

## TANZANIA: Accredited Drug Dispensing Outlets—*Duka la Dawa Muhimu*

---

**Problem:** *Duka la dawa baridi* (DLDB) are authorized by the Tanzania Food and Drugs Authority (TFDA) to provide nonprescription medicines in the private sector. With an estimated 4,600-plus stores, DLDB constitute the largest network of licensed retail outlets for purchasing medicines in Tanzania. Problems with DLDB include the following—

- DLDB are authorized to sell only a limited list of medicines, not including basic essential prescription medicines
- Prescription medicines that are prohibited for sale in DLDB by the TFDA invariably are available illegally
- Quality of medicines cannot be assured
- Difficulty in finding reliable and legal sources of medicines and other health care commodities to sell
- Lack of adequate facilities for storing medicines properly
- Dispensing staff lack basic qualifications, and training, and shop owners lack business skills
- High prices charged to consumers
- Inadequate regulation and supervision

### *Duka la Dawa Baridi*



**Strategy for Change:** The goal of the accredited drug dispensing outlet (ADDO) project was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or periurban areas where there are few or no registered pharmacies. To achieve this goal, the SEAM Program took a holistic approach that combined changing the behavior and expectations of individuals and groups who use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this was achieved by combining training, incentives, consumer pressure, and regulatory coercion with efforts to affect client demand for and expectations of quality products and services. Major program activities that contributed to this strategy and the ultimate creation of *Duka la Dawa Muhimu* (Swahili for essential drug shops) included—

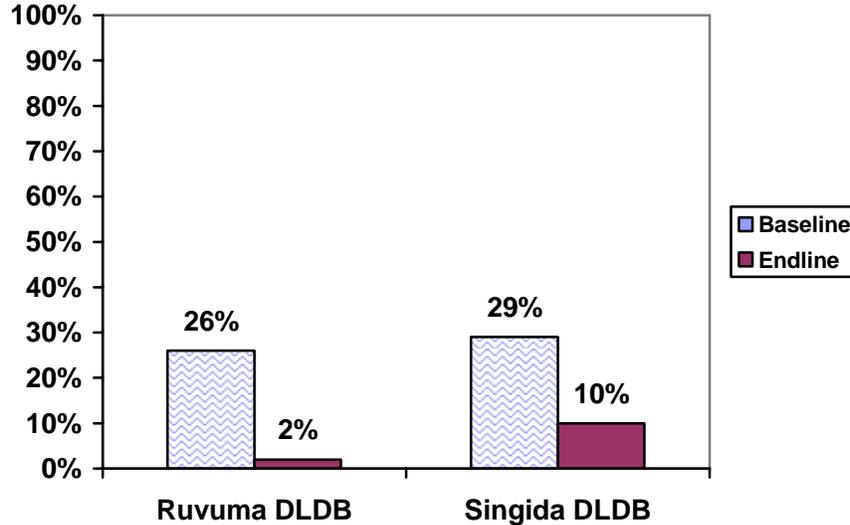
- Developing TFDA accreditation based on Ministry of Health/TFDA-instituted standards and regulations
- Developing business skills and supervising ADDO owners
- Changing behavior of dispensing staff through training, education, and supervision
- Changing behavior of ADDO owners by providing commercial incentives (e.g., access to loans, authorization to sell some prescription medicines)
- Improving awareness of customers regarding quality and the importance of treatment compliance through marketing and public education
- Improving legal access to a limited list of basic, high-quality prescription and nonprescription essential medicines
- Focusing on regulation and inspection and improving local regulatory capacity

**Results:** The first ADDO shops received accreditation by the TFDA in August 2003. As of August 2005, more than 150 shops were accredited across the Ruvuma region. The SEAM Program conducted an evaluation of the ADDO shops in October and November 2004, comparing them with a control group of DLDB in the Singida region. Significant results relate to improvements in accessing medicines, including the following—

#### *Quality of Medicines*

- The proportion of unregistered medicines (which includes TFDA-registered drugs and locally manufactured drugs) in Ruvuma was reduced by a factor of 13, from 26 percent to 2 percent. In Singida, the proportion of unregistered medicines was also reduced from 29 percent to 10 percent, showing the effect of the broader work of the TFDA to improve registration, but the effect was not as great as in Ruvuma. As a result of this improvement, people in Ruvuma now have a 1 in 50 chance of buying an unapproved medicine, compared to a 1 in 10 chance for the people of Singida.

