CONCEPT NOTE TO ROLL-OUT THE ACCREDITED DRUG SHOPS (ADS) INITIATIVE IN UGANDA

September 2013

Background

In Uganda, pharmaceutical services in the community can be accessed through the public sector network of health centers (I-IV) and hospitals and through the private sector's Class C drug shops and pharmacies. Public sector facilities are distributed in all districts of Uganda, but are faced with a number of challenges such as delays in pharmaceutical distribution, which contributes to stock-outs.[1] In addition, a number of these facilities are difficult to access because of distance and restrictions on hours of operation. This has led to proliferation of both legal and illegal drug shops in these underserved areas, which overwhelms the National Drug Authority's (NDA) capacity to undertake the appropriate enforcement mechanisms as enshrined in the law, owing to a limited number of staff, inadequate transport, and other logistical issues. Moreover, most shops do not use signage to identify themselves as drug sellers, which allows them to evade NDA inspectors more easily. Therefore, effectively monitoring and supervising the operations of these drug shops is challenging, leaving many outlets operating with little or no inspection.[2]

The demand for pharmaceutical services in the countryside has led to pharmaceutical malpractice in these drug outlets, such as stocking and selling commodities beyond those stipulated under the law, administering injections, operating without licenses, and storing medicines in substandard conditions.

Reviewing existing laws related to private practice and developing and enforcing laws and regulations in the pharmaceutical sector are among the strategies to strengthen the policy and legal environment governing the access to and production, procurement, and distribution of pharmaceuticals in Uganda.[3] Under section 13, subsection 3 of the National Drug Policy/Authority Act Cap 260, NDA is mandated to develop regulations that would allow dispensing of medicines by other cadres and outlets so as to improve access to medicines, especially in areas that are not sufficiently served with pharmacies. As part of its strategic plan, NDA has made it a priority to review and draft regulations that set standards for personnel and facilities to improve access to essential medicines and strengthen the enforcement mechanisms necessary under the National Drug Policy /Authority Act.[1]

Addressing the problem

NDA in collaboration with Management Sciences for Health (MSH) conceptualized and implemented an accredited drug seller initiative that involved transforming existing Class C drug shops into regulated, profitable Accredited Drug Shops (ADS). National and local stakeholders in 2008 developed an accreditation model based on the Tanzanian accredited drug dispensing outlet model, but adapted to the Ugandan context. A combination of training, marketing, commercial incentives, supervision, inspection, and support strategies was used to

[1] National Drug Authority Uganda-Strategic Plan July 2011–June 2016
[2] National Pharmaceutical Sector Strategic Plan 2009/10–2013/14
[3] Health Sector Strategic Investment Plan 2010/11–2014/15

transform existing Class C drug shops into ADS that are authorized to provide a range of select quality prescription medicines and associated professional services, including referrals. This model was piloted in Kibaale with Mpigi as a control district.

NDA and the local authorities collaborated to assure that ADS had access to and appropriately used dispensing logs, referral forms, job aids, and other records. NDA gave an exemption to the initiative to allow ADS to stock and sell a limited range of prescription medicines that treat common illnesses and that cannot be legally stocked by unaccredited shops.

Justification for rolling out the concept

The ADS pilot demonstrated improved access to quality medicine, dispensing practices, and pharmaceutical services. For example, availability of injectables, which are illegal in all drug shops, dropped from 61% to 0% in ADS compared to the control district, where availability remained unchanged at 35% ($p<0.05$). The percentage of malaria encounters with appropriate malaria treatment in Kibaale rose from only 6% at baseline to 68% at endline. In addition, the percentage of mystery shopper encounters where the drug seller inquired about prior medicines given to the child rose from 31% to 64% in Kibaale compared to a much smaller increase (from 40% to 43%) in Mpigi ($p=0.136$).

The legal availability of essential prescription-only medicines improved, as would be expected. For example, legal availability of essential antibiotics in Kibaale increased from 57% to 84% compared to Mpigi where their illegal availability remained unchanged at 64% ($p<0.05$).

Medicine prices did not change on average, despite concerns that costs might rise in ADS because of the expenses associated with meeting new regulatory standards. Seventy-three out of the 85 licensed shops at baseline converted to ADS at endline in 2010. In addition, three shops converted to full-service pharmacies, which increased access in the community as well as serving as suppliers to ADS in the district.

