

SEAM Tanzania

ADDOS: The Role of Regulation

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Regulation and Monitoring at the Local Level

Close regulation and monitoring both of accredited drug dispensing outlets (ADDOS) and nonaccredited drug shops will be required to ensure that established service and product standards are maintained. Because



the Tanzania Food and Drugs Authority (TFDA) does not have the resources to regulate all retail drug shops, local governments, acting on behalf of the TFDA, will be responsible for routine inspections and reporting on ADDOS and *duka la dawa baridi* (DLDB). However, the TFDA will retain overall responsibility for regulation. For remedial actions and sanctions, local inspectors will report deviations and findings to a district body composed of health and other government officials, as well as consumer representatives.

Why Regulation and Monitoring?

- Previous regulation violations at DLDB (e.g., selling prescription drugs, engaging in clinical practice)
- Prescription drugs will be introduced into shops without pharmacists
- New ADDO regulations need supervision and enforcement
- Need to prevent the sale of prescription drugs in nonaccredited shops

TFDA's Role and Limitations

- Has legal responsibility and authority for all drug regulatory matters
- Has regulatory and inspection staff
- Has the authority to appoint officials and individuals from other bodies to act as inspectors on its behalf (e.g., Regional Pharmacist, Regional Medical Officer)
- Does not have sufficient resources for all regulatory activities (more than 4,600 DLDB nationwide)
 - ✓ Has fewer than 10 full-time inspectors, and additional, part-time inspectors have other responsibilities competing for their time
 - ✓ In 2002, inspected just 148 of more than 4,600 DLDB

Expanding the TFDA's Inspection Capability at the Local Level

- Work in partnership with local government and health sector reforms
- Appoint a District Drug Technical Advisory Committee (DDTAC), consisting of—
 - ✓ District Commissioner, chair
 - ✓ District Executive Director, vice-chair
 - ✓ District Drug Inspector or Regional Drug Inspector, secretary
 - ✓ District Medical Officer
 - ✓ Four other local government officials
 - ✓ One representative from a nongovernmental organization
 - ✓ Consumer representative

Roles and Responsibilities

DDTAC

- Decides whether or not to accept ADDO and DLDB licensing applications
- Inspects all ADDOS and DLDB in district
- Works through Ward Development and Ward Health Committees
- Receives, reviews, and acts on all inspection reports from within district
- Reports quarterly to the TFDA

Ward Development Committee (WDC)

- Responsible for all types of shops within its boundaries
- Will appoint a small team to carry out inspections

Inspection Methods

- At least two people carry out inspections
- Present identification credentials
- Report to the authority of the inspected area before and after inspection
- Sign and report findings in inspector's book kept at shop
- No decision making power—only collecting and reporting factual information
- Inspectors must follow a predefined inspection checklist



Local inspectors visit a DLDB.

Reporting Structure

- Inspectors report to ward authorities
- Ward authorities report to DDTAC
- DDTAC decides on what actions, if any, are needed based on each report
- DDTAC provides summary reports quarterly to TFDA with copies to regional authority
- DDTAC requests TFDA assistance to deal with serious breaches of law and regulations
- All owners have right of appeal to regional authority and TFDA

