SDSI
Sustainable Drug Seller Initiatives

SUSTAINABLE DRUG SELLER INITIATIVES PROGRAM

UGANDA

ENSURING REGULAR INSPECTION AND ENFORCEMENT OF STANDARDS IN ACCREDITED DRUG SHOPS

A consolidated report based on research, situational and options analyses, and stakeholder input

MARCH 2013

pharmaceutical systems africa

Prepared by Pharmaceutical Systems Africa for the Sustainable Drug Seller Initiatives Program

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ACKNOWLEDGMENTS

The following individuals from Pharmaceutical Systems Africa led the work that resulted in this report: James Olweny, Paul Kutyabami, and Lloyd Matowe, as well as consultant Juliet Kiguli.

PREFACE

The Sustainable Drug Seller Initiatives (SDSI) program continues Management Sciences for Health's efforts in Africa to involve private drug sellers in enhancing access to essential medicines. It builds on two previous MSH programs, which focused on creating and implementing public-private partnerships using government accreditation to increase access to quality pharmaceutical products and services in underserved areas of Tanzania and Uganda. SDSI's goals include ensuring the maintenance and sustainability of these public-private initiatives in Tanzania and Uganda, and introducing the initiative in Liberia.

In Uganda, SDSI objectives are to enhance the accredited drug shops' long-term sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and health system context. In order to achieve these objectives, SDSI commissioned local organizations ("contractors") to assess various components of the Accredited Drug Shop (ADS) initiative and develop recommendations for improvements.

Annex 1 provides further information about each component and identifies the contractor and their objectives. Nine factors affecting ADSs in Uganda were examined:

1) ADS Regulatory System
2) Supportive Supervision
3) ADS Seller Training
4) Mobile Technology
5) Geographic Information Systems
6) ADS Associations
7) ADS Supply Chain
8) Engaging ADS Consumers
9) Community-Based Health Initiatives

In completing their assignments, each contractor undertook three primary activities:

- Preparing a situation analysis based on qualitative and quantitative data on their topic gathered through extensive interviews and use of questionnaires;
- Analyzing the options for future action;
- Present the data, analyses, and options to stakeholders in a workshop, followed by a plenary meeting, so they could review and comment on the analyses and conclusions and make recommendations.

The contractors submitted their findings in three reports, one on each of the above. The reports were then compiled into single reports, like this one on ensuring regular inspection and enforcement of standards in accredited drug shops.

ACRONYMS AND ABBREVIATIONS

ADDO	accredited drug dispensing outlet
ADS	Accredited Drug Shop
DADI	District Assistant Drug Inspector
DHO	District Health Officer
DHT	district health team
EADSI	East African Drug Seller Initiative
HR	human resources
MoH	Ministry of Health
MSH	Management Science for Health
NDA	National Drug Authority
PSA	Pharmaceutical Systems Africa
PSU	Pharmaceutical Society of Uganda
RID	Regional Inspector of Drugs
SDSI	Sustainable Drug Seller Initiatives
SEAM	Strategies for Enhancing Access to Medicines
TFDA	Tanzania Food and Drugs Authority
VHT	village health team

1. EXECUTIVE SUMMARY

Studies in 2007 by the Medicines for Malaria Venture (MMV) on the antimalarial supply chain study in Uganda, and assessments by Management Sciences for Health (MSH) in 2008 in Mpigi and Kibaale Districts revealed irregularities in regulation and operations of Class C drug shops that require redress. These irregularities involved the selling of unauthorized medicines, dispensing of drugs by unqualified personnel, inadequate storage space and conditions for stocking of medicine, poor facilities, poor record keeping, and inadequate assortment of medicines for sale, as well as high and variable prices, inadequate regulatory oversight with infrequent inspections by NDA and irrational drug use. These anomalies denied the public access to quality, safe, effective and affordable medicines particularly in rural and peri-urban areas, in contradiction with the National Drug Policy objective.

As a result of the irregularities revealed in Class C drug shops, the Sustainable Drug Sellers Initiatives (SDSI) was established in Uganda. In 2008, the Ministry of Health (MoH), through the Uganda National Drug Authority (NDA) and in collaboration with MSH, explored the potential for adapting the accredited drug dispensing outlet (ADDO) model successfully implemented in Tanzania to Uganda. The aim was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural, underserved areas where there are few or no registered pharmacies. A pilot project establishing a network of Accredited Drug Shops (ADS) to provide selected essential medicines and other health supplies was established and implemented in Kibaale District in 2009.

Pharmaceutical Systems Africa (PSA)-Uganda undertook situational and options analyses to document the ADS regulatory system and experience in Kibaale District, explore options for a sustainable ADS regulatory system, and recommend strategies and tools that would help ensure regular inspection, reaccreditation, and enforcement of ADS standards. The objective was to find out how to enhance the ADS initiative's long-term sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and the health system context.

MAIN RESEARCH FINDINGS

PSA-Uganda's main findings centered on the regulatory system processes, inspection, licensing and accreditation, and enforcement of standards.

Regulatory System Processes

The regulatory experience used by NDA during the pilot phase had five basic steps, as shown.

- The licensing and accreditation cycle begins in October when the ADS shops collect the forms and pay the fees. By January all shops should have submitted their applications.
- The licenses are issued for one year (January 1 to December 31).

Inspection of Premises

- Each shop was inspected from three to five times in 2011. Local/district teams conducted most of these inspection encounters, rather than the NDA/central teams. Both local and central inspections were structured and used a checklist. In general, the Local Inspectors strengthened the Central Inspectors with the overall regulatory function of ADS shops.
- Most Inspectors spent between 15 and 45 minutes on the premises, and the working relationship was described as "very good" and "friendly."
- The main problems or "deficiencies" at pre-inspection were with records, dispensing, supervision and management support, shelves and cupboards, roofs, and floors—in that order. Most of these were rectified during the accreditation process.
- The numbers of active Local Monitors declined from 19 in 2001 to 13 in 2010 to 8 in 2011. This drastic decrease in numbers was due to the end of the pilot phase of the program.

Licensing and Accreditation

- The study found that a majority of drug shops were licensed (97 percent) and accredited (86 percent).
- By July 2012 there were 204 licensed drug shops in Kibaale District for both human and veterinary medicines.
- The preferred period for reaccreditation was one year.
- Over the years, the total number of drug shop enterprises inspected declined, mainly because unworthy ones were dropping out. At the same time, the number of shops accredited was constantly increasing, and the number of shops recommended for closure fell sharply.
- The majority (70 percent) had no difficulty complying with ADS Standards.

Enforcement of Standards

- The drug shop owners and sellers appreciated the ADS regulatory system. They tried to follow and adhere to the regulations, as guided by the Inspectors from the NDA and Local Monitors.
- Inspection and enforcement of standards among the ADS drug shops was regular and structured, and the drug shops had shown significant improvement during the pilot phase in the Kibaale District in standards of practice and premises. However, when there is no regular inspection and supportive supervision, there is deterioration of the standards of practice and premises among the ADS.
- From focus group discussions and stakeholders' interviews, three ways were reported to be effective in the enforcement of the ADS standards:
  - Dialogue, "they change when we talk to them"
  - Closure of premises & the impounding of drugs
  - Litigation, only in extreme circumstances (this was the least preferred by regulatory enforcers).

RECOMMENDATIONS

Following the options analysis, financial and human resources stood out as being strongly linked to the success of several components of the ADS program. To sustain and improve the model for ensuring regular inspection and enforcement of standards, these bases need to be supported. Specific recommendations follow.

Regular Inspection

- ***Self-regulation.*** ADS regulation from the inside can be enhanced by strong associations, which have the potential to be a strong factor in self-regulation. Models can be found in successful shop associations like the one in Mityana District, where all drug sellers—including herbalists, drug shops, and pharmacies—are controlled and standards enforced by the association, whose membership is

compulsory. Group self-regulation is less expensive, friendlier, less prone to corruption, and sustainable.

- ***Community policing.*** Community sensitization, for example using radio talk shows, will facilitate community policing to uphold the ADS standards. An informed community can be more aware, active, and effective in providing outside scrutiny.
- ***Annual fees***. The annual fees paid can be discounted/amortized for inflation and other economic shocks, but no fees should be added. What is paid should be utilized for regular supportive supervision and inspection. Any addition will be prohibitive**.**

Ensure Enforcement of Standards

- ***Closure and impounding****.* Improve the closure and impounding model to improve enforcement. This involves follow-up of the deficiencies identified and dialogue to rectify them. This will limit the number of unproductive litigations.
- ***Licensing and accreditation***. Clearly defined, legally instituted regulations and consequences—including shop closure and impounding of stocks or delay, denial, or revocation of a license or accreditation certificate—should be linked to failure to uphold standards. Use revocation or denial of a license or accreditation certificate in next issuance to enforce standards if standards (e.g., human resources, premises, practice) are not upheld. Specifically, link the recommendations by the association, Local Monitors, DADI, SDSI Coordinator, and the Regional Inspector of Drugs (RID) to denial of accreditation certificate if the shop does not work to carry out the recommendations.
- ***ADS in existing laws and regulations****.* Incorporate ADS in existing laws and regulations, specifically, rescheduling the expanded list of medicines, and standards of premises and practice, to improve medicine regulation within Uganda's legal framework.

Cross-cutting Issues

The following recommendations require communication and coordination among various actors and will contribute to the success of the program in multiple ways.

- ***Foster multisectoral linkage****.* Linkage among the NDA, the district local governments, the Ministry of Health, drug sellers associations, and development partners is critical because the interventions proposed do not fall under one core regulatory body.
- **Gender-sensitive planning, ethics, and integrity.** Gender sensitivity should be considered in selection of Local Monitors.
- ***Supplies****.* The NDA should develop, update, and issue uniform supplies for accreditation (e.g., dispensing logs, reference books and job aids, referral books, white coats) at a reasonable fee or make them available through associations at a further subsidized fee. This will ensure standardization.

2. BACKGROUND

The Bill & Melinda Gates Foundation provided Management Sciences for Health with a three-year grant to continue its efforts in Africa to involve private drug sellers in enhancing access to essential medicines. The Sustainable Drug Seller Initiatives (SDSI) program builds on MSH's Strategies for Enhancing Access to Medicines (SEAM) and the East African Drug Seller Initiative (EADSI) programs, which focused on creating and implementing public-private partnerships using government accreditation to increase access to quality pharmaceutical products and services in underserved areas of Tanzania and Uganda.

Studies in 2007 by the MMV on the antimalarial supply chain in Uganda and assessments by MSH in 2008 in the districts of Mpigi and Kibaale revealed irregularities in regulation and operations of Class C drug shops that required redress. The anomalies included the selling of unauthorized medicines; dispensing of drugs by unqualified personnel; inadequate storage space and conditions for the stocking of medicine; poor facilities that were not well maintained; inadequate record keeping; inadequate assortment of medicines for sale; high and variable prices; inadequate regulatory oversight, with infrequent inspections by the National Drug Authority; and the irrational use of medicines. Such problems deny the public access to quality, safe, effective, and affordable medicines, particularly in rural and peri-urban areas, and contradict the objective of Uganda's National Drug Policy.

SDSI was established in Uganda in response to the problems revealed in the regulation and operation of Class C drug shops. In 2008, the MoH, through the NDA and in collaboration with MSH, explored the potential for an Accredited Drug Shop program similar to the successful accredited drug dispensing outlet (ADDO) program in Tanzania. In Uganda, the SDSI objective is to enhance the ADS initiative's long-term sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and the health system context. The program aims to improve access to affordable, quality medicines and pharmaceutical services in rural, underserved areas. A specific activity within these objectives is to strengthen the ADS regulatory system, including ADS reaccreditation.

EADSI determined what it would take to successfully adapt the ADDO model for Uganda, and a pilot project establishing a network of Accredited Drug Shops to provide selected essential medicines and other health supplies was introduced successfully in Kibaale District in 2009, with the Mpigi District as the control. Results from the project evaluation showed that district health officials, shop owners, and sellers have embraced the ADS initiative. The EADSI program evaluation also identified regular inspection as a critical element to ensure that the ADS shops maintain the standards and don't engage in illegal activities, such as administrating injections.

The regulatory inspection was conducted by the District Assistant Drug Inspector (DADI) and the National Drug Authority's ADS Coordinator in collaboration with the Regional Inspector of Drugs (RID) for the Western Region. Health Assistants were also trained as Local Monitors to support the routine inspections. The Local Monitors had no powers to close any licensed drug shop but would make recommendations to the DADI and the NDA to take action in the event that some ADS or drug sellers failed to adhere to the set standards.

2.1 Objectives of the Study and Analyses

Pharmaceutical Systems Africa (PSA)-Uganda undertook situational and options analyses to document the ADS regulatory system and experience in Kibaale District, explore options for a sustainable ADS regulatory system, and recommend a strategy and tools that would help ensure regular inspection, reaccreditation, and enforcement of ADS standards. The study aimed at finding out how to enhance the ADS initiative's long-term sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and the health system context.

2.2 Specific Study Activities

The seven principal study activities, starting with data collection and ending with shaping the final recommendations at the Stakeholders' Meeting, are summarized below.

1) Develop data collection tools for and conduct interviews with a random sample of 30 ADS owners/sellers in Kibaale District (10 in Buyaga, 10 in Buyanja, 10 in Bugangaizi), district health officials, Local Monitors, the DADI, and the Regional Inspector of Drugs of the Western Region.
2) Document the ADS regulatory experience to date in Kibaale District and gather information on how to improve the current ADS regulatory inspection system, enforce standards, and establish requirements for reaccreditation. The documentation of the ADS regulatory system in Kibaale included frequency of inspection and local monitoring visits, actions taken by teams, results of regulatory activities (were enforcements carried out? were instructions for improvement followed?), and costs.
3) Draft data collection instruments and conduct central-level key informant interviews with the NDA ADS coordinator, NDA Inspectors, and SDSI staff who participated in the Kibaale pilot program to document their views on the ADS regulatory experience to date and collect information on improving the current ADS regulatory inspection system, enforcement of standards, and requirements for ADS reaccreditation.
4) Draft a situational analysis report on the experiences, challenges, and opportunities for ADS regulatory enforcement of standards in Kibaale.
5) Determine crucial issues that need to be addressed and recommendations for future strengthening and sustainability of the system, including processes and requirements for ADS reaccreditation, by conducting an options analysis;
6) Present situational analysis findings and the recommendations based on the options analysis at a key stakeholders' workshop, and document workshop discussions and final recommendations through the development of a workshop report.
7) Based on stakeholders' discussions and recommendations, recommend a strategy for ensuring regular inspection and enforcement of standards in the ADS and requirements for ADS reaccreditation.

