SIAPS Ethiopia End of Project Report

March 2017

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SIAPS
Systems for Improved Access
to Pharmaceuticals and Services

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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

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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
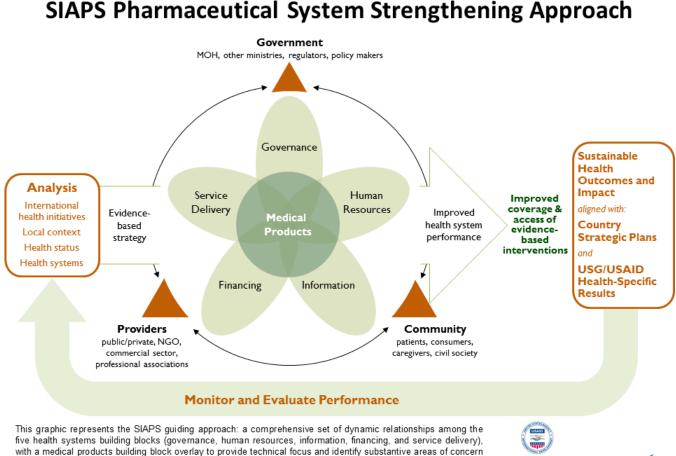Website: www.siapsprogram.org

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BACKGROUND

In Ethiopia, the pharmacy practice at public health facilities (HFs) and community pharmacies has largely been commodity centered rather than patient centered. This has prevented pharmacists from being active members of the health care team and contributing to better health outcomes. The lack of auditing practices and of transparent and accountable systems for managing medicine transactions and services at public health facilities have resulted in wasted resources, particularly those obtained through donations, including medicines for opportunistic infections and antimalarial medicines.

When the USAID-funded SIAPS Program was launched in 2011, irrational medicine use was widespread and manifested itself in irrational prescribing, poor dispensing practices, and inappropriate medicine use by patients. The fourth National Health Sector Development Program (HSDP) (2010/11–2014/15) report[1] states that the percentage of antibiotic prescribing was 58% and that for antibiotic use in the treatment of non-pneumonia acute respiratory tract infections was 61%, both of which indicate a major deviation from recommended norms. The report also indicates that only 68% of patients were given adequate information on dispensed medicines; that 35% of HFs experienced stock-outs of essential medicines; and that approximately 8% of medicines in stock were wasted due to expiry. The overprescribing and inappropriate use of antibiotics have contributed to many of these agents becoming ineffective, which necessitates the use of newer, more potent, toxic, and more expensive medicines.

Over the past few years, Ethiopia has made remarkable advancements with regard to increasing access to antiretroviral therapy (ART); reducing malaria-related deaths; and improving reproductive, maternal, neonatal, and child health (RMNCH). In addition, a number of interventions were implemented to improve the quality of service at HFs. However, the executive bodies at different levels of the health system have had limited capacity to coordinate multiple stakeholders and lead those initiatives in an effective and sustainable manner. Although the provision of ART to adults has been successful, there have been significant challenges in increasing patient enrollment, particularly for children; quality of care; treatment retention; monitoring adherence; and detecting treatment failure. Moreover, despite the impressive progress that has been made, Ethiopia still has high rates of morbidity and mortality from preventable maternal, child, and neonatal causes. The quality of health care in terms of improving patient safety, effectiveness, and patient centeredness, in both public and private facilities, is often inconsistent and unreliable.[2]

THE SIAPS STRATEGY IN ETHIOPIA

SIAPS/Ethiopia provided "next generation" technical assistance and leadership to the Ethiopian health sector in pharmaceutical systems strengthening with a deliberate focus on patient-centered services to improve health outcomes for all health elements. More importantly, SIAPS/Ethiopia supported USAID and the Government of Ethiopia to reconcile the long-term goals of country ownership and sustainability with the immediate need of scaling up and expanding prevention and treatment programs without adversely affecting health outcomes. The focus of SIAPS/Ethiopia was to enhance pharmaceutical services through patient-centered solutions while continuing to support essential supply chain functions at the interface of medicines and patients. This was attained through a health systems strengthening approach by implementing interventions targeted at different health system building blocks with a focus on medicines and technologies/pharmaceuticals.

Figure 1. The SIAPS approach

Over the past five years, SIAPS partnered with key Ethiopian institutions to alleviate these challenges by implementing interventions that contribute to the President's Emergency Plan for AIDS Relief, the President's Malaria Initiative (PMI), USAID, and the Government of Ethiopia's shared goal of reducing HIV, AIDS, malaria-related morbidity and mortality, and RMNCH deaths. To realize this, SIAPS/Ethiopia worked in partnership with the Federal Ministry of Health (FMOH); the Food, Medicines, and Ethiopian Healthcare Administration and Control Authority (FMHACA); the Pharmaceutical Fund and Supply Agency (PFSA); regional health bureaus (RHBs); HFs; universities; and professional associations with the overall goal of strengthening the pharmaceutical system to ensure access to medicines and quality pharmaceutical services that will improve health outcomes.

Table 1. SIAPS/Ethiopia Implementation Partners and Areas of Collaboration, 2011–2016

Implementing Partner	Intervention(s)	Year(s)
World Health Organization	DTCs	All years
Clinton Health Access Initiative Foundation	DTCs	2014–2016
	Building capacity of pharmacists on ART (train the trainer course)	2016
Supply Chain Management System	MRIS	2015–2016
Promoting Quality of Medicines	MRIS	2015–2016
John Hopkins University, Centre for Communication Programs	Health Regulatory Information Center	2016
Columbia University	Supporting pharmaceutical management information systems at ART sites	All years
ENHAT-CS	Capacity building for ART service	2012

Table 2. SIAPS/Ethiopia Stakeholders and Areas of Technical Assistance, 2011–2016

