

TRAINING MANUAL FOR SUPPORT SUPERVISION TEAMS

First Edition

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CHAPTER ONE: STANDARDS FOR OPERATING ACCREDITED DRUG SHOPS

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.
- 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 cease operation within one calendar year of 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 accredited drug seller shall not dispense damaged, counterfeit, substandard or expired medicines

- d) The accredited 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 on the prescription form

3.2 Counseling 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 will render 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.

4.0 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 purchased,
 - 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 reaction forms maintained in each Accredited Drug Shop for the purpose of recording patient drug related adverse reactions. The forms shall be collected by the DADI forwarded to the NDA Pharmacovigilance centre
- 4.7** Every Accredited Drug Shop shall keep and maintain –
- a. a special file for keeping all correspondence 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.

5. 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

6. 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.

Accredited drug shop extended medicines list

DRUG AND FORM	Intended ailments
<i>Anti-asthmatics & Cough preparations</i>	
Aminophylline tablet	Wheezing & bronchitis
Salbutamol tablet	Wheezing & bronchitis
Non-narcotic cough preparations (e.g. antitussives, expectorants and herbal)	Symptomatic relief of Dry and chesty cough
<i>Anti-Bacterials/Antibiotics</i>	
Amoxicillin capsules/ tablets	URTIs, UTIs,
Amoxicillin oral suspension	URTIs, UTIs, Skin infections
Co-trimoxazole suspension	URTIs
Co-trimoxazole tablets	URTIs
Doxycycline capsules/tablets	UTIs
Erythromycin oral suspension	URTIs, UTIs,
Erythromycin tablets	URTIs, UTIs,
Metronidazole tablets	Amoebiasis, trichomoniasis
Metronidazole suspension	Amoebiasis,
Nitrofurantoin tablets	UTIs
Phenoxymethyl Penicillin suspension	URTIs
Phenoxymethyl Penicillin tablets	URTIs
Ciprofloxacin 250mg & 500mg tablet	Gonorrhoea and other UTIs
<i>Dermatological products</i>	
Silver sulfadiazine cream	Wounds and burns
Iodine tincture 2%	Wounds
Calamine lotion 15%	Anti-inflammatory and Pruritus
Benzyl benzoate lotion 25%	Scabies
Malathion lotion aqueous 0.5%	Pediculosis
Hydrocortisone cream	
<i>Anti-helminthics</i>	
Mebendazole tablet and suspension	Intestinal worms
Albendazole tablet and suspension	Intestinal worms
<i>Anti-Inflammatory/Analgesics</i>	
Diclofenac sod. Tablets	Musculo-skeletal pain
Ibuprofen tablet 200mg and syrup	Musculo-skeletal pain
Acetylsalicylic acid tablet 300mg	Musculo-skeletal pain
Paracetamol tablet 500mg and suspension	Musculo-skeletal pain

<i>Anti – Allergic</i>	
Chlorphenamine tablet 4mg and syrup	Pruritus
Promethazine tablet 25mg and syrup	Pruritus and vomiting
Cetirizine tablet and syrup	
<i>Anti-Fungal</i>	
Nystatin oral suspension/ tablets/ lozenges	Oral candidiasis
Nystatin pessaries	Vaginal candidiasis
Clotrimazole pessaries	Vaginal candidiasis
Clotrimazole cream	Skin infections e.g. ringworms
Sulphur ointment	Skin infections e.g. ringworms
Benzoic acid + salicylic acid ointment 6% + 3%	Skin infections e.g. ringworms
<i>Anti Malarials</i>	
Artemether /Lumefantrine Tablet	Uncomplicated malaria
Artesunate/Amodiaquine tablet and other ACTs	Uncomplicated malaria
Quinine tablet and suspension	
<i>Disinfectants and antiseptics</i>	
Cetrimide + chlorhexidine solution 0.5% + 0.05%	Skin wounds antiseptic
Chlorhexidine gluconate solution 20%	Skin wounds
Hydrogen peroxide solution 6%	Skin wounds and mouth gargle
Calcium or sodium hypochlorite solution 5%	Disinfectant
<i>Oral Contraceptives</i>	
Ethinylestradiol + Norethisterone	Combined contraceptive
Ethinylestradiol + Levonorgestrel	Combined contraceptive
<i>Anti Diarrhoea</i>	
Zinc Sulphate tablets	Diarrhoea in children
ORS	Diarrhoea in children
<i>Anti-convulsant</i>	
Diazepam rectal tube 2mg/mL	Convulsions in children
<i>Antidotes</i>	
Charcoal activated tablet 250mg	Food poisoning
<i>Ophthalmologic preparations</i>	
Chloramphenicol eye ointment 1%	Eye infections
Chloramphenicol eye drops 0.5%	Eye infections
Tetracycline eye ointment 1%	Eye infections
Combined antibiotic plus steroid eye preparations	Eye infections
<i>Antianaemia medicines, Vitamins&Minerals</i>	

