

# STRATEGY FOR SCALE-UP AND MAINTANANCE OF ACCREDITED MEDICINE PROGRAM (AMS) IN LIBERIA, NOVEMBER 2013

## I. Background

With support from the Bill & Melinda Gates Foundation to Management Sciences for Health (MSH), the Sustainable Drug Seller Initiative (SDSI) has been working in Liberia, Tanzania, and Uganda to implement drug seller accreditation programs. Adapting the Tanzania accredited dispensing drug outlet (ADDO) model, SDSI has worked with the Ministry of Health and Social Welfare (MOHSW), the Liberian Medicines and Health Products Regulatory Authority (LMHRA), and the Liberia Pharmacy Board (LPB) to create the Accredited Medicines Stores (AMS) program. Regulations have been changed to recognize AMS, and standards have been established for personnel, products, and facilities. The focus has been on Montserrado County, which includes close to 40% of the country's population and the majority of its medicine stores.

SDSI's objective in Liberia is to launch a nationwide strategy by phasing in one county and scaling up to Liberia's other 14 counties. The strong political commitment in Liberia made the situation suitable for immediate implementation and accelerated institutionalization. To move AMS forward, this strategy<sup>1</sup> document provides guidance and outlines activities. The key components of the AMS scale-up and maintenance strategy in Liberia are to (1) complete work in Montserrado county by consolidating what has worked and addressing outstanding challenges; (2) scale-up AMS program to the remaining 14 counties; and (3) mobilize funding for sustainability and maintenance work.

## II. Status of AMS

On February 12, 2013, Liberia's MOHSW and LMHRA and the LPB marked the successful launch of the AMS program in Liberia's largest county, Montserrado. The launch event at Monrovia City Hall was attended by a number of health sector stakeholders and interested community members. Health Minister, Dr. Walter Gwengigale, unveiled the AMS logo and presented accreditation certificates to 120 proprietors who met AMS standards and 358 dispenser's certificates to AMS dispensers who successfully completed the training.

In addition, SDSI has completed these activities—

- Established a National Steering Committee with its terms of reference. The National Steering Committee met regularly to coordinate activities.
- Geo-mapped all 635 medicines stores in Montserrado and conducted pre-inspection visits.
- Provided a US\$50,000 sub-grant to LMHRA to pay for an additional staff member, inspection activities, and office equipment.
- Developed standards for AMS premises, personnel, and practices, in conjunction with the LMHRA and LPB.
- Developed an M&E strategy for evaluating AMS implementation in Montserrado County.
- Completed a baseline assessment of the price and availability of medicines and quality of dispensing in unaccredited drug stores in Montserrado County.
- Conducted sensitization and dissemination workshops with more than 500 medicines stores owners and dispensers regarding new AMS standards.
- Developed the training curriculum and materials for AMS dispensers, inspectors, and proprietors.
- Trained 23 trainers to conduct AMS dispensers' training.
- Developed an AMS inspection strategy and trained 17 LMHRA and LPB inspectors.
- Trained 358 AMS dispensers on regulation and ethics, common illnesses in the community, communication, maternal and reproductive health, and dispensing.

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<sup>1</sup> This strategy assumes that donor support will be needed for scale up of all remaining counties.

- Trained 160 proprietors on business management and regulations.
- Conducted formative research to understand communities' behaviors, opinions, and preferences regarding medicine store services and their recommendations for how the AMS program should function. The findings informed the development and launch of a marketing and communications strategy for the AMS program in Liberia.
- Printed 500 AMS logo signs and 350 T-shirts as part of AMS branding. Additionally, road shows and media campaigns to promote AMS were carried out in two months in Monrovia.
- Two LMHRA staff members who worked with the AMS initiative traveled to Tanzania in September–October 2013 for a four-week work attachment at Tanzania Food and Drugs Authority (TFDA) to learn about TFDA's inspection and registration system.