Stakeholder	Intervention(s)	Year(s)
FMHACA	ADE monitoring/PV	All years
	Updating treatment guidelines, formularies, manuals, frameworks, and job aids.	2012–2016
	Rural drug vendors: Intervention on appropriate medicine management and use	2012–2014
	AMR	All years
	MRIS	2015–2016
	Health Regulatory Information Center	2013–2017
	Standards for health services	2012
	Development of formulary for RMNCH medicines	2015–2016
FMOH	Hospital reform implementation guideline: Pharmacy chapter development and implementation	All years
	Development of training materials	All years
	APTS	All years
	Redesigning infrastructure of pharmacy premises at newly built health facilities	2015–2016
	Organizational adjustment for pharmacy services	All years
	Management of D4T phase-out in adult and pediatric ART	2013–2016
	RMNCH	2015–2016
	Development of medicines management handbook for health extension workers in four languages (English, Amharic, Tigrigna, and Afan Oromo)	2016
RHBs	Hospital reform implementation guideline: Pharmacy chapter implementation	All years
	APTS	All years
	Redesigning infrastructure of pharmacy premises at newly built health facilities	2015–2016
	Organizational adjustment for pharmacy services	All years

Stakeholder	Intervention(s)	Year(s)
	Clinical pharmacy services/pharmaceutical care/good dispensing practice	All years
	EDT: Electronic and paper-based tools	All years
	Pharmaceutical management information system	All years
	RMU (DTC, DIS, AMR, ADR/PV)	All years
PFSA	RMU (DTC, DIS)	All years
	Clinical pharmacy services	All years
	Capacity building for pharmacists on ART from curriculum development to training of trainers	2015–2016
	Pharmaceutical management information system	All years
Schools of Pharmacy at Jimma, Mekelle, and Gondar University	In-service training on clinical pharmacy	2012–2014
	Site-level supportive supervision and mentoring on clinical pharmacy services	2013–2015
	National assessment on status of clinical pharmacy services	2015
	Implementation of APTS at university hospitals	2014–2016
	Preservice ART training	2012
School of Pharmacy, AAU	Postgraduate regulatory affairs program	2015–2016
Health Facilities	Hospital reform implementation guideline: Pharmacy chapter implementation	All years
	APTS	All years
	Redesigning infrastructure of pharmacy premises at newly built health facilities	All years
	Organizational adjustment for pharmacy services	All years
	Clinical pharmacy services/pharmaceutical care/good dispensing practice	All years
	EDT: Electronic and paper-based	All years
	Pharmaceutical management information system	All years
	RMU (DTC, DIS, AMR, ADR/PV)	All years
Ethiopian Pharmaceutical Association	Model community pharmacy initiative	All years
	Training of private-sector pharmacists on the rational management and use of family planning and RMNCH products and contributions to appropriate referral systems	2015–2016
	In-service training on ART	2012
	In-service training on pharmaceutical ethics	2012
	Supporting annual scientific conference	All years
MOFED, Regional Finance Bureaus, Audit Bureaus, Justice Bureaus, and Civil Service Bureaus	Redesigning financial vouchers, receipts, and other financial transaction tracking tools followed by approval for use at public health facilities	All years
	Redefining auditing requirements for pharmacies at HFs	All years
	Drafting legislation to enforce implementation and consensus building among stakeholders followed by enactment by the respective parliaments	All years
	Adjusting human resource needs for pharmacy departments at HFs to increase the number of pharmacy personnel and include new cadres, such as pharmacy accountants and pharmacy cashiers	All years

SIAPS INTERVENTIONS AND ACHIEVEMENTS

Strengthening Pharmaceutical-sector Governance

Key Interventions and Achievements

SIAPS supported key government stakeholders in developing, updating, and implementing regulations and directives, standards, policies, guidelines, and standard operating procedures (SOPs) that govern pharmaceutical-sector operations. Below are some highlights of the technical assistance provided by SIAPS to address priority gaps in pharmaceutical governance. These activities have established better mechanisms for ensuring transparency, accountability, and efficiency in pharmaceutical management and services. Activities included:

- Developing national minimum standards for pharmacy practices in health care settings

- Expanding the review of and updates to the Ethiopian medicines formulary and standard treatment guidelines (STGs)

- Developing and enacting legislation for Auditable Pharmaceutical Transactions and Services (APTS)

- Developing a national strategic framework for the prevention and containment of antimicrobial resistance (AMR)

- Optimizing and automating the medicine registration system

- Launching a postgraduate program in regulatory affairs

- Developing facility-specific medicines lists

- Developing SOPs to guide the effective implementation of clinical pharmacy and medicine information services

Developing Standards for Good Pharmacy Practice

To ensure the safety and quality of health care services in the private and public sectors, 39 HF standards[3] for good pharmacy practice were developed and are being implemented by the FMHACA. Health care settings are being relicensed under the new requirements, which is a major step toward improving the quality of health services and ensuring government ownership and sustainability.

Developing and/or Updating the STGs, Medicine Formulary, Medicines List, Manuals, and SOPs

The STGs[4-6] for the three levels of care (health centers, primary hospitals, and general hospitals) were revised and updated in 2014 to expand the coverage of health conditions. In addition, the Ethiopian medicines formulary[7] was updated in 2013, and manuals on good prescribing[8] and good dispensing practices[9] were developed and implemented in 2012. The formulary, manuals, and STGs have been distributed to hospitals and health centers to standardize prescribing practices, improve access to evidence-based information, and optimize treatment, thereby contributing to improved health outcomes. In March 2016, 88% of target HFs were implementing good standards for medicine dispensing, an increase from 75% in June 2014. SIAPS/Ethiopia supported the development of a national AMR strategy and a plan of action to guide efforts in the prevention and containment of AMR. With assistance from SIAPS, 89 hospitals have developed and implemented facility-specific medicines lists. SIAPS supported the development of the first RMNCH medicines formulary, which is a key step in prioritizing lifesaving maternal and child health products at all levels of the health system. The *Medicines Management Handbook for Health Extension Workers* and a working manual for the establishment and operation of drug and therapeutics committees (DTCs) were developed and printed. In addition, SOPs for the provision of drug information services (DIS)[16] and SOPs for clinical pharmacy services were developed and implemented in hospitals to standardize processes and maintain uniformity of practice across hospitals. SOPs for managing information on dispensing antiretrovirals (ARVs) and patient medication records have been updated, which allows health managers to access information that guides decision making.

