

TRAINING MANUAL FOR LOCAL MONITORS

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CHAPTER ONE: LEGAL REQUIREMENTS AND STANDARDS FOR OPERATING ACCREDITED DRUG SHOPS

Bodies responsible for the control of Accredited and Class C drug shops

There are several bodies that will be involved in the regulation of the Accredited Drug Shops. These include:

1. National Drug Authority (NDA)
2. Pharmaceutical Society of Uganda (PSU)
3. The Office of the District Health Officer (DHO)
4. The Association of Accredited Drug Shops

The NDA takes the central role in the regulation while the others bodies provide support supervision and self regulation.

Regulation of the Accredited and Class C drug shops

The ADS will be regulated through the current regulatory frame work of Class C drug shops that involves the district assistant drug inspector (DADI) and the NDA regional inspectors. The inspection process will be re-enforced by the EADSI coordinator based at the NDA. Local monitors shall also be utilized to act as the ears on the ground for NDA.

Before a premise is licensed as an ADS, it must undergo an accreditation process that will include inspection of the premises and training of drug sellers. The accreditation and issuance of an accreditation certificate will be the responsibility of the Inspectorate department at the NDA head office.

Conditions for accreditation

For a premise to be accredited, the inspectors must verify the following conditions are met:

- The drugshop in charge and the person who will be operating the ADS, i.e., the seller, are qualified for the task. That is to say, the drugshop incharge must have a minimum qualification of an enrolled nurse while the drug seller must have attained a UCE certificate, a minimum of six months training of nursing assistant course. Both the in-charge and the seller have undergone and passed the ADS accreditation training program.
- The applicant must satisfy all the condition indicated for licensing a Class C drug shop.
- The premises meet the requirements set out in the standards for operating an Accredited drugshop

Why is it necessary to accredit the ADS?

- Surveys have shown that some Class C shops are currently selling prescription medicines. In addition to being illegal, this practice has resulted in detrimental effect such as the emergence of drug resistance.
- Appropriate storage is not assured as most of the drug shop operators hide the illegally-sold medicines.

Application, Inspection and Accreditation process

1. Issuance of application forms for accreditation

In the accreditation process the DADI shall be the contact person to issue the application forms for the class C drug shops applying for accreditation.

However, to further simplify the process, the Private Drug Sellers' Association shall be utilized in the distribution of application forms to Class C drug shops intending to be accredited.

2. Submission of forms

Duly filled out forms shall be submitted back to the association contact person at the sub-county who shall then forward them to the DADI.

3. Inspection of premises

The current NDA inspection system, in which the DADI inspects the shops that have applied for accreditation, shall be employed. In addition, the EADSI coordinator will be involved in the inspection.

There shall be a pre-inspection of the premises during which inspectors will identify deficiencies as per expected standards of the accredited drug shops and will advise accordingly. Class C shops with noted deficiencies shall be re-inspected, to ascertain whether corrective action was done, prior to accreditation.

4. Accreditation

The accreditation process involves authorizing Class C drug shops and new premises which have met standards to operate as accredited drug shops. Following a final inspection of premises, the inspection report shall be submitted to the regional drug Inspector who shall then forward it to the NDA headquarters.

The successful applicant will be issued with the Accreditation Certificate upon fulfillment of NDA requirements to operate the accredited drug shop among which includes attending training for both the owner and the drug seller.

The certificates shall be distributed by the DADI and the EADSI coordinator at the sub-county headquarters.

Standards for operating Accredited Drug Shop

The standards for operating ADS have been developed to provide a basis for which services will be measured.

A standard refers to a level of quality or a specified level of quality that will be measured. Services will be considered to be of poor quality if they are perceived to fall below the stipulated standard.

Standards for operation are relevant to the running of an ADS shop since it will help judge the impact ADS practice has on the quality of care rendered to the patient. This information will be used to determine if the ADS program should be adopted in other regions of Uganda.