### **SDSI Next Steps**

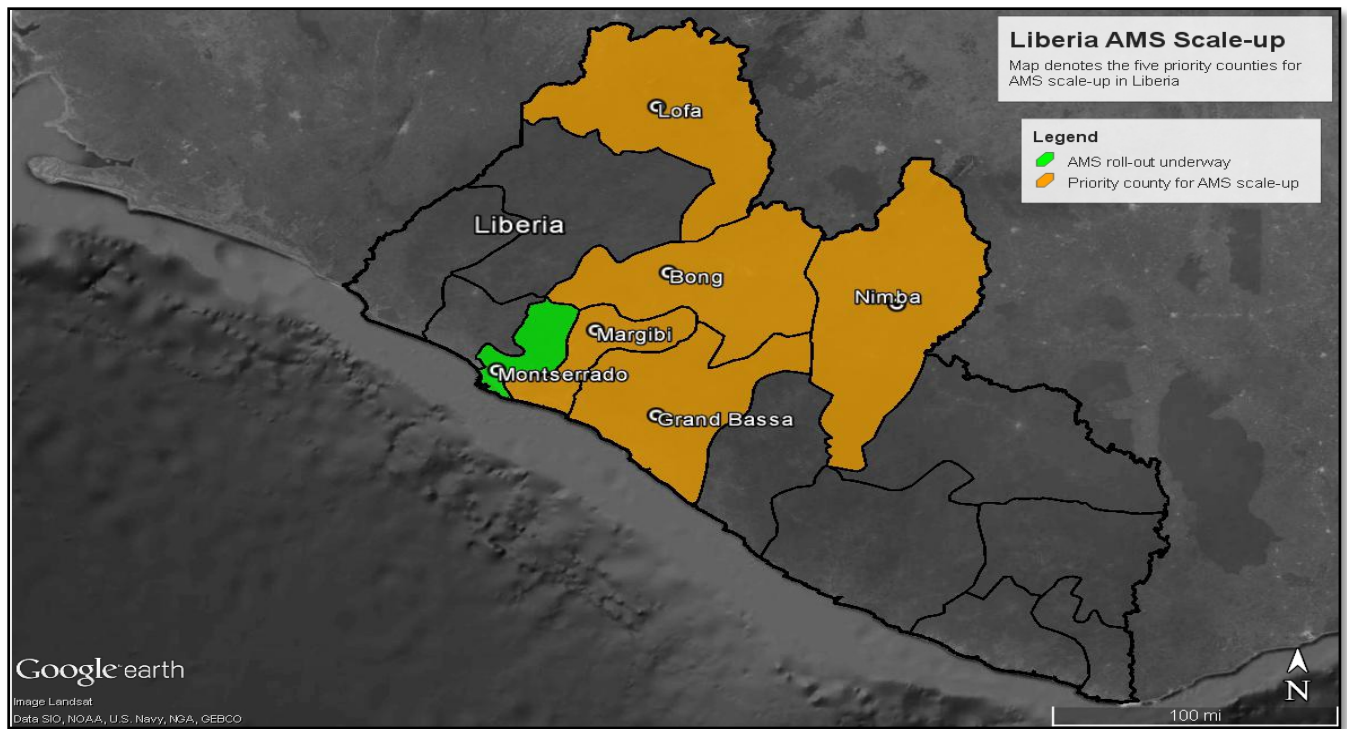
A number of medicine stores are yet to meet premises standards to qualify for accreditation. This includes both stores with trained dispensers and stores with dispensers that have not yet been trained. SDSI will work through the end of August 2014 to complete the following activities—

- Train an additional 150–210 dispensers from medicine stores that have meet the premises standards
- Support the LMHRA and LPB joint inspection in Montserrado
- Print and distribute inspection registers to all AMS
- Conduct an end line evaluation and disseminate results to stakeholders on AMS program's impact
- Work with Pharmaceutical Association of Liberia and Liberia University School of Pharmacy to institutionalize AMS dispensers' training
- Support LMHRA/LPB to accredit additional AMS

### **III. Scale-up and Maintenance and of AMS Program in Liberia**

Preliminary experiences from the AMS program in Montserrado County will inform scale-up to Liberia's 14 remaining counties as part of a countrywide strategy that will require all medicine stores to become accredited. All new medicines stores applying for registration must meet the AMS standards for premises, personnel, training, dispensing, and record keeping before they can be registered and licensed to sell the products on the AMS medicines list. To successfully roll out AMS in the other counties while consolidating the work in Montserrado, LMHRA and LPB will need additional personnel and other resources. Neither LMHRA nor LPB have offices in addition to their Montserrado headquarters. Therefore, all County Pharmacists who are designated as LPB inspectors would need to be oriented on the AMS program to play a substantial role in the scale-up.

