS and the Pharmaceutical Department (PD) agreed to update the national essential medicines list (NEML) to streamline procurement activities, minimize institutional costs, and optimize patient care; support the MOH to develop the concept note and terms of reference (TOR) for updating the National Formulary Manual (NFM); provide technical support for implementation of the national PV system to improve medicine safety; develop a monitoring and evaluation (M&E) system for the PD that would assess its performance, guide its activities toward achieving desired results, foster a culture of evidence-based decision making, and contribute to a reduction in morbidity and mortality through increased access to and rational use of medicines; develop an electronic medicine registration system to improve data management by streamlining the medicines registration process; and support the Department of Hospital Pharmacy (DHP) to establish and strengthen Drug and Therapeutics Committees (DTCs).

KEY INTERVENTIONS AND ACHIEVEMENTS

SIAPS used the MSH Pharmaceuticals and Health Technologies Group framework for capacity building—a critical aspect of SIAPS' technical assistance—to help the MOH strengthen its institutional and individual capacity across relevant departments and functions within the Ministry.

Using a systemic approach that involved strengthening governance, human resources, information, finance, and service delivery while taking into account relevant local reforms, SIAPS began working in 2013 to strengthen the capacity of relevant departments in the MOH and improve their function and performance. Key areas of intervention and achievements recorded during the five-year lifespan of the project are presented below.

Drug and Therapeutics Committees

Inefficient and irrational use of medicines is a well-documented problem in developed and developing countries, leading to increases in cost and adverse clinical effects in patients. This inappropriate use of medicines can be reduced when health care professionals engage in promoting the principles of rational medicine use.[2] In Mozambique, the DHP at the National Directorate for Medical Care (DNAM) identified the establishment of DTCs within hospitals as a priority intervention to foster and improve appropriate medicine use at the hospital level. In 2013, the DTC legal framework was approved and the MOH requested that hospitals establish DTCs. By August 2013, the DHP had established DTCs in 13 hospitals in all provinces of the country. Although committee members were motivated to address the safety and rational use of medicines, the DTCs lacked the infrastructure, finances, staff, processes, tools, and monitoring capability to begin work.

One of the main objectives for SIAPS in making the DTCs functional was to strengthen governance and improve human resource capacity for subsequent performance. To accomplish this, SIAPS collaborated with the DHP in the following strategic areas:

- **Governance:** SIAPS developed the capacity of DTCs to function as a governing body to effectively and sustainably oversee pharmaceutical management and develop effective policies by supporting the DHP to clearly outline the TOR/functions of a DTC. SIAPS also supported the DHP to develop hospital pharmacy guidelines and standard operating procedures for pharmaceutical management and medicine use studies.

- **Human resource capacity:** In 2014, using an orientation program strategy, SIAPS trained DTC members and key supply chain stakeholders on the TOR, functions, roles, and responsibilities of a DTC and on how to interpret results of medicine use studies, identify medicine use problems, and improve medicine use. SIAPs also supported the DHP to carry out supportive supervision for DTCs and organized a lessons learned workshop to share experiences, achievements, and challenges from developing rational medicine use strategies and from the supervisory visits.

A key achievement of DTCs is the increase in the number of pharmaceutical management and drug policy activities seen between March 2015 and August 2016 in the 13 health facilities that established DTCs. Specifically:

- Seventy medication error studies; 13 ABC/VEN analyses, and 28 prescribing studies were conducted by the DTCs.

- Five DTCs had either developed or implemented treatment/prophylaxis guidelines and formularies.

- Four DTCs had developed rational medicine use policies, one of which was a hospital policy for good prescribing and dispensing procedures. In Jose Macamo General Hospital's emergency pharmacy unit, average completion of information on prescriptions improved from 51% to 72% between January and June 2016.

- Three DTCs conducted in-service trainings on rational medicine use or responsibilities of DTCs.

- Seven DTCs designed, implemented, and evaluated interventions to address low levels of compliance with national prescribing guidelines. One such intervention was to display prescribing guidelines and distribute a list of approved medicines to all hospital departments and to create a subcommittee at Polana Caniço General Hospital to develop strategies for preventing antibiotic resistance. After one month of implementation, the average completeness of relevant information on prescriptions increased from 10% to 27%.

- The DTCs implemented a system to identify rational medicine use problems by applying problem solving tools (e.g., root cause analysis (fishbone diagram), pareto diagram, run charts, A3 reports) to investigate the root causes of medicine-related problems; develop and implement solutions; and evaluate and adapt such solutions to promote rational, effective, and efficient medicine use.

In July and October 2017, SIAPS supported the DHP to conduct two studies aimed at improving medicine use at the hospital level. One study looked at the average wait time for patients to fill their antiretroviral (ARV) prescriptions at the Lichinga Provincial Hospital pharmacy. The sample included 289 patients, and the results showed the average time to fill one prescription to be 8 minutes and 8 seconds, while the maximum time to complete the dispensing process was 30 minutes and 5 seconds.