1. Standards for personnel

- 1.1 Every Accredited Drug Shop shall have a licensed person or in-charge with one of the following as a 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, approved by the National Drug Authority.

- 1.2 Every accredited drug seller shall:
 - (a) have as a minimum qualification one of following qualifications:
 - 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 the accredited drug seller training course approved by the Pharmaceutical Society of Uganda.
 - (c) 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 pertaining to operation of the Accredited Drug Shop.
- VII. observe laws contained in the National Drug Policy and Authority (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

1.3 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 the shop 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.

1.4 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.

1.5 All accredited drug sellers shall be required to attend and complete continuing education that is 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 premise shall be required to meet minimum requirements as follows –

- 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 unauthorized entry;
 - II. one room that shall be at least of **16m² (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.

CHAPTER TWO: LOCAL MONITORING AND INSPECTION

2.0 Introduction

This chapter will discuss issues of local monitoring of class C and accredited drug shops. The chapter will also describe what is required to be inspected during the local monitoring, the different types of inspections, the things that the local monitors should not do and the reports expected from them. Therefore it's important for the local monitors to read and understand this chapter before being engaged in the local monitoring processes.

2.1 What is inspection?

Inspection is to scrutinize or closely look at something or someone more keenly to find out if it conforms to set criteria, standards, and expected or required actions.

2.2 The purposes of inspection

Inspection aims at ensuring that all drug shops (Accredited and class C) sell medicines in accordance to set standards and regulations.

This is because:

- Medicines are not ordinary commodities or a luxury, but social goods which are important in improving both an individual's and the public's health.
- Use of medicines by an individual concerns the whole population, e.g. misuse of antibiotics by an individual may result in microbial resistance that may impact other parts of the population.
- Medicines are vulnerable and undergo changes under different storage conditions and this can lead to deterioration and toxicity
- Mis-use of medicines can lead to health and economic damage

Inspection does not only mean to identify problems and shortcomings. It also includes building mutual understanding between health care service providers and law enforcers and providing guidance on how to correct deficiencies and eventually provide quality services to the communities.

2.3 Types of inspection

- Preliminary Inspection** The inspection conducted for the first time on new premises, when ownership of a drug shop is being transferred, or when an existing Class C drug shop is seeking accreditation as an Accredited Drug Shop. It is aimed at providing guidance and instructions on how to improve physical facilities and equipment in order to meet the standards set. This is a function of the NDA EADSI coordinator working together with the DADI and the NDA Regional Inspector.
- Routine Inspection** This inspection is done to routinely determine if the drug shop business is being carried out in accordance with the set standards and the NDA Act. This is where the local monitors will play a role by checking whether the drug shop premises meet the set standards. They will also report any unlicensed premises carrying the business of selling medicines. Enforcement will however be done by the NDA (see iii below).
- Follow-up inspection** This inspection is done as a follow-up to the routine inspection in order to determine whether guidance provided during previous inspections has been implemented. These will be conducted by the NDA inspectors upon receipt of the reports from the local monitors.
- Investigative Inspection:** This inspection is conducted following reports of complaints on violation of regulations and Act and is carried out by NDA inspectors.

2.4 Areas for inspection

For purposes of ensuring quality of medicines and medical appliances, brought in the country and sold to communities, the following sites involved in medical services must be inspected frequently.

- i. The borders through which medicines enter the country
- ii. Pharmacies and drug shops (Class C and ADS)
- iii. Health facilities like health centers, hospitals and clinics.
- iv. Any other suspected area including shops selling normal commodities involved in selling drugs.

2.5 Local monitors

2.5.1 Composition

The official inspection of both Accredited and Class C drug Shops will involve the DADI and EADSI coordinator in collaboration with the regional inspector of drugs for western region. These individuals will be involved in pre-inspection, follow-up, and investigative inspections.

However in order to strengthen and enforce the standards and regulations effectively, cadre from the district have been selected to locally monitor the shops and carry out routine inspections.

