

EADSI

The logo features a stylized yellow house with a white pill integrated into its right side. The house has a simple gabled roof and a solid yellow body. The pill is white with a black outline and a horizontal line across its middle, positioned as if it is part of the house's structure.

East African Drug Seller Initiative

Training of local monitors and support supervision teams.

Speaker name and organization here

The ADS concept

- An ADS is a special category of class C drug shop that is accredited by the NDA and allowed to stock medicines that are generally not allowed in an ordinary Class C drug shop.
- ADS will be promoted to the public as safe and good quality sources of medicines.

Conditions for accreditation

- The seller must satisfy all the conditions indicated for licensing a Class C drug shop.
 - The seller must have attained UCE certificate, and have a minimum of six months training of nursing assistant course
- In addition to the usual requirements for a Class C shop—
 - The seller in an ADS must complete the ADS training program and pass an examination.
 - The shop itself must pass an inspection.

ADS accreditation process

1. Obtain application forms for accreditation (from DADI or PDSA).
2. Submit completed forms (to DADI or PDSA).
3. Pre-inspection is carried out by the DADI and the EADSI coordinator and advice given to rectify noted deficiencies
4. Wait for final NDA Inspection (done by DADI and EADSI coordinator).
5. Inspection report is sent to Regional Drug Inspector for NDA approval.
6. Successful applicants will be issued Accreditation Certificates upon fulfillment of NDA requirements to operate the ADS among which includes attending training for both the owner and the drug seller

Regulation of ADS

- Regulatory bodies involved include PSU, NDA and other players (e.g., PDSA and Local Authorities).
- Role of PSU:
 - Personnel accreditation training
 - Support supervision
 - Sets the standards of Conduct and Ethics, and ensures that they are met

Role of NDA

- ❖ Establish standards for accredited drug shop facilities
- ❖ Determine a list of prescription medicines that can be appropriately dispensed by accredited drug shops
- ❖ Provide regulatory oversight/inspection of drug shops (in collaboration with local government)
- ❖ Promote the rational use of drugs through training

Standards for operating ADS

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

- **Standards for Personnel:** Qualification, code of conduct, dress code, commitment letters, training
- **Standards for Premises**
- **Standards for Dispensing:** Dispensing procedure, counseling of patients, dispensing containers, labels, sources of supply, storage and hygiene
- **Standards for Record Keeping and Documentation:** Purchase record, Rx books, expiry record book, sales record, inspectors' record book

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. Under this, the violator may be subjected to appear before a court of law and, upon conviction, may be punished by either paying a fine or be imprisoned or both.
- Examples of offences include:
 - Selling expired medicines or medicines outside the ADS extended medicines list
 - Purchasing medicines from non-licensed dealers
 - Dispensing medicines purchased from unauthorized dealers
 - Illegally opening an ADS
 - Not paying officially assessed business taxes

INSPECTION

❖ Inspection is to scrutinize or closely look at something more keenly to find out if it conforms to the set criteria and standards.

❖ PURPOSE OF INSPECTION

- ❖ Ensure that the accredited and Class C drug shops sell medicines in accordance to the set standards and regulations
- ❖ Identify short comings and provide education on how to correct deficiencies and provide quality services .

Types of Inspection

- ❖ Preliminary inspection
- ❖ Routine inspection
- ❖ Follow up inspection
- ❖ Investigative inspection

Preliminary Inspection

- ❖ inspection carried out for the first time on new premises or when the business is being transferred or when an existing Class C drug shop is seeking accreditation as an Accredited Drug Shop.
- ❖ Its 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 EADSI coordinator, the DADI and regional inspector

Routine Inspection

- ❖ Inspection done to identify if the drug business is carried out in accordance to the law and set standards.
- ❖ Local monitors will play a role by inspecting the premises and their surroundings using the available checklist.
- ❖ They will also be the ears on the ground for NDA to report
 - ❖ the unlicensed premises selling medicines
 - ❖ accredited and class c drug shops that are operating in violation of the NDA laws.