3. METHODOLOGY

3.1 STUDY DESIGN AND SCOPE

A descriptive, cross-sectional design was adopted that used both quantitative and qualitative methodologies for the study. The qualitative assessment used questionnaires, coupled with observations and interviews, to look at how ADS shop owners and sellers deal with ADS standards, inspections, and the accreditation process; how inspectors, monitors, and government officials perceive the inspection process; and how the association supports the drug shops.

A semi-structured questionnaire, interview guides, tape recorders, and photography equipment were used to gather and document data. The quantitative assessment looked at the challenges being experienced and opinions on how to mitigate the challenges in meeting ADS standards of practice. The aim of using different methods of collecting information was for triangulation purposes.

3.1.1 Study Area

The survey was conducted in Kibaale District among 30 drug shops found in its three counties—Buyanja, Buyaga, and Bugangaizi.

3.1.2 Study Sample and Sampling Techniques

The 30 drug shops used in the study were randomly selected from a list of 204 registered drug shops (annex 8). If a veterinary outlet was accidently selected, it was dropped and another shop was picked to replace it. A total of 30 shop owners or sellers were interviewed and used for the analysis.

Additionally, 10 key informants were selected to be interviewed for this study: five Local Monitors (out of seven in the whole district), a District Assistant Drug Inspector, a Secretary of the Kibaale Association of private drug shops, a SDSI Coordinator at the NDA, a Western Regional Inspector of Drugs, and a SDSI Program Manager at MSH.

3.2 Study Process and Procedure

3.2.1 Desk Review

A desk review of the available literature on the ADS regulatory system was conducted. The following documents were reviewed:

- The National Drug Policy and Authority Act, 1993;
- The National Drug Policy and Authority Regulations, 1995;
- Review of court notes on the penalties and sentences in 2011 in Kagadi grade 1 magistrate court;
- Inspection of Drug Shops in the Kibaale District for Licensing and Accreditation Report, 2009;
- Follow-up inspections for ADS, April 2011;
- Kibaale District Local Monitors' inspection reports, 2010;
- Pre-inspection report for Class C drug shops seeking accreditation in Kibaale District, 2009;
- Enforcement activities report in Kibaale District (Buyaga County), August 2010.

The aim of the desk review was to inform the study team on the ADS regulatory system so as to develop and present options for ensuring sustainable regular inspection and enforcement of standards among the accredited drug shops.

3.2.2 Standardization and Adoption of Field Questionnaire and Interview Guide

The study team developed a questionnaire based on the standards of practice stipulated by the program and sections of the laws, including how misconduct is handled and the penalties assessed. The emerging themes were then developed into questions. The questionnaire and the key informant guides were then discussed with the team from MSH. Afterward, the tools were pretested for validity and appropriateness. The final tools were then revised and any issues raised by MSH and as a result of the pretest were addressed, and the changes were incorporated prior to field data collection.

3.3 Data Collection

3.3.1 Questionnaires

The 30 shop owners or sellers were assessed at their shops (annex 2). Four trained Research Assistants were used to administer the questionnaire. They would paraphrase the questions, when necessary if the respondent did not understand what was being asked. All 30 questionnaires were filled out, with accompanying field notes.

3.3.2 Key Informant Interviews

The key informants selected were district health officials, District Inspectors, five Local Monitors, and the one Association Secretary. A media player and a recorder were used to collect information from the key informants. The interview would begin once consent to record the conversation was requested and attained from the respondent (annex 6). For each interview, there was an interviewer and another person as a note taker present using a recorder and taking notes. When required, a researcher would probe the respondents for more information. (See annexes 3–5.)

3.3.3 Direct Observation

The Research Assistants made direct observations of the operations of the drug shops. They were looking to see whether drug shop sellers followed the ADS regulatory system practices, for example, whether they wore white coats while serving customers or if they were filling out the logbook or prescription book. They also observed the dispensing practices and stock management as well as the physical state of the shop and premises. Additionally, they checked records kept by the drug shop owners and sellers on visits by the Local Monitors and NDA Inspectors to see what the Inspectors had written about how the drug shops needed to improve or ADS regulations that needed be followed.

3.3.4 Photography and Voice Recording

Photographs were taken of the different drug shops to depict what ADS drug shops looked like in the different counties. Permission was requested before the photographs were taken of the drug shop premises.

3.4 Data Management and Analysis

The recorded interviews were transcribed and the data collected were entered into an Excel spreadsheet. It was reviewed to avoid any unwanted or irrelevant words. Themes were identified and information was coded for analysis. It was manually analyzed and interpreted using manifest content analysis. Photovoice[1] was applied to existing situations to emphasize the interpretation of what drug shops in Kibaale District looked like after the ADS program began.

The quantitative data were summarized into frequencies and measures of central tendency and dispersion. The findings in this report are presented descriptively, accompanied by visual representations of the data.

4. Study Findings

4.1 Description of the Personnel and Shops Surveyed

Thirty drug shops were surveyed. The majority of shop attendants interviewed were sellers (n=26, 90 percent). Only three owners (10 percent) participated in the survey (figure 1).

[1] http://en.wikipedia.org/wiki/Photovoice

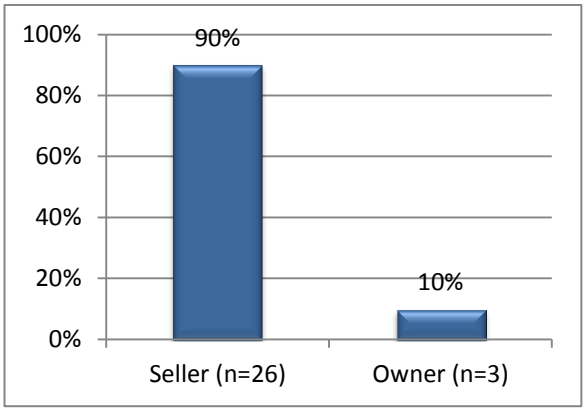

Figure 1. Position of attendants interviewed (N=29)

Most of the staff had worked in the shops for an average of two years, but the length of service ranged from three weeks to nine years. Figure 2 shows the distribution of the period worked in the shops.

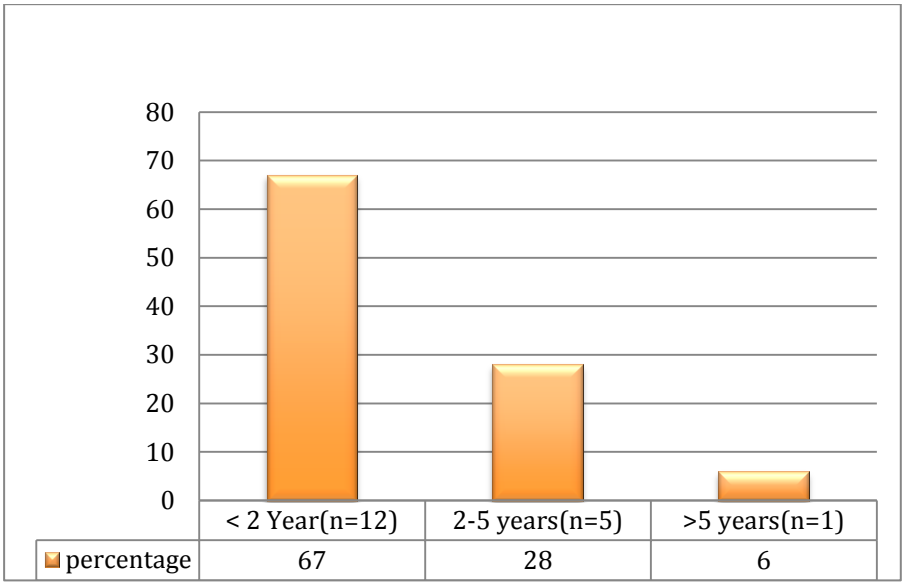

Figure 2: Period worked in the drug shop

4.2 LICENSING

In Kibaale District, the licensing and accreditation cycle begins in October, when the ADS shops collect the forms and pay the fees. By January all shops should have submitted their applications. The licenses are issued for one year (January 1– December 31). By July 2012 there were 204 licensed drug shops in Kibaale District for both human and veterinary medicines.

Of the shops assessed, 97 percent (28) held a Class C license, and 86 percent (24) held the accreditation certificate from the National Drug Authority (figure 3).

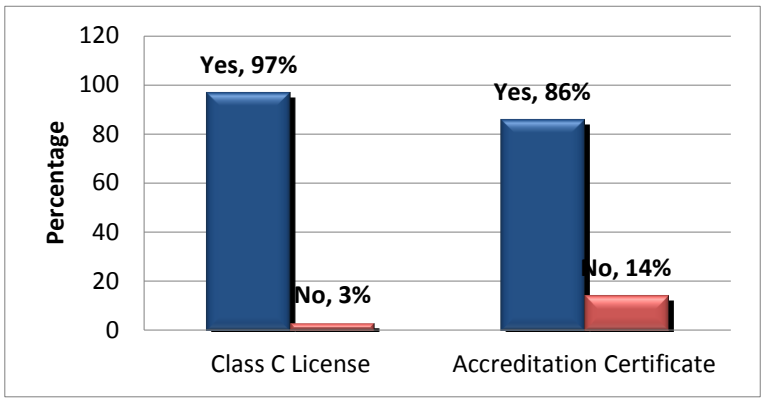

Figure 2. Shops assessed with a current Class C license and accreditation certificate

Typically, most of the drug shops had their certificates prominently displayed in the shop to indicate they were licensed and accredited, as seen in the accompanying photo taken in the Muhorro trading center.

4.3 ACCREDITATION

4.3.1 Knowledge of the Accreditation Process

The ADS program conducted training for drug shop owners, and many drug shop owners were aware of the necessary accreditation requirements for ADS (figure 4). Annex 7 illustrates the procedure that was used for application, inspection, accreditation, and support process.

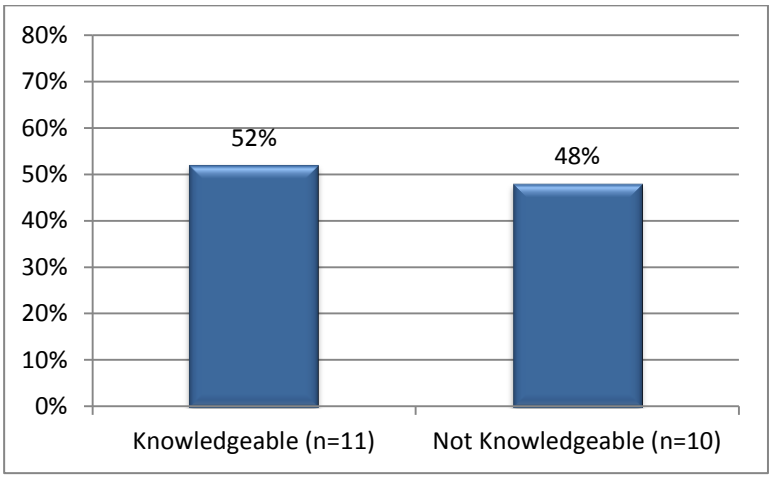

Figure 3. Sellers' and owners' knowledge about the accreditation process

4.3.2 Human Resource for ADS

Most drug shop owners work somewhere else, such as in public- or government-owned health facilities. They employ mostly nursing assistants to sell in their drug shops.

Experience with the accreditation process

"Enjoyed training, like dispensing, hygiene topics, patient care. Yes, would like a refresher."

"Interesting, learned how to record."

"Learned a lot."

"Learned a lot, how to treat."

"Enjoyed eating, sharing experiences."

4.3.3 Period for Reaccreditation

The preferred period for reaccreditation expressed by owners and sellers was one year (figure 5).

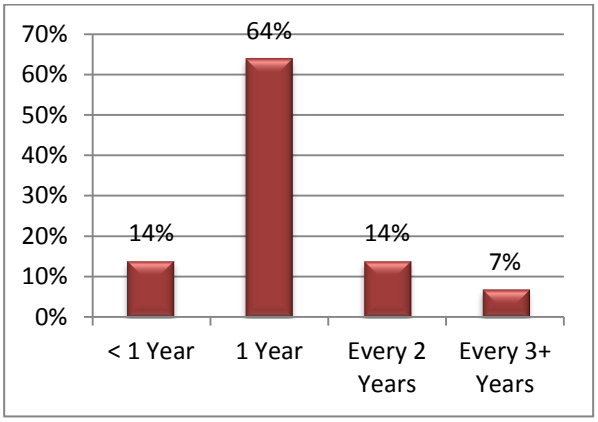

Figure 4. Preferred period for reaccreditation

4.4 INSPECTIONS

Regular inspections of ADS shops were done using a structured inspection checklist. Personnel doing the inspections were both the local district health team (DHT), including the District Assistant Drug Inspector (DADI), and inspectors from the NDA (the Western Regional Inspector of Drugs and the SDSI focal person).

4.4.1 Reporting Structure and Coverage

Seven Local Monitors, who each cover two or three sub-counties, inspected the drug shops. These monitors report to the DADI and the District Health Officer's (DHO) office. During the pilot phase, the SDSI Coordinator and the Western Regional Inspector of Drugs, who covers 11 districts, were both NDA employees.

Roles performed in the shops by the Local Monitors or Inspectors

"Ask on patient treatment; malaria, diarrhea, customer care."

"Ask questions about the business, check the drugs for expiry, cleanliness, advise on treatment (e.g., diarrhea, zinc, and metronidazole or ORS)."

"Ask questions, check premises, drugs, and records; suggest changes, sign, and go."

"Check for expired drugs, cleanliness, daily sales book, and patient turnover."

"Check medicines records, stock records, dusting of shelves."

"Check the dispensing log, sign Inspector's book."

"Use checklist for ADS."

In 2011, Central Inspectors had visited the majority of drug shops at least three times. However, some shops had not been visited at all. The Local Monitors visited drug shops regularly and reported to the DADI. It was found that once they were inspected and told to improve, the drug shops did so, as directed. In most cases, no penalties were enforced.

4.4.2 Human Resources for Inspection

In the NDA inspection system, the Regional Inspector, together with the DADI, carried out the inspections of the shops that had applied for accreditation. In addition, in order to strengthen and enforce the standards and regulations effectively, a cadre of Health Assistants from the district was selected to locally monitor the shops and carry out routine inspections.

Local Monitors in the pilot phase were Health Inspectors; initially there were eight active members, and then there were six. They had the minimum qualification of a Health Inspector Certificate and were employed by the district.

The Local Monitors have no powers to close any licensed drug shop but will make recommendations to the DADI and NDA to take action in the event that some accredited drug shops or drug sellers fail to adhere to the set standards. They will also be the ears on the ground for NDA to report the unlicensed premises involved in the sale of medicines.[2.]