District health officials have embraced the ADS initiative as an avenue for addressing some of the public health needs. *'We have the DADI who has been working with the NDA people and MSH. His office is primarily meant to link the shops (private sector) and my office. We have increased the time and money towards private sector control especially mobilization and support supervision"* —District Health Officer, Kibaale District.[4]

In another interview with the Secretary for Health of Kibaale district local government, *"ADS are very good; we are now budgeting for it in our integral activities for health. We pay staff to do support supervision for ADS shops which we used not to. We also facilitate them by giving them transport. Even in our sensitization and mobilization activities, ADS are now included. If*

[4] *Assessment of Perceptions, Satisfaction and Attitudes of the ADS Program Stakeholders in Uganda*. A qualitative study conducted by ADRET in 2010.

you look at our meeting minutes notes you can see ADS featuring strongly. ADS have really helped our people supplement the government in provision of quality health services. We are proud of it and are extremely satisfied with the ADS implementation in Kibaale."[4]

In addition to the benefits highlighted above, ADS are potential avenues for other health-related interventions, such as initiatives for child health and survival, HIV/AIDS information and health-related services, and malaria, after the accredited drug sellers have been equipped with the necessary knowledge and skills. As part of the strategy to increase access to family planning products and maternal and child health care, STRIDES (a US Agency for International Development-funded project) has supported implementation of the ADS initiative in the districts of Kamuli, Kyenjojo, Kamwenge, and Mityana.

The NDA has also embarked on the process of re-classification of medicines that will result in some additional prescription-only antibiotics, antifungal medicines, and other medicines legally availed to accredited drug shops. These changes largely resulted from changes to Uganda's standard treatment guidelines and the Ministry of Health directive to have some of the medicines re-classified to be accessible at the community level. Consequently, it would be prudent for the drug shop operators to be trained on proper dispensing of these re-classified medicines, for example zinc and artemisinin-based combination therapies, to avoid misuse.

