

**STANDARDS FOR OPERATING ACCREDITED DRUG SHOPS IN THE PILOT DISTRICT OF KIBALE**

**The standards have been developed by consulting the following reference documents;**

- The National Drug Policy and Authority act, 1993
- The National Drug Policy and Authority regulations, 1995
- The Tanzania Accredited Drug Dispensing Outlet (ADDO) standards
- The Pharmaceutical Society of Uganda 'Standards of Pharmacy practice in Uganda'

**1. Standards for personnel**

1.1 Every Accredited Drug shop shall have a licensed person or in-charge with the following minimum qualification

- (a) pharmacy technician
- (b) nurse/ midwife (enrolled or registered)
- (c) medical clinical officer and other cadres of the allied health professional with basic training in pharmacology

1.2 Every Accredited drug seller shall:

- (a) have a minimum qualification of:
  - I. pharmacy technician
  - II. nurse/ midwife (enrolled or registered)
  - III. medical clinical officer and other cadres of the allied health professional with basic training in pharmacology
  - IV. nursing assistant. The nursing assistant shall work as an auxiliary staff under supervision of the above cadres in 1.1. He/She should have at least O'level certificate, 1 year working experience in a hospital setting, undergone a minimum training period of 6 months and acquired a certificate as a nursing assistant.
- (b) be required to successfully complete an Accredited drug seller training course approved by the Pharmaceutical Society of Uganda.
- (c) shall observe and maintain the following:
  - I. high standard of personal hygiene;

- II. dress in a professional manner, for example, wear a clean white coat;
- III. not work under the influence of alcohol or illicit drugs;
- IV. prominently display his/her Accredited drug seller certificate in the accredited drug shop;
- V. wear a photo identification badge which identifies him/her as an accredited drug seller;
- VI. observe all regulations pertained to operating the Accredited Drug Shop.
- VII. observe laws contained in the NDP/A act
- VIII. be of sound mind and in sound medical condition
- IX. conduct him/her self in a manner that does not cause professional disrepute

1.2 Every Accredited Drug Shop owner shall:

- (a) ensure that operating procedures comply with the Accredited Drug Shop minimum standards and the existing laws in the NDP/A act;
- (b) ensure that there is a trained accredited drug seller in the Accredited Drug Shop at all times when the accredited drug shop is open.
- (c) if he/she works in the capacity of a drug seller, ensure that he/she has a valid Accredited drug seller certificate;
- (d) display Accreditation certificate prominently in the premises of which the certificate is issued;
- (e) notify the NDA in writing within 7 days, when the Accredited Drug Shop is permanently closed ; in so doing, the NDA shall inspect the inventory and provide advice for proper disposal of any inventory or medication.
- (f) notify the NDA in writing within 7 days, when an Accredited Drug Shop is temporarily closed and the anticipated date of re-opening. In case the Accredited Drug shop is closed for one year it shall be considered as a new applicant.
- (g) If there is theft or unexplained loss of drugs and records, the incident shall be immediately reported to the nearest police station and NDA office.

- 1.3 Commitment letters shall be written and signed by the drug sellers committing to work with an Accredited Drug Shop for a specific period of time. The letters will be endorsed by the Accredited Drug Shop owner. A three month's notice shall be required if a drug seller is to resign from a particular accredited drug shop.
- 1.4 All Accredited drug sellers shall be required to attend and complete continuing education to be recognised by the PSU. The continuing education shall be mandatory and shall constitute a pre-requisite for annual licence or permit and their renewal.