Local Monitors and Inspectors on their role

"We like our work, and we are always with these people, if we are passing by always visit the shops we and we advise them." —A Local Monitor

"We feel that the name Local Monitors should be changed to Health Inspectors, the word local is demoralizing. We like our work and it's easy to do." —A Local Monitor

"They know their work, and they are always in touch with me. They help me reach far places I take long to go." —DADI, Kibaale District

[2] SDSI/MSH inspection model used in the pilot phase.

- They would like to have their titles changed from "Local Monitors" to "Health Monitors." The word "local" held negative connotations not relating to the work they did.
- Gender sensitive planning, ethics, and integrity should be considered in the selection of Local Monitors to ensure gender balancing of the roles and attitudes of monitoring in the ADS regulatory system. Female monitors (2) were found to be friendly and less forceful, unlike their male counterparts (5), who were more aggressive, assertive, and accusatory toward shop owners/sellers. The men were also more susceptible to bribery, but did not take any money offered by drug shop owners/sellers when carrying out their supervisory roles.

4.4.3 Frequency of Inspector Visits

In 2011, Local Monitors visited a shop four or more times, compared to Central Inspectors, as illustrated in figure 6.

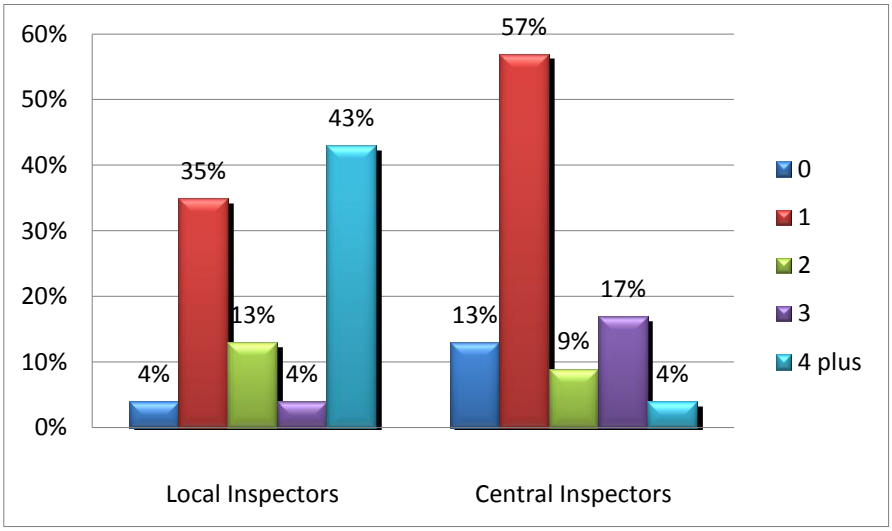

Figure 5. Number of times in 2011 drug shops were visited by Local Monitors and Central Inspectors

4.4.4 Time Inspectors Spent in Shops

Time spent by Inspectors in the shops ranged from a few minutes up to one hour. Their activities in the shops varied from a detailed check of records and stock to a simple courtesy call, as illustrated in figure 7.

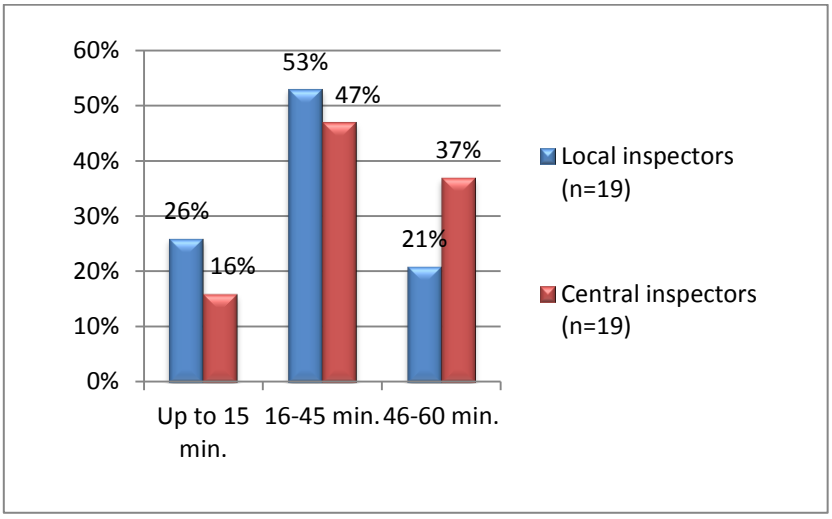

Figure 6. Approximate time spent by Inspectors in each shop

Few shop sellers had experiences with the Inspectors, but one who did described it thus:

> *"They come just to drop the licenses." —A shop seller in Karuguza.*

4.4.5 Preference for Central Inspectors or Local Monitors

A preference for Central or Local Inspectors by the drug shop dispensers was assessed during the survey. The majority did not express a preference for one over the other (figure 8).

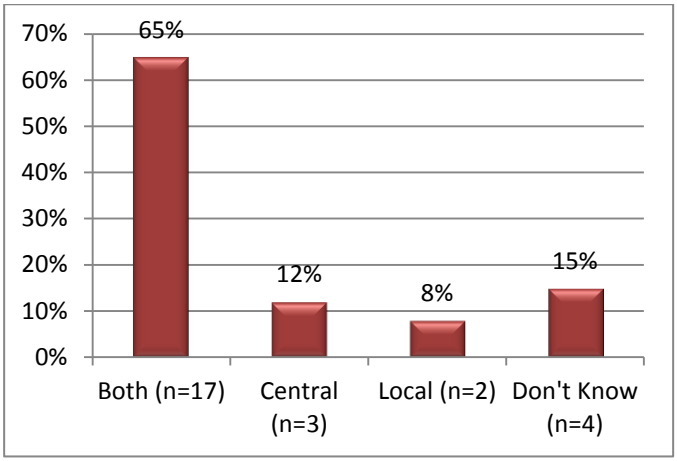

Figure 7. Preference for Local Monitors or Central Inspectors, or both

Experiences of shop attendants with the Inspectors

"Good, they correct me where am wrong, give advice."

"I like it so much, helps me to be up to date."

"Inspection is very important, learned how to keep drugs safe, and cleanliness."

"I like them, they give advices."

"I like them, they are the ones who inform us about ADS, advise cleanliness, how to buy drugs."

"Little experience with Inspectors; only comes and drops the licenses."

"Okay, no problem with them." "Provide guidance."

"We like them because they give advice on our work."

"They are good, they visit us, advise us to be good."

"Check for expired drugs."

"Tells me what to do, clean, remove bad drugs, expired drugs."

"They are good, keep advising us on how to handle our patients."

"Very good, all that is requested have been done."

"Very helpful when they come, this year has not been regular as in the past."

"Very nice, they advise us, update us on new things."

4.4.6 Working Relationships

The working relationship among the shop owners and sellers, the Inspectors, and the Local Monitors was generally described as "very good" and "very friendly."

> *"Just that trading license to the local government is killing us."*

Working relationship between shop owner/seller and the association:

> *"We have not heard of the association."*

4.4.7 Reasons for Accrediting Drug Shops

The main reasons the shops had accredited were discussed, and the shop attendants told us why the shop was accredited, as below:

Reasons for Accreditation

"It is compulsory."

"Make more money; no longer run away when Inspectors come."

"In the past, we used to stock many drugs, they gave us a list of drugs to sell, they taught us how to arrange and clean the place and referral."

"Wanted to sell expanded list, (not limited to Class C) more profits."

4.4.8 Difficulties Experienced Accrediting Drug Shops

The 14 shops that responded said they had experienced no difficulties in accrediting the shop.

> *"It is not hard…Don't think there are any problems." —A Shop Seller in Karuguza.*

The main difficulty reported was human resources for the ADS shops.

> *"Retaining trained sellers is hard, maybe we should have a policy where the trained sellers work for some specified time." —A Shop Owner in Kagadi.*

4.5 Medicine Schedules

The medicines on the ADS-approved list were considered adequate for community demand and the qualification of the health worker in the ADS. The majority of illnesses treated among the shops were asthma, gonorrhea, respiratory tract illness, fever, malaria, upper respiratory infection, and injuries.

Despite having many medicines, even ones beyond the Class C schedule, some medicines that were not on the ADS list were still being requested (figure 9).

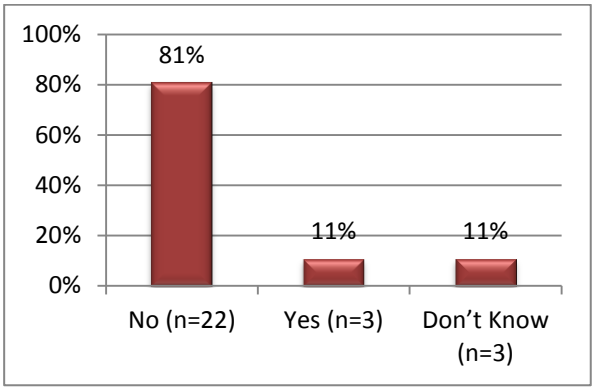

Figure 8. Respondents' opinions: Does expanded list of medicines adequately cover medicine needs? (*N*=28)

In addition, many shop attendants admitted to people preferring injectables because they think diseases are cured by injectables. However, none of the shop sellers admitted that the owners bring unregistered medicines to the shops.

Other problems expressed by owners and sellers concerning the medicines list

"The medicines we have cannot cover patients with prescriptions."

"People ask for more than the list."

"Some we don't have because we are not allowed to have them."

"We miss a lot of money from medicines not on the ADS list."

List of some medicines commonly requested, but not included in the list:

- Ampiclox capsules
- Cloxacillin capsules
- Diclofenac injection
- Cephalexin capsules
- Fansidar tablets
- Chloroquine tablets
- Oral antifungals
- Antivirals
- Injectables
- Hypertension medicines
- Man power enhancers (male impotence pills)
- Mediven (betamethasone cream)
- Ketoconazole tablets and cream
- Omeprazole
- Piroxicam capsules
- Injectables—penicillin procaine fortified, quinine, inject-a-plan
- Propranolol tablets
- Ampicillin
- Ergometrine
- IV fluids (e.g., dextrose 5%)

4.6 STANDARDS OF PREMISES

Some of the shops needed to work on different areas to meet the standards of premises recommended by the Inspectors and Local Monitors in 2011 (figure 10).

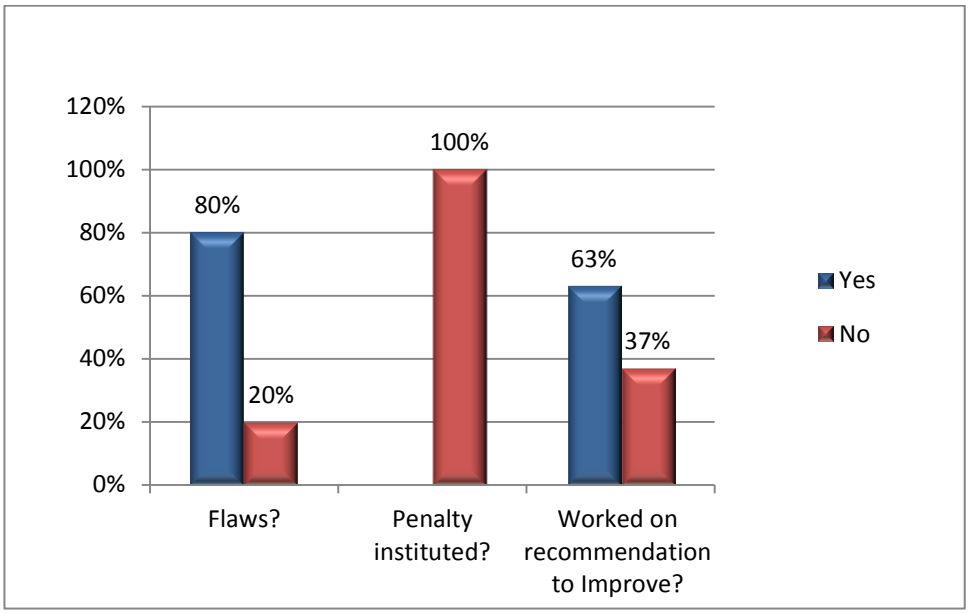

Figure 9. Shops found to have flaws in standards of premises, and actions that followed

Advice shops received to meet ADS standards
"Advised to buy more drugs, renovate, paint the wall and ceiling."
"Advised to dust daily."
"Buy carpet; repaint walls, shelves, and ceiling; replace broken glass."
"Dirty walls—repaint. No glass—buy glass."
"Recommended to buy carpet, provide a washing facility, keep purchase records."
"Renovation of the whole house, verandah, paint walls and ceiling, put a carpet."
"Told to renovate verandah and put a carpet."

Respondents had a mixed response when asked how difficult it was to get premises that meet ADS standards in Kibaale. Some sellers expressed the fact that it is difficult to find premises for a drug shop because one needed to be financially capable.

Opinions expressed by shop owners/sellers on attaining appropriate premises

"It would mean that you needed 800.000/-to 1 million Ugandan shillings to set up a drug shop. The ADS required one to meet some basic standards indicating quality of a drug shop, and these were: have a ceiling, clean and plastered floor and others. It is difficult to set up a new drug shop because one needs a lot of money." —Drug seller, Kakumiro

"Expensive." "Cost one million."

"Financial constraints, most no shops are constructed without a ceiling or painting, it is difficult, you are given a room with no ceiling, shelves, and floor."

"Hard, no good shops."

"Hard, you have to rehabilitate your shop."

"Very difficult, requirements involve making adjustments on the house, yet the landlord cannot bear the cost."

"You have to construct it yourself, landlords don't allow to change their house and can chase you any time."

"It is easy."

4.7 Standards of Practice

Of the shop owners and sellers interviewed, 70 percent said they did not have any difficulties complying with the ADS regulations when working as a dispenser (figure 11). Those that expressed problems said it was because the medicines list needed to be expanded, they were not allowed to sell injectables, and their clients cannot afford to buy full doses.

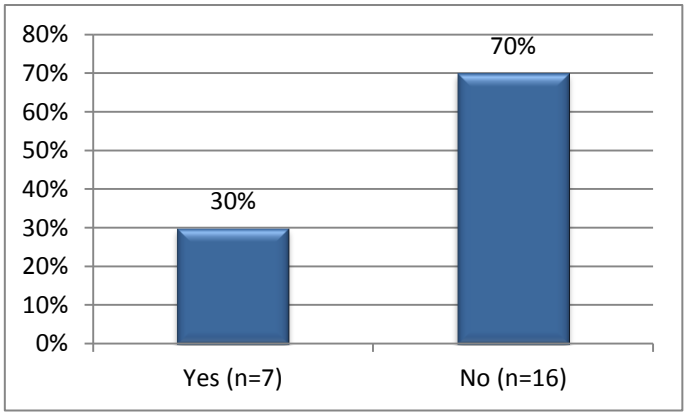

Figure 10. Sellers' difficulty complying with ADS standards

4.7.1 Compliance with the "White Coat" Regulation

Both sellers and owners reported difficulty complying with the ADS regulation requiring them to wear a white coat while dispensing. Some reasons given included:

- "Coat was stolen."
- "Don't have white coat."
- "It is hot."
- "White coat can be inconveniencing."