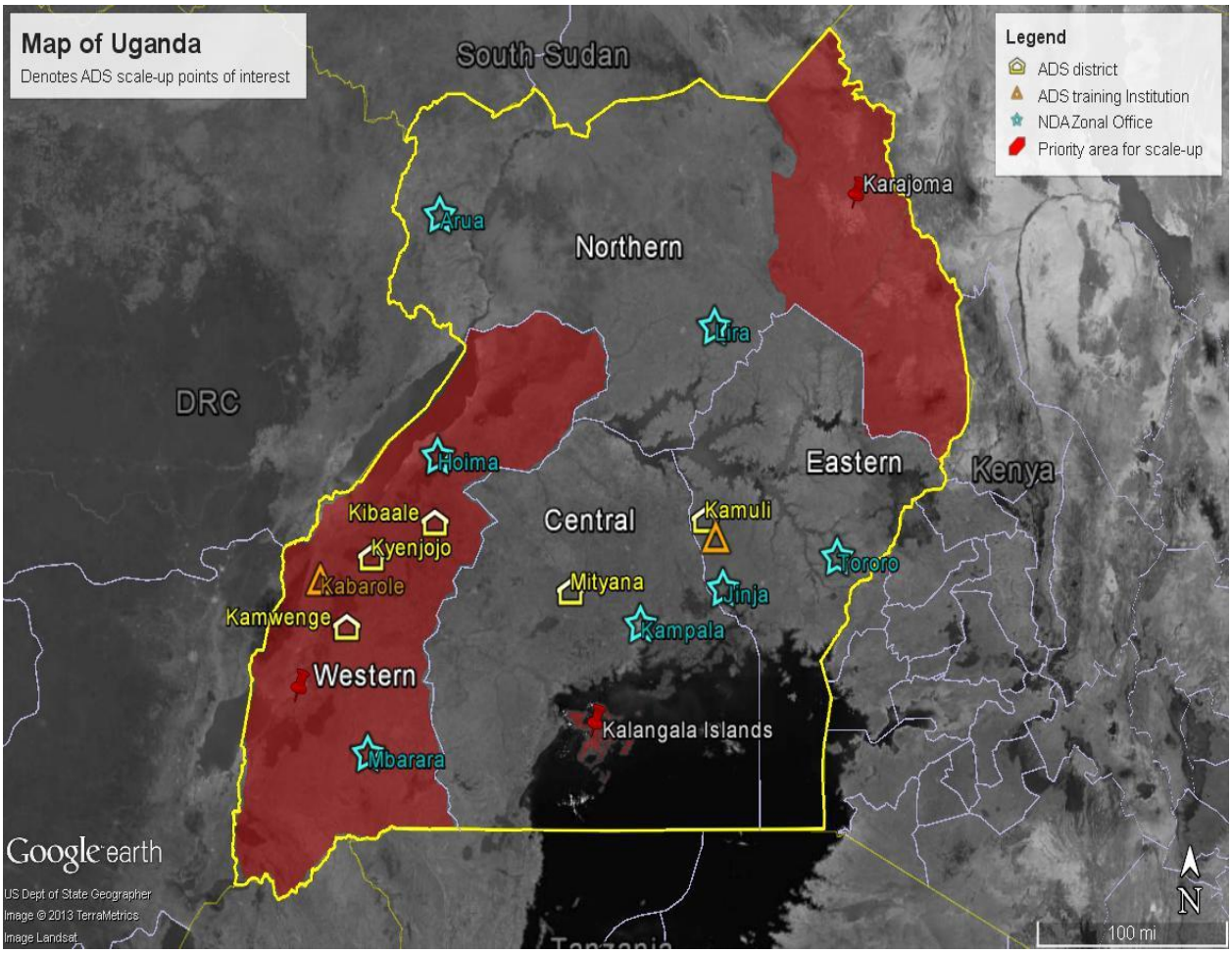
ADS roll-out strategy

Rather than scale-up districts on a one-by-one basis as donor funding becomes available, Uganda plans to implement a countrywide strategy that will require all Class C drug shops to gradually attain accredited status or be closed. Existing Class C drug shops will begin phasing in the high ADS standards for premises, personnel, training, dispensing, and record-keeping that are part of the ADS initiative while still operating under Class C drug shop rules and regulations. These accreditation requirements will be incorporated into the next set of regulations that will be put into place in 2014 to renew licenses prior to 2015. Once a Class C shop meets all ADS requirements, that shop will be designated as an ADS and be able to take on the added responsibilities afforded accredited shops. On a regional/zonal priority basis, NDA will put into place the staffing and regulatory Infrastructure and other supportive requirements for a scaled up initiative as Class C shops are converting their status. NDA currently has seven regional offices as designated on the map on the next page. The plan is to create 21 zones by dividing each region into three zones and to recruit zonal drug inspectors to handle the ADS program inspection and supervision functions in place of the district drug inspectors, who currently play that role. This zonal decentralization will facilitate ADS scale-up and the sustainability of inspection and supervision operations.

NDA will select the order that regions/zones will be scaled up based on a number of factors, such as lack of access to pharmaceutical and health services, availability of training institutions, and political considerations. For example, the Western region is the likely first candidate for scale-up because it already includes three of the five ADS districts, a training institution in the region (Fort Portal) is being capacitated to provide ADS training, and the drug sellers from

Kiruhura together with their local government have expressed a desire to have the concept implemented in the district.

Other candidates for selection include the Karamoja sub-region in the northeast and the Kalangala district comprising island communities. These areas suffer from a greater lack of access to health services is due to their remote and harsh geographies and weak transportation infrastructure. Depending on the availability of human resources as the zonal offices come on board, it is likely that NDA will prioritize districts within the target zones to be phased in. See the map below for details.



Other scale-up activities will include nationwide (by region/zone) sensitization of local government authorities, drug shop owners, and the public and drug shop mapping using GIS technology. In addition, private sector support mechanisms, such as engaging training institutions to establish ADS training programs and ADS provider associations to implement ADS support programs such as facilitating access to financing and peer supervision, will be created.

NDA seeks to increase community awareness regarding drug shop quality and assure that people can easily distinguish the legally operating drug shops from outlets operated by

unscrupulous individuals. The scale-up of ADS, which are easily identifiable by their branding , will help isolate and eliminate the illegal operators who have avoided regulatory enforcement by closing their shops during inspector visits.

Drug shops in rural areas have been used as dumping areas for counterfeit/ substandard products; therefore, NDA plans to conduct routine sampling and testing of suspect products from ADS, specifically antimalarials and antibiotics, as part of a product quality assurance scheme.

This roll-out strategy will build on the hard work and commitments of the Ministry of Health, NDA, and other key Ugandan stakeholder organizations and the work that MSH's East African Drug Seller Initiative and Sustainable Drug Seller Initiatives have done in helping Uganda develop the approaches, tools, and materials needed for scale-up. Funding for the NDA-related components of the work will largely come from their annual budgeting, which will incorporate regulatory, supervisory, and public health protection costs as appropriate. Local government budgeting will cover district-level activities that require financial support. Since ADS scale-up will be incorporated into existing NDA and district work flow and processes, the budgetary impact will not be as great as when the ADS roll-out was considered a separate activity and implemented district by district. A rough approximation of these costs is provided in Annex 1.