The second study was based on the 2004 *International Conference for Improvement of Medicines Use,* which highlighted the urgent need to develop strategies to improve adherence to ARV treatment and the fact that in 2010, an estimated 7% of people starting antiretroviral therapy (ART) in developing countries had drug-resistant HIV and that some countries have recently reported levels at or above 15% among those starting HIV treatment and up to 40% among people restarting treatment. This second study looked at ARV treatment adherence among the patient population of Polana Caniço General Hospital.

The study sampled 100 patients and was intended to pilot the World Health Organization (WHO) methodology to evaluate the possibility of implementation. Specific objectives were to verify its applicability, relevance, and lessons learned; adjust the methodology to the Mozambican context; and evaluate adherence, evaluate ARV dispensing, monitor patient compliance to doctors' recommendations, and identify areas for improvement in the health facility.

Following the methodology developed by the International Network for the Rational Use of Drugs Initiative on Adherence to Antiretroviral, five indicators were selected to assess the adherence performance of the patient population of Polana Caniço General Hospital:

- Percentage of patients with total adherence to ARVs
- Average percentage of days covered by ARVs dispensed for a sample of patients for a defined period (180 days)
- Percentage of patients who experienced a stock-out of ARVs for more than 30 days within a period of 30 days
- Percentage of patients who visited the clinic on or before their appointment day
- Percentage of patients who visited the clinic within three days of their appointment day

Another aspect of patient and clinical care that was noted was the percentage of patients achieving CD4 count >300 cells per µl on their most recent lab test.

Results showed that the study methodology was able to be adjusted to the Mozambican context. It achieved and obtain results, which proved the relevance of the study as evidence-based information of ARV treatment adherence was available. On average, patients had 96% of their days covered by medicines; 8% of patients presented a gap in medicine supply of more than 30 days, and 52% of patients achieved CD4 count >300 cells per µl on their most recent lab test.

National Essential Medicines List

According to WHO, careful selection of a limited range of essential medicines results in a higher quality of care for patients, improved access, better management and use of medicines, and more cost-effective use of health resources. In 2010, Mozambique's first NEML was published to support public-sector procurement. It remained largely unknown as it was not properly disseminated, owing to limited consultation of key stakeholders in the health sector and the lack of a proper development mechanism.[1]

The regulatory system assessment conducted by SIAPS in 2012 found that Mozambique's NEML did not ensure that the medicines being procured, supplied, used, and regulated in the country were cost-effective and consistent with the population's needs. There was also no established review mechanism for the existing NEML. The assessment recommended that the NEML undergo a systematic and transparent revision based on internationally recommended criteria.

Using its system strengthening approach, SIAPS supported the PD to strengthen governance and build the capacity of the NEML Committee Secretariat and key health sector professionals on the meticulous processes involved in establishing a Committee and selecting medicines based on evidence of their safety and efficacy and their relevance in addressing the priority health care needs of the populace.

- **Governance:** In 2014, SIAPS engaged key national stakeholders (medical specialists, hospital and clinic practitioners, DTCs, and MOH public health departments) to develop a detailed concept note to revise the NEML.

  SIAPS also supported the development of policies and procedures for establishing a NEML committee, membership criteria, standardized and evidence-based criteria for selecting the medicines, key steps for revising and updating the list, and mechanisms for monitoring its use. An initial list comprising 925 medicines (active substances) was finalized in 2015.

- **Human resource capacity**: Using a series of trainings, orientation workshops, and reviews between April 2014 and March 2015, SIAPS worked with staff of the MOH and stakeholders to ensure a common understanding of the concept of an essential medicines program, the process of developing a NEML, and the concept and evidence-based practices used in selecting medicines for a NEML in accordance with WHO principles.

A key achievement of this intervention was the institutionalization of a transparent, participatory, evidence-based, and consensus-oriented mechanism for developing and updating the NEML for the first time in the country. Specific achievements included:

- Training 75 MOH staff on the NEML review process

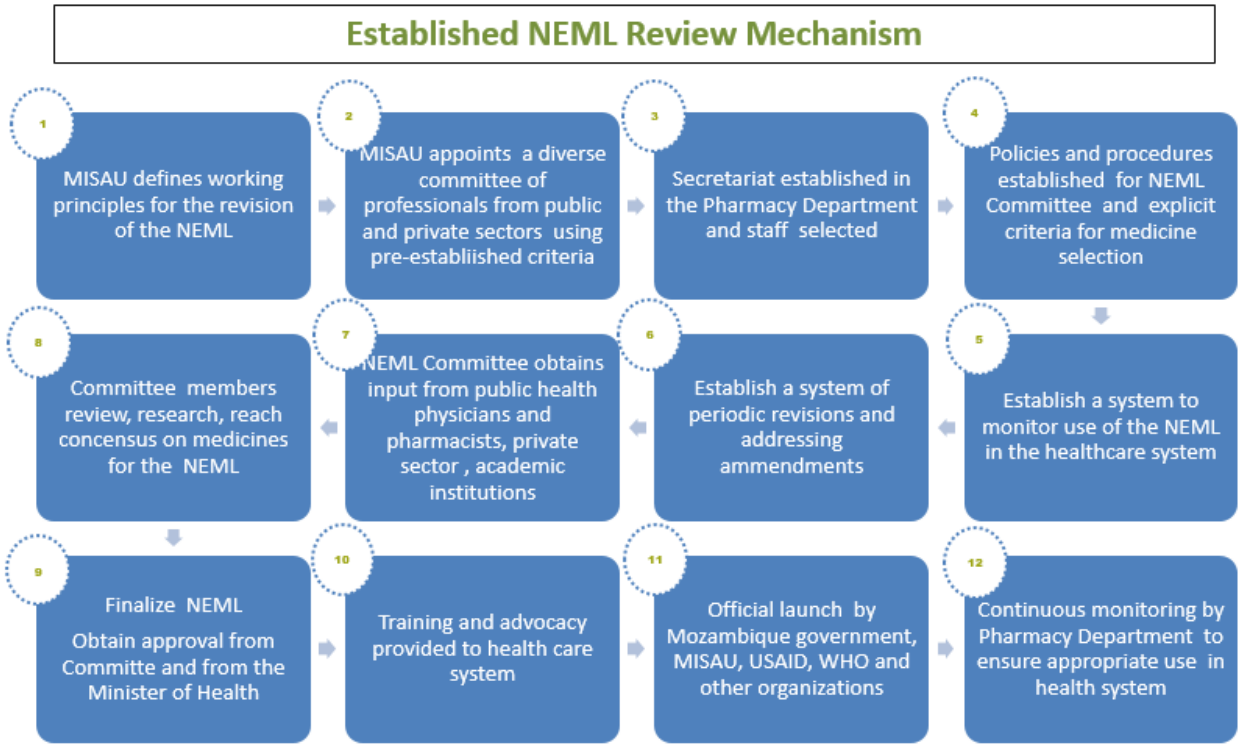
- Developing an approved and publicly launched NEML that included 310 medicines (active substances) in September 2015

- Creating approved TOR for the NEML Committee

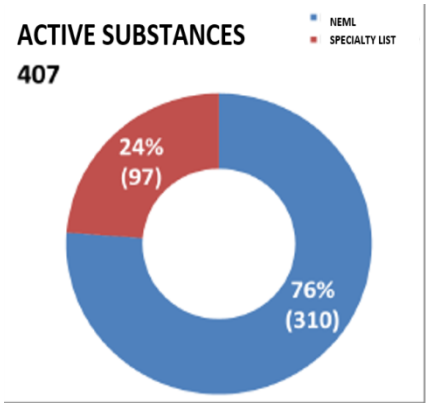
- Establishing criteria and procedures for evidence-based selection and review of medicines on the list in line with recommended WHO procedures, leading to an approved mechanism to guide future revisions and ensure standardization and sustainability

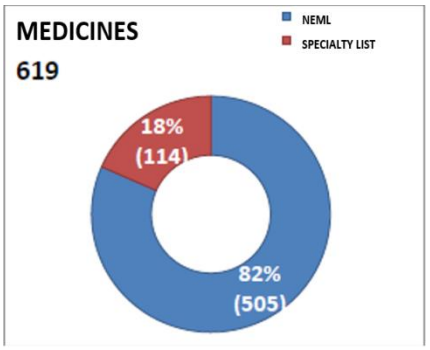
- Establishing an M&E plan with defined indicators to ensure use of the NEML in national health services, availability of NEML medicines at health facilities, and availability of the list, as well as a distribution plan for all the provinces and key stakeholders in the country