Owners' influence on sellers abiding by ADS regulations

"Yes—was good influence to abide by the ADS regulation."

"There is more money in selling full doses."

"She is helpful, encourages me to obey the ADS regulations."

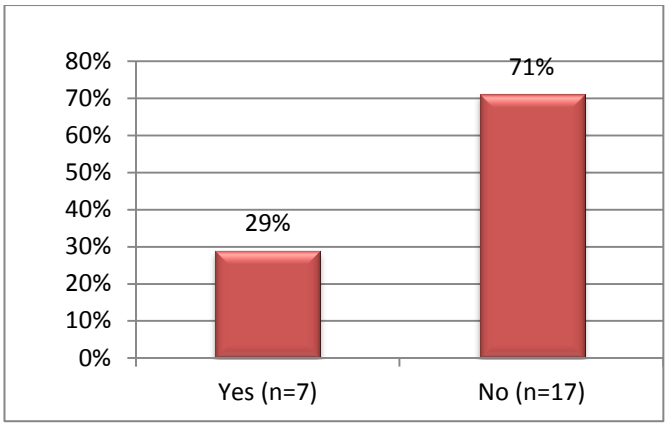

Figure 11. Reported influence on sellers by the owners on ADS regulations (*N*=24)

4.7.2 Record Keeping

A majority of the drug shops had dispensing logbooks and prescription books. A few shops did not have them or had their own black books (not provided by the ADS) to record patients and drug dosage. The purpose of the logbooks is to track patients and record the dosage for the treatment of the diseases. Many of the shops tried to comply with the required standards of record keeping; however, the records and comments given by the Local Monitors indicated that some shops needed to improve bookkeeping.

Drug shop dispensers' experiences filling in the dispensing logbook

"We only write full doses, but it's easy."

"Do not use it."

"Easy to use."

"But too big."

"I don't have a log, not difficult, my boss wants the records locked up, only In-charge uses it."

"Logbook used up."

"My boss has locked away the register for inspection but I have a personal black book."

"No dispensing log."

"Remove column for complaints since person comes from health center when has received some drugs."

"It's difficult to ask men their name and age for everything they buy."

"Even diclofenac for 500/- you write? eeh"

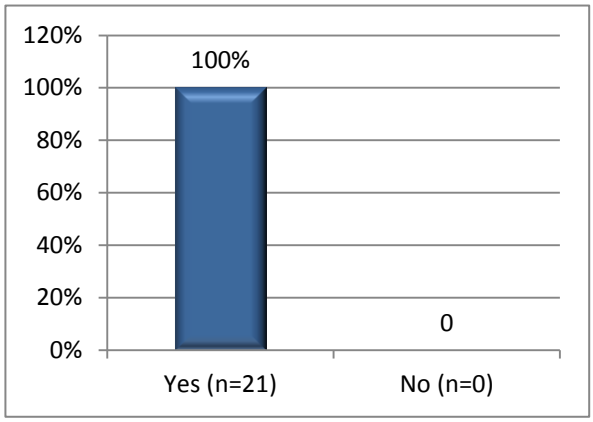

Figure 12. Opinion on whether use of the logbook should be continued

Reasons drug shop dispensers give for the benefits of using logbook

"For inspection."

"Keeps up to date on drug stock."

"Helps follow up patients."

"Helps provide information on treatment which can be reviewed and corrections made."

"Helps seller to do accountability with owner."

"Helps track money made and drugs sold (accountability)."

"Helps us calculate properly how much we have sold."

"Helps track number of patients per month."

"Monitor patients' response and what to give if the first medicine does not work."

"Helps you to assess the performance of the business."

Suggestions to improve efficiency of the logbook registration process

"The logbook had been used up already."

"Remove the column for complaints."

"Reduce some lines, like patient complaints."

"Book is too big."

4.8 SUPPORTIVE SUPERVISION

Regular supportive supervision is one of the main methods used to maintain and enforce ADS standards. The Kibaale Private Medicine Association was selected to head this during the pilot phase. It was formed in 2009 as a result of the work envisaged by drug sellers to help themselves operate properly. The association's executive members as well as a few other key members go to the drug shops and give supportive supervision. This self-regulation function encourages public-private partnership and community acceptance of regulatory guidelines. The association holds a membership meeting once a year, but would like to have two meetings a

year in the future. It was suggested that supportive supervision involving association members be performed at least quarterly.

4.9 Enforcement of Standards

The ADS system required all drug shops to abide by both the standards of practice and premises, such as record keeping, shop renovation, training, regular inspection, and supportive supervision.

The enforcement of standards was usually accomplished through discussions with the shop owners and sellers. Most of these cases were handled amicably, with the DADI and Inspectors discussing the violations with the shops, who later met the standards. In extreme cases, violations were reported to the police and the courts of law.

Addressing the enforcement of standards

"We usually talk with them, and they comply." —A Local Monitor

"When we talk to them, they usually change." —DADI, Kibaale District

"It's only in big cases that we call the DADI, and he advises that we close the shop." —A Local Monitor

"It's only when we see that the case is beyond, we close them" —DADI, Kibaale District

"We confiscate their drugs, but when they rectify what we want, they come and take the medicines." —DADI, Kibaale District

4.9.1 Case Study: *Uganda v Muhendo*

In *Uganda v Muhendo*, the drug seller was selling drugs that were meant for a Kibaale public health facility and were illegally in his possession.

Court Case: *Uganda v Muhendo*, a drug seller

DPP case Number: Kib-CO-124-2011

Court case No: 73-2011

Count 1: Unlawful possession of government stores according to Section 316 (1) and (2) PCA

Count 2: Places from which restricted drugs may be supplied sub section (b) of the NDP Act and Authority Act.

Judgment:

Overall Count 1 was dismissed

Count 2 was charged 30 currency points equivalent to UGX 600.000 or face 10 months imprisonment

Concluding the court case: The drug seller paid UGX 600.000 and was free to go.

Altogether six counts had been recorded against the drug seller, but only two were presented in court because the police file could not be located. In the end, he was only found guilty of being in possession of restricted

medicines and was freed after paying a fee of UGX 600.000. In other instances, some illegal practices were reported to the police, but they could not follow up on the crimes because of a shortage of funds.

> *"The outcome of such cases is very demoralizing. It takes long, and you are called to court on short notice. Look, the first count was dismissed! This option doesn't help us; it's not the best" — DADI, Kibaale District*

Another case raised by key informants involved a drug shop that was selling beer as well as dispensing medicines. Following inspection, it was ordered to close, and the drug shop owner complied and went out of business. However, other cases were noted where drug shop owners would forge the ADS certificate, claiming to have paid. This evidence suggests that a big fine or penalty assessed to wrongdoers directly would improve compliance with the ADS standards.

> *"But one can today say that there are few cases as drug sellers have learned since ADS trained them." —DADI, Kibaale District*

4.10 Suggested Changes

We asked the shop attendants what additions or modifications they wanted added into the program, and their responses were as below:

Shop attendants' suggestions for changes to ADS program

"Allow dispensing of non-full/half doses."

"Allow us to treat like other health units, allow us to use injectables."

"Call for more in-service training on a regular basis."

"Expand the list further."

"Call for more trainings and expand the drug list further."

"Trained ADS be involved in training of others."

"Give certificates."

"Should increase on the number of times per year so we can have trained staff."

"Program already adequate."

"Keep coming for support supervision to help solve problems."

"Don't understand how many licenses to pay for."

"Restrain ADS sellers from going to another ADS without first serving with the current ones for some time."

"The ADS advert on the radio should continue."

"We need new NDA books for records."

5. Situational Analysis Conclusions and Recommendations

During the pilot phase, inspection and enforcement of standards among the ADS drug shops was regular and structured, and it resulted in significant improvements in standards of practice and premises of drug shops in Kibaale District. Despite the success shown during the pilot phase, when regular inspection and supportive supervision is lacking, the standards of practice and premises among the ADS deteriorate.

Three ways were found to be the most effective in the enforcement of the ADS standards:

- Dialogue—"they change when we talk to them"
- Closure of premises and the impounding of drugs
- Litigation, only in extreme circumstances

In order to strengthen the inspection model, there should be increased focus on the human resource contributions (especially by the Local Monitors and the DHT) and the association to enhance self-regulation; more integration into the district activities and hence financing; and the inclusion of expanded medicine lists and inspections by Local Monitors into legislation.

The following are intended to sustain and improve the pilot's achievements in standards of practice and premises of the ADS:

- In the long term, have the current legislation tightened such that the penalties for noncompliance with ADS standards are prohibitive. In the short term, deny licenses for the next licensing cycle to those who are noncompliant with ADS standards.
- Integrate inspection, monitoring, and supportive supervision within the district health service, and have the whole district health team involved with budgetary provisions so as to achieve quarterly shop visits.
- In the short term, strengthen the association and Local Monitors by equipping them with skills, information, and knowledge on how to keep the ADS standards; in the long term, have policy provisions to support the same.
- Gender-sensitive planning, ethics, and integrity should be considered in selection of Local Monitors.
- Review the expanded medicine list for appropriateness for dosage form and use in the communities against the cadre categories handling them. In addition, sensitize the community in matters regarding rational medicines use, with emphasis on the buying of half doses and injections use practices.
- Despite nursing assistants being the main frontline staff in the drug shops, those with qualifications below a nurse should not be allowed to open a drug shop. Mandates, duties, commitment for the supervisor or person in charge should be clearly stipulated at each licensing/accreditation cycle.

6. Options Analysis

6.1 Trends in Inspection, Accreditation, and Enforcement

Over the years, the total number of drug shop enterprises inspected declined, mainly because unworthy ones were dropping out. At the same time, the number of shops accredited was constantly increasing, and the number of shops recommended for closure fell sharply (figure 14).

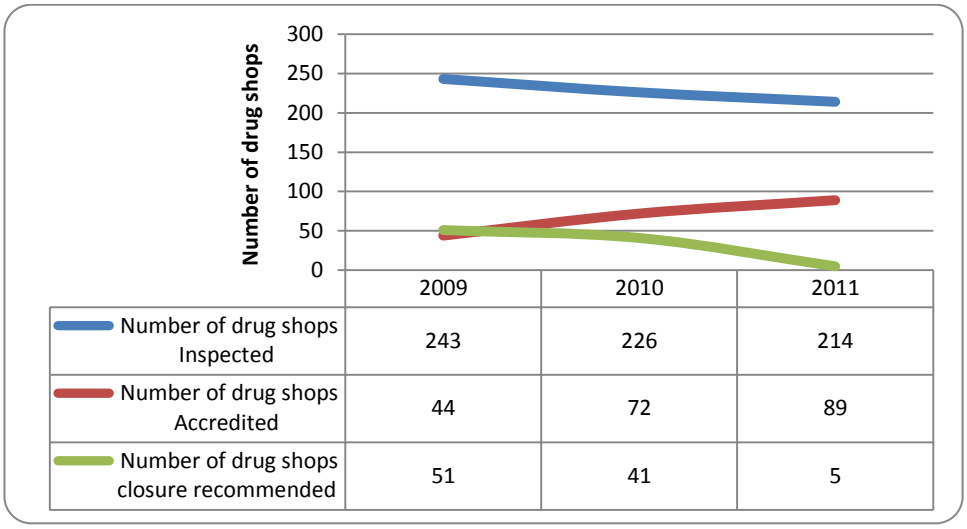

Figure 13. Trends in inspection, accreditation, and enforcement

6.2 Enforcement of ADS Standards

The majority of the enforcements of standards were communicated by dialogue, and the shops complied. For the small number that didn't comply, the medicines were impounded and the shops closed. The litigation option was applied to the shops that failed to comply or in which there was a gross breach in standards of practice or standards of the premises.

In 2011, the DADI closed 10 shops and impounded their drugs. Five of the cases were resolved amicably, and the litigation option was applied to the other five shops that failed to comply or in which there was a gross breach in standards of practice or standards of premises. One of the shops was penalized (figure 15).

Figure 14. Trends in litigation to enforce ADS standards

There were three main counts for which the shops were taken to court: operating drug shops in unsuitable premises, unlicensed persons, and Illegal possession of restricted drugs. The convictions and penalties for these cases were as follows: a fine of UGX 100,000 to UGX 300,000 or conviction of 6 to 14 months of imprisonment. These consequences were considered light, and they required a lot of follow-up time and resources on the part of the enforcement staff, to a degree that was not sustainable.

6.3 Human Resources for Inspection of Premises

The current NDA inspection system, in which the DADI inspects the shops that have applied for accreditation, shall be employed. In addition, the SDSI Coordinator will be involved in the inspection.

There shall be a pre-inspection of the premises during which Inspectors will identify deficiencies as per expected standards of the accredited drug shops and will advise accordingly. Class C shops with noted deficiencies shall be re-inspected, to ascertain whether corrective action was done, prior to accreditation.

However, in order to strengthen and enforce the standards and regulations effectively, a cadre of Health Assistants from the district were selected to locally monitor the shops and carry out routine inspections.

As in the pilot phase, the Local Monitors will have no powers to close any licensed drug shop but will make recommendations to the DADI and NDA to take action in the event that some accredited drug shops or drug sellers fail to adhere to the set standards. They will also be the ears on the ground for NDA and report any unlicensed premises involved in the sale of medicines[3].

Figure 16 shows the trend in the numbers of Local Monitors actively involved with shop inspection.

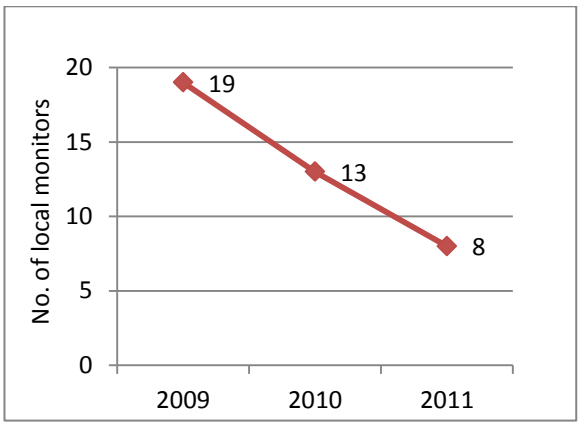

Figure 15. Trend in the number of active Local Monitors in Kibaale District

To maintain the achievements and have a sustainable way of ensuring that the standards are upheld, human resources for health needs to be looked into and strengthened.