Establishment of a Health Regulatory Information Center at the FMHACA

SIAPS supported the establishment of a health regulatory information center within the FMHACA, which has been responding to phone calls and written requests from the public on medicine use, circulation of counterfeit/substandard medicines, unethical practices, and other health-related issues, thereby improving the public's access to information. From June 2014 to June 2015, the center received and responded to 1,290 calls from nine regions. Questions were related to food quality and safety issues (19%), rational medicine use (RMU) (17%), unethical professional practices (16%), maternal health (14%), and quality of service (10%). The majority of these questions (60%) came from the public. With continuous support to improve the center's efficiency, the number of calls increased from 1,290 in 2014/15 to 22,006 in 2015/16. Of those calls, 5,577 related to FMHACA mandates, with approximately 40% of those related to medicine, 24% to food, 13% to health, 12% to general information, and 11% to other topics.

Automation of the Medicine Registration System

In support of the medicine registration system at the FMHACA, SIAPS helped with the systematic review and optimization of product registration processes and tools to improve the system's efficiency in preparation for automation. Eight types of applications were identified, and the processes and associated tools for each were reviewed. Of the 46 tools, including guidelines, SOPs,

checklists, and forms, 28 (approximately 60%) were modified or optimized and eight new tools were developed and introduced based on international best practices. SIAPS developed the Medicines Registration Information System (MRIS), a web-based software program, to reflect the optimized processes and requirements. Efficiencies facilitated by the MRIS include online application submissions, tracking of progress, and the issuance of market authorization certificates. An organizational change management plan was developed with assistance from SIAPS to guide the transition from a manual to an automated system.[10] The MRIS was successfully piloted in September 2016, and all applications are now submitted online and processed electronically.

The Launch of a Postgraduate Program in Regulatory Affairs

SIAPS provided technical assistance to the FMHACA and Addis Ababa University (AAU) to develop a postgraduate training program on regulatory affairs to support further capacity development. Based on a needs assessment, SIAPS supported an experience-sharing visit to South Korea and the US for four key individuals, two from the FMHACA and two from AAU's School of Pharmacy.[11] Sixty experts from 14 South Korean and US institutions provided a comprehensive overview of best practices in the regulatory arena. The study tour was highly successful, and the team gathered a wealth of information to help advance the postgraduate regulatory affairs training program in Ethiopia. Key lessons learned included the need for strong collaboration between regulatory authorities and AAU; the development of in-house short-term training programs; and the creation of partnerships among industry, academia, and regulatory authorities to teach and advise students. Following the visit, the postgraduate curriculum was approved by the University Senate in June 2016, and the program was officially launched in August 2016 with a first cohort of 15 students.

Establishment of the Pharmacy Directorate

The continued advocacy and technical support provided by SIAPS to establish a body that would address pharmacy services at the national and regional levels resulted in the formation of a separate directorate with adequate staffing at the FMOH. SIAPS developed a concept note to guide structural adjustments and participated in technical working groups that were designing the organizational structure. Following this, many RHBs upgraded their pharmacy structure to a level of core process. This is a key step toward creating appropriate leadership in the pharmaceutical sector at the national and regional levels, which is the foundation that will sustain the successful interventions SIAPS has worked to implement.

Improving Pharmaceutical Services to Achieve Better Health Outcomes

Key Interventions and Achievements

Recognizing the importance of effective pharmaceutical services in optimizing health outcomes, SIAPS provided technical assistance to strengthen different components of the pharmaceutical system that contribute to improved availability of medicines and better quality services. SIAPS provided technical assistance to public health facilities to implement innovative interventions,

such as APTS and clinical pharmacy services. In addition, SIAPS collaborated with stakeholders and partners to promote RMU as part of the effort to improve quality of care, adherence to treatment, and patient safety by increasing the judicious prescribing, dispensing, and use of medicines by prescribers, dispensers, and patients, respectively.

Auditable Pharmaceutical Transactions and Services

APTS is a data-driven, innovative, and comprehensive package of interventions designed to address issues of efficiency, accountability, transparency, and quality of service at the HF level. As of December 2016, 77 health facilities, 70 hospitals, and 7 health centers have implemented APTS. These HFs have shown remarkable improvements in quality of service, patient satisfaction, waiting time at pharmacies, and patients' knowledge of medicines dispensed to them. In most hospitals, availability of key medicines increased from 65% to more than 95%. Changes in pharmacy layouts, which were introduced with APTS, dramatically improved patient convenience at service delivery points, particularly for mothers with children and for the elderly. Wastage of medicines due to expiry decreased from 8.24% to less than 2%.

Before APTS: pharmacy visits were inconvenient, time consuming, and unsafe, particularly for mothers with children and for the elderly

After APTS: pharmacies had improved facilities, workflows, waiting times, privacy, and services

APTS helped to identify human resource needs, which facilitated hiring of pharmacy staff for an optimized pharmacist-to-patient ratio. The introduction of new cadres, such as pharmacy accountants and cashiers, has transformed access to financial information related to medicine sales, enabled regular auditing, and reduced waste. The change in design of pharmacy premises and the incorporation of cashiers within the pharmacy created a streamlined process and contributed to a significant decrease in waiting time and improved patient convenience.

A national APTS assessment in 2016 revealed substantial improvements at APTS sites compared to non-APTS sites in multiple results areas. In terms of producing information for decision making, 94% of APTS sites generated monthly financial and service reports. Appropriate labelling practices were low at both types of sites. However, APTS sites performed better than non-APTS sites (3.9 vs 0.7 on a 5-point scale). Excluding cost-related variables and across the eight domains, patients were significantly more satisfied with services at APTS sites than at non-APTS sites (overall mean satisfaction: 3.49±0.85 vs 3.11±0.91). Similarly, higher satisfaction

was recorded at APTS sites compared to their own baselines. The availability of key tracer medicines was found to be higher at APTS sites than at non-APTS sites (90% vs 70%). Percent availability showed a significant increase at APTS sites compared to their baseline (66% to 85%). Stock-out duration was also shorter at APTS sites than at non-APTS sites (43 vs 61 days). The average wastage rate was 1.1%, which was much lower than the target set in the HSDP[17].