## 2. Standards for Premises

2.1 Every Accredited Drug Shop premises shall be required to meet minimum requirements as follows, namely –

- a) be of a permanent nature
- b) be roofed with materials which shall make it free from leakages and with a leak proof ceiling;
- c) be well protected from entry of rodents, birds, vermin and pets;
- d) have adequate space to carry out primary functions of storage, dispensing and sales;
- e) have a design which includes:
  - I. doors and windows which are well secured to prevent theft and unauthorised entry;
  - II. one room that shall be at least of **16m<sup>2</sup> ( sixteen square meters) and height of 2.5m;**
  - III. a separate lockable dispensing area with no access to the public. Approved prescription medicines shall be kept in the dispensing area in secure fixed lockable cupboards.
- f) have surfaces/floors with smooth finish that can be washed with disinfectants;
- g) painted with washable white or any bright colour;
- h) have adequate supply of clean and safe water, soap and clean and safe drinking water;
- i) have facilities to wash hands which are clearly marked with a ' wash hands ' sign;
- j) have adequate toilet facilities in clean and good working order

- k) observe general hygiene in and outside the premises
- l) shall not be shared with any medical clinic, veterinary surgery or any other business of a similar nature

2.2 The premises shall have the following necessary signage:

- a) an officially approved identification logo, to differentiate it from the non Accredited Class C Drug shops;
- b) the name of the accredited Drug Shop and any other authorised branding conspicuously displayed on the wall or shop boards; and
- c) a “NO SMOKING” sign conspicuously placed to prohibit smoking in the shop.

2.3 Accredited drug shops shall have a minimum separation distance of 500m from any existing retail pharmacy and a distance of 100m from another accredited drug shop.

If a new pharmacy is opened within 500m from the accredited drug shop, the accredited drug shop shall be given an opportunity to upgrade to a pharmacy, relocate as per the equitable distribution guidelines or wind up operation within one calendar year or from the time a new retail pharmacy starts operation in the location.

### **3. Standards for dispensing**

#### **3.1 Dispensing procedure**

- a) Every Accredited drug seller shall bear legal liability and professional responsibility for the pharmaceutical products and services provided under his/her care
- b) Every Accredited Drug Shop shall only dispense pharmaceutical products registered by the National Drug Authority in accordance with the National Drug Policy and Authority act, 1993
- c) The drug seller shall not dispense damaged, counterfeit, substandard or expired medicines
- d) The drug seller shall not dispense or sell medicines to children.

- e) Dispensing procedures must ensure that dispensing takes place with reasonable promptness.
- f) Patients whose conditions can not be handled should be referred to the nearest health facility.
- g) Every drug seller shall ensure that –
  - I. prescription drugs are only dispensed against a prescription;
  - II. a full dose is dispensed
  - III. tablets and capsules are dispensed using an appropriate device for counting the tablets or capsules, such as a counting tray
  - IV. a record of all medicines dispensed by him/her is maintained in a register approved by the National Drug Authority;
  - V. no drug is dispensed unless in accordance with the Accredited Drug shop dispensing and training guidelines and in accordance with the existing National Drug Authority laws.
  - VI. For each prescription dispensed, the date of issue, the quantity of drug supplied and the signature of the one who dispenses the prescription must be indicated in red

### **3.2 Counselling of patients**

- a) An Accredited drug seller must ensure that the patient or their agent understands the information and advice given (including directions on the labels of dispensed products) well enough to ensure safe and effective use of the medicine.
- b) Information for drugs requiring particular instructions for use must be clearly pointed out to the patient before he/she or their agent leaves the Accredited Drug shop.
- c) Patients or their representatives must be warned to keep medicines well out of reach of children.

### **3.3 Dispensing containers**

- a) All oral liquid preparations must be dispensed in their original re-closable containers
- b) All containers for medicinal products must be protected from and free of contamination
- c) The containers must be appropriate for both the product dispensed and the user

### **3.4 Labels**

- a) Labelling of dispensed products must be clear and legible
- b) Dispensed medicines must bear the necessary cautionary and advisory labels
- c) The label on the container must indicate the name, strength, dosage and total quantity of the product sold.