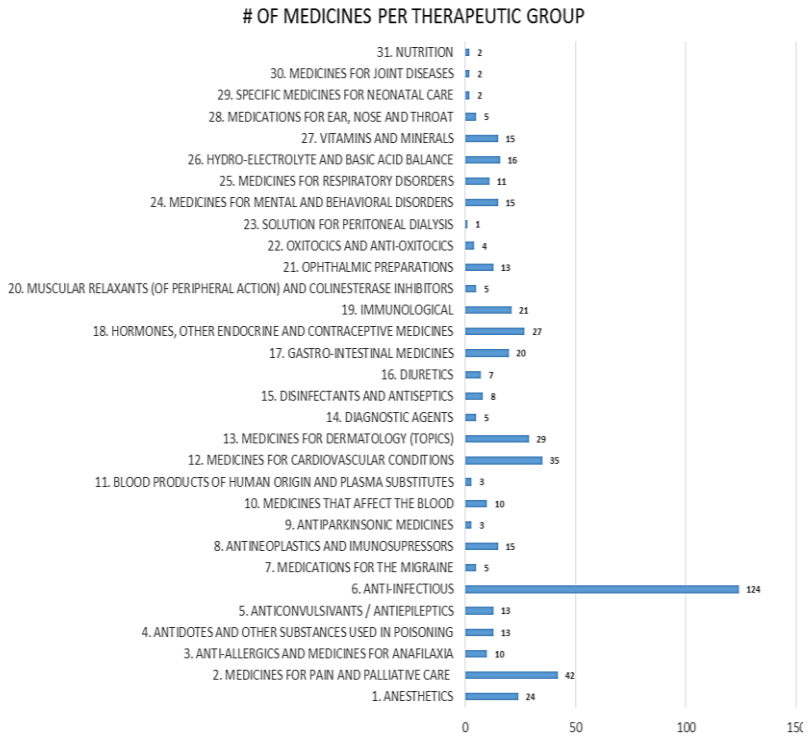
Ultimately, the approved list will be the basis for the selection of medicines to be procured in the public sector, thereby helping to ensure the availability of medicines in primary health care facilities for the most prevalent diseases, such as malaria, tuberculosis, HIV/AIDS, and diarrhea, as well as those affecting maternal and child health. It is expected that this list will improve the supply of medicines, lead to rational prescribing, and improve the quality of patient care.



Established NEML Review Mechanism—NEML DASHBOARD







National Formulary Manual

According to WHO, an adequate NEML is the appropriate tool to guide public-sector medicine purchases. It is recommended that after developing a NEML, countries should develop an NFM containing information on medicines in the updated NEML and information to orient health professionals on how to use them.

An NFM combines independent information on the use of essential medicines with local health contexts and drug use policies to guide health care providers on how to prescribe, dispense, and administer medications correctly and what information should be given to caregivers and patients to promote adherence to treatment.

SIAPS supported the MOH PD to develop a concept note and TOR aimed at providing the general principles for review and revision of the NFM. These should include information on objectives; updates to the required policies; a list of target users; recommended content for the NFM; recommended structure, roles and responsibilities; activities for performing the review and revision; expected deliverables; and continuous monitoring and evaluation.

Specific achievements included:

- Availability of a concept note to inform future updates of the NFM. This can be revised in accordance with any changes in relevant policies, structures, or scope of work. It can also be used to guide the development of related policies if needed.

Strengthening the Medicines Marketing Authorization System in Mozambique

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, including rapid scale up in use of ART. 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.[4]

However, there was a shortage of quality essential medicines in the country, exacerbated by the time it took for medicine importers and distributors to get authorization to import and sell medicines. The longest wait times were for ARVs, antimalarials, and new molecule medicines that require more complex documentation. To help close these gaps, Mozambique engaged SIAPS to strengthen the pharmaceutical sector's institutional and individual capacity.[4]

SIAPS focused on improving governance, strengthening capacity, and enhancing information for decision making to make medicine registration (premarketing evaluation, marketing authorization, and post-marketing surveillance) and PV more efficient and ensure that products approved for sale meet the country's criteria for efficacy, safety, and quality.

- **Governance:** To strengthen data requirements and ensure the quality of imported medicines, the PD, with support from SIAPS, revised the guidelines on data requirements for granting marketing authorization to medicines in 2013. SIAPS also supported the PD

to streamline the registration process by defining and documenting medicine approval procedures and evaluation criteria.

It also supported the PD to implement Pharmadex, an automated registration management system designed to improve the registration process and reduce the average number of days needed for registration. Between July and September 2016, SIAPS supported the PD to develop a user manual to standardize all procedures on how to use Pharmadex.

- **Human resource capacity:** In 2015, to ensure that solutions are locally relevant, well understood, and sustainable, SIAPS worked closely with the technical working group of the PD registration unit through a series of workshops and trainings to build the capacity of individuals to play key roles in the medicine registration process.
    - Super users were identified and trained to test, provide feedback, and detect technical errors with Pharmadex and to teach their colleagues.
    - Reviewers were trained on regulatory tools, such as guidance on data requirements for medicine registration and the standard operating procedure for review of registration dossiers for essential medicines.
    - IT staff were trained to provide support for frequently encountered operational and hardware issues related to Pharmadex.
    - A Pharmadex support team, comprising two super users and one IT staff member, was created to receive all notifications of errors and requests from users and share them with the IT team in the home office.
    - PD staff were trained on the common technical document format.
    - SIAPS organized a self-taught training on the Pharmadex user/trainer manual for all users.
- **Information for decision making:** SIAPS and the PD developed an indicator-based module for Pharmadex to monitor key indicators and improve the decision making process. Key indicators to monitor included the average number of days to evaluate and reach a final decision on applications for registration and the percentage of items on the country's NEML that were registered.