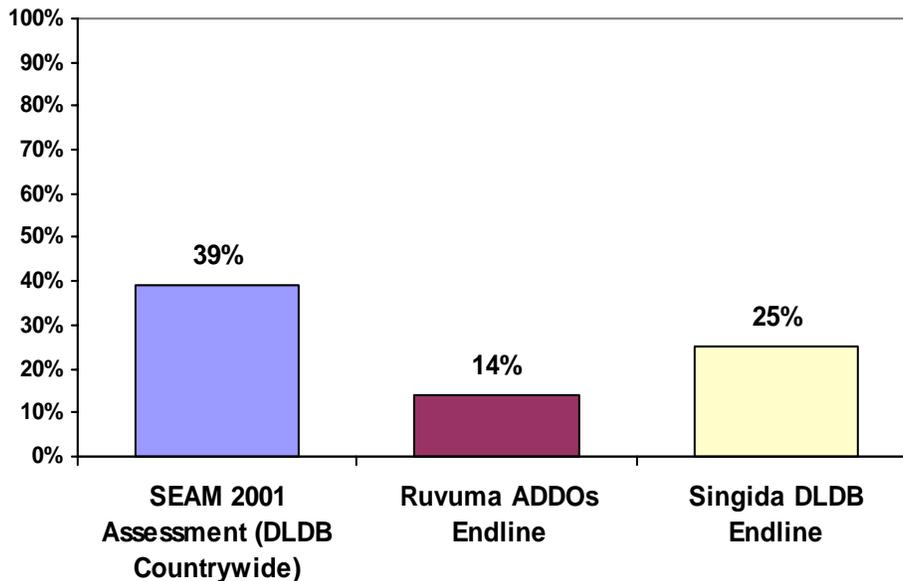
**Percentage of unregistered drugs for sale in Ruvuma and Singida at baseline and endline**



*Quality of Dispensing Services*

Endline data showed that fewer ADDO attendants (14 percent) sold or recommended antibiotics for upper respiratory tract infections (URTI) in Ruvuma than during the SEAM assessment of DLDB nationwide in 2001 (39 percent) or in Singida during the endline evaluation (25 percent). Antibiotics would not be the recommended treatment for URTI. ADDOs in Ruvuma now have a legal right to sell selected antibiotics and are selling them more responsibly than in 2001, while DLDB, including those in Singida (the control region), are still legally restricted from selling prescription medicines.

**Percentage of simulated URTI clients dispensed or recommended antibiotics during 2001 countrywide DLDB assessment and at endline in Ruvuma and Singida**