Rational Medicine Use

To promote RMU, SIAPS/Ethiopia had supported the establishment and strengthening of DTCs at 195 hospitals (149 public and 46 private) and 409 health centers as of September 30, 2016. These DTCs have been used to scale up interventions to promote RMU at the HF level. As of March 2016, 75% of DTCs had documented evidence-based improvements in medicine use (up from 54% in March 2013); nearly 60% of DTCs had implemented AMR advocacy or containment-related activities (up from 29%); 128 HFs were providing evidence-based information on medicines on a regular basis (up from 20); 49 DTCs had conducted prescription reviews to identify medicine use problems (up from 12); 59 DTCs conducted ABC value analyses (up from 3); and 177 HFs used standardized prescription blanks (up from 0). A total of 15 hospital DTCs had conducted medicine use evaluations on different medicines and diseases (up from 0). Among the 33 target facilities, 29 (88%) had implemented good dispensing standards for medicines (up from 13 [54%]); 118 HFs had provided patient education on medicine use on a regular basis (up from 0); and the diagnosis was recorded in 46% of prescriptions (up from 0). In terms of prescribing indicators, prescriptions containing injections decreased from 28% in 2013 to 22% in 2016 and prescriptions containing antibiotics showed a slight decrease, from 62% in 2013 to 58% in 2016. A total of 13 (55%) hospital DTCs closely tracked the availability of priority lifesaving RMNCH medicines and commodities[18].

Antimicrobial Resistance

SIAPS/Ethiopia supported a coordinated national effort through the National AMR Advisory Committee to advance the prevention and containment of AMR by developing the national *Strategy for the prevention and containment of antimicrobial resistance for Ethiopia, 2015–2020*[19] and a plan of action to guide interventions. The multidisciplinary AMR Advisory Committee meets regularly and is being used as a national platform to intensify and coordinate efforts around the prevention and containment of AMR.
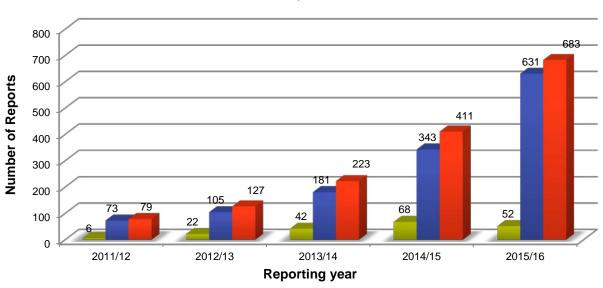
SIAPS, in coordination with the World Health Organization, the FMOH, RHBs, training and research institutions, professional associations, and other partners, has supported the annual celebration of AMR Day to raise awareness among policy makers and the general public. SIAPS assisted in the revision and development of treatment guidelines, formularies, good medicine prescribing and dispensing manuals, and job aids to support this effort. To complement national-level interventions, SIAPS built the capacity of health facility DTCs to establish audit and feedback mechanisms on the use of antibiotics in hospitals and supported them to conduct regular antimicrobial use evaluations. To date, approximately 54% of DTCs have implemented AMR advocacy or containment-related activities, and prescriptions containing antimicrobials showed an overall decrease from 62% in 2013 to 58% in 2016. Further analysis of aggregate prescribing practices at six hospitals indicated a reduction in antimicrobial prescriptions from 53% to 37%.

Another important intervention was the use of mass media to empower the public by creating awareness and educating them on AMR prevention and containment. To achieve this, SIAPS/Ethiopia employed an innovative strategy to build the capacity of journalists to disseminate AMR-related information to the public via print and electronic media. Through this effort, 286 journalists from different mass media agencies were trained on AMR prevention and containment, resulting in unprecedented access to the media. From 2012 to 2015, mass media outlets broadcast 368 stories on AMR and RMU. The highest number of broadcasts was in 2015 (41%) followed by 2014 (25%), 2012 (19%), and 2013 (16%). According to data collected in 2014, most stories were on radio (83%), followed by newspapers (9%) and television (8%). The messages were broadcast in 10 languages throughout the country. Among the broadcast topics were self-medication and sharing of medicines, infection prevention, and counterfeit medicines (37%); antimicrobial use and resistance prevention and containment (26%); RMU (18%); medicine use in treating tuberculosis (10%); ARV use and adherence (10%); and medicine use in treating malaria (5%).[20]

Pharmacovigilance

The approaches used by SIAPS/Ethiopia to strengthen the national pharmacovigilance (PV)/adverse drug event (ADE) monitoring center have resulted in remarkable success in increased ADE reporting, data management, and decision making. The automated Pharmacovigilance Data Management System (PVDMS), designed and introduced by SIAPS, has transformed the recording, aggregation, and reporting of PV data at the FMHACA. The tool incorporates the standard terminology used in the *Medical Dictionary for Regulatory Activities*, which strengthened data management and information sharing. The PVDMS is now a web-based system and is being piloted for online reporting (www.fmhaca.gov.et). The ADE reporting guidelines and form were revised to incorporate medication errors and product defects in addition to adverse drug reactions (ADRs), which has enabled the tracking of counterfeit and substandard medicines. SIAPS supported the distribution of tools to promote ADE reporting, train more than 4,500 health care providers from 168 public and private HFs and 59 market authorization holders, and familiarize 122 stakeholders from three regions with the national PV framework. To improve communication of risks, SIAPS supported the publication of a quarterly newsletter and published 16 issues to date.

These interventions, combined with facility-level in-service training, face-to-face discussions and regular feedback on ADE reports, have contributed to a progressive increase in the ADE reporting rate since 2011. The cumulative number of health facilities involved in ADE reporting has increased from 18 in 2012 to 168 in 2016.The annual number of ADE reports has increased from 79 to 683, an increase of more than 700%.[21]

Figure 2. ADE reporting progress, 2011–2016

Of the 1,523 reports received through September 2016, 220 were related to suspected product quality issues. Reports on suspected product quality problems are reviewed by the PV forum, which makes recommendations for regulatory decisions to be taken by the authority. Of the reported quality problems, 48% had visual/physical changes, 28% had unexpected/unintended results, and 24% had packaging problems. Further follow-up and investigation of these products resulted in the recall of 22 products, the temporary closure of one manufacturing facility, the suspension of a market authorization license, and the permanent cessation of production for one product. In 2016 alone, analyses of ADE reports received by the PV center resulted in regulatory measures on nine products.[22]

Clinical Pharmacy Services and Pharmaceutical Care

Recognizing the potential benefits of patient-centered care on health outcomes, SIAPS/Ethiopia supported the introduction of clinical pharmacy services in Ethiopia. The FMOH also adopted clinical pharmacy as one of the key services in the pharmacy chapter of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG), but the pharmacy staff, who were trained using the old, product-focused curriculum, lacked the specific knowledge and skills to actually implement it at hospitals. Accordingly, SIAPS supported the development and implementation of a well-structured in-service training program[23] to build the clinical knowledge and skills of practicing hospital pharmacists. Between May 2012 and September 2014, 200 pharmacists from 65 hospitals were trained and deployed. The training program and subsequent advocacy and consultative meetings contributed to raising awareness among policy makers and managers at the FMOH, RHBs, and hospitals on the importance of clinical pharmacy services to improving the quality of patient care. That awareness has encouraged them to emphasize and support the implementation of clinical pharmacy initiatives.