In 2015, SIAPS hired a company to scan and archive all dossiers from the PD registration unit to improve the process of reregistration and variation.

Key achievements of this intervention included:

- The live launch of Pharmadex on a new PD local server on October 1, 2015

- A reduction in the average number of days for registering a product (including submission, screening, review, and final decision) from 400 to 176 days, exceeding the project goal of 287 days

- Development and implementation of a module in Pharmadex to facilitate direct submission of registration documents by applicants; three applicants were trained to use the module

- Reduction in the workload for registration unit staff as applicants could submit their application documents, giving staff time for other value-adding activities

- An increase in the number of dossiers submitted for registration

- Successful archiving of old registration dossiers to facilitate the reregistration process, with 4,248 of 5,142 old dossiers successfully archived in the internal network developed to support Pharmadex

Strengthening the M&E System of the Pharmaceutical Department

Prior to 2013, the PD did not have a formal, comprehensive system to measure its performance on its regulatory functions, including granting of marketing authorization; medicine quality control; PV; licensing of health professionals and establishments (pharmacies, wholesalers, and manufacturers); inspection of pharmaceutical establishments; and clinical trials. One of the PD's priorities was to develop an M&E system to assess its 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. Between 2013 and 2016, SIAPS worked with the PD to create, implement, and institutionalize a comprehensive M&E system.[5]

- **Governance:** In 2015, SIAPS worked with the PD to determine and agree on the roles and responsibilities of PD stakeholders in the M&E system, and in May 2016, a workshop for key PD stakeholders was organized to agree on a shared vision and goals for the PD's M&E system.

  To ensure systematic data collection and reporting, SIAPS supported the M&E subunit in 2016 to develop performance indicator reference sheets, a performance monitoring plan, and M&E reports. It also supported the establishment of fora (e.g., units' monthly data review meetings, quarterly board meetings) for periodic data review.

  Nine indicators were selected to reflect the pharmaceutical regulatory authority's performance and its impact on the population:

  1. Number of regulatory actions taken in the previous year as a result of national PV activities
  2. Average number of days taken to evaluate and approve regulatory applications
  3. Percentage of medicine samples analyzed from the total received
  4. Percentage of good quality medicines from the total samples analyzed

5. Percentage of imported products that are registered
6. Percentage of NEML products that are registered
7. Number of notifications of suspected adverse reactions reported by provinces
8. Percentage of adverse drug reactions revised
9. Number of professionals trained on PV

- **Human resource capacity:** From 2015 to 2016, SIAPS trained two PD M&E staff on the development and use of basic M&E tools. M&E staff were also trained on data quality assessment to verify the quality of reported data; assess the ability of data management systems to collect, manage, and report quality data; and implement corrective measures when necessary.

  In May 2016, SIAPS organized a multisectoral workshop to build capacity and chart a clear path to foster evidence-based decision making at all levels in the department using M&E as a tool, help staff understand the capabilities of M&E as a management tool, and ensure that all participants have solid understanding of M&E language and principles.

- **Information for decision making:** SIAPS supported the PD in the following activities aimed at addressing problems related to data quality, including quality of data reported by the provinces:

  - M&E system data quality assessment
  - Extension of the data quality assessment to the provincial level in December 2016
  - Engagement of a computer technician to improve PD databases

Overall, the M&E system has contributed to improving the PD's transparency, accountability, and efficiency in providing pharmaceutical services.

Pharmacovigilance

In 2012, SIAPS used its systems strengthening approach to begin supporting the PV system. This support began with a workshop aimed at strengthening communication among health professionals at different levels of the health sector. The meeting achieved consensus on how to improve the PV system and increase drug and vaccine safety. It was also agreed that training of health professionals on PV and reporting of adverse drug reactions (ADRs) will form the basis for assessing progress in the PV system.

SIAPS continued to strengthen the capacity of health professionals to identify and report ADRs by:

- Conducting seminars to train health professionals on identifying and reporting ADRs

- Providing in-service training of health professionals in some health units in all provinces in the country

- Providing preservice training of students in health courses in the provinces of Nampula and Beira

- Training members of Hospital Therapeutics and Pharmacy Committees in seven provinces

- Actively searching for ADRs in some health units across the country

- Organizing a PV national meeting with the aim of improving the detection, notification, evaluation, registration, and prevention of ADRs and monitoring their occurrence

A key achievement of these activities was the observed steady increase in the number of ADR reports received by health facilities in different districts across the country (figure 1).