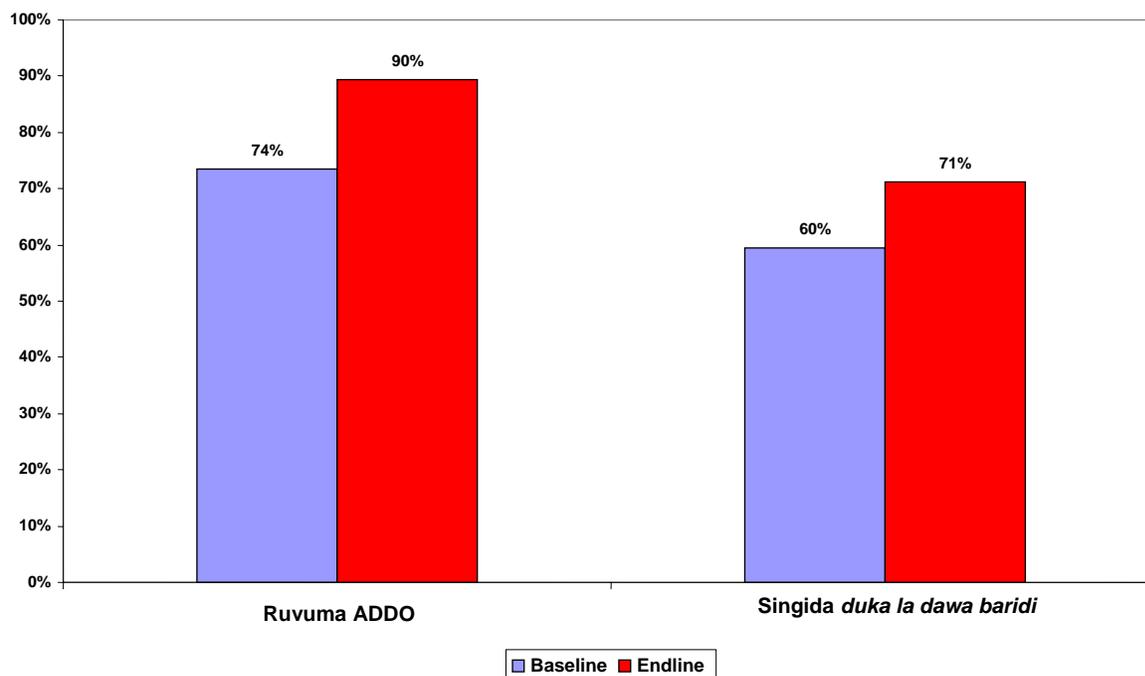
- Thirty-two percent of malaria treatment encounters at ADDOs included the sale of an appropriate first-line antimalarial (sulfadoxine-pyrimethamine), compared with only 16 percent at baseline. In 24 percent of encounters, medicines were dispensed exactly according to standard treatment guidelines, compared with 6 percent at baseline.

- There was a significant increase in the percentage of referrals for malaria symptoms in Ruvuma, from 42 percent to 62 percent. Medical personnel interpreted this finding as evidence of the efforts of ADDO dispensers to conduct business in an ethical and professional manner; however, future training will focus on increasing dispensers' knowledge and confidence regarding their ability to provide appropriate malaria treatment without referral.
- At the time of the assessment, only three ADDOs had been closed because of ethical or regulatory infractions, indicating that general adherence to standards is good. The closures are noteworthy since they indicate that violations are not tolerated and that regulations are being enforced.

*Availability of Essential Medicines*

- The average availability of prescription medicines in Ruvuma was 50 percent better than the average availability in Singida (80 percent versus 53 percent). For example, in Ruvuma, the average availability for antimalarials increased from 74 to 90 percent. Singida also experienced an increase in the availability of antimalarials (60 to 71 percent).

**Average availability of antimalarials in Ruvuma and Singida at baseline (DLDB) and endline (ADDOs and DLDB)**



- In response to increased demand generated by the ADDO shops, a Dar es Salaam-based drug wholesaler opened two branch divisions in the Ruvuma region. One branch serves as a full-service wholesaler in Songea, while the second branch is a wholesaler in Mbinga that restricts its service to ADDOs only.

*Affordability of Medicines and Pharmaceutical Services*

- Although average median prices increased slightly from baseline to endline in both regions, prices in Ruvuma are more in line with national market prices than they had been previously. The average median price for a set of tracer items was the same at both Ruvuma ADDOs and Singida DLDB at endline.
- The median cost of a course of treatment for malaria and URTI was better in Ruvuma: 60 percent less for malaria (200 Tanzanian shillings [TZS] in Ruvuma and TZS 500 in Singida); 10 percent less for URTI (TZS 900 in Ruvuma and TZS 1000 in Singida).

- Analysis of patient registers shows that the customer base has remained stable after the conversion from DLDB, suggesting that prices have not affected sales at ADDOs. The consensus of regional stakeholders is that the increase in prices has not affected access in Ruvuma.