Table 3. Frequency of drug therapy problems identified and intervened by pharmacists, April 2015 (N=31 hospitals)

Type of drug use problems (DTPs) identified	# DTPs	# Interventions	%
Unnecessary drug therapy	1,708	1,455	85.2
Needs additional drug therapy	2,405	2,101	87.4
Ineffective drug	771	642	83.3
Dosage too low	868	780	89.9
Adverse drug reaction	361	274	75.9
Dosage too high	751	665	88.5
Noncompliance	1,393	1,266	90.9
Total	8,257	7,183	87.0

Hospitals were also provided with standardized documentation and reporting formats, supported by SOPs, on the delivery of the service.[24] The SOPs helped to standardize practices across hospitals. Hospitals were also mentored and supervised by teams of experts from universities, RHBs, and the PFSA. As a result, of the 65 hospitals involved in the training, 64 (98.5%) started providing clinical pharmacy services.[25] Pharmacists monitored patients from admission to discharge and participated in multidisciplinary rounds and morning sessions. Based on best practices and experiences learned in these hospitals, 41 additional hospitals located in various regional states have started the service by deploying new graduates who were educated with the revised, patient-oriented curriculum.
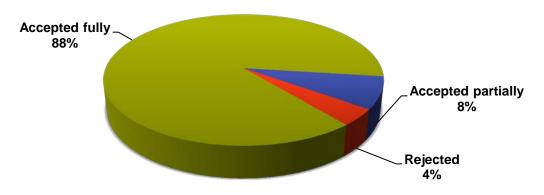

Figure 3. Acceptance rate of pharmacists' recommendations by clinicians, 2016

In collaboration with stakeholders, SIAPS conducted a cross-sectional study in 2016[26] at 43 hospitals that took part in the in-service training program to review the overall status of the implementation of clinical pharmacy services. The results showed that 17 (40%) hospitals had assigned pharmacists in wards on a full-time basis. Of the 41 (95%) hospitals that started providing ward-based clinical pharmacy services, pharmacists attended both morning sessions and ward rounds with the multidisciplinary team in 23 (56%). Twenty-nine (67%) pharmacy departments had an annual plan of action on clinical pharmacy services for the 2007 Ethiopian plan period (July 2014–June 2015). Clinical pharmacy interventions were being documented in 36 (88%) hospitals. The study further showed that 8,257 drug therapy problems (DTPs) had been

identified since the service was initiated. Of the DTPs identified, 29% were related to the need for additional drug therapy, followed by unnecessary drug therapy (21%) and noncompliance (17%). Additional drug therapy was recommended in 2,101 (87%) cases, and in 1,455 (85%) cases, unnecessary medicines were interrupted. In addition, interventions were provided for 1,266 (91%) patients who were non-compliant with their treatment. Overall, pharmacists were able to intervene in 87% of the DTPs. The multidisciplinary team accepted 88% of the pharmacists' recommendations. With regard to the views of other health care providers on the contributions of clinical pharmacy services to improving treatment outcomes, 37 of 38 CEOs (97%); 31 of 33 chief clinical officers (94%); 37 of 39 ward physicians (95%); 40 of 40 nurses (100%), and 38 of 39 pharmacists (97%) gave favorable responses and indicated acceptance of the services provided by pharmacists in wards.

Overall, this initiative has created a paradigm shift in pharmacy practice in Ethiopia. Clinical pharmacy has now become an integral part of hospital services, but continuing support is still needed to scale up and consolidate the service at all hospitals.

Antimalarial Drug Management

With funding from PMI, SIAPS/Ethiopia worked with RHBs and FMOH agencies to address the challenges in managing and dispensing antimalarial drugs (AMDs). SIAPS assisted in improving the storage and dispensing practices at 90 sites by refurbishing premises (37 sites) and supplying equipment and furniture (53 sites), which resulted in better medicine handling and the segregation of expired and obsolete products. SIAPS supported the Oromia RHB in the development and implementation of AMD stock transfer guidelines to help reduce the frequency of stock-outs and unnecessary expiry due to overstock at regional stores and service delivery points. SIAPS also assisted Oromia and other RHBs in collecting quarterly stock status data from health facilities using stock monitoring tools. The findings were compiled and reported to stakeholders at the central, regional, and zonal levels for decision making, which resulted in the transfer/exchange of excess AMDs and those nearing expiry between health facilities to minimize wastage. As an example, 542 ampoules of arthesunate injection and 3,870 doses of artemisinin-based combination therapy were redistributed among HFs in the Oromia region in April 2016.

In addition, a new medicine management handbook[27] was developed in the local language and distributed to health extension workers to provide guidance on managing antimalarial and other essential medicines. As part of the effort to improve the rational use of AMDs, SIAPS supported DTCs at hospitals in the Oromia and Amhara regions to conduct medicine use evaluations of artemether-lumefantrine (Coartem), which enabled hospitals to identify key gaps related to adherence to treatment guidelines. For example, a baseline evaluation conducted at Woldia Hospital showed that most patients treated for malaria with artemether-lumefantrine had no laboratory diagnosis or confirmation, resulting in the inappropriate use of medicines and the potential for AMR. SIAPS supported Woldia Hospital's DTC in designing and implementing a set of interventions to address these challenges. The key interventions included introducing a new patient treatment record sheet that captures diagnosis and treatment information, conducting monthly case presentations on the chart review of selected malaria patients, and training selected hospital staff on current antimalarial treatment guidelines. A second-round evaluation in March 2016 of the interventions found dramatic improvements in the hospital's diagnosing, prescribing,

and dispensing practices. For example, all malaria cases treated since April 2015 were diagnosed through laboratory tests, which eliminated unnecessary prescriptions. Appropriate indication improved by 47%, suggesting that appropriate AMDs are being prescribed and leading to better treatment outcomes. Other indicators, such as appropriate dosage and duration, contraindications, and interactions, also improved significantly.
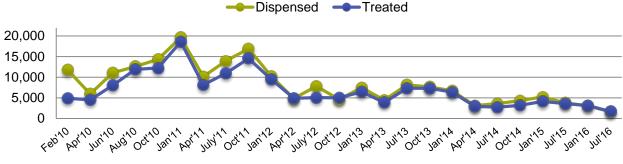