For each sub-county, there shall be a health assistant who will work with the Local council chairperson during the local monitoring exercise. The county health inspectors will also be utilized as local monitors

The local monitors have no powers to close any licensed drug shop but will make recommendations to the DADI and NDA to take action in the event that some accredited drug shops or drug sellers fail to adhere to the set standards. They will also be the ears on the ground for NDA to report the unlicensed premises involved in the sale of medicines.

2.5.2 Local monitors' authority/ responsibility

- i. For each Accredited and Class C Drug Shop in the sub-county, to conduct routine checks on the premises and personnel involved in selling medicines using the provided checklist.
- ii. During the monthly monitoring exercise, to verify whether the premises are licensed to carry out the business of selling medicines by checking for the availability of documents related to the business, e.g., NDA license, accreditation certificate (for ADS),
- iii. To recommend to the DADI, to take action against Accredited and Class C Drug Shops and/or drug sellers that are in violation of the set standards and regulations.
- iv. To recommend to the DADI, to close non-licensed premises selling medicines.
- v. The teams may report to the police when the violation of regulations warrants doing so. (e.g., sale of stolen drugs or government drugs)

2.5.3 The powers of NDA over the local monitors

- i. NDA has the powers and authority to remove any local monitor found to be unethical in his/her work and his/her powers/responsibilities will cease immediately

2.5.4 Ethics of the local monitors

Local monitors selected to serve in this capacity will have to adhere to the following code of ethics:

- i. To carry out his/her duties by following regulations and procedures set by the NDA Act.
- ii. To protect his/her professional image and not to collaborate with any person by breaking the law or show the behavior which will be detrimental to carrying out his/her responsibilities.

- iii. Not to give his/her decisions during inspection based on tribalism, favoritism, political affiliation, business structure or competition.
- iv. To base their actions and recommendations on fact, and not to be influenced by any other factor while carrying out his/her duties, like interest to protect personal interest of an individual, which will affect his/her ability to make right decisions.
- v. To disclose to NDA his/her relationship and/or ownership of any pharmaceuticals-related business or that of his/her close family or people related to him/her.
- vi. To keep information collected by the local monitoring team and its recommendations confidential and not to use the information for individual or for any other person's gain.
- vii. Not to use abusive language, stubbornness, threats or ridicules that may affect an individual's mental well-being while carrying out his/her duties.
- viii. Not to receive presents/gifts, favoritisms, bribes or any kind of payment.
- ix. Must have and wear his/her identity card, be ethical during routine inspection visits, and protect and portray the good image of NDA.

Note: Not complying to set Act, regulations and instructions given above is an offence which may lead to disciplinary action.

2.5.5 Preparation before carrying out an inspection

Before conducting any routine inspection, it's important for the teams to prepare and/or have available the following items;

- i) The inspection visit timetable and inform all team members who will participate in the inspection
- ii) The list and locality of all shops which will be visited per sub-country. The schedule for inspection of the shops will not be shared with the drug shops to be inspected.
- iii) Inspection checklists for conducting inspection visits.

2.5.6 The procedure during visits by local monitors

The local monitors must adhere to the following procedures when they enter into the area for conducting inspection:

- i) To inform the leadership of the village immediately when they arrive in the area.
- ii) When in the targeted drug shops explain the purpose of the visit and show their identity cards.
- iii) Use diplomacy and other convincing tactics to enable collection of relevant information; don't use threats (intimidation).
- iv) If the owner of the drug shop refuses to be inspected or give required information on the operations of the shop, he/she should be told that it's a criminal offence and the police need to be informed to take legal action.
- v) To conduct inspection activities step by step as indicated in the local monitoring checklists. During questioning, ask questions one at a time and not all together to avoid confusion of the respondent.
- vi) Fill out the checklists while conducting inspection. It's not allowed to fill the checklists after the visit has been completed.
- vii) Enter information collected on the checklists to accurately reflect observations and data collected. Cheating or false additions to add to the weight of the report is not allowed

2.5.7 Local monitoring checklist

Section one: Shop records

- Record the name of the shop, address and locality of the shop in the checklist.
- Fill in the date of local monitoring visit.

