



STANDARD OPERATING PROCEDURES FOR ADDOs

August 2009

Specific Objectives

- At the end of this presentation, participants are expected to
- Understand the criteria for establishing accredited drug dispensing outlets (ADDOS)
- Know the procedures to registration, transfer ownership, and relocate an ADDO
- Understand ADDO operating procedures
- Know about ADDO restricted wholesaler

Introduction

Introduction of ADDO program is aimed at
Addressing problems related to—

- Availability and access of medicines and pharmaceutical services in the country
- Lack of basic knowledge on medicines and dispensing by drug sellers
- Poor condition of *duka la dawa baridi* (DLDB) premises and storage facilities

Regulating ADDOS

To regulate ADDOs operations, specific regulatory and guiding documents were developed that included—

- The 2004 ADDO regulations
- ADDO establishment criteria
- ADDO implementation of guidelines

Criteria for Establishment of ADDOS

ADDOS dispenser (for humans) should be trained in one of the following areas—

- Pharmaceutical technician
- Pharmaceutical assistant
- Nursing officer
- Nurse/midwife
- Clinical officer
- Clinical assistant
- Nursing assistant
- Any other individual possessing desired qualifications as approved by the Minister for Health and Social Welfare in consultation with Tanzania Food and Drug Authority (TFDA)

ADDO Dispenser (Livestock)

Should at least have the following training background—

- Livestock officer
- Assistant livestock officer
- Any other individual possessing desired qualifications as shall be approved by the Minister for Health and Social Welfare in collaboration with TFDA

Location for Establishing ADDOs

Location for the establishment of an ADDO should be—

- Easily accessible to clients
- Priority for opening an ADDO should be given to rural/urban areas where there are few or no registered pharmacies
- The distance between ADDOs in urban settings should not be less than 300 meters, not less than 200 meters in rural areas and small towns, and not less than 500 meters from any existing pharmacy
- Location must not be in or close by an area where there are open sewage systems, dumping sites, or industries that use toxic chemicals

ADDO Premise Requirements (1)

- Should be strong and durable
- Have a sturdy, leak-proof roof and ceiling
- Should have sturdy walls painted white and floors that can be easily cleaned
- Have handwashing facility available
- Have a minimum of two rooms—one for dispensing and the other for storage. The dispensing room shall be at least 10 feet long by 9 feet wide and 8-foot ceilings, while the store room shall have shelves and adequate ventilation.
- Have sturdy, secure doors (one with glass) and windows to keep insects, dust, and rodents out

ADDO Premise Requirements (2)

- Shop and storeroom should not be accessible from any other building
- Display a “No Smoking” sign to prohibit smoking inside the premises
- Display the ADDO logo on a sign board on the outside of the shop



Requirements for ADDO Ownership

- Any Tanzania national individual above 18 years of age and mentally sound can be an owner
- Will attend a compulsory training on entrepreneurship, code of ethics, and regulations governing daily operation of ADDOs
- Should possess a written and agreed upon contract with a dispenser recognized by TFDA
- The business premise should be inspected and meet all requirements as stipulated in the ADDO regulations

ADD0 Registration

- Only outlets that fulfill all ADDO requirements should be accredited and certified by TFDA
- The accreditation certificate will expire on June 30 of each year and reissued annually after remittance of the set renewal fee to TFDA through the Council on Food and Drugs Committee (CFDC) secretariat
- Accreditation certificate awarded for an ADDO is not transferable to new location or person without the consent of CDFC in collaboration with TFDA
- If an ADDO owner wants to operate another premise, all required procedures should be followed and a new accreditation certificate issued for the new outlet only

Relocation of an ADDO

- Any relocation of an ADDO should be reported in writing by the owner to the respective CFDC before relocation takes place; the written information should clearly state the new location
- Once application for relocation is approved, the owner will be obliged to follow all required procedures for opening an ADDO
- CFDC should be notified once an ADDO owner decides to close his/her business. Disposal of products should also be discussed with CFDC and the issued accreditation certificated surrendered to the CFDC
- Any transfer of ADDO ownership or relocation should be approved by CFDC

Operating Procedures (1)

Medicine quality and dispensing

- ADDO shall dispense all over the counter medicines as specified by TFDA
- ADDO shall dispense only TFDA-approved list of prescription only medicine
- ADDOs shall only dispense pharmaceutical products registered by TFDA with registration starting with **TAN**
- Selling expired drugs is prohibited and is a serious offense
- ADDOs shall procure their products from TFDA–registered wholesaler or local manufacturers (receipts for purchased products shall be kept in the shop)
- All pharmaceutical products held in inventory shall be stored in the manufacturer’s original packaging and labelled with the manufacturer’s original label

Operating Procedures (2)

Record keeping and documentation

- **Purchasing records:** All invoices and receipts for non-prescription drugs and permitted prescription medicines shall be kept at the premises in an easily retrievable file for not less than two years
- **Ledger book:** Information on amount of medicines received, issued for dispensing, and balance remaining in stock must be noted in ledger book by dispenser only
- **Drugs register:** This register shall be used in recording and storing patient information in relation to the dispensed medicines

Operating Procedures (3)

Record keeping and documentation

- Adverse drug reaction (ADR) forms for reporting any ADRs due to medicines dispensed by ADDOs or elsewhere as reported by patient
- Inspection forms
- Visitors' book

Reference books

- Good Dispensing Practice, ADDO Regulations, ADDO Dispenser Training Manual, and list of authorized drugs to be sold in ADDOs

ADDO Restricted Wholesaler (ARW)

- Shall be registered with TFDA and located in districts having no wholesale pharmacy
- Shall be supervised by a pharmaceutical technician
- Shall sell only all nonprescription and approved ADDO-prescription medicines
- Will be established with same criteria as used for ADDOs
- Requires three rooms (dispensing, store room, and office)
- Application for opening ARW shall be directed to TFDA Director General

Conclusion

Communities living in rural and peri-urban areas will enjoy improved pharmaceutical services if ADDOs adhere to regulations and standard operating procedures as stipulated.



A RELIABLE PARTNER
THANK YOU VERY MUCH