#### *Evidence of Financial Sustainability of ADDO Shops*

Based on the available evidence and perceptions to date, accredited drug outlets would seem to be financially sustainable—

- A study of Mbinga ADDOs concluded that all businesses are able to gauge profitability; the majority earn a profit each month; and each shop earns an average of about TZS 80,000/month (range: TZS 10,000 to TZS 500,000). Out of 23 business owners interviewed, all but one believed that it was worth the investment to become an ADDO.
- New applications for ADDO shops continue to come in, indicating that the business is perceived by the private sector as financially successful—at the end of the SEAM Tanzania initiative, 36 applications were on the waiting list, 26 for new shops and 10 for DLDB conversions. No DLDB are continuing business in their former shops because the 10 remaining DLDB awaiting conversion are not currently operating.
- In late 2004, 200 dispenser applicants showed up for interviews for 100 available training slots.

#### *Improvements in the Regulatory System*

- The TFDA implemented a system of regulation in which the local government, acting on behalf of the TFDA, is responsible for regulating ADDOs, including licensing and inspection.
- Regional and district drug technical committees have been formed in all Ruvuma districts and are beginning to carry out basic regulatory functions.
- TFDA established a special ADDO unit to oversee, coordinate, and support all ADDO-related regulatory activities.

#### **Training session for ADDO dispensers**

#### **Key Lessons Learned:**

- Pharmaceutical services in developing countries can be substantially improved through training, accreditation, and regulation of private-sector drug sellers. Even prescription medicines can be rationally dispensed at grass roots drug outlets, but supervision and monitoring are needed to support improvements in rational use, and regulatory inspections are essential.
- The key to the ADDO program achievements has been the broad-based support from all stakeholders from the public and private sectors built through a participatory approach to the project's design and implementation.
- Building on existing systems, whether in the public or private sectors, and building in appropriate incentives to support commercial success are important for sustainability.
- Defining the appropriate, country-specific mix of public- and private-sector responsibilities in a drug seller initiative is critical for timely scale up and sustainability: The private sector should assume more of the routine set-up and implementation functions, such as training and marketing, while government focuses on activities to protect public health, such as establishing regulations and standards, licensing, and providing enforcement through regular inspections.
- Owner, dispenser, and local regulatory/inspector training (both initial and ongoing) is expensive and time-consuming and needs to be adequately addressed when developing sustainability and rollout strategies.
- Decentralization of regulatory authority shows some promise, but needs strengthening and an adequate commitment of resources.
- Supervision and mentoring, distinct from regulation and inspection, are complex, time-consuming, and expensive, and pose enormous challenges (e.g., number of shops, intensity of supervision, cost, and lack of institutions and infrastructure for providing appropriate supervisory support).



**ADDO Initiative Update (December 2007):** The TFDA, Ministry of Health, and local and regional government representatives determined that the ADDO program has contributed significantly to improving both access to and rational use of essential medicines in Ruvuma. This decision was supported by the results of the RPM

Plus Program's evaluation of work done in Morogoro and an independent assessment of the ADDO initiative that was funded by Danish International Development Agency (Danida) in 2006. The success of the ADDO initiative has led to pressures within the Tanzanian government to roll out the concept nationwide (over 20 additional regions) as quickly and as inexpensively as possible. At the same time, the success has generated interest from other programs and donors to use ADDOs as a base for additional public health services (e.g., child health, HIV/AIDS support). To date, post-SEAM Program funding for rollout and enhanced services has come from the Government of Tanzania, the U.S. Agency for International Development (USAID), and Danida.

As of mid-2006, the number of accredited ADDO shops in the Ruvuma region established as part of the SEAM Program had risen to 210. In the Morogoro region (with USAID support), 279 shops were accredited by the end of December 2006 with another 357 shops scheduled to complete the accreditation process by August 2007. Rollout in two additional regions (Mtwara and Rukwa) was initiated in mid-2006 with support coming from the Government of Tanzania.