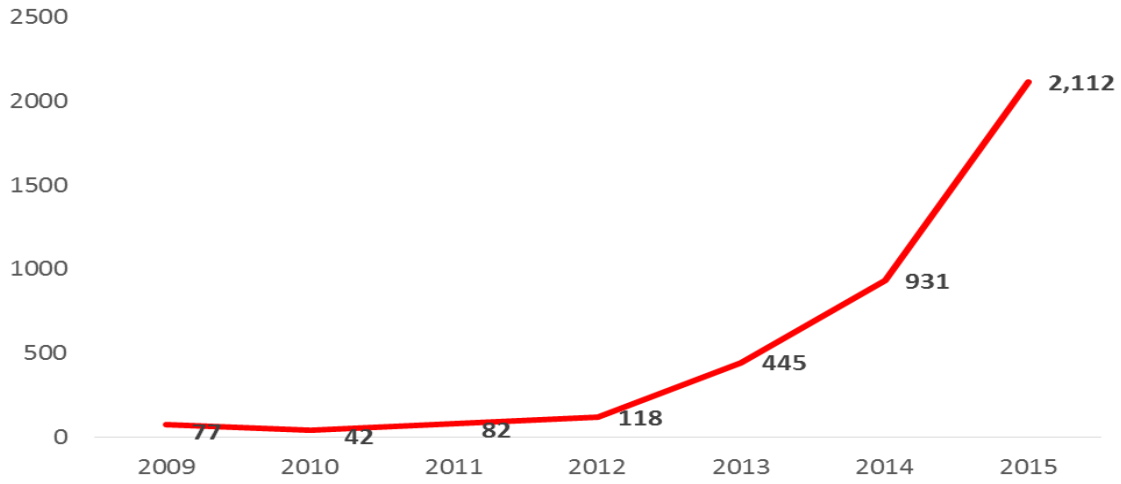


Figure 1. Annual number of ADR reports received across the country

Strengthening the Fight against Antimicrobial Resistance

SIAPS collaborated with the National Pharmacy Directorate (DNF) to implement a package of activities aimed at furthering the first objective of the AMR global action plan: "Improve awareness and understanding on AMR". These activities included:

- **Training workshop for journalists on AMR:** In October 2017, SIAPS collaborated with the DNF, the USAID International Research & Exchanges Board (IREX), and the Mozambique Media Strengthening Program to organize a two-day workshop to train journalists on their role in combating AMR, starting with raising awareness and understanding on the strategic action. Fifteen journalists from local newspapers and radio and television stations were trained. Since the training, an AMR newspaper article was written that was estimated to have reached approximately 80,000 readers. Three AMR live radio interviews were done, and a DNF website article on the training had nearly 25,000 views.

- **Workshop for academia on containing AMR:** In November 2017, a two-day workshop for representatives of health disciplines in universities was held to establish the role of universities in combating AMR in line with the WHO recommendation to include the issue of AMR in curricula as a sustainable, low-cost intervention to contain AMR. A total of 25 participants representing health courses, such as clinical analysis, nursing, pharmacy, medicine, public health, and veterinary, attended the workshop. At the end of the workshop, data were compiled to develop guidelines to help the universities develop a joint action plan based on the one-health approach.

- **Development of spots on AMR:** In collaboration with the DNF, MOH office of Communication, Minister of Agriculture and Food Safety, and USAID, SIAPS developed the first two of a set of educational spots about AMR. The aim of the spots was to raise public awareness and understanding of AMR, warn about the dangers of antimicrobial resistance, and trigger behavior change. One spot will record a strategic message from the USAID Director and the Minister of Health and the other from the Minister of Agriculture and Food Safety.

Contribution to USG Goals

USAID invests in health system strengthening with the aim to help people and institutions, both public and private, improve health outcomes over the long term by ensuring affordability, quality, and delivery of health services in an equitable and sustainable manner that ultimately protects people against unforeseen risks.

By using its systemic approach, which involves strengthening governance, human resources, information, finance, and service delivery while taking into account relevant local reforms, to support the implementation of the interventions outlined earlier, SIAPS contributed to efforts to realize the USG's aim of improving health outcomes over the long term.

All of the interventions implemented by SIAPS in Mozambique were geared toward building local capacity to achieve positive outcomes and ensure sustainability. Specifically, individual and institutional capacity building for both DTCs and the NEML committee has promoted evidence-based decision making and improved effective delivery of pharmaceutical services and proper selection/procurement of more effective medicinal products. Furthermore, streamlining and automating the medicine registration process has improved the availability of and access to quality assured essential medicines, which is an important component for achieving the USG's universal health coverage goal. A strengthened M&E system also ensures constant monitoring of processes and outcomes so that all gains are sustained in the short term and improved upon in the long term.