The 14 remaining counties have an estimated 1,500 medicines store, with roughly 1,000 located in Nimba, Bong, Lofa, Maghibi, and Grand Basa. Scale-up could be phased in by starting with these counties first (see map below) and then expanded to the remaining nine. Other priority factors include current degree of access to pharmaceutical and health services, availability of training venues, and danger of illegal importation of poor quality medicines across the country borders.



The initial step in the AMS scale-up would be to combine nationwide sensitization of County Health Teams and medicine stores proprietors and dispensers with GIS mapping and preliminary inspection, which will occur on a county-by-county basis. This will allow the LMHRA, LPB, and Liberia GIS team to travel to the field only once, thereby reducing transportation costs and time. County Pharmacists are expected to be part of the team that does the mapping and preliminary inspections in their respective counties in addition to participating in the sensitization activities. The mapping exercise will provide updated data on the number of medicine stores in each county, which will better inform the roll out plan and budget estimates.

The medicine stores' owners and dispensers will be expected to contribute to the costs of renovating facilities and the training required to meet standards for accreditation. As needed, other public health programs such as the National Malaria Control Program (NMCP) will be asked to help support specific roll-out activities related to their respective missions.

LMHRA, with input from the AMS National Steering Committee, will coordinate the AMS roll-out, especially the inspection and oversight components. Strengthening the role of County Pharmacists in regulatory functions under LMHRA and LPB mandates should be a priority; this will contribute to sustainability and facilitate routine inspection and supervision activities within the counties.

Both LMHRA and LPB are eager to increase community awareness regarding the quality of products and services that they should expect from medicine stores and assure that people can easily distinguish between legally operating AMS and unlicensed sellers. Furthermore, the promotion of the AMS brand, which included a limited public education campaign coupled with joint inspection efforts by the LMHRA/LPB teams in Montserrado, has had some effect on the problem of drug peddling in parts of greater Monrovia. The scale-up of AMS, which are easily identifiable by their logo, will help isolate and eliminate the illegal operators who have avoided regulatory enforcement by closing their medicine stores during inspector visits. Maintaining the quality of services and products will require regular inspection and sustained public education using all media avenues. Training dispensers from the retail pharmacies in Monrovia which was outside the scope of the AMS program will also contribute to the overall improvement in the quality of pharmaceutical products and services in Liberia.

The allocation of government resources from Liberia’s budget to maintain LMHRA and LPB regulatory and enforcement activities will be necessary to assuring the program’s functioning. The LMHRA and LPB will need general technical assistance to scale-up and maintain the AMS program, while specific technical assistance will need to link additional interventions to the AMS program, such as the NMCP’s planned strategy to increase access to artemisinin-based combination therapies and rapid diagnostic tests in the private sector.

The table below summarizes key stakeholders roles and responsibilities.