Figure 4. Gap between the number of patients treated and doses dispensed

In collaboration with the Oromia RHB, SIAPS designed and implemented the Continuous Results Monitoring System (CRMS), which is a comprehensive, indicator-based performance management system that tracks the availability, storage, and proper use of AMDs. The system was implemented at 44 HFs in the Oromia region and helped health managers at different levels monitor performance of the sites using key performance indicators. Data from the CRMS show significant changes to diagnostic and prescribing practices. For example, the number of malaria cases treated without a laboratory diagnosis decreased from 54% in 2011 to almost none in 2016 in the targeted HFs. As a result, the amount of medication consumed through inappropriate prescriptions decreased by more than half during the same period. The discrepancy between the doses of AMDs dispensed and the number of patients treated decreased from 58% in February 2010 to 2% in July 2016, indicating a significant improvement in the recording and control of AMD transactions. The CRMS has also increased the availability of artemether-lumefantrine, a medicine used to treat *Plasmodium falciparum* malaria, from 79% in 2012 to 88% in 2016. As the CRMS continues to support improvements at these HFs, SIAPS determined that scaling back routine support was essential to ensuring sustainability. With this objective, 28 HFs in the Oromia region were graduated in 2015 and 2016 after taking steps to fully own their CRMS and demonstrating the capacity to monitor the availability, handling, and appropriate use of AMDs.

RMNCH Medicines and Commodities Management and Use

Knowing that access to and appropriate use of medicines for maternal and child health is a shared responsibility of the health system and its prescribers, dispensers, and end users, SIAPS supported the Ethiopian government in resolving bottlenecks to help achieve RMNCH goals. SIAPS identified gaps and designed interventions focused at building the capacity of community pharmacies and developing an RMNCH formulary and a medicines management handbook for health extension workers.

SIAPS conducted a baseline assessment at 34 hospitals to determine their current status and empower their DTCs to continually monitor the availability of priority lifesaving RMNCH medicines. The information gathered during this assessment guided development of interventions aimed at strengthening HF DTCs to continually monitor and ensure the availability of these lifesaving medicines. Understanding the potential of community pharmacists to contribute to improving maternal and child health, SIAPS, in collaboration with the Ethiopian Pharmaceutical Association and the FMOH, designed and implemented in-service training for community pharmacists. A standard training curriculum and materials were developed and training of trainers was provided to 22 participants, resulting in training of 133 community pharmacists. SIAPS and the FMHACA developed the formulary for RMNCH medicines and supplies, which provides basic information on their management and appropriate prescribing, dispensing, and use to health care providers at different levels of the system. In addition, a job aid on emergency contraception was developed for community pharmacists. SIAPS also supported the FMOH to develop the *Medicines Management Handbook for Health Extension Workers*[14] as a reference for health extension workers at health posts. It provides basic information on proper storage, inventory control and reporting, prescribing, dispensing, and use of medicines approved for use at the health post level. Five thousand copies each of the English and Amharic versions were printed. The translation of the handbook into Afan Oromo and Tigrigna has been completed, which will facilitate expanding its use to all regions of the country, and the FMOH has committed to their distribution.

Enhancing Capacity for Pharmaceutical Management and Services

Key Interventions and Achievements

SIAPS/Ethiopia's capacity-building intervention focused on filling gaps in government priorities related to human capital, systems, and institutional preparedness to provide quality pharmaceutical services in a sustainable manner. A series of in-service trainings was conducted to effectively implement necessary tools and systems. To ensure sustainability, SIAPS provided various training of trainers courses and developed standardized training manuals that have been approved by the FMOH. To build system capacity and support transparency and accountability, SIAPS introduced new tools, including guidelines, regulations, manuals, frameworks, SOPs, and supervision checklists, into the pharmaceutical sector to support and streamline the delivery of patient-centered pharmacy services and the management of pharmaceutical transactions in hospitals. Regulations that govern the proper management of pharmacy operations in HFs were introduced at both the federal and regional levels and have increased institutional capacity through the allocation of adequate human, financial, and material resources. These capacity-building interventions directly affect gaps related to governance, service delivery, information, and finance that affect access to medicines and services.
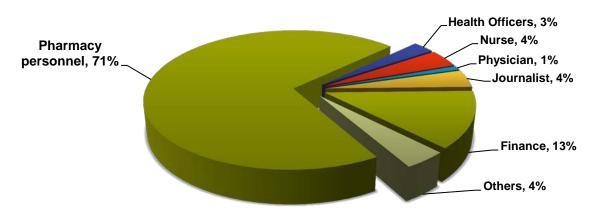
Figure 5. Professional mix of trainees, 2011–2016

A total of 7,720 professionals, including pharmacy personnel, medical doctors, hospital CEOs, finance professionals, journalists, and managers, were trained over the past five years, 31% of whom were female. Major areas of in-service training included the prevention and containment of AMR, clinical pharmacy services, DISs, DTCs, RMU, ART, AMD management, manual and electronic dispensing (EDT) tools, APTS, and leadership and management. The SOPs introduced in the health system have helped to standardize pharmacy practices across HFs. The enactment of new regulations has given health managers the authority to recruit more pharmacists and new cadres, such as accountants, as well as to engage in facility improvement activities. The number of pharmacists has almost doubled in APTS-implementing hospitals. The tools introduced in connection to APTS have enabled hospitals to track information on product movement, revenues, financial performance, services, and performance of the pharmacy work force. The use of the resulting information and analyses have not only helped to ensure transparency, but also facilitated evidence-based decision making. The hospital pharmacy layout designs provided to hospitals have contributed to dramatic improvements in dispensing premises at 74 APTS sites. Instituting user-friendly systems and tools has enabled HFs to deliver services that meet patients' expectations. The training in clinical pharmacy has brought a paradigm shift to the provision of pharmaceutical care by introducing a new patient-centered service delivery model to pharmacy services.