LESSONS LEARNED

Implementation of the interventions was a learning process for SIAPS and the MOH (including the relevant departments within the ministry) as the major implementers of all interventions. Key lessons learned included:

Start small with what is achievable to record early quick wins and boast moral for continuation

By starting with the implementation of medicine use studies, many DTCs were able to easily and quickly appreciate how undertaking some of their functions can inform practice and improve patient outcomes. This was a success factor, as it created awareness of medicine use problems that exist in the hospitals, showcased the use of simple solutions to solve potentially big problems, and boasted the morale of HPDs and hospital DTCs.

Similarly, the process of undertaking an M&E baseline data collection using pilot indicators and sharing the results was a game changer for the PD as it revealed the usefulness of quality data in decision making. This encouraged and led to improvement of administrative processes within the PD.

Central support is critical for sustaining gains and expanding the implementation of interventions

Mozambique's DTCs and NEML Committee are still in early stages of development and need strong central support. Although the government has taken ownership of most SIAPS-supported interventions, there is still much to be done to ensure that gains made will be sustained and improved. There is a need to build an intersectoral decision making forum, promote accountability, put in place reporting systems, and make developed tools and resources available to support and strengthen the NEML Committee. More DTCs need to be created at the provincial level. Strong leadership, political will, and commitment are required to achieve these goals and encourage the work of the existing committees.

Stakeholder engagement and coordination will enhance achievement of results

Engaging a wider range of stakeholders in the NEML review process, though time consuming, was a worthwhile exercise as it increased visibility and acceptance of the revised NEML and consolidated the established review mechanism. Similarly, engaging the DPC in the selection process for performance indicators to be included in the MOH's overall result framework helped to institutionalize the indicators and speed up the process.

Early stakeholder engagement in piloting the M&E process and indicators also proved to be a success factor. Early adopters and users of the monitoring system saw its benefits while others saw monitoring as a control tool rather than a quality enhancing measure. Engaging stakeholders in ways that focused on finding the root cause of problems and solving them rather than apportioning blame helped improve buy-in and system acceptance.

Stakeholders tend to support the same activities but use different technical approaches. This often leads to duplication of financial support but does not necessarily lead to the realization of additive or synergistic results, and in some cases, an overall negative effect may be obtained. For better results, stakeholder support needs to be well coordinated and jointly planned (when possible) to ensure that it aligns with the organization's goals (system strengthening and improving service delivery) and meets its desired geographic coverage (central, province, district).

Continuous training and retaining of personnel involved in the process is a must

Everyone involved in Pharmadex agreed that capacity building will be a critical factor in its success going forward. SIAPS recommended establishing an in-house continuous training and certificate program to improve reviewer qualifications. Another significant task will be to build the capacity of the country's National Quality Laboratory to enable inclusion of product test results as a part of the registration review process.

Continuous training of NEML Committee members and health professionals on how to use and review the NEML is necessary to ensure system sustainability, particularly since committee membership will be dynamic. Similarly, training DTC members on the various functions of DTCs will help improve knowledge about quality health care delivery among health care professionals.

SUSTAINABILITY

DTCs

SIAPS trained DTC members on the TOR of DTCs to enable them function as the governing bodies for pharmaceutical policies within their hospitals. It also worked with a number of DTCs to undertake medicine use studies and understand how to interpret and use results from those studies. With continuous support from the government and with approved TOR and operating guides in place, the established DTCs will be able to guide other hospitals to establish functional DTCs to improve pharmaceutical services and ensure positive outcomes for patients.

NEML and NFM Review Mechanisms

SIAPS worked with the MOH and the NEML Committee Secretariat to develop tools for review, dissemination, and implementation of a revised NEML as well as a concept note to guide development and review of the NFM. A plan was developed to ensure that subsequent revisions will occur in a continuous, uninterrupted, and sustainable manner. The plan also included an estimated budget that will allow the MOH to advocate for funding from different sources early in the process. These processes, together with the involvement of stakeholders, are geared toward facilitating sustainability of the process.

In addition, a monitoring component with defined indicators was approved by the MOH to ensure use of the list in the national health system, availability of essential medicines, and availability of the list itself at health facilities across the country.

Medicines Marketing Authorization System

The use of a local server to host Pharmadex was geared toward ensuring ownership of the product by the MOH. The establishment of a support team for Pharmadex will further enhance a sense of ownership by the MOH, improve user confidence and satisfaction, and encourage continued use of the tool.

Continuous training of staff of the registration unit in application submission and dossier review ensures that there will be sufficient staff with the technical capacity to use the tool and make improvements when necessary after SIAPS. Also, the planned interfacing with the National Quality Laboratory to ensure inclusion of results of quality testing of samples will further institutionalize the tool for sustainability.

Strengthening the M&E system

After the PD's M&E system was established in December 2015, the PD began monitoring activities geared toward achieving project objectives. The department now reviews performance data at monthly staff meetings and board meetings, and the PD issues quarterly progress reports to compare performance against its annual work plan. Nine of the PD's 62 indicators were

included in the MOH results framework to inform evidence-based decisions at the managerial level. These measures will ensure sustainability.