A strategy for an expanded focus on child health (demand creation, capacity building, and oversight and regulation) has been developed and piloted in the Ruvuma region with USAID funding and in collaboration with the Basic Support for Institutionalizing Child Survival (BASICS) Project. The pilot's evaluation is near completion. Plans are to make the ADDO child health component part of the country's integrated management of childhood illnesses initiative and include it in the standard ADDO package for rollout to all regions. Similar piloting of an ADDO component focusing on HIV/AIDS-related information and education is part of the rollout strategy for Morogoro region.

In August 2006, the TFDA finalized and gained Ministry of Health approval of its strategy to roll out ADDO shops throughout mainland Tanzania. This strategy addressed both rollout costs and maintenance costs. Although the Government of Tanzania plans to budget money to continue the expansion (they have already committed over USD 1 million to support the rollout effort in Mtwara and Rukwa), the Government will require additional international donor support to complete rollout to all mainland regions in a five-year period. By accepting the expansion strategy, the Government recognizes its responsibility to cover the program's maintenance costs once rollout has been completed.

In early 2006, Tanzania's National Malaria Control Program adopted the ADDO concept as part of its national strategy to provide access to malaria treatment. Based on this decision, the Government of Tanzania in 2007 successfully applied for funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Round 7) to roll out ADDOs in high-impact regions. The aim is to improve access to artemisinin-based combination therapies (ACTs) to rural children under five using ADDO shops as the platform. The President's Malaria Initiative is already using ADDOs in Morogoro and Ruvuma as a platform for increasing access to malaria drugs and commodities, including subsidized ACTs.

In late 2007, the Bill & Melinda Gates Foundation awarded a new grant to MSH for continued work with the ADDO initiative in East Africa. The Tanzania arm of the project will focus on review and revision of the existing ADDO model to make implementation and nationwide scale-up more cost-efficient and to help ensure the long-term sustainability of the initiative.

**Next Steps:** The temptation to do too much too fast, without adequate planning, coordination, and resources could be problematic to the long-term success of the ADDO program. With the existing ADDO model, the cost of mounting a nationwide rollout is likely to approach USD 1 million per region, depending on issues such as size and existing resources. Seventeen regions are still without the funding necessary to roll out the program. In addition, implementation in major urban centers such as Dar es Salaam will add to the cost and complexity of rollouts because ADDOs in highly urbanized areas will likely require a different model that would have to be piloted and perfected.

#### ***Duka La Dawa Muhimu in Ruvuma***



To help ensure rational program growth, some short-term challenges and program needs include the following—

- Providing effective coordination of rollout and management of multiple donors
- Ensuring rollout sustainability with continuing government and donor commitment
- Redefining the most appropriate mix of government and private-sector involvement in planning and implementation; focusing government involvement in those areas where only the government can do the work (e.g., policy and standards settings, regulation, inspection) and allowing increased use of the private/NGO sector in other activities, such as training, supervision, and accreditation
- Ensuring that in regions where the ADDO initiative is already established (i.e., Ruvuma, Morogoro) maintenance and nurturing efforts continue during the intense rollout period to other regions in Tanzania
- Finding and sustaining human resource capacity for rollout (both management and implementation)
- Effectively managing the incorporation of expanded public health services (e.g., HIV/AIDS, malaria); too much, too soon may be problematic
- Minimizing rollout and maintenance costs without compromising quality
- Developing more cost-efficient models for training and continuing education; including zonal training centers in future training strategy
- Developing a sustainable plan for re-accreditation of shops and dispensers
- Strengthening cost-efficient approaches to supervision, monitoring, and inspection; exploring potential role of owner and dispenser associations in these activities
- Strengthening the private-sector side of the equation, including business practices; marketing; reliable access to quality, affordable inventory; and review of incentives
- Addressing urban population needs; new model needed
- Addressing very remote population needs; new model needed
- Working with insurance programs to enhance access for the very poor