Strengthening Capacity to Use Information for Decision Making

Key Interventions and Achievements

The SIAPS approach to improving information systems is to strengthen pharmaceutical data collection, processing, analysis, and presentation of information to help staff at all levels of the health system make evidence-based decisions that improve health outcomes. To achieve that, SIAPS/Ethiopia designed and implemented information systems to address both disease-specific and overall health system strengthening needs. SIAPS continued to support HFs that are providing ART services to properly implement the EDT and its paper-based versions. Similarly, SIAPS helped introduce the CRMS and End Use Verification Survey tools at PMI sites to respond to information needs related to AMD management and use. SIAPS also designed and introduced

paper-based data capturing and reporting tools at HFs implementing APTS and clinical pharmacy services. Recently, SIAPS was engaged in optimizing and automating the country's medicines registration system to ensure efficiency, transparency, and accountability. These interventions have a synergy with other interventions designed to strengthen pharmaceutical systems by empowering health system managers and practitioners to make effective decisions.
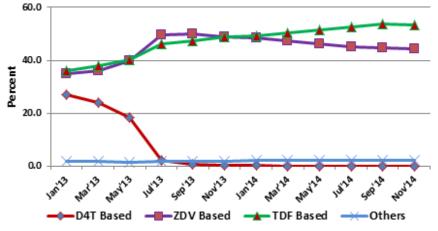

Figure 6. Adult ARVs prescribing trend: January 2013–December 2014

In the HIV and AIDS program, 100% of SIAPS-supported pharmacies at ART sites keep complete patient information for those undergoing ART. This activity is supported by an SOP[28] developed for this purpose. As a result, bimonthly national reports with information from 680 sites collecting ART patient uptake data and 380 ART sites with data on regimen breakdown are produced and disseminated to decision makers. This strategic information is also used as a key resource for national quantification of ARVs. This information also allowed the country's ART program to successfully transition stavudine-based treatment to a tenofovir-based regimen.[29] Close monitoring of regimen prescribing patterns and trends generated by ART pharmacies on a bimonthly basis provided timely data for plan adjustments. This not only helped achieve a smooth transition but also saved resources by preventing wastage and expiry of the phased-out D4T.

For front-line pharmacists, the information on patient-medication history is being used routinely to detect and prevent medication errors, drug interactions, and other adverse events. Health facility data showed an increasing number of medication errors that were identified and prevented by dispensers at ART pharmacies. Over a three-year period, 687, 466, and 164 medication errors were identified and resolved by pharmacists in 38 HFs (2016), 19 HFs (2015), and 8 HFs (2014), respectively. Had they gone unnoticed, patients may have been adversely affected. Most of the errors were related to an inadvertent change in regimen, and all errors were communicated to prescribers and corrected. ART pharmacies also used the system to track patient adherence to appointment dates and worked with patients to improve adherence.
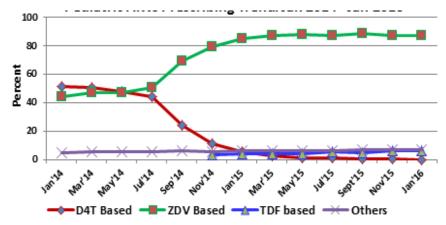
Figure 7. Pediatric ARVs prescribing trend: January 2014–January 2016

In support of the malaria program, 44 PMI sentinel sites implemented the CRMS to report logistic and patient data on malaria treatment, and 180 PMI sites are using a malaria treatment register to document and report data on AMD dispensing and use. These information systems have helped managers make informed decisions to ensure the availability and proper use of AMDs by minimizing overstock and wastage and by adhering to national malaria treatment guidelines.

The CRMS has also provided important information for guiding the quantification, procurement, and distribution of AMDs at all levels. For example, the FMOH and PFSA are using regimen and age group breakdown data from the CRMS to quantify the national demand for malaria medicines between July 2016 and June 2019.

SIAPS' data capture and information generation at APTS and clinical pharmacy implementing sites has a wider impact on essential health services, including HIV and AIDS, malaria, and RMNCH. Hospital CEOs and pharmacy heads are applying information generated from these two initiatives to improve medicine availability, optimize budget utilization, minimize stock-outs and wastage, prevent medication errors, and enhance treatment outcomes by promoting multidisciplinary teamwork for better access to effective medicines and quality pharmaceutical care. The monthly reports generated through APTS provide current information on the availability of key medicines, affordability, wastage rate, revenue, level of effort, and other key product- and service-related indicators, which is key to monitoring progress for further performance improvement.

SIAPS' efforts to modernize the medicine registration system at the FMHACA resulted in the development of a web-based software program that enabled the regulatory authority to transition from a manual to a fully automated and optimized system. As of December 2016, 222 registration applications had been received and processed, of which 158 (71%) were new applications, 43 (19%) were variations, and 21 (10%) were renewals. In addition, 321 purchase order applications were received online, of which 219 (68%) were approved and others were in different stages of processing. This is transforming the efficiency and transparency of managing medicine registration in Ethiopia because an application is submitted online and clients can follow the status remotely without having to visit the FMHACA.

Strengthening Financing Mechanisms to Improve Access to Medicines

Key Interventions and Achievements

SIAPS has geared its finance interventions toward optimizing the use of existing financial resources allocated to medicines. SIAPS/Ethiopia worked to build the capacity of HFs to achieve cost savings when selecting and prioritizing medicines for procurement to maximize revenue from medicine sales and minimize wastage due to expiry and pilferage. SIAPS/Ethiopia also provided technical assistance to RHBs and HFs to improve their financial management systems (e.g., cash and credit sales, dispensing to exempted/free patients) and implement ABC value analyses and subsequent reconciliations with VEN analyses in their medicines list to identify products that are still being procured and consuming HF budgets but have little or no impact on the health needs of the population in the catchment area. In addition, SIAPS supported HFs to conduct stock status analyses to identify stock at risk of expiry and take appropriate measures, such as redistribution to other HFs, to avoid unnecessary losses. In addition, new product and financial management tools were introduced to help ensure transparency and accountability, which significantly reduced stock-outs, wastage, and loss of cash collected from medicine sales.