Ferrous salt tablet 60mg	Anaemia
Folic acid tablet 5mg	Anaemia
Ferrous/Folic acid	Anaemia
Multivitamin tablets and suspensions	Appetite
Vitamin A capsules	
Vitamin C tablets	

CHAPTER TWO: SUPPORT SUPERVISION

2.1 SUPPORT SUPERVISION TEAMS

2.1.1 Selection

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. Support supervision shall be carried out at least every 2 months.

The support supervision team shall be constituted as follows,

- A member of the Pharmaceutical Society of Uganda (PSU) who will take the lead
- In-charge HC 3 or HC 4.
- A member of the district health team (DHT)
- A member of the association with technical competency such as a clinical officer, pharmacy technician

2.1.2 Preparation before carrying out a support supervision visit

Before conducting any type of support supervision visit, it's important for the teams to prepare the following items;

- i) The support supervision time table and inform all those who will participate in the exercise
- ii) The list of all shops which will be visited with their specific information like, license number, drug sellers and locality per sub-county
- iii) Support supervision checklists.
- iv) The Accredited Drug Shop standards
- v) List of drugs registered and allowed to be sold in Accredited Drug Shops

2.1.3 The procedure during support supervision

The teams must adhere to the following procedure when they enter into the area for conducting support supervision activities:

- i) To inform the leadership of the village immediately when they arrive at the area.
- ii) When in the support supervision areas explain the purpose of the support supervision.
- iii) Use diplomacy and other convincing tactics to enable you collect relevant information; don't use threats (intimidation).
- iv) 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.
- v) Fill the checklists and mentor the drug seller on the identified areas of weakness.
- vi) Write the right report for all the observations.

2.1.4 Support Supervision checklist

The support supervision checklist is divided into the following sections: location, identification of owner, in-charge and drug sellers, knowledge of the drug seller, and appropriate dispensing.

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

- Check whether drugs are in the original manufacturers packaging with labels
- Presence of shelves or cabinets for storing drugs. Drugs should never be kept on the floor
- Check arrangement of drugs on the shelves and the counter
- Check for any expired drugs on the shelves

Check if any of the following drugs are available:

- Drugs which are not on the list of drugs allowed to be sold by an Accredited Drug Shop.
- Government-purchased 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 kept in these books includes; supplier, medicine bought, manufacturer, batch number, 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”**
Note: The owner of the ADDO shop is required to transfer the expired drugs to NDA through the DADI for their destruction.
- *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.

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.

ANNEX 1: SUPPORT SUPERVISION CHECKLIST

NATIONAL DRUG AUTHORITY

Tel. 255665 / 347391/ 347392

Fax: 255758

E-mail : nda@ndaug.or.ugWebsite : <http://www.nda.or.ug>

P.O Box 23096, Kampala

Plot 46-48 Lumumba Avenue

ACCREDITED DRUG SHOP SUPPORT SUPERVISION CHECKLIST

(Two copies should be filled in and one copy to remain in the Accredited drug shop)

District:	Parish:	Village:
Date of Supervision:		

General Information

Name of accredited drug shop:	
Address:	
Accreditation Certificate No:	
Date of Accreditation:	
Accredited drug shop Owner's name:	
Accredited drug shop in-charge personnel	
Accredited Drug sellers	
Name:	Cert. No:
Name:	Cert. No:
Name:	Cert. No:

Medicine storage, record Keeping and Reporting	Yes	No
1. Are the pharmaceutical products in the premises in the manufacturer's original packing (with labels)?		
2. Is the arrangement of medicines appropriate?		
3. Are there any expired medicines on the shelves?		
4. Are purchases being recorded properly?		
5. Are purchase receipts being kept properly?		
6. Is the prescription book being filled correctly and regularly?		
7. Has accredited drug shop reported expired medicines in the last 3 months?		
8. Have reported expired medicines collected for disposition?		
9. Has accredited drug shop reported Averse Drug Reaction in the last 3 months?		
10. Has an inspection or supervision been conducted in the last quarter?		
Comments/areas for improvement/advice given to drug seller:		

Knowledge of the drug seller	Yes	No										
<p>1. Satisfactory knowledge of general danger signs of a child of age group 2 months up to 5 years? (<i>Drug seller must mention 3 out of 4 signs</i>)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">† Not able to drink or breastfeed</td> <td style="width: 50%; padding: 2px;">† Lethargic or unconscious</td> </tr> <tr> <td style="padding: 2px;">† Convulsions</td> <td style="padding: 2px;">† Vomits everything</td> </tr> </table>	† Not able to drink or breastfeed	† Lethargic or unconscious	† Convulsions	† Vomits everything								
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† Convulsions	† Vomits everything											
<p>2. Satisfactory knowledge of general danger signs of a child age one week up to 2 months? (<i>Drug seller must mention 5 out of 10 signs</i>)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">† Not able to breastfeed at all</td> <td style="width: 50%; padding: 2px;">† Fever (37.5⁰C or more or feels hot) or temperature below normal-35⁰C</td> </tr> <tr> <td style="padding: 2px;">† Convulsion</td> <td style="padding: 2px;">† Skin rashes with pus</td> </tr> <tr> <td style="padding: 2px;">† Fast breathing (60 breaths or more per minute)</td> <td style="padding: 2px;">† Very sleepy or unconscious</td> </tr> <tr> <td style="padding: 2px;">† Severe chest in-drawing or</td> <td style="padding: 2px;">† Unusually Inactive</td> </tr> <tr> <td style="padding: 2px;">† Redness of the skin around the umbilicus</td> <td style="padding: 2px;">† Grunting</td> </tr> </table>	† Not able to breastfeed at all	† Fever (37.5 ⁰ C or more or feels hot) or temperature below normal-35 ⁰ C	† Convulsion	† Skin rashes with pus	† Fast breathing (60 breaths or more per minute)	† Very sleepy or unconscious	† Severe chest in-drawing or	† Unusually Inactive	† Redness of the skin around the umbilicus	† Grunting		
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† Fast breathing (60 breaths or more per minute)	† Very sleepy or unconscious											
† Severe chest in-drawing or	† Unusually Inactive											
† Redness of the skin around the umbilicus	† Grunting											
Comments/areas for improvement/advice given to the drug seller:												

Referral	Yes	No
1. Is there evidence that children with signs of severe illness are being referred to a health facility?		
2. Are referrals sent with referral note?		
Comments/areas for improvement/advice given to the drug seller:		

Appropriate Dispensing per Disease

From the prescription book, randomly select 5 cases of **uncomplicated malaria** from the previous 3 months and record how they were treated.

Treatment for <5 uncomplicated malaria	Correct Dose	
	Yes	No
1.		
2.		
3.		
4.		
5.		

From the prescription book, randomly select 5 cases of **non-pneumonia respiratory infections** and record how they were treated.

Treatment for <5 non-pneumonia	Correct Dose	
	Yes	No
1.		
2.		
3.		
4.		
5.		

From the prescription book, randomly select 10 cases of **<5 uncomplicated diarrhoea** from the previous 3 months and record how they were treated.

Treatment for <5 uncomplicated diarrhoea	Correct Dose	
	Yes	No
1.		
2.		
3.		
4.		
5.		

Comments/areas for improvement/advice given to the drug seller on dispensing:

Support supervision team:	Signature	Accredited drug shop personnel:	Signature
1.....	1.....
2.....	2.....
3.....	3.....