### **3.5 Sources of supply**

- a) There shall be an approved extended list of medicines to be sold by the Accredited Drug shop
- b) Drugs shall be procured from wholesale pharmacies registered in Uganda.
- c) Wholesale pharmacies may sell products on the extended medicines list to the Accredited Drug shop.
  - I. It shall be the responsibility of the wholesale pharmacy to verify the credentials of an accredited drug shop prior to the sale of drugs provided in the extended list of medicines. The wholesale pharmacy shall honour orders from the accredited drug shop only when the orders are on standard medicines order forms designed for the accredited drug shops.
  - II. Wholesale pharmacies selling prescription drugs to accredited drug shops shall be required to keep easily retrievable documents related to sales and shall also provide to the accredited drug shop an invoice/sales receipt in respect of all drugs sold to them
  - III. It shall be an offence for a wholesaler to sell any medicine on the extended list to Class C drug shops

### **3.6 Storage**

- a) All pharmaceutical products held in inventory shall be stored in the manufacturer's original packaging and properly labelled with the manufacturer's original label.
- b) Removal of labels from containers is prohibited and it renders the product unfit for dispensing
- c) Repackaging and re-labelling of pharmaceutical products not for the purpose of immediate dispensing to the patients is prohibited.

- d) Measures shall be taken to protect pharmaceutical products from heat, sunlight, moisture, adverse temperatures, insects, rodents and contamination.
- e) Damaged and/or expired drugs shall be recorded, sealed, quarantined and labelled with red ink with the statement "Expired/damaged Drugs – Not for sale" by the accredited drug seller.

### **3.7 Hygiene**

- a) Accredited drug shop personnel should not be allowed to work if they are suffering from contagious diseases such as scabies, tuberculosis, etc.
- b) Dispensing must always be carried out under conditions which meet acceptable standards of hygiene including high standards of personal cleanliness
- c) Use of bare hands for counting tablets and capsules must be avoided.

## **4. Standards for record keeping and documentation**

4.1 All invoices and receipts for non-prescription drugs and permitted prescription drugs shall be stored in the premises in an easily retrievable file for not less than two years.

4.2 A purchases record book shall be kept, which shall minimally include –

- a. name of supplier;
- b. date of purchase;
- c. name and quantity of the drugs,
- d. manufacturer, batch number and expiry date.

4.3 All accredited drug shops shall maintain for each permitted prescription drug a prescription book, which shall minimally include:

- a. name of the patient and condition/disease for which the prescription was written;
- b. name of drug and quantity dispensed;
- c. date on which the drug was dispensed; and
- d. origin of the prescription and the prescribing doctor.

4.4 The records relating to prescription drugs shall be kept and maintained within the premises for not less than two years.

4.5 There shall be a record for expired products which shall be kept and maintained by the accredited drug seller.

- a. The owner of an accredited drug shop shall, quarterly, provide the list of all expired products to the NDA Drug Inspector and meet the costs of their destruction.

4.6 There shall be NDA adverse drug reactions forms maintained in each accredited drug shop for the purpose of recording patient drug related adverse reactions

4.7 Every accredited drug shop shall keep and maintain –

- a. a special file for keeping all correspondences related to drugs, guidelines from the NDA and other regulatory authorities; and
- b. an Inspector's record Book for the purposes of recording all inspections undertaken therein.

#### **4.8 Reference Materials**

Each accredited drug shop shall have and maintain for easy reference, the recent editions of the following reference materials:

- a) Accredited drug shop extended medicines list;
- b) Accredited drug shop Standards and Code of Ethics;
- c) Accredited drug seller training manual;
- d) National Standard Clinical guidelines
- e) Essential Medicines List for Uganda
- f) The British National Formulary
- g) Relevant legislations, including:
  - The National Drug Policy and Authority Statute 1993
  - The Allied Health Professionals Statute 1996
  - The Nurses and Midwives Statute 1996

#### **5. OFFENCES AND PENALTIES**

Any person who contravenes any provisions of these standards commits an offence and shall be liable upon conviction to a fine and/or to imprisonment specified under the National Drug Authority Act, 1993.