Over the past five years, the number of HFs that regularly track sales of medicines using APTS tools has increased from 0 to 77. Data collected from 10 hospitals indicate a reduction in wastage of more than 70%. The number of HFs that conducted ABC/VEN analyses increased from 0 to 59. As a result, the availability of medicines at these sites increased from 65% (HSDP baseline) to more than 95%. Overall, HFs' capacity to monitor revenue and wastage of medicines has improved significantly, which has contributed to improved availability of essential and lifesaving medicines. Results of the national assessment on APTS conducted in 2016 revealed significant improvements at APTS sites in multiple areas. Overall budget utilization efficiency increased by 16% from the 2010 to the 2015, while sales revenues showed an average growth of 42.5% between the 2012 and 2014.

LESSONS LEARNED

Over the course of the program (2011–2016), SIAPS/Ethiopia learned several lessons that should inform the design and implementation of future interventions, including:

- Building the capacity of individuals and institutions, based on clearly identified gaps and shared goals, is essential to create local capacity to advance pharmaceutical system strengthening interventions.

- Aligning the work plan with government counterparts is imperative to secure the commitment and political will of the host institutions for optimal involvement and participation.

- Creating strong partnerships with and leveraging the engagement and participation of key stakeholders, donors, and implementing partners unifies understanding and messaging of the government's role in promoting country ownership.

- The performance of the pharmaceutical sector is influenced by multiple factors, some of which go beyond the health sector. Therefore, engaging relevant actors outside of the health sector, including ministries of finance, economics, justice, and civil service, can have a powerful impact on improving pharmaceutical sector performance through targeted interventions.

- Generating evidence using data-driven information and showcasing or demonstrating how it can be used to support organizational goals can have a tremendous influence on managers' and policy makers' behavior and their use of information for decision making.

- Institutionalizing key interventions by incorporating them into government guidelines and legislation is a powerful tool for ensuring ownership and sustainability.

SUSTAINABILITY

SIAPS/Ethiopia consistently encouraged country ownership and invested in country-led plans; built sustainability through systems strengthening; and leveraged key multilateral organizations, global partnerships, and the local private sector where possible. SIAPS promoted learning and accountability by effectively monitoring and evaluating results and using research, innovation, documentation, and dissemination to accelerate those results. Central to SIAPS/Ethiopia's system strengthening efforts was the alignment of its work plan with that of government stakeholders, particularly the FMOH, PFSA, FMHACA, and RHBs.

All of the interventions were planned with the ultimate goal of increasing access to quality medicines and services, improving treatment outcomes, and ensuring that these achievements are fully owned by stakeholders in a sustainable way. To achieve this, SIAPS/Ethiopia emphasized building the capacity of the FMHACA, PFSA, RHBs, and schools of pharmacy so that they can provide technical assistance and better support the implementation of plans at the HF level. DTCs were strengthened to own and lead the implementation of facility-level interventions, including RMU and AMR. Providing intensive support for the implementation of the pharmacy chapter of the EHRIG and the CRMS at selected HFs was key to creating model facilities that others could learn from. Recently, nine EHRIG sites and 28 CRMS sites graduated and took on additional responsibility to support and mentor other HFs within their vicinity. RHBs and zonal and district health offices have taken responsibility to provide close follow-up and support as needed. By employing a training of trainers approach, SIAPS has created a pool of trainers in different regions on various thematic areas, including DTCs, APTS, and ART, to build local training capacity. Training manuals for these areas have been developed and approved by the FMOH.

The enactment of APTS regulations has institutionalized many of the critical interventions, thereby creating accountability on the part of implementers and ensuring sustainability. The inclusion of PV and AMR courses in the university curriculum has integrated these interventions into preservice education. SIAPS' efforts to create a strong pharmacy structure within the health sector and ensure the engagement of FMOH, RHB, and PFSA experts in supportive supervision and mentoring activities have paved the way for ownership and sustainability by building their capacity to takeover this role in the long term.

THE FUTURE OF PHARMACEUTICAL SYSTEMS STRENGTHENING

The many interventions implemented by SIAPS over the past five years laid the foundation for further advancements in the Ethiopian pharmaceutical system. Ownership has been secured for most of the activities. However, some of the interventions, such as APTS, clinical pharmacy services, DIS, and MRIS, have not yet reached at the desired level of maturity to ensure sustainability. Therefore, further technical support is needed to support scale up, consolidate interventions, and fully transition to government counterparts. There is also a need to support efforts to incorporate existing trainings into preservice curricula so that new graduates can manage activities directly without (or with minimal) in-service training. The pharmacy directorate at the FMOH was formed at the end of the SIAPS program, and a similar structure is in development at most RHBs. Based on this restructuring, staff recruitment is under way. Most staff are new to the system and require a great deal of capacity-building support to be effective in their new roles. This implies that there is a need for technical assistance to create effective leadership capacity at the FMOH and RHB levels to ensure appropriate guidance and oversight for interventions at lower-level structures, including HFs.

As the government proceeds with the implementation of the health insurance system, there will be an increased demand to support services related to medicines benefit management, including reimbursement, rational prescribing, dispensing, and use of medicines. Interventions, such as medicine use evaluations that HF DTCs were conducting with support from SIAPS, are expected to be instrumental in auditing prescribing practices as part of ensuring adherence to treatment guidelines and containment of cost escalations in support of the health insurance program. Key reform documents recently developed by the health sector, such as the Health Sector Transformation Plan, the Ethiopian Hospital Services Transformation Guideline, and EHRIG, have prioritized interventions that enhance the capacity of the pharmaceutical sector. Ensuring equitable access to affordable, quality-assured essential medicines and their rational use is also recognized by the Sustainable Development Goals as a critical step toward achieving the key development targets. This becomes even more important as Ethiopia moves toward universal health coverage. Ethiopia has been aggressively expanding the construction of new hospitals, health centers, and health posts as part of its effort to improve access to health services. The additional infrastructure will increase the need for support in pharmaceutical systems strengthening at all levels. Therefore, it is highly recommended that health sector stakeholders, partners, and funding agencies continue to engage with country counterparts and provide support for the required pharmaceutical systems strengthening in line with potential future needs.

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