The Future of Pharmaceutical Systems Strengthening

Given the intervention and capacity built by SIAPS to strengthen the pharmaceutical system over the years, some key activities in each intervention area that should be carried forward beyond SIAPS are discussed below.

Continuous conduct of research that informs better practice

With approved TOR and operating guides in place and having received hands-on training on several studies aimed at improving pharmaceutical services to ensure better treatment outcome for patients, DTCs are expected to continue conducting medicine use evaluations and prescribing audits, wait time, and medication adherence studies and provide useful feedback that can inform rational medicine use by health care providers and patients/care givers. The results of these interventions should also be used to inform regular updates to standard treatment guidelines.

Strengthening the fight against antimicrobial resistance

The fight against AMR should move forward by enhancing the antimicrobial stewardship role of the pharmaceutical system through sustained implementation of systematic, organized antimicrobial management programs at the hospital level, including provision of sound policies and guidelines to facilitate rational use of antimicrobials, ensure multidisciplinary cooperation among health workers, advocate for enhanced infection prevention and control practices within hospitals, and provide sustained pre- and in-service training on AMR.

Other roles that the pharmaceutical system can play outside the hospital to improve its antimicrobial stewardship role include the use of mass media to create awareness on issues around AMR and limiting over-the-counter availability of antimicrobials, circulation of substandard and falsified antimicrobials, and unethical promoting of antimicrobials by pharmaceutical companies.

Wide dissemination of NEML, NFM, and standard treatment guidelines

It is expected that the NEML, NFM, and standard treatment guidelines will be adopted throughout the country. Publishing these documents on relevant websites will ensure that they are widely availability and readily accessible to potential users. Regular monitoring of their use will also assist in institutionalizing them as reference documents to guide procurement and use.

Inclusion of quality data as requirement for granting marketing authorization to medicines

The planned interfacing with the National Quality Laboratory to ensure inclusion of results of quality testing of samples is an activity that needs to be carried forward as a system strengthening mechanism as it will ensure that marketing authorization is only granted to those

medicines that meet international standards of quality, safety, and efficacy. In addition, post-marketing surveillance activities for quality and safety should be strengthened as a necessary backup for monitoring registered products.

Continuous conduct of M&E activities

An M&E unit should be created to coordinate all pharmaceutical system M&E activities, perform regular data quality assessments, and provide feedback for improvement.

Table 1. Implementation Partners

Implementing Partner	Intervention(s)	Year(s)
Ariel Glaser	Training of hospitals to implement DTC functions	2016
IREX	Training of journalists on AMR	2017

Table 2. Stakeholders

Stakeholders	Intervention(s)	Year(s)
Direcção Nacional de Farmácia	NEML, Pharmadex, M&E	2012–2016
WHO	NEML	
CMAM	NEML	
MOH DNAM and other departments	NEML	
Hospital Pharmacy Department	DTCs	2013-–2016
Mozambique Province Health Directorates	DTCs	2013–2016
MOH Planning and Cooperation Department	M&E	2016
Quelimane Provincial Hospital	DTCs	2013–2016
Lichinga Provincial Hospital	DTCs	2013–2016
Polana Caniço General Hospital	DTCs	2016
Tete Provincial Hospital	DTCs	2013–2016
Jose Macamo General Hospital	DTCs	2013–2016
Mavalane General Hospital		
Matola Provincial Hospital	DTCs	2015–2016
Mavalane General Hospital	DTCs	2013–2016
Chimoio Provincial Hospital	DTCs	2013–2016
Xai-Xai Provincial Hospital	DTCs	2013–2016
Maputo Central Hospital	DTCs	2013–2016
Maputo Central Hospital		
Nampula Central Hospital	DTCs	2013–2016
Beira Central Hospital	DTCs	2013–2016

REFERENCES

1. SIAPS (draft technical brief). Establishing the mechanism to review the national essential medicines list in Mozambique.

2. Kathleen H, Terry G (2003). *Drug and therapeutics, a practical guide.* France: WHO.

3. WHO. How to develop a National Essential Medicines List. Available at: http://www.who.int/selection_medicines/committees/expert/18/policy/policy2/en/

4. SIAPS (2017). Implementing a computerized medicine registration process 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. Available at: http://siapsprogram.org/publication/altview/technical-brief-implementing-a-computerized-medicine-registration-system-in-mozambique/english/

5. SIAPS (2017). Strengthening capacity for monitoring and evaluating Mozambique's pharmaceutical department. 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. Available at: http://siapsprogram.org/publication/altview/strengthening-capacity-for-monitoring-and-evaluating-mozambiques-regulatory-system/english/