



MINISTRY OF HEALTH



NATIONAL DRUG AUTHORITY



Pharmaceutical
Society of Uganda



Management Sciences for Health

Accredited Drug Shops Training *Uganda*

Module I: Law, Regulations and Ethics

Module Outline



- Introduction to the Accredited Drug Shop (ADS) model
 - The pharmaceutical sector of Uganda
 - The ADS concept
 - Position of drug sellers in service delivery
- Legal requirements and standards for ADS
- ADS Code of Ethics and Conduct

Introduction to the ADS Model



Aim

To understand the Pharmaceutical Sector in Uganda and the role of the Accredited Drug Shops (ADS) in improving use of medicines in areas underserved in Pharmaceutical services.

Objectives



- Outline the pharmaceutical sector of Uganda
- Understand the ADS concept
- Discuss the role of ADS in service delivery

The Public Healthcare System



Administrative Structure	Local Council Level	Health Structure
Village	I	HC 1
Parish	II	HC 2