6.4 Analysis of the Deficiencies for Shops Seeking Accreditation

The main problems or "deficiencies" with drug shops in Kibaale District at pre-inspection were with records, dispensing, supervision and management support, shelves and cupboards, roof, and floors—in that order (figure 17). Most of these were rectified when accrediting.

[3] This is the SDSI/MSH inspection model used in the pilot phase.

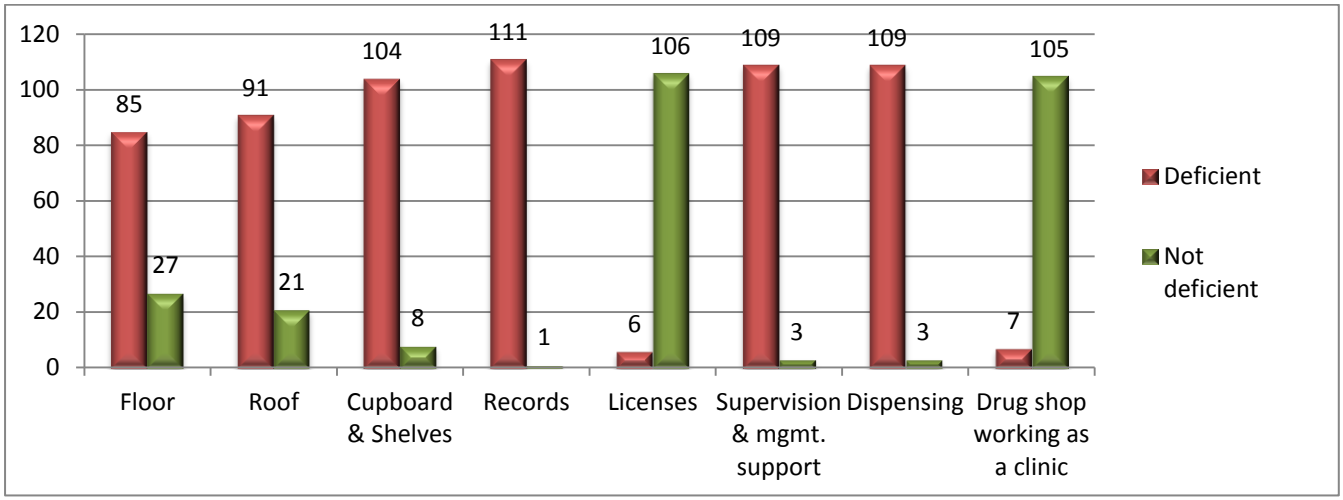

Figure 16. Number of shops with or without deficiencies at pre-inspection, 2009 (*N*=112)

Key to Figure 17	***Attribute***
Floor	Floor is cracked, shelves and floor dusty
Roof	Ceiling peeling off, ceiling of papyrus, walls and shelves dusty
Cupboard/shelves	No lockable cupboards
Records	No records for sales, purchase, expiries
License	No NDA license
Supervision and management support	No sign post, no hand washing facility, no reference materials, no drinking water, misleading sign post
Dispensing	No counting tray, no drug envelopes, more than one drug mixed in one tin, relabeling of tins
Drug shop working as clinic	Drug shop used as clinic, has bed for injections, lab services offered

6.5 Cost Structure for Regular Inspection and Enforcement of Standards in 2011

Table 1 shows the institutions that meet the costs for inspection and enforcement of standards of the ADS in Kibaale District.

Table 1. Institutions that paid for inspection and enforcement, Kibaale District

ADS Activity	Cost Met by Donors	Cost Met by the Shop	Cost Met by NDA	Cost Met by Kibaale District
Inspection	x		x	
Supportive supervision	x		x	
Mobilization	x		x	x
Training	x			
Licensing and accreditation	x	x	x	

For sustainability, the drug shops and the districts need to be more involved in meeting the costs of ensuring regular inspection and enforcement of standards.

6.6 Options Analysis Matrix

Table 2, below, shows the findings of the options analysis of the ADS model, other regulatory models, and the proposed model recommendations for 10 key components.

Table 2. Options analysis of key components of the ADS model, other regulatory models, and recommendations

Key Components		Current ADS Model ensuring regular inspection and enforcement of standards	Other Regulatory Models ensuring enforcement of standards	Draft Option Recommendations for ensuring regular inspection and enforcement of standards
1	**Issuance of application forms**			
		DADI is the district contact person	DADI is the district contact person, in collaboration with the SDSI co-coordinator and the RID.	Shop associations, if organized, could be the contact person in the sub-counties to assist the DADI. This will eliminate the illegal new outlets.
2	**Submission of forms**			
		Duly filled forms submitted to association[4] contact person at the sub-counties or the DADI, who forwards them to the NDA.	Duly filled forms are submitted back to the DADI, who forwards them to the NDA.	Strengthen association contact persons at sub-counties to ensure duly filled forms are submitted for even new entities to avoid unauthorized new shops from opening and to ease the process of submission.
3	**Annual fees paid**			
		NDA: 85,000/- to 110,000/- *PSU: 12,000/-* Local govts: 60,000/- to 90,000/- Others: Sub-county fees 80,000/-	*NDA: 85,000/- to 110,000/-* *PSU: 12,000/-* Local govts: 60,000/- to 90,000/- Others: Sub-county fees 80,000/- In Tanzania, districts collect the money from the ADDOs, spend 60%, and send 40% to TFDA. Was abused.	We can discount for inflation. No additional fees should be added. What is paid should be utilized for regular supportive supervision and inspection. Any addition will be prohibitive. District, PSU and NDA Plan on scheduled activities on how to regularly inspect, supportive supervise and enforce standards.
4	**Inspection of premises**			
	Process	Was regular and structured NDA Inspectors/Local Monitors more "friendly"	Was arbitrary and not very structured "A heavy-handed" approach was used NDA the only body.	Regular inspections at least 4 times a year or every quarter NDA is opening Zonal offices to have at least 3 districts under the Zonal Inspector. This will have a greater focus on inspection

[*4] Kibaale District drug sellers association was not active.

Key Components		Current ADS Model ensuring regular inspection and enforcement of standards	Other Regulatory Models ensuring enforcement of standards	Draft Option Recommendations for ensuring regular inspection and enforcement of standards
		NDA had an SDSI Coordinator at the pilot phase.	In Tanzania, the district teams were empowered to do this function.	and enforcement of standards. These will report to the RID.
	Pre-inspections	SDSI Coordinator, DADI, and RID	DADI and RID	Association and Local Monitors be added to strengthen SDSI Coordinator, DADI, and RID
	Follow-up inspections	DADI, SDSI Coordinator and RID were involved	RID is responsible	Local Monitors strengthened to inform the DADI and the RID. The association can strengthen this role, once active.
	Investigative inspections	Local Monitors, DADI, and RID were involved.	DADI and RID	Local Monitors and the association strengthened to inform the DADI and the RID.
	Human resources	DADI, SDSI Coordinator, RID, and Local Monitors were used.	DADI and RID	Involvement of DADI, SDSI Coordinator, RID, and Local Monitors and other members of the DHT. The first training is necessary but the subsequent annual meetings by the RIDs are necessary to standardize the process. Orientation, especially in the areas of medicine legislation. Changing the name "Local Monitors" to "health monitors" will improve vigilance.
	Standards of premises	Easy to get premises that meet the standards, but cost depends on market forces. Standards like the carpets in the floor were difficult to maintain and were still found on the floor old and torn.	Easy to get premises that meet the standards but cost depends on market forces.	Revise ADS standards like the carpet requirement so that it can easily be maintained.
5	**Accreditation**			
	Human resource for Accreditation	Registered or enrolled nurse, comprehensive nurse, registered or enrolled midwife, clinical officer (medical, psychiatric, orthopedic, dental), anesthetic assistant, veterinary surgeon, animal husbandry officer. Nursing assistants are the main frontline staff.	Registered or enrolled nurse, comprehensive nurse, registered or enrolled midwife, clinical officer (medical, psychiatric, orthopedic, dental), anesthetic assistant, veterinary surgeon, animal husbandry officer.[5]	These qualifications for supervision should be maintained. Acceptance of qualifications below the listed,[1] NDA and DHOs formulate criteria and tool to make this objective.

[5] National Drug Authority 2012, Licensing Requirements and Guidelines for 2013.

Key Components		Current ADS Model ensuring regular inspection and enforcement of standards	Other Regulatory Models ensuring enforcement of standards	Draft Option Recommendations for ensuring regular inspection and enforcement of standards
		Few (3) were permitted to supervise the hard-to-reach areas.		
	Training	Training offered to sellers and owners	No training offered to sellers and owners.	Need to have at least two trainings a year to have trained staff available. Need to have a mechanism to retain trained staff.
	Certification	Certification offered following meeting of standards (HR, premises, and practice).	No certification offered	Certification should be revoked in cases when standards (HR, premises, practice) are not upheld.
	Record keeping	Was required, books provided, and users trained on record mgt. Some modification in the use of the logbook was required. Slightly more shops maintain records regularly.	Was required, books not provided, and users not trained on record management. Few shops maintain records regularly.	Revise the record, especially the dispensing log so that it's more user friendly. Supportive supervision should emphasize this component. Availability of standardized books at a fee should be available at NDA for continuity. Simplify the books, especially the logbooks.
	References	Required, like the Uganda clinical guidelines, BNF, etc. Some shops didn't have reference books	Required like the Uganda clinical guidelines, BNF, etc.	More training on use of reference books. Check availability of reference books during supportive supervision.
	Premises	Difficult to get premises. Premises required that meet the ADS standards. Carpets were deteriorating fast and were kept in the shops even when torn.	Premises required that meet the public health standards.	Review standards of ADS premises, especially the carpets.
	Process	Was combined with the licensing process and was done annually.	Nonexistent	This should be combined with the annual licensing cycle to keep the process cost low.
6	**Supportive supervision**			
	# of times			Four times a year was adequate.
	Human Resources			Association be strengthened to do this
7	**Medicine schedule**			
		Allowed to stock the expanded list of	Limited to stocking Class C drugs	In the long run, reschedule the expanded list of medicines to Class C. In the interim, have waivers for the expanded list in the

Key Components		Current ADS Model ensuring regular inspection and enforcement of standards	Other Regulatory Models ensuring enforcement of standards	Draft Option Recommendations for ensuring regular inspection and enforcement of standards
		medicines		districts implementing ADS and in accredited shops.
8	**Enforcement of standards**			
	Dialogue	Was the main method of enforcing standards All recommendations on standards and deficiencies put in writing.	Was the main method of enforcing standards. All recommendations on standards and deficiencies put in writing.	Dialogue should be fostered to uphold standards of ADS as the first choice. A mechanism for follow-up, specific deficiencies identified be put in place. It should be tagged with revocation or "not next licensing / accrediting" after a set period, e.g., four times. Community sensitization by NDA, e.g., in radio talk shows to make the masses aware and contribute to community policing.
	Impounding/ closure	Used in cases of noncompliance by shops, after dialogue.	Used in cases of noncompliance by shops, after dialogue.	Make association more active to assist in self-regulation.
	Litigation	Fewer cases being resolved using this means.	More cases being resolved using this means.	"The penalties are not prohibitive." "The process is too long and bureaucratic." "Process is expensive." "Process is cluttered by corruption."
9	**Drug shop association**			
		Not active in Kibaale District. Thought to play a pivotal role in regulation of standards.	Success of Mityana drug sellers association where hawkers, herbalists, and all drug shops are regulated by the association with overall oversight by NDA.	Strengthen the association. In the short, run borrow provisions from successful shop associations like Mityana District. In the long run, have policy provisions to enhance self-regulation.
10	**Issuance of supplies to run the accredited drug shops** [dispensing logs, reference books and job aids, referral books, white coats, etc.]			
		NDA issued these articles to the drug shops.	No white coat requirement; dispensing logs and other books were improvised.	NDA develops and updates these and issues the supplies for accreditation (Dispensing logs, reference books and job aids, referral books, white coats etc.) at a reasonable fee directly or through the association. This will ensure standardization.

7. RECOMMENDATIONS

Following the options analysis, financial and human resources stood out as being of strongly linked to the success to several components of the ADS program. To sustain and improve the model for ensuring regular inspection and enforcement of standards, these bases need to be supported. Specific recommendations follow.

7.1 REGULAR INSPECTION

ADS regulation from the inside can be enhanced by strong associations, which have the potential to be a strong factor in self-regulation, and an informed community can be more aware, active, and effective in providing outside scrutiny.

- ***Self-regulation.*** Strengthen the association, for example, borrow provisions from successful shop associations like the one in Mityana District, where all drug sellers, including herbalists, drug shops, and pharmacies, are controlled and standards enforced by the association, whose membership is compulsory. Group self-regulation is less expensive, friendlier, less prone to corruption, and sustainable.
- ***Community policing.*** Community sensitization, for example using radio talk shows, will facilitate community policing to uphold the ADS standards.

> *"Once you empower the community, work becomes easy, the people are on our side" — Inspector of Drugs*

- ***Annual fees***. The annual fees paid can be discounted/amortized for inflation and other economic shocks, but no fees should be added. What is paid should be utilized for regular supportive supervision and inspection. Any addition will be prohibitive**.**

7.2 ENFORCEMENT OF STANDARDS

Clearly defined, legally instituted regulations and consequences—including shop closure and impounding of stocks or delay, denial, or revocation of a license or accreditation certificate—should be linked to failure to uphold standards.

- ***Closure and impounding****.* Improve the closure and impounding model to improve enforcement. This involves follow-up of the deficiencies identified and dialogue to rectify the same. This will limit the number of unproductive litigations.
- ***Licensing and accreditation***. Use revocation or denial of a license or accreditation certificate in next issuance to enforce standards. Certification should be revocable or next issuance of accreditation certificate denied or delayed in cases when standards (e.g., human resources, premises, practice) are not upheld. Specifically, link the recommendations by the association, Local Monitors, DADI, SDSI Coordinator, and the RID to denial of accreditation certificate if the shop does not work to carry out the recommendations.

- ***ADS in existing laws and regulations.*** Incorporate ADS in existing laws and regulations, specifically, rescheduling the expanded list of medicines, and standards of premises and practice to improve medicine regulation within the legal statutes of Uganda.

7.3 Cross-cutting Issues

The following recommendations require communication and coordination among various actors and will contribute to the success of the program in multiple ways.