Section two: Licensing requirements

- Check for the NDA license and certificate of suitability

- Check whether the shop is accredited (accreditation certificate)
- Check to see whether drug seller certificates are publicly displayed in the shop
- Check if drug sellers are wearing a white coat with identity card
- Check if the drug seller is wearing his/her accreditation ID card.

Section three: Premises/building

Inspect all criteria of the premises/building as indicated in the checklist. Things to observe:

- Cleanliness of the building - (roof, ceiling, walls, doors, windows, and floor)
- Cleanliness of the premises and surroundings
- Lighting and enough air circulation in the facility.
- Facility for washing hands
- Cleanliness and working condition of the toilet

The Drug Shop personnel and the local monitors have to fill in their names, signature, and date of visit. And a copy of the local monitoring form is left at the shop for filing by the shop owner/ drug seller.

Exercise

CASE STUDY: Offences and penalties for breaking regulation of ADS shops

Ateenyi leaves in Mugarama village. He became very much interested to establish an ADS after visiting his friend Amooti who has an ADS in Mpeefu town. Ateenyi sent his application for establishing the ADS through the required levels. After Ateenyi and his drug seller had attended ADS training, he was successful to open the shop.

Ateenyi had expectations that he would get profit from the business and build a modern house. For the purpose of making reasonable profits, Ateenyi searched for medicines from different sources to equip his shop, including buying drugs from illegal drug vendors and stolen drugs from Mugarama health centre III. He also wanted to maximize his sales by instructing the drug seller to sell drugs to patients regardless of whether they have or have no prescriptions and sell expired drugs. Ateenyi also thought of reducing the running cost for operating his ADS by sacking the drug seller and replacing her with his wife, a simple house wife who did not know how to read or write.

After three months of running his business, ADS local monitors from the district arrived to inspect drug shops in the area including Ateenyi's ADS. The local monitors conducted the inspections and in their report to the DADI, they recommended closure of Ateenyi's ADS. After the closure of the shop, Ateenyi could not finish building his modern house.

Questions:

- (1) Why did Ateenyi fail to finish constructing his house?
- (2) Identify the offences which might have caused the local monitors to recommend the closure of Ateenyi's shop.
- (3) What dangers which might have happened if Ateenyi's shop was not closed?

ANNEX 1: LOCAL MONITORING CHECKLIST

NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392

Fax: 255758

E-mail : nda@ndaug.or.ug

Website : <http://www.nda.or.ug>



P.O Box 23096, Kampala

Plot 46-48 Lumumba Avenue

LOCAL MONITORING CHECKLIST

(Two copies should be filled; one copy should remain in the premise and the other copy should be kept by the local monitor)

GENERAL INFORMATION

Name of drug shop:		Date:
Address		Phone Number
Village:	Parish	Sub-county

LICENSING REQUIREMENTS		Yes	No
1.	Does the drug shop have a current NDA license and certificate for suitability of premises displayed?		
2.	Does the drug shop have an accreditation certificate displayed?		
3.	Is the drug seller accreditation certificate displayed?		
4.	Is the drug seller wearing a white clean coat?		
5.	Is the drug seller wearing his/her accreditation ID card?		
CONDITION OF THE PREMISES		YES	NO
6.	Is the floor clean?		
7.	Are the walls inside clean and well painted?		
8.	Is there dust on the shelves?		
9.	Is the ventilation sufficient?		
10.	Is the light sufficient?		
11.	Is the ceiling in good condition?		
12.	Is there a hand washing facility in the premise?		
13.	Is the cleanliness of the surroundings of the premise adequate?		
14.	Is the toilet clean and in good working condition?		
15.	Recommendations /advice given to drug seller:		
Local monitors: Signature		Accredited drug shop personnel: Signature	
1.....	1.....
2.....	2.....