 Enforcement will be done by NDA.
East African Drug Seller Initiative

Follow up Inspection

- ❖ This inspection is done as a follow up to whether the suggestions given during the previous inspection have been implemented. This would be done by NDA upon receiving reports from the self regulation teams.

Investigative Inspection

- ❖ This inspection is carried out by NDA upon receipt of reports or complaints on violation of regulations and the Act.

Local monitors

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Composition

- ❖ For each sub-county, the local monitors will include
 - ❖ Sub-county health assistant
 - ❖ County health inspector
- ❖ The local monitors will be the ears on the ground for NDA and they will report/recommend to NDA for action to be taken in the event that some drug shops or drug sellers fail to adhere to the set standards

Scope of work for local monitors

- ❖ For purposes of ensuring quality medicines, the local monitoring teams shall check
 - ❖ premises and the surroundings
 - ❖ personnel working in the premises especially with regard to whether they are trained
- ❖ They will also report the unlicensed premises involved in the sale of medicines

Roles and responsibilities

- ❖ Conduct monthly inspections of both accredited and class c drug shops using the available checklist.
- ❖ Act as the ears on the ground for NDA to report to the DADI
 - ❖ the unlicensed premises selling medicines
 - ❖ accredited and class c drug shops that are operating in violation of the NDA laws..
- ❖ The team may report to police when violation of regulations warrants doing so e.g. sell of government drugs or stolen drugs.

NDA powers over local monitors

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

Ethics

- ❖ Carry out his/her duties in accordance with the regulations and procedures set by NDA.
- ❖ Protect his/her professional image and not to collaborate with any person in breaking the law or show behavior which will be detrimental to carrying out his /her responsibilities.
- ❖ Not to give his/her decisions during inspection based on tribalism, favoritism, political affiliation, business structure and competition.

Ethics...

- ❖ To declare conflict of interest e.g. accredited drugshops owned/ operated by his/her close family or relatives.
- ❖ Ensure confidentiality of information obtained and recommendations made.
- ❖ Not allowed to use abusive language, stubbornness, threats or ridicules during inspections.
- ❖ Not allowed to receive presents, favoritisms, bribes or any kind of payment.
- ❖ Must have and wear his/her identity card and be ethical during inspection.

Regular inspection/monitoring process

Speaker name and organization here

Preparation for inspection

- ❖ Before carrying out an inspection, the local monitor must prepare the following
 - ❖ The inspection time table that should list all shops to be inspected with their specific information like, license number, drug sellers and locality per sub county
 - ❖ Local monitoring checklists for conducting inspection.
 - ❖ The Accredited drug shop standards

Procedure during Inspection

- ❖ Inform the leadership of the village immediately when you arrive at the area.
- ❖ When in the inspection areas explain the purpose of the inspection and show their identity cards.
- ❖ Use diplomacy and other convincing tactics to enable you collect relevant inspection information; don't use threats (intimidation).
- ❖ If the owner of the premise refuses to be inspected or give required information on operationalization of the drug shop, he/she should be told that it's a criminal offence and the police needs to be informed to take legal actions.

Procedure...

- ❖ To conduct inspection step by step as indicated in the self regulation checklists. During questioning, ask one at a time and not all together to avoid confusion of the respondent.
- ❖ Fill the checklists while conducting inspection. It's not allowed to fill the checklists after inspection.
- ❖ Write the right report for all the observations. Cheating or false additions to add to the weight of the report is not allowed

Local monitoring checklist

❖ Section one: General information

- ❖ Record the name of the shop, address and locality of the shop in the checklist i.e. Village, Parish and Sub-county.
- ❖ Fill in the date of inspection

Local monitoring checklist

❖ Section two: Licensing requirements

- ❖ Check for the availability of the NDA license, certificate for suitability of premises and accreditation certificate, which include name of the shop, address and expiry date.
- ❖ Make sure the information collected is correct and that the permit has not been transferred from another shop.
- ❖ Check whether drug sellers certificate photocopies are hanged in the shop
- ❖ Check if they are wearing a white coat with identity card