- ***Foster multisectoral linkage.*** Linkage among the NDA, the district local governments, the MoH, drug sellers associations, and development partners is critical because the interventions proposed do not fall under one core regulatory body.
- **Gender-sensitive planning, ethics, and integrity.** Gender sensitivity should be considered in selection of Local Monitors.
- ***Supplies.*** The NDA should develop, update, and issue uniform supplies for accreditation (e.g., dispensing logs, reference books and job aids, referral books, white coats) at a reasonable fee or make them available through associations at a further subsidized fee. This will ensure standardization.

8. Stakeholders' Meeting

MSH, in partnership with National Drug Authority, convened the October 29–30, 2012, Shareholders' Meeting in Entebbe to give stakeholders an opportunity to review the findings and recommendations of Pharmaceutical Systems Africa-Uganda and other contractors.

The objectives of the meeting were to:

1) Provide a background and overview of the SDSI objectives;
2) Review findings and recommendations from recent assessments and analysis of various ADS components;
3) Discuss options and agree on feasible interventions to ensure maintenance and sustainability of the ADS initiative.

8.1 Stakeholders' Workshop

PSA-Uganda presented its findings on "Ensuring Regular Inspection and Enforcement of Standards in Accredited Drug Shops." At breakout sessions following the presentation, teams of experts and implementers discussed assessment findings. The proceedings of the group on regulation and inspection were guided by the following questions:

- How can the NDA be better utilized in the regulation of ADS?
- Who should take on the role of providing supportive supervision to the ADS?

- What should be the role of the district, associations, and Local Monitors in supportive supervision and regulation of ADS?
- How can the various players be supported in carrying out their functions?

8.2 PSA-Uganda's Main Findings and Recommendations

PSA-Uganda's main findings and recommendations centered on the regulatory system processes, inspection, licensing and accreditation, and enforcement of standards.

8.2.1 Regulatory System Processes

The regulatory experience used by NDA during the pilot phase had five basic steps, as shown in figure 18.

Figure 17. ADS pilot regulatory system flow

- The licensing and accreditation cycle begins in October when the ADS shops collect the forms and pay the fees. By January all shops should have submitted their applications.
- The licenses are issued for one year (January 1 to December 31).

8.2.2 Inspection

- Each shop was inspected from three to five times in 2011. Local/district teams conducted most of these inspection encounters, rather than the NDA/central teams. Both local and central inspections were structured and used a checklist. In general, the Local Inspectors strengthened the Central Inspectors with the overall regulatory function of ADS shops.
- Most Inspectors spent between 15 and 45 minutes on the premises (see figure 7) and the working relationship was described as "very good" and "friendly."
- The numbers of active Local Monitors declined from 19 in 2001 to 13 in 2010 to 8 in 2011. This drastic decrease in numbers was due to the end of the pilot phase of the program (figure 16).

8.2.3 Licensing and Accreditation

- By July 2012 there were 204 licensed drug shops in Kibaale District for both human and veterinary medicines.
- The preferred period for reaccreditation was one year.
- The majority (70%) had no difficulty complying with ADS Standards.

8.2.4 Enforcement of Standards

Three approaches were reported in focus group discussions and stakeholders' interviews to be effective in the enforcement of the ADS standards:

- Dialogue: "they change when we talk to them"
- Closure of premises and the impounding of drugs
- Litigation, only in extreme circumstances (this was the least preferred by regulatory enforcers).

In general, the numbers of accredited shops is increasing over time (figure 19).

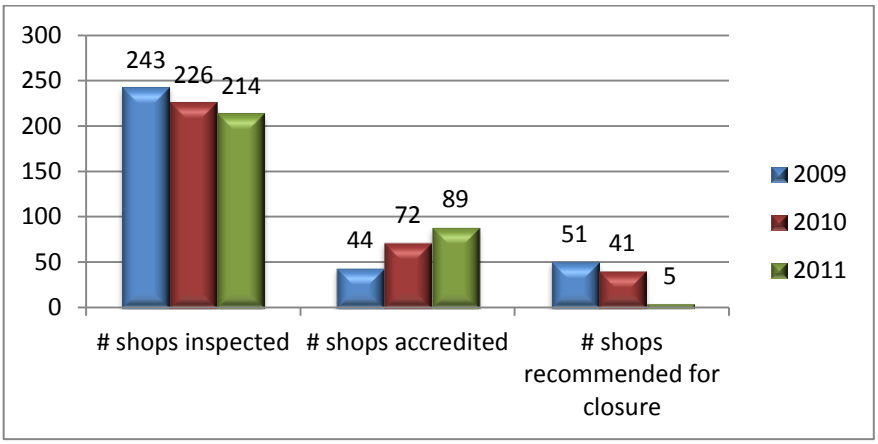

Figure 18. Trends in inspection, accreditation, and enforcement among ADS, 2009–2011

8.3 Finalized Strategy to Improve Regulatory System, Including Reaccreditation

Using the research findings and the analyses, the participants at the stakeholders' meeting sought to come up with recommendations and a strategy for improving the regulatory system. Table 3 presents these strategies and the perceived feasibility of implementing each.

Table 3. Proposed strategies and the perceived feasibility of implementing each

Thematic Area	Strategy	Brief Description	Comments on Feasibility
Ensuring regular inspection	Instituting self-regulation	Strengthen the association. Standards should be set and enforced by the association, whose membership is compulsory with NDA. This group self-regulation is less expensive, friendlier, and less prone to corruption, and it is sustainable.	[High effort, High impact] *Notes*: Having an association up and running with committed people is difficult.
	Community policing	Community sensitization, e.g., radio talk shows, involving local political institutions such as the local councils	[High effort, low impact] *Notes*: Community interventions do not have an impact quickly as it takes a lot of time and resources to implement them in

Thematic Area	Strategy	Brief Description	Comments on Feasibility
			the community.
Ensuring enforcement of standards	Revocation or denial of license/ accreditation certificate in next issuance	Certification should be revocable or next issuance of accreditation certificate delayed in cases when standards (HR, premises, practice) are not upheld. Specifically, link the recommendations by the association, Local Monitors, DADI, SDSI Coordinator, and the RID to denial of accreditation certificate if recommendations are not worked upon.	[Low effort, High impact] *Notes*: This intervention is already being done in an informal and unstructured way.
	Incorporate ADS in existing laws and regulations	Specifically, rescheduling the expanded list of medicines, and standards of premises and practice to improve medicine regulation within the legal realms of Uganda.	[High effort, High impact] *Notes*: This would take a very long time to achieve in Uganda.
	Improve the closure and impounding model to improve enforcement	This involves follow-up of the deficiencies identified and having dialogue about rectifying the same. This will limit the number of unproductive litigations.	[High effort, High Impact] *Notes*: This is currently being done, but on ad-hoc basis. It needs to be done in a standardized and systematic fashion and with the involvement of the police and local councils. The shop associations need to be more visible in implementing this.
How the NDA can be better utilized in the regulation of ADS, including reaccreditation	Constant supplies for accreditation/reaccr editation (dispensing logs, reference books and job aids, referral books, white coats, etc.)	NDA to develop, update, and issue supplies at a reasonable fee or through the association at a further subsidized fee. This will ensure standardization.	[Low effort, High impact] *Notes*: Currently NDA is developing and selling to pharmacies and drug shops stationery at a fee. It is possible to include ADS supplies as well.
	Accreditation and licensing should be done together	Accreditation and licensing, including reaccreditation, should be done together and annually.	[Low effort, High Impact] *Notes*: Will soon be feasible for the NDA since Zonal Inspectors will soon be deployed.
	Gender-sensitive planning, ethics, and integrity	Review human resource aspects for inspection, where the stipulated cadres supervise shop operations as per NDA guidelines, and the association assists to achieve the same.	[High effort, Low Impact] *Notes*: The Local Monitors are health Inspectors employed by the district. They need to be oriented and trained in drug regulation aspects, including the medicine legislations.
	Foster multisectoral linkages	The involvement and cooperation of the NDA, the district local	[High effort, High Impact] *Notes*: Especially at the district

Thematic Area	Strategy	Brief Description	Comments on Feasibility
		governments, MoH, drug sellers associations, and development partners are critical since the interventions proposed do not fall under one core regulatory body.	level, mobilization needs the district political wing involved.

PSA-Uganda recommends that each of the thematic areas shown in table 3 be considered for implementation. Both analysis and the outcome of the Stakeholders' Meeting indicate priority should be given to:

- Instituting self-regulation, with community policing;
- Improving the closure and impounding model to improve enforcement;
- Incorporating ADS in existing laws and regulations**.**

The time frame for implementing the strategies varies. Recommendations 1 and 2 are short term (one year), and recommendation 3 is a long-term endeavor (several years).

The short-term recommendations need to be strengthened with technical assistance, coupled with annual evaluations and feedback of the regulatory system so as to strengthen the system and ensure regular inspection and enforcement of standards, including those for reaccreditation of ADS in Uganda.

The areas for periodic evaluation and strengthening include:

1) Rescheduling the expanded list of medicines, including testing its appropriateness countrywide;
2) Operationalization of functional drug shop associations, including the involvement of local councils in the districts;
3) Utilization of the inspection reports from ADS to generate feedback for action by the NDA.

9. CONCLUSION

Inspection and enforcement of standards among the ADS drug shops was regular and structured, and resulted in significant improvements in standards of practice and premises among drug shops in Kibaale District during the pilot phase. Despite the success shown during the pilot phase, when regular inspection and support supervision is lacking, the standards of practice and premises among the ADS deteriorate.

In order to strengthen the inspection model, there should be increased focus on the human resource contributions (especially by the Local Monitors and the DHT); self-regulation through the association; more integration into district activities, and hence district budgeting; the inclusion into legislation expanded medicine lists and inspections by Local Monitors.

ANNEXES

Annex 1. SDSI Partners and Their Activity Objectives

SDSI partners and their activity objectives as related to SDSI's goal in Uganda		
Contractor	**Activity Objective**	**Period of Performance**
Pharmaceutical Systems Africa (PSA)	To document the **ADS regulatory system** and experience in Kibaale, explore options for sustainable ADS regulatory system, and recommend a strategy and needed tools to ensure regular inspection, reaccreditation and enforcement of ADS standards.	August–November 2012
Pharmaceutical Society of Uganda (PSU)	To document the experience of **supportive supervision** teams in Kibaale since start of ADS initiative, explore options for sustainable ADS supportive supervision, and recommend a strategy and needed tools that would help ensure delivery of quality pharmaceutical services by ADS providers.	August–November 2012
Makerere University- Kampala Department of Pharmacy (MUK)	To review the current **ADS seller training** initiative and recommend short and long-term solutions that will result in the sustainable availability of trained ADS sellers.	August–November 2012
Avytel Global Systems	To assess and develop a strategy on the feasibility and utility of using **mobile technology** to strengthen ADS services in areas of product availability and quality.	August–October 2012
G1 Logistics Ltd	To develop a **geographic information system (GIS)** strategy for Uganda's National Drug Authority (NDA) in order to improve its regulatory capacity over Accredited Drug Shops.	July–October 2012
Ugandan Health Marketing Group (UHMG)	To determine the status of the **ADS associations** and develop a strategy for facilitating the establishment of ADS associations in Uganda.	May–October 2012
Pharmaceutical Systems Africa (PSA)	To assess the **ADS supply chain** deficiencies and identify possible solutions and recommendations for strengthening the ADS supply chain system.	August–November 2012
Coalition for Health Promotion and Social Development (HEPS Uganda)	To identify current needs, experiences, and expectations of selected consumer populations where ADS have been implemented and to develop strategies for **engaging consumers** in ensuring the quality, appropriateness, and affordability of the services provided in their communities.	May–October 2012
Community Integrated Development Initiatives (CIDI)	To identify and characterize **community-based health initiatives** in Uganda to determine the best options for collaboration between such initiatives and ADS in an effort to improve access to medicines.	September–November 2012

Annex 2: General ADS Shop Survey Tool

ADS REGULATORY SYSTEM: FORMATIVE RESEARCH GUIDE

General ADS Shop Survey Tool

Hello, my name is _____ and I am carrying out interviews on behalf of Pharmaceutical Systems Africa, an organization working with the Ministry of Health of Uganda, to document the ADS Regulatory System and experience in Kibaale. We are exploring options to make the ADS regulatory system sustainable and will recommend a strategy and tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards. We would be grateful for any information you can share with us.

Session I: Drug Shop Information

1.1 Name of shop:	
1.2 Location:	

Session II: Profile of Discussant

1.1 Name:	
1.2 Phone number:	
1.3 Age:	
1.4 Sex:	
1.5 Position (Circle one):	Seller / Owner
1.6 Number of years worked in facility:	
1.7 Qualification (Circle one):	Pharmacy technician / Clinical officer / Nursing officer / Nursing assistant / Other, specify: _____
1.8 Responsibilities: (Check all that apply)	☐ Quantification & forecasting ☐ Ordering ☐ Purchasing ☐ Transporting ☐ Dispensing ☐ Inventory management ☐ Other, specify:

Session III: ADS Questionnaire

3.1 Is the shop licensed by the NDA?

- ☐ Yes
- ☐ No

3.2 Is the shop accredited?

- ☐ Yes
- ☐ No

3.3 How many times was the shop visited by inspectors in 2011? (verify with book)

a. Central inspectors: ……..
b. Local inspectors: ……

3.4 What is the average time (in minutes) spent on-site per ADS facility inspection?

a. Central inspectors: ……..
b. Local inspectors: ……

3.5 In 2011, were there any non-compliance issues identified at the shop by the inspectors?

- ☐ Yes
- ☐ No

a. If YES, list the ones that can be verified from the inspector's book at the facility.

b. Did the shop rectify the non-compliance issues identified above?

- ☐ Yes
- ☐ No

c. Were there penalties for non-compliance issues?

- ☐ Yes
- ☐ No

3.6 What is your experience with the inspection of ADS? (Please probe more on the processes.)

a. Who carries out the inspection?

- ☐ Local inspectors
- ☐ NDA inspectors
- ☐ Both

b. Who do you prefer and why?

c. Are you happy with inspectors coming to your premises? (Probe detail)

- ☐ Yes
- ☐ No

Explain:

3.7 Describe the working relationship between you and the following:

a. NDA inspectors:	
b. District inspectors/ Local inspectors:	
c. Support supervision team:	
d. Association:	

3.8 Why did you accredit your shop? (Probe on regulatory benefit.)

3.9 What difficulties, if any, did you experience in accrediting your shop?

- ☐ Pre-inspection
- ☐ Inspection/routine inspection
- ☐ Licensing/accreditation
- ☐ Meeting the standards for ADS
- ☐ Human resource/staffing for ADS

Please, explain:

3.10 What suggestion can you propose to overcome those difficulties?

3.11 Has the extended list of medicines been adequate to cover the medicines that you need in your shop?

3.12 Are there any medicines that are not on the expanded list that patients ask for? (Probe for detail and provide list.)

