

Training for self regulation and support supervision teams



INTRODUCTION



- **DEFINITION OF INSPECTION**
- **PURPOSES OF INSPECTION**
- **TYPES OF INSPECTION**
- **AREAS FOR INSPECTION**





- **DEFINITION OF 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 accredited drug shops sell medicines in accordance to the set standards and regulations
- It does not only mean finding out problems and short comings but also building mutual collaboration between service providers and law enforcers by giving education on how to correct deficiencies and provide quality services .





- **TYPES OF INSPECTION**

- Preliminary inspection-inspection carried out for the first time on new premises or when the business is being transferred for purposes of giving instructions to improve buildings to observe the set standards.

This was carried out by the EADSI coordinator with 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. This is where the self regulation teams will play a role by looking at the premises ,medicine storage and record keeping. Enforcement to be done by NDA.





- 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 following reports or complaints on violation of regulations and the Act.
- **AREAS FOR INSPECTION**
 - For purposes of ensuring quality medicines, the self regulation teams shall check the premises, medicine storage and record keeping to ascertain whether the shops conform to the set standards.



SELF REGULATION TEAMS



- **SELECTION**
- **SELF REGULATION TEAM AUTHORITY**
- **POWERS OF NDA OVER SELF REGULATION TEAMS**
- **ETHICS OF MEMBERS OF SELF REGULATION TEAMS**
- **PREPARATION BEFORE CARRYING OUT AN INSPECTION**
- **PROCEDURE DURING INSPECTION BY THE SELF REGULATION TEAMS**
- **SELF REGULATION CHECK LIST**





- **SELECTION**

- Team comprised of
 - ✦ Sub-county health assistants
 - ✦ County health inspector
 - ✦ Representative of drug seller association
- Representative shall be a qualified person of cadre of pharmacy technician, clinical officer or nurse.
- The team has no powers to close any licensed drug shop but can recommend to NDA through the DADI.





- **SELF REGULATION TEAM AUTHORITY**

- Conduct self regulation through checks on the premises involved in selling medicines using the checklist.
- Carry out inspection on documents related to business eg sales books ,purchase books and receipts.
- Recommend to NDA through the DADI to take action on drug shops that are in violation of the set standards and regulations.
- Recommend to NDA through the DADI to close unlicensed drug shops.
- The team may report to police when violation of regulations warrants doing so e.g. sell of government drugs or stolen drugs.





- **POWERS OF NDA OVER THE SELF REGULATION TEAMS**
 - NDA has powers to dissolve any member of the team.
 - Powers of any member of the team will cease when nomination of the member is nullified.





- **ETHICS OF THE MEMBERS OF THE SELF REGULATION TEAMS**

- 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.
- Not to be influenced by any thing 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.





- To speak openly to NDA his/her relationship and ownership of any drugs business or that of his/her close family or people relate to him.
- Not allowed to use information obtained during inspection individual, family or any other person's gains.
- Not allowed to use abusive language, stubbornness, threats or ridicules, which may affect individual personality during carrying out of his/her duties.
- 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 and his/her actions should portray the good image of NDA.





● PREPARATION BEFORE CARRYING OUT AN INSPECTION

- Before conducting any type of inspection, it's important for the teams to prepare the following items;
 - ✦ The inspection time table and inform all those who will participate in the inspection
 - ✦ The list of all shops which will be inspected with their specific information like, license number, drug sellers and locality per sub county
 - ✦ Self regulation checklists for conducting inspection.
 - ✦ The Accredited drug shop standards
 - ✦ List of drugs registered and allowed





● **PROCEDURE DURING INSPECTION BY THE SELF REGULATION TEAMS**

- To inform the leadership of the village immediately when they 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 accredited drug shop should be told that it's a criminal offence and the police need to be informed for taking legal actions.
- 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





- **SELF REGULATION CHECK LIST**

- **Section one: Shop records**

- ✦ Record the name of the shop, shop owner, in-charge, address and locality of the shop in the checklist.
- ✦ For the operating shop, check on the NDA license and 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.
- ✦ Fill in the date of inspection

- **Section two: Drug sellers**

- ✦ Record information of dispensers (names, experience and if has a training certificates)
- ✦ Check whether drug sellers certificate photocopies are hanged in the shop
- ✦ Check if they are wearing a white coat with identity card
- ✦ Check if the drug seller is sober, clean and well dressed





- **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

- **Section four: Storage and record keeping**

- ✦ 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.





- Check if the following drugs are available:
 - Drugs which are not in the list of the drugs allowed in the accredited drug shop.
 - Government drugs
 - Expired drugs

- Check for the following records:
 - **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.
 - **Sales book:** Check the prescription book and check if all sections are correctly filled.
 - **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”**

- *Note: The owner of the ADDO shop is required to produce the expired drugs to NDA through the DADI for their destruction.*

- The owner of the accredited drug shop and the inspection team has to fill their names, signature and date of inspection. And a copy of the inspection form is left at the shop for filing by the shop owner/ drug seller.



SUPPORT SUPERVISION TEAMS



- REASON FOR SUPPORT SUPERVISION
- SELECTION
- PREPARATION BEFORE CARRYING OUT A SUPPORT SUPERVISION VISIT
- PROCEDURE DURING SUPPORT SUPERVISION
- SUPPORT SUPERVISION CHECKLIST





- **REASON FOR 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.

- **SELECTION**

- 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





- **PREPARATION BEFORE CARRYING OUT A SUPPORT SUPERVISION VISIT**
 - 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 CHECKLISTS
- **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: Record keeping and reporting**
- 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.





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- *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