<b>Key AMS Stakeholders and Their Roles</b>	
<b>Stakeholders</b>	<b>Key Actions and Responsibilities</b>
<b>MOHSW National Public Health Programs</b>	<ul style="list-style-type: none"> <li>• Plan and mobilize resources</li> <li>• Coordinate partnerships</li> <li>• Establish and communicate priority policies</li> <li>• Design and implement information systems</li> <li>• Monitor and evaluate</li> </ul>
<b>LMHRA in Collaboration with LPB</b>	<ul style="list-style-type: none"> <li>• Develop or revise guidelines; draft regulations and standards</li> <li>• Inspect and enforce</li> <li>• Maintain licensing and accreditation process</li> <li>• Develop training strategy and curricula</li> <li>• Oversee supervision and monitoring</li> <li>• Develop and implement information systems</li> <li>• Develop strategy and budget for program scale-up</li> </ul>
<b>County Health Team</b>	<ul style="list-style-type: none"> <li>• Coordinate at county level</li> <li>• Support licensing and accreditation processes</li> <li>• Conduct county-level inspection and enforcement</li> <li>• Conduct county-level supervision and monitoring</li> <li>• Support county-level implementation</li> <li>• Assure monitoring and reporting to national levels</li> </ul>
<b>Pharmaceutical Society of Liberia Training Institutions</b>	<ul style="list-style-type: none"> <li>• Conduct training needs assessment</li> <li>• Contribute to development of training strategy and curricula</li> <li>• Conduct training of proprietors and dispensers using different modalities</li> </ul>
<b>Private Sector</b>	<ul style="list-style-type: none"> <li>• Ensure availability of quality products to sell</li> <li>• Provide business practice support and linkages</li> <li>• Facilitate business financing</li> </ul>
<b>AMS</b>	<ul style="list-style-type: none"> <li>• Undertake shop renovations to meet AMS standards</li> <li>• Acquire AMS branding materials (signage and dispensing jackets)</li> <li>• Complete required training for AMS owners and sellers</li> <li>• Market services to consumers</li> <li>• Maintain standards and ethics</li> <li>• Counsel consumers and dispense medicines rationally</li> </ul>
<b>Technical Partners</b>	<p>Provide technical assistance to support the following:</p> <ul style="list-style-type: none"> <li>• Planning and resource mobilization</li> <li>• Development of policies, guidelines, regulations, and standards</li> <li>• Design and implementation of information systems</li> <li>• Implementation of select interventions</li> <li>• Development of strategy and budget to scale-up program Consumer Advocacy</li> <li>• Monitoring and evaluation</li> </ul>

#### **IV. Lessons Learned and Challenges from AMS Implementations in Montserrado**

Adapting the accreditation model to Liberia context has presented both significant challenges and opportunities that dovetail with Liberia's progress in building the pharmaceutical sector. For example, the newly formed LMHRA has been putting in place a more systematic and rigorous regulatory system for product registration and inspection of wholesalers/importers and has been making progress toward addressing issues of product quality in retail outlets and medicine peddling in the streets. The MOHSW and the NMCP in particular emphasize using retail outlets to deliver quality malaria medicines and to improve overall quality of pharmaceutical services. These policies, along with the strengthened regulatory framework and support from Liberian stakeholders, have been central to the successful adaptation of the ADDO model in the highly populated urban setting of Montserrado. Additionally, considerable interest and enthusiasm have come from the medicine stores themselves, who see accreditation as opportunity to enhance their skills and improve their business. Liberia's political commitment and support for the AMS program create a situation suitable for accelerated scale-up.