3.13 How difficult is it to get a business premises that meets the ADS requirements/standards? (Probe for detail.)

3.14 Do you have any of the following difficulties in complying with the ADS regulations when working as a dispenser?

- ☐ Stocking and selling only ADS-approved medicines
- ☐ Selling prescription medicines by prescription only
- ☐ Putting on the white coat when working
- ☐ Not stocking or selling expired medicines
- ☐ Not stocking or selling non-registered medicines
- ☐ Other, specify:

3.15 What influence does the owner have in the dispensers abiding by ADS regulations or in carrying out technical duties? Why?

a. Does the owner do any of the following?

- ☐ Interfere with technical decisions made by the dispenser
- ☐ Bring in stock of non-registered medicines
- ☐ Bring in stock of medicines not on the ADS-approved list
- ☐ Dispenses medicines even though he/she is not trained
- ☐ Other, specify:

3.16 Do you know the procedures for an outlet to be accredited? (If NO or forgotten, remind discussant on the procedure)

- ☐ Yes
- ☐ No

3.17 What is your experience with the accreditation process?

a. Do you think this accreditation procedure should be repeated?

- ☐ Yes
- ☐ No

b. If YES, how often?

- ☐ Every 1 to 2 years
- ☐ Every 2 to 3 years
- ☐ Every 3 to 4 years

3.18 What is your experience in filling the dispensing logbook and prescription book?

a. Do you think the use of these books should continue?

- ☐ Yes
- ☐ No

Please, explain:

b. Do you think any of the following would improve the efficiency of the process?

- ☐ Remove the register altogether
- ☐ Have only a few medicines on the register
- ☐ Have a register for specific health problems (e.g., malaria)
- ☐ Have register for under-fives only
- ☐ Other, specify:

c. Is the dispensing logbook useful in any way?

- ☐ Yes
- ☐ No

Please, explain:

3.19 Do you have any additional information or opinions that you would like to share with us? (Probe: questions, advice, problems, etc.)

Annex 3. Association Survey Tool

ADS REGULATORY SYSTEM: FORMATIVE RESEARCH GUIDE

Association Survey Tool

Hello, my name is _____ and I am carrying out interviews on behalf of Pharmaceutical Systems Africa, an organization working with the Ministry of Health of Uganda, to document the ADS Regulatory System and experience in Kibaale. We are exploring options to make the ADS regulatory system sustainable and will recommend a strategy and tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards. We would be grateful for any information you can share with us.

Session I: Profile of Discussant

1.1	**Name:**	
1.2	**Phone number:**	

Session II: Association Information

2.1	**What is the name of association?**
2.2	**Where is it located?**
2.3	**How many members does the association have?** Active members: _____ Passive members: _____
2.4	**Do members pay any fees to the association?** ☐ Yes ☐ No **If YES, how much?**
2.5	**When was the association formed?**
2.6	**Is the association registered?**

☐ Yes ☐ No **If YES, where is it registered?**
2.7 Who is eligible for membership in your association?
2.8 What committees does your association have? Is there a disciplinary committee?

Session III: Association Questionnaire

3.1 How have the ADS regulations impacted your members' businesses?
3.2 How does the association ensure that its members comply with the ADS regulations?
3.3 Do you hold any association meetings? ☐ Yes ☐ No
a. How regular are the meetings
b. How many meetings have been held in the last six months?
c. Have regulation issues that govern your members' businesses ever been discussed? ☐ Yes ☐ No

d. If YES, what were the issues discussed?

e. Have violations or non-adherence to regulatory requirements by members been discussed?

- ☐ Yes
- ☐ No

f. If YES, what was the violation?

3.4 Have you witnessed any serious violations committed by a member in the past?

- ☐ Yes
- ☐ No

If YES, continue with the questions below.

a. What was the violation?

- ☐ Selling expired medicines
- ☐ Stocking medicines not on the approved list
- ☐ Having a non-ADS trained seller working in the shop
- ☐ Selling prescription medicines without prescription
- ☐ Selling or stocking non-registered medicines
- ☐ Other, please specify:

b. How was the violation handled?

c. Was the violation disclosed to the NDA?

- ☐ Yes
- ☐ No

d. Have there been any ADS shops closed by the NDA due to serious violations?

- ☐ Yes
- ☐ No

e. Have any of your members been taken to court or had any disciplinary measures taken against them by the NDA for a serious violation?

- ☐ Yes
- ☐ No

If YES, what was the violation?

f. What other organizations do you collaborate with and in what areas?

3.5 What is your opinion about the inspection process carried out by inspectors? Why?

a. What is your impression of the inspectors' behavior while carrying out inspections?

- ☐ Friendly
- ☐ Polite
- ☐ Aggressive
- ☐ Rude
- ☐ Do not know
- ☐ No comment

3.6 What do you think should be done to maintain or improve the ADS standards?

- ☐ Drug sellers retrained periodically
- ☐ Owners trained
- ☐ Introduction of reaccreditation after a certain period
- ☐ I do not know.
- ☐ Other, please specify:

3.7 Would you recommend that accreditation be for a fixed period, after which the owner should apply for re-accreditation?

- ☐ Yes
- ☐ No

a. If YES, what do you think could be a reasonable period for reaccreditation?

- ☐ 1 to 2 years
- ☐ 2 to 3 years
- ☐ 3 to 4 years
- ☐ Other, please specify:

b. If NO, please explain why.
3.8 Do you have any additional information or opinions that you would like to share with us?

Annex 4. ADS Coordinator NDA, Regional Inspector of Drugs, DADI, SDSI Staff, and DHO Survey Tool

ADS REGULATORY SYSTEM: FORMATIVE RESEARCH GUIDE

ADS Coordinator NDA, Regional Inspector of Drugs, DADI, SDSI Staff and DHO Survey Tool

Hello, my name is _____ and I am carrying out interviews on behalf of Pharmaceutical Systems Africa, an organization working with the Ministry of Health of Uganda, to document the ADS Regulatory System and experience in Kibaale. We are exploring options to make the ADS regulatory system sustainable and will recommend a strategy and tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards. We would be grateful for any information you can share with us.

Session I: Profile of Discussant

1.3	Name:	
1.4	Phone number:	

Session II : Questionnaire

2.1	How many drug shops are there in Kibaale? Specify the numbers that are ADS, and non-ADS. ADS:_____ Non-ADS:_____
2.2	Why have some drug shops not converted?
2.3	What is the total number of inspectors for the ADS in Kibaale district? Local: _____ Central (NDA): _____
2.4	What is the total number of facilities inspected in Kibaale in 2011?

2.5 Of the number of inspected facilities, how many were recommended for accreditation?

2.6 What number were initially accredited but fell below standard in 2011?

2.7 How long does it take for ADS to be accredited when applications are submitted to NDA?

2.8 Does the inspection cover the following areas? (Tick all that apply; ask for the reports and inspection checklists as evidence.)

- ☐ Pharmacovigilance
- ☐ Dispensing practices
- ☐ Inventory management
- ☐ Facility maintenance

2.9 How many administrative measures were taken in 2011?

a. Notice of noncompliance:	
b. Warning letters issued:	
c. Withdrawal of license/accreditation:	
d. Other, please specify:	

2.10 What other steps are taken after the administrative measures above are instituted?

2.11 Are the penalties adequate to ensure compliance to the rules? (Probe for details.)

2.12 What number of criminal prosecutions submitted to court and/or penal sanctions were requested in each of the last three years?

2009:

2010:

2011:

2.13 What number of court rulings was applied by the judiciary in each of the last three years? (Get details of the cases.)

2009:

2010:

2011:

2.14 Do the inspectors feel they have the adequate powers and authority to carry out their responsibilities?

- Yes
- No

2.15 In your opinion, does the existing policy framework give you enough authority and guidance to execute your duties in regards to ADS? (Probe for more explanation.)

2.16 In your opinion, are the policy guidelines clear on the following:

a. Who should be allowed to run an ADS	Yes No
b. Standard of premises	Yes No
c. Training	Yes No
d. Operations of an ADS	Yes No
e. Penalties for non-compliance	Yes No
f. Issuance, renewal and withdrawal of accreditation	Yes No

Please, explain:

2.17 What is your experience/opinion with the drug inspection and regulatory system of ADS?

2.18 What is the district and NDA budget for ADS activities for year 2011 and 2012? (Probe for detailed reports.)

2011

ADS Activity	Cost met by donors(state)	Cost met by the shop	Cost met by NDA	Cost met by Kibaale district
Inspection				
Support supervision				
Mobilization				
Training				
Licensing and accreditation				

2012

ADS Activity	Cost met by donors(state)	Cost met by the shop	Cost met by NDA	Cost met by Kibaale district
Inspection				
Support supervision				
Mobilization				
Training				
Licensing and accreditation				

2.19 Are there clearly prescribed roles for the different players in the ADS?

- Yes
- No

Please, explain:

a. Describe the role of the NDA Inspectors:

b. Describe the role of the District/Local Inspectors:

c. Describe the role of the Support Supervision Team:

d. Describe the role of the Association:

2.20 Describe how ADS shops are regulated:

a. How has it changed from the way it was done in the past? (Probe for detail.)

2.21 How do you supervise the performance of the local monitors?
2.22 Do you think the local monitors have ever acted unethically? If YES, please give examples.
2.23 Has the NDA ever received any information or complaints from the ADS providers about unethical behavior from the local monitors? ☐ Yes ☐ No
a. If YES, what was the nature of the complaint?
b. What was done in response?
2.24 Are there measures in place to ensure the integrity of the local monitors? ☐ Yes ☐ No **Please, explain:**
2.25 How do you ensure drug shop owners/sellers adhere to the regulations and enforcement of the law, policy and bye-laws?
2.26 Does the current medicines schedule take into consideration the expanded medicines list? (If NO, probe for plans to include it in the policy.) ☐ Yes ☐ No **Please, explain:**
2.27 Findings from the pilot showed that most of the ADS are managed by nursing assistants, yet the Act recommends a minimum of a nurse or a licensed person. How is the Ministry of Health reconciling its policy with the reality of the level of human resource available?

2.28 Do you have any policy, practice or regulatory recommendations to improve and sustain the ADS system?
2.29 To what extent are you satisfied with the current ADS regulatory model? *Where 1 represents "extremely dissatisfied" and 4 represents "extremely satisfied".* Extremely dissatisfied 1 2 3 4 Extremely satisfied **Please, explain:**
2.30 Do you have any additional information or opinions that you would like to share with us?
Additional areas that need to be measured

Annex 5. Local Inspectors Survey Tool

ADS REGULATORY SYSTEM: FORMATIVE RESEARCH GUIDE

Local Inspectors Survey Tool

Hello, my name is _____ and I am carrying out interviews on behalf of Pharmaceutical Systems Africa, an organization working with the Ministry of Health of Uganda, to document the ADS Regulatory System and experience in Kibaale. We are exploring options to make the ADS regulatory system sustainable and will recommend a strategy and tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards. We would be grateful for any information you can share with us.

Session I: Profile of Discussant

2.1 Name:	
2.2 Phone number:	
2.3 Age:	
2.4 Sex:	
2.5 Qualification:	
2.6 Position:	
2.7 Number of years in position:	
2.8 Location:	

Session II: Local Inspectors Questionnaire

2.1 Are you involved in the inspection of ADS facilities? ☐ Yes ☐ No
a. If YES, what exactly is your role?
b. How many ADS facilities did you inspect last year? (Ask for inspection reports.)

	c. Who do you report to regarding ADS inspections?
2.2	Does the inspection cover the following areas? (Tick all that apply; ask for the reports/inspection checklists as evidence.) ☐ Pharmacovigilance ☐ Dispensing practices ☐ Inventory management ☐ Facility maintenance
2.3	How many administrative measures were taken in 2011?
	a. Notice of noncompliance:
	b. Warning letters issued:
	c. Withdrawal of license/accreditation:
	d. Other, specify:
2.4	What other steps are taken after the administrative measures above are instituted?
2.5	How many criminal prosecutions were submitted to court and/or penal sanctions requested in each of the last three years? 2009: 2010: 2011:
2.6	How many court rulings were applied by the judiciary in each of the last three years? (Get details of the cases.) 2009: 2010: 2011:
2.7	Are the penalties adequate to ensure compliance to the rules? (Probe for details.) ☐ Yes ☐ No Please, explain:
2.8	Do inspectors believe they have adequate power and authority to carry out their responsibilities? ☐ Yes ☐ No Please, explain:
2.9	In your opinion, does the existing policy framework give you enough authority and guidance to

execute your duties in regards to the ADS?

☐ Yes
☐ No
Please, explain:

2.10 What is your opinion of the drug inspection and regulatory system of ADS?

2.11 Who funds your ADS activities?

2.12 How would you describe your relationship with:

a. NDA inspectors:	
b. DADI:	
c. Association:	

2.13 Describe how ADS shops are regulated. How has it changed from the way it used to be done? (Probe for detail.)

2.14 How is your performance monitored?

2.15 Do you have any policy, practice or regulatory recommendations to improve and sustain the ADS system?

2.16 To what extent are you satisfied with the current ADS regulatory model? *Where 1 represents "extremely dissatisfied" and 4 represents "extremely satisfied".*

Extremely dissatisfied 1 2 3 4 Extremely satisfied

Please, explain:

2.17 Do you have any additional information or opinions that you would like to share with us?

Annex 6. Informed Consent Form

INFORMED CONSENT FORM

[Read Out]

Hello, my name is _____ and I am carrying out interviews on behalf of Pharmaceutical Systems Africa, an organization working with the Ministry of Health of Uganda, to document the ADS Regulatory System and experience in Kibaale. We are exploring options to make the ADS regulatory system sustainable and will recommend a strategy and tools that would help ensure regular inspection, re-accreditation and enforcement of ADS standards. We would be grateful for any information you can share with us. The survey will take about 30 minutes to 1 hour. All of the information you provide will be kept private.

[*Have the person sign on the appropriate line.*]

Yes: _____

No: _____

Name of Interviewer: _____

Date of Interview: ____ /___ /_____

Annex 7. Inspection Model Used in Kibaale

Inspection Model Used in Kibaale
Application, Inspection, Accreditation and Support process

1. Issuance of application forms for accreditation

In the accreditation process the DADI shall be the contact person to issue the application forms for the class C drug shops applying for accreditation.

However, to further simplify the process, the Private Drug Sellers' Association shall be utilized in the distribution of application forms to Class C drug shops intending to be accredited.

2. Submission of forms

Duly filled out forms shall be submitted back to the association contact person at the sub-county who shall then forward them to the DADI.

3. Inspection of premises

The current NDA inspection system, in which the DADI inspects the shops that have applied for accreditation, shall be employed. In addition, the EADSI coordinator will be involved in the inspection.