The owners and sellers of the private sector drug shops will be expected to pay for the costs of renovating facilities to meet standards and the training required for accreditation and licensure. As needed, other government agencies and public health initiatives will be asked to help support specific roll-out activities related to their respective missions. In addition, donors will be identified and asked to fund certain activities as opportunities arise.

NDA, with input from its ADS Steering Committee, will coordinate the concept roll-out, especially the inspection and supervision components, which are critical for monitoring the operation of drug shops throughout the country. A decentralized system using the NDA regional offices and zonal inspectors will contribute to sustainability and facilitate inspection and supervision activities within the regions. Local monitors at the sub-county level will help to ensure regular, cost-effective inspection and reporting of drug shop violations.

The Gates Foundation-supported SDSI program will work through its end in April 2014 to put into place a number of ADS maintenance activities along with developing and piloting some new concepts designed to contribute to ADS's long-term sustainability. Stakeholder activities to support the ADS initiative nationwide roll-out include the following—

SDSI (funding available through current Gates Foundation grant)

- Institutionalize ADS training (contractor: Makerere University)
    - Develop consensus on the roles of various stakeholders in the institutionalization process

- Develop criteria to accredit training institutions to conduct training of sellers
- Select and build capacity of at least two training institutions to regularly conduct training of ADS owners and sellers
- Revise ADS dispensing and business curricula to reflect medicines re-classification and other changes in dispensing and business practice, including methods of educational delivery, so as to maximize learning

- Complete ADS association development strategy and tool kit (contractor: CIDI)
  - Develop tools for formation, effective planning, and management of associations.
  - Develop and implement mechanisms for the associations' and individual members' long-term financial security through establishment of SACCOs

- Pilot a non-health commodities supply and sales project to show how a broadened range of commodities for sale affects shop profitability (in collaboration with Living Goods)
- Develop, pilot, and evaluate a consumer advocacy strategy that uses community leaders to engage consumers to help ensure the quality, appropriateness, and affordability of the services provided in their communities (contractor: HEPS)
- Develop, pilot, and evaluate a peer supervision strategy that uses the drug shop sellers' and owners' associations to conduct continuous supportive supervision to shop sellers (contractor: PSU)
- Define, pilot, and evaluate a strategy for village health teams (VHTs), ADS, and health facility linkage that enhances community health services and their sustainability (contractor: CIDI)
  - Promote ADS support to and mentoring of VHTs
  - Facilitate referrals between ADS, VHTs, and health facilities
  - Provide incentives for VHTs and ADS to naturally sustain this linkage
- Work with IFC-World Bank to support NDA's development and finalization of regulations
- Support GIS training of NDA staff
- Map out the work of other public health initiatives and donors in Uganda to determine potential for collaboration in the ADS roll-out

NDA (funding through the SDSI sub-grant to NDA for limited support through 30 April 2014 and through annual budgeting process)

- Coordinate ADS roll-out effort with the assistance of the ADS Steering Committee
- Identify and empower an NDA staff member to lead ADS coordination effort
- Establish 2015 re-licensure guidelines (in early 2014) that include ADS standards
- Revise regulations and re-classify drug lists as needed
- Incorporate ADS scale-up as part of NDA regulatory processes and allocate necessary budget

- Print scale-up resources such as informational materials, training manuals, guidelines, forms, inspection checklists
- Build capacity of the NDA regional and zonal offices in their understanding of revised standards, inspection processes, and tools
- Sensitize district stakeholders, including district and community health officials and drug shop owners and sellers, about the new standards
- Map Class C drug shops to identify potential ADS in each region using GIS technology
- Inspect shops to identify deficiencies and provide guidance on how to modify or construct their premises as per the expected standards
- Complete final inspections to verify whether premises identified during preliminary inspection comply with the new standards
- Brand all drug outlets in the country
- Select and train local monitors
- Conduct regular inspections using local monitors
- Conduct routine sampling and testing of suspect products from the ADS—mainly antimalarials and antibiotics

Class C drug shop owners and sellers

- Renovate Class C shops to meet ADS standards
- Acquire ADS signage and dispensing jackets
- Complete required training for ADS shop owners and sellers
- Market services to local market
- Join and be active members of district ADS associations

ADS associations (some pilot work to be funded by SDSI—see SDSI section above)

- Provide membership services
- Represent ADS interests in relation to regulatory and other governmental actions
- Coordinate peer supervision
- Help ensure an adequate supply of medicines and other health care products in ADS
- Help ensure adequate private sector sources of credit/loans for ADS businesses