❖ **Section three: Premise/building**

- ❖ Inspect all criteria of the premise/building as indicated in the inspection checklist. Things to observe:
- ❖ Quality, strength and cleanliness of the building - (roof, ceiling, walls, doors. Windows and floor)
- ❖ Cleanliness of the premise and surroundings
- ❖ Lighting and enough air circulation in the premise.
- ❖ Facility for washing hands

Support supervision teams

Speaker name and organization here

Role of support supervision

- ❖ Support Supervision is an essential element of the Program.
- ❖ It includes routine monitoring of records and dispensing practices.
- ❖ Its objective is to support drug sellers and owners in order to strengthen/ maintain the quality of services provided

Composition

- ❖ A member of the Pharmaceutical Society of Uganda (PSU) who will take the lead
- ❖ In-charge HC 3 or HC 4.
- ❖ Member of the district health team
- ❖ Representative of drug seller association (Cadre of pharmacy technician, clinical officer or nurse).

Preparation for support supervision

- ❖ The support supervision time table and inform all those who will participate in the exercise
- ❖ The list of all shops which will be visited with their specific information like, license number, drug sellers and locality per sub county
- ❖ Support supervision checklists.

Procedure during support supervision

- ❖ To inform the leadership of the village immediately when they arrive at the area.
- ❖ When in the support supervision areas explain the purpose of the support supervision.
- ❖ Use diplomacy and other convincing tactics to enable you collect relevant information; don't use threats (intimidation).
- ❖ Conduct support supervision step by step as indicated in the checklists. During questioning, ask one at a time and not all together to avoid confusion of the respondent.
- ❖ Fill the checklists and mentor the drug seller on the identified areas of weakness.
- ❖ Write the right report for all the observations. Cheating or false additions to add to the weight of the report is not allowed

Support supervision checklist

- ❖ **Section one: General Information**
- ❖ Name and address of the shop, shop owner, in-charge, drug sellers and accreditation certificates
- ❖ Fill in the date of inspection.
- ❖ **Section two: Medicine storage, record keeping and reporting**
- ❖ Presence of shelves for keeping drugs. Drugs should never keep on the floor
- ❖ Check arrangement of drugs in the shelves and the counter
- ❖ Check for any expired drugs on the shelves
- ❖ Check whether drugs are in the original manufacturers packaging with labels.

Support supervision checklist

- ❖ Check for the availability and proper filling of the following required records in the shop:
- ❖ *Prescription book*: The team should check for proper filling of the prescription book. Information stored includes the medicines, quantity and doses dispensed, the prescriber and disease condition.
- ❖ *Adverse Drug Reaction forms*: These are to be provided by NDA
- ❖ *File for Referral notes*: A file should be maintained where copies of referral notes will be maintained.

- ❖ *Purchases record book:* This is the book where all accredited drug sellers need to record drugs procured. Information to be stored in these books includes; supplier, medicine bought, batch no, manufacturing date, expiry date and quantity bought.
- ❖ *Register/ file for expired drugs:* Every accredited drug shop is required to have a special register/ file for expired drugs. Check if the register is correctly filled and these drugs are sealed in a container and labeled in red. **“Expired drugs – should not be sold”**
- ❖ *Not: The owner of the ADDO shop is required to produce the expired drugs to NDA through the DADI for their destruction*

❖ **Section Three: knowledge of the drug seller**

- ❖ The team should inquire about the danger signs in pediatrics that warrant referral. The team can go ahead to do mentoring and on site training after assessing the knowledge of the drug seller in order to improve his/ her patient management skills.

❖ **Section Four: Evidence of referrals**

- ❖ The team should check for the file where copies of referral notes are kept so as to be able to ascertain evidence of referral.

❖ Section Five: Appropriate dispensing per disease

- ❖ From the prescription book, the team should randomly select 5 cases of each of the most common conditions such as uncomplicated malaria, non pneumonia respiratory infections, and uncomplicated diarrhea and ascertain whether the correct dosages were issued.

THANK YOU FOR LISTENING