There shall be a pre-inspection of the premises during which inspectors will identify deficiencies as per expected standards of the accredited drug shops and will advise accordingly. Class C shops with noted deficiencies shall be re-inspected, to ascertain whether corrective action was done, prior to accreditation.

The official inspection of both Accredited and Class C drug Shops will involve the DADI and EADSI coordinator in collaboration with the regional inspector of drugs for western region. These individuals will be involved in pre-inspection, follow-up, and investigative inspections.

However in order to strengthen and enforce the standards and regulations effectively, cadre from the district have been selected to locally monitor the shops and carry out routine inspections.

For each sub-county, there shall be a health assistant who will work with the Local council chairperson during the local monitoring exercise. The county health inspectors will also be utilized as local monitors

The local monitors have no powers to close any licensed drug shop but will make recommendations to the DADI and NDA to take action in the event that some accredited drug shops or drug sellers fail to adhere to the set standards. They will also be the ears on the ground for NDA to report the unlicensed premises involved in the sale of medicines.

4. **Accreditation**

The accreditation process involves authorizing Class C drug shops and new premises which have met standards to operate as accredited drug shops. Following a final inspection of premises, the inspection report shall be submitted to the regional drug Inspector who shall then forward it to the NDA headquarters.

The successful applicant will be issued with the Accreditation Certificate upon fulfillment of NDA requirements to operate the accredited drug shop among which includes attending training for both the owner and the drug seller.

The certificates shall be distributed by the DADI and the EADSI coordinator at the sub-county headquarters.

5. Support Supervision

Support Supervision is an essential element of the Program. It includes routine monitoring of records and dispensing practices. Its objective is to support drug sellers and owners in order to strengthen/ maintain the quality of services provided. Support supervision shall be carried out at least every 2 months.

The support supervision team shall be constituted as follows,

- In-charge HC 3 or HC 4.
- A member of the district health team (DHT)
- A member of the association with technical competency such as a clinical officer, pharmacy technician

PRE-INSPECTION CHECKLIST

NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392
Fax: 255758
E-mail : nda@ndaug.or.ug
Website: http://www.nda.or.ug

P.O Box 23096, Kampala
Plot 46-48 Lumumba Avenue

PRE-INSPECTION CHECKLIST FOR CLASS C DRUG SHOP SEEKING ACCREDITATION

(Two copies should be filled; one copy should remain in the premise and the other copy should be kept by Inspectors for final inspection.

	CONDITION OF THE PREMISES	YES	NO
1.	Is the size of the premise adequate?		
2.	Is the ventilation sufficient?		
3.	Is there a ceiling?		
4.	Is a ceiling in good condition?		
5.	Is the quality of the floor acceptable?		
6.	Is there a front door?		
7.	Is the front door acceptable?		
8.	Is there any hand washing facility in the premise?		
9.	Are the walls painted with washable white or any bright colour?		
	STORAGE AND DISPENSING OF MEDICINES	**YES**	**NO**
1.	Are there sliding glass shelves in the premise?		
2.	Are there lockable cupboards for prescription medicines?		
3.	Is there a counter with glass makeup in the premise?		
4.	Is there an appropriate device for counting tablets/ capsules?		
5.	Are the dispensing containers for tablets/ capsules appropriate?		
6.	Are the pharmaceutical products stored in the manufacturer's original packaging?		
	RECORD KEEPING AND REFERENCE MATERIALS	**YES**	**NO**
7.	Are there proper records of for purchases?		
8.	Are there records for sales		
9.	Are there any records for expired medicines?		
10.	Are there any reference materials?		

RESULTS AND RECOMMENDATIONS OF THE PRE-INSPECTION

Name of class C drug shop: ……

Name of the Owner……

Village…..…… Parish……Sub-county……

Address……Phone number……...……

Observation of pre-inspection	Recommendation
…… ……	…… ……
Name of inspectors: Signature 1…… …… 2…… …… 3…… ……	Drug shop personnel: Signature 1…… …… 2…… . …… 3…… ……..

LOCAL MONITORING CHECKLIST

NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392
Fax: 255758
E-mail : nda@ndaug.or.ug
Website: http://www.nda.or.ug

P.O Box 23096, Kampala
Plot 46-48 Lumumba Avenue

LOCAL MONITORING CHECKLIST

(Two copies should be filled; one copy should remain in the premise and the other copy should be kept by the local monitor)

GENERAL INFORMATION

Name of drug shop:		**Date:**
Address		**Phone Number**
Village:	**Parish**	**Sub-county**

	LICENSING REQUIREMENTS	**Yes**	**No**
1.	Does the drug shop have a current NDA license and certificate for suitability of premises displayed?		
2.	Does the drug shop have an accreditation certificate displayed?		
3.	Is the drug seller accreditation certificate displayed?		
4.	Is the drug seller wearing a white clean coat?		
5.	Is the drug seller wearing his/her accreditation ID card?		
	CONDITION OF THE PREMISES	**YES**	**NO**
6.	Is the floor clean?		
7.	Are the walls inside clean and well painted?		
8.	Is there dust on the shelves?		
9.	Is the ventilation sufficient?		
10.	Is the light sufficient?		
11.	Is the ceiling in good condition?		
12.	Is there a hand washing facility in the premise?		
13.	Is the cleanliness of the surroundings of the premise adequate?		
14.	Is the toilet clean and in good working condition?		
15.	**Recommendations /advice given to drug seller:**		

Local monitors:	Signature	Accredited drug shop personnel:	Signature
1……	……	1……	
2……	……	2……	……

NDA INSPECTORS CHECKLIST

NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392
Fax: 255758
E-mail : nda@ndaug.or.ug
Website: http://www.nda.or.ug

P.O Box 23096, Kampala
Plot 46-48 Lumumba Avenue

SECTION A: General Information

Name of Accredited drug shop	
Address:	
Accreditation Certificate No:	
Date of Accreditation:	
Accredited drug shop owner:	
Accredited drug shop in-charge personnel	
Accredited Drug sellers	
Name:	**Cert. No:**
Name:	**Cert. No:**
Name:	**Cert. No:**

SECTION B: Condition of premises & professional conduct

Premises	**Yes**	**No**
1. Clean and tidy		
2. Posters well displayed		
3. Accreditation certificate displayed (Original)		
4. Business license displayed		
5. Drug sellers certificate (copy) displayed		
6. Extended list of medicines for accredited drug shops		
7. Hand washing facilities available		
8. Shelves available		
9. Lockable cupboards for prescription medicines available		
10. Drugs protected from heat		
11. Drugs protected from light		
12. Which of the following are available?		

a. NDP/A act □ **YES**□ **NO** b) NSCG □ **YES**□ **NO** c)EMLU 2007□ **YES**□ **NO**

d. BNF (no.) □ **YES**□ **NO** e) Accredited drug shop standards□ **YES**□ **NO**

f) Accredited drug seller code of ethics □ **YES**□ **NO**

g) Accredited drug seller training manual □ **YES**□ **NO** h) Counting tray □ **YES**□ **NO**

i. Other ref book(s)

13. a) Prescription book available? □ **YES**□ **NO**

b) Prescription book correctly filled? □ **YES**□ **NO**

14. Purchase records book kept for each item purchased or otherwise obtained?

a) Date of receipt □ **YES**□ **NO** b) Invoice no. □ **YES**□ **NO** c) Origin (Supplier) □ **YES**□ **NO**

d) Quantity received □ **YES**□ **NO** e) batch no. □ **YES**□ **NO** f) expiry date □ **YES**□ **NO**

15. Packaging materials satisfactory? □ **YES**□ **NO**

16. Labels, on stocks of medicines kept, satisfactory? □ **YES**□ **NO**

SECTION C:VALIDITY OF THE MEDICINES CURRENTLY IN THE ACCREDITED DRUG SHOP

Conduct inspection of the medicines currently in the premise. If there are unauthorized medicines, the DADI should confiscate them and hand them to the regional drug inspector. Unauthorized medicines include medicines that appear to be of questionable standard or fake, expired, not registered with NDA, not included in the list allowed to be stocked and sold in the Accredited drug shop

		Yes	**No**	**Qty and batch confiscated**
1	Are there any unauthorized medicines in the accredited drug shop?			
2	Are there any unregistered (with NDA) medicines in the accredited drug shop?			
3	Are there any public medicines with UG gov't label?			
4	Are there any medicines that are not included in the extended medicines list?			
5	Are there any expired medicines?			
6	Are there any medicines with questionable standard of quality/fake?			

Comments and Recommendations

a) Inspector:

Signed:……Name……Designation……..Date…….

SUPPORT SUPERVISION CHECKLIST
NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392
Fax: 255758
E-mail : nda@ndaug.or.ug
Website : http: www.nda.or.ug

P.O Box 23096, Kampala
Plot 46-48 Lumumba Avenue

ACCREDITED DRUG SHOP SUPPORT SUPERVISION CHECKLIST

(Two copies should be filled in and one copy to remain in the Accredited drug shop)

District:	**Parish:**	**Village:**
Date of Supervision:		

General Information

Name of accredited drug shop:	
Address:	
Accreditation Certificate No:	
Date of Accreditation:	
Accredited drug shop Owner's name:	
Accredited drug shop in-charge personnel	
Accredited Drug sellers	
Name:	**Cert. No:**
Name:	**Cert. No:**
Name:	**Cert. No:**

Medicine storage, record Keeping and Reporting	**Yes**	**No**
1. Are the pharmaceutical products in the premises in the manufacturer's original packing (with labels)?		
2. Is the arrangement of medicines appropriate?		
3. Are there any expired medicines on the shelves?		
4. Are purchases being recorded properly?		
5. Are purchase receipts being kept properly?		
6. Is the prescription book being filled correctly and regularly?		
7. Has accredited drug shop reported expired medicines in the last 3 months?		
8. Have reported expired medicines collected for disposition?		
9. Has accredited drug shop reported Averse Drug Reaction in the last 3 months?		

10. Has an inspection or supervision been conducted in the last quarter?		
Comments/areas for improvement/advice given to drug seller:		

Knowledge of the drug seller	**Yes**	**No**
1. Satisfactory knowledge of general danger signs of a child of age group 2 months up to 5 years? *(Drug seller must mention 3 out of 4 signs)* † Not able to drink or breastfeed — † Lethargic or unconscious † Convulsions — † Vomits everything		
2. Satisfactory knowledge of general danger signs of a child age one week up to 2 months? *(Drug seller must mention 5 out of 10 signs)* † Not able to breastfeed at all — † Fever (37.5^0C or more or feels hot) or temperature below normal-35^0C † Convulsion — † Skin rashes with pus † Fast breathing (60 breaths or more per minute) — † Very sleepy or unconscious † Severe chest in-drawing or — † Unusually Inactive † Redness of the skin around the umbilicus — † Grunting		
Comments/areas for improvement/advice given to the drug seller:		

Referral	**Yes**	**No**
1. Is there evidence that children with signs of severe illness are being referred to a health facility?		
2. Are referrals sent with referral note?		
Comments/areas for improvement/advice given to the drug seller:		

Appropriate Dispensing per Disease

From the prescription book, randomly select 5 cases of **uncomplicated malaria** from the previous 3 months and record how they were treated.

Treatment for <5 uncomplicated malaria	**Correct Dose**	
	Yes	**No**
1.		
2.		
3.		
4.		
5.		

From the prescription book, randomly select 5 cases of **non-pneumonia respiratory infections** and record how they were treated.

Treatment for <5 non-pneumonia	**Correct Dose**	
	Yes	**No**
1.		
2.		
3.		
4.		
5.		

From the prescription book, randomly select 10 cases of **<5 uncomplicated diarrhoea** from the previous 3 months and record how they were treated.

Treatment for <5 uncomplicated diarrhoea	**Correct Dose**	
	Yes	**No**
1.		
2.		
3.		
4.		
5.		

Comments/areas for improvement/advice given to the drug seller on dispensing:	
Support supervision team: Signature	Accredited drug shop personnel: Signature

1……. …… 2…… ……... 3……. …….	1…… …….. 2…… …….. 3…… ……..

Annex 8. List of Shops Interviewed

S. Number	Name of Shop	Location of shop	Name of person interviewed	Phone contacts
1	Tuma Drug Shop	Isunga TC	Gensi Martin	0771692206
2	Kyesinge Drug shop	Kyesinge TC	Kule Tito	0776760368
3	All Saints	Kyesinge TC	KyomushaSaddress	0775706879
4	Ashermans	Nakulabye	Katushabe Rosemary	0774014949
5	St Luke	Kagadi TC	Mbabazi Alice	0789609580
6	Baata	Muhoro TC	NyamahungeEularia	0774935039
7	Ahumuza drug shop	kanguza	Mirembe Scholastic	0778344732
8	MK drug shop	Kikaada TC	MbabaziShamim	0778745428
9	St Mary's	Kitutu	Kisimbo Mary Gorreti	0779397731
10	St Immaculate	Kitutu	BusingeProssy	0781083532
11	Mirembe Drug shop	Bukondotc	Night Teddy	0777045283
12	Mugarama Drug shop	Mugarama TC	AikirizaArigiza	0773238883
13	Ikonko drug shop	Nyamakundatc	KamuduSamson&JhunguJetrace	0782735485,0783508781
14	Bethel	Isunga	OyesigireVastine	0788746048
15	The Ark Drug shop	Isunga	Mugabi Robert(Nursing Assistant)	0781525520
16	Kabimbiri	Kyansigetc	Kiconco Gloria(nursing assistant)	0784231515
17	AbesigaMukama	Kagadi TC	NsungwaJaqueline	0757964399
18	St Jude	Muhoro TC	Banyomire Faith	0772466800
19	Kayi Drug Shop	Kakumirotc	MuhindoFedris	o775706828
20	Kakumiro Joint Drug shop	Kakumirotc	Asimwe Night	0782866052
21	AkwataEmpola	Kakumirotc	Kitome Rosemary(Enrolled Midwife)	0772934209,
22	Katonoko	Kasambya	Kazibwe Josephine	0750154945
23	Multi Care	Igayaza	Nabitosi Sharon	0773751204
24	Joy	Igayaza	Namata Grace(nursing assistant)	0774354600
25	Ayebare Drug Shop	Kagadi TC	Mercy Josephine	0774312016
26	Lord is my Shepherd	Kagadi TC	Mary GorretiKirabo	0779626746
27	Mulungi Drug Shop	Kakumiro TC	Katushabe Harriet	073333147
28	God's Will	KaruguzaTc	Aliganyira Charity	0783488731
29	Miracle Drug Shop	Kagadi TC	Kobusingye Eva	0773719814
30	People's Care drug shop	Muhororo TC	Birungi Jane	0772967312