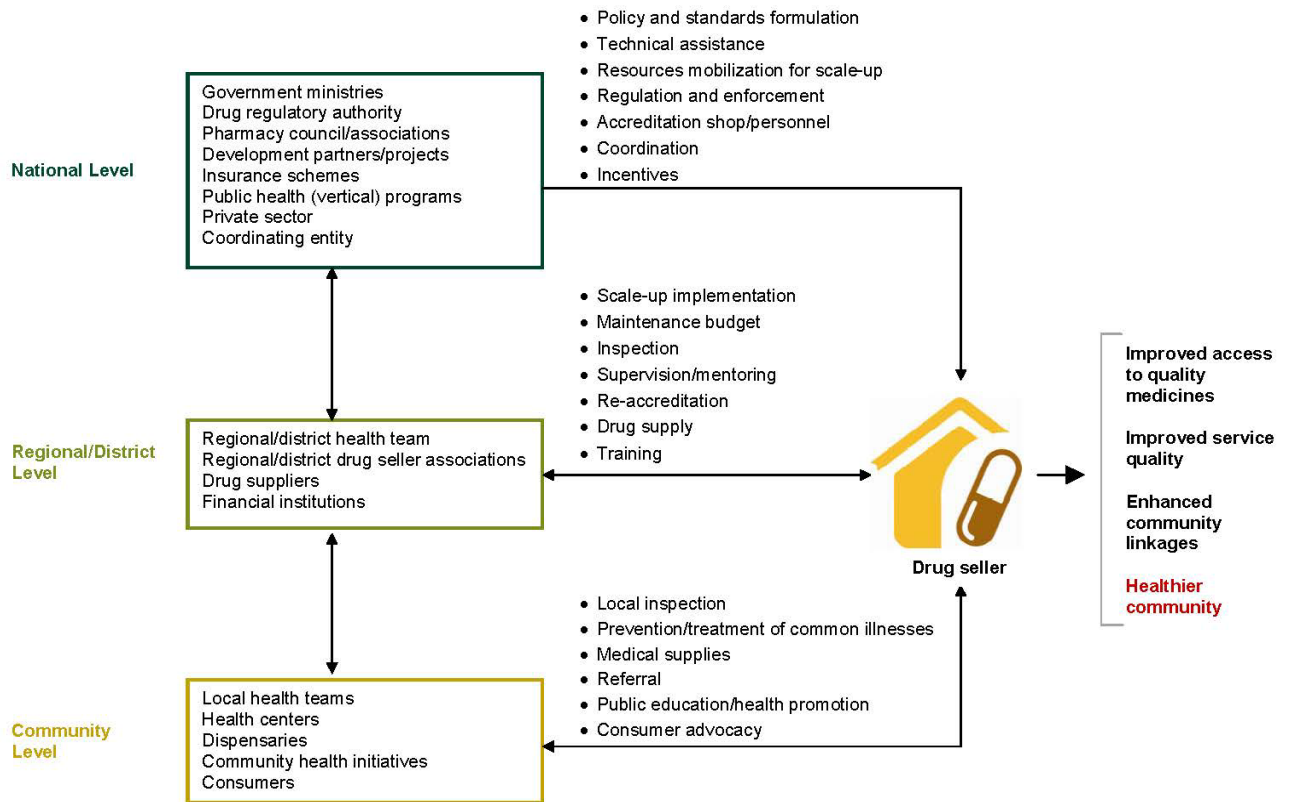
The experiences from implementing AMS in Montserrado County provide many lessons and challenges that need to be addressed as AMS expands. These include the following—

- Compliance with premises standards has been gradual but steady. To accelerate the pace, LMHRA and LPB will set a deadline by which all medicine stores in Montserrado must become accredited.
- The LMHRA/LPB joint inspection and monitoring strategy has worked well and standardized tools and checklists have improved the objectivity and thoroughness of the inspection process; however, better coordination of all inspection activities is needed to improve efficiency.
- A few medicines stores continue to avoid regulatory enforcement by closing during inspector visits. In addition, trained dispensers were not found in the stores during inspection.
- Some of the products sold at the AMS continue to be of sub-standard quality; AMS proprietors reported having purchased these products from legal pharmacies or wholesalers, which has been verified by inspectors. This situation underscores the importance of LMHRA's continued efforts to strengthen product registration and inspection of wholesalers/importers.
- The limited sensitization of consumers through various avenues—radio, newspapers, and road shows—appears to have improved consumer awareness of AMS, but only a sustained campaign focusing on consumer advocacy will have a lasting impact.

#### **V. AMS Enhancements and Linkages with Public Health Programs**

According to the World Health Organization, medicines play a major role in protecting, maintaining, and restoring people's health. The provision of appropriate medicines of assured quality, in adequate quantities, and at reasonable prices is therefore a concern of global and national policy makers and agencies implementing health activities and programs. As the accredited drug seller program has taken off in Tanzania and Uganda, its potential to increase access to essential medicines and serve as a platform for community-based public health interventions has been recognized. For example, the child health training module includes training the dispenser to recognize danger signs of pneumonia in children and take appropriate action. The dispenser training also includes a family planning component and accredited shops are permitted to sell family planning medicines and supplies, such as oral contraceptives and condoms. In Tanzania, early TB case identification and referrals by ADDOs are currently being tested. As a result of the increasing interest in an integrated model, the ministries of health, regulators, and other organizations and programs in Tanzania and Uganda have helped to expand the services that accredited drug shops provide.

Liberia stands to gain from these countries' experiences as it rapidly enhances the role of the AMS program in health care service delivery at the community level. The framework below shows the public-private sector (AMS) links at the national, county, and community levels.



**Figure: Drug Seller (AMS) as part of Health System Delivery Conceptual Framework**

## VI. Budget

Based on SDSI’s experience in implementing the program in Montserrado, the budget below shows the approximate cost of individual components. Scale-up costs will require development partner funding along with government support. As scale-up is completed; all maintenance costs will shift to the central and local government budgets and the private sector. Any vertical program would meet program-specific needs—for example, training relating to malaria case management using rapid diagnostic tests and ACTs. If multiple stakeholders share general scale-up costs, then specific initiatives can pick up costs specific to their disease or area of interest (e.g., training materials development, supervision and mentoring, evaluation).

## General Cost Estimates to Scale-up 14 Remaining Counties

Component	Specific Activity	Budget Assumptions	Budget
Stakeholder coordination	Hold quarterly National Steering Committee [NSC] coordination meetings	Meeting – lunch and refreshments for 20 participants	\$5600
Sensitization, implementation planning	Hold sensitization meetings with medicines stores owners and dispensers in 14 counties	Lunch allowance for 1500 proprietors, venue hiring charges etc. Costs already piggy backed with mapping below	\$23,200
GIS mapping and preliminary inspection	In collaboration with Liberia GIS Institute, map retail pharmaceutical outlets in 14 counties	7 teams @ with 3 people (inspector central, County Pharmacist and LIGIS GIS technician), 12 days, car hire & per diem.	\$45,850
Training of dispensers, owners of medicines store	Refresher training for 20 AMS trainers and orientation of 14 County Pharmacists	3-day workshop-34 participants- venue - meals	\$5400
	Conduct training of dispensers-of medicines stores in 14 counties	26 Days- 1500 PAX – 6 Trainers per county- No Lodging/PD, per diem for facilitators; lunch and tea included	\$343,290*
	Business training	5 days-for 1500 proprietors	\$147, 956*
Regulatory strengthening	Conduct inspector’s training for 14 counties pharmacist on AMS inspection strategy	14 participants, per diem and lunches for 2 days	\$5,400
Communication and marketing strategy	Implement marketing strategy at county level using different media for communication (14 counties)	Bill boards, medicines store boards, text messages, road shows, local radio messages and jingles	\$53,000
Final inspection, accreditation and launch	Conduct final inspection of medicines stores in 14 counties	7 Teams @ with 2 people (inspector central, county pharmacist), 12 Days Period, Car hire & Per Diem.	\$45,850
	AMS program launch with handling of AMS certificates, AMS logo and dispenser’s Coats]	Printing of 1500 Coats, AMS logo board and certificates	\$103,500
<b>TOTAL</b>			<b>\$779,046</b>

\*Assumes a 50% cost share from dispensers/proprietors

## Maintenance-Annual Budget Estimates\*\*

Component	Specific Activity	Budget Assumptions	Budget
Inspection	Conduct joint LMHRA/LPB quarterly inspection visits in all 15 counties	Cover car rental, per diem and venue for meetings	\$130,000
Stakeholder coordination	Conduct quarterly National Steering Committee [NSC] coordination meetings	Meeting – Lunch and refreshments for 20 participants	\$5600
Consumer and public education strategy	Implement national wide public education strategy using different media for communication [text messages, local radio messages, talk show and call-in program, printing of brochures and jingles]		\$53,000
<b>TOTAL</b>			<b>\$188,600</b>

\*\*Assumes 100% funding from government, this annual estimates is for a limited number of activities related to AMS program. Also assumes 100% pick up of other component funding by AMS dispensers/proprietors (e.g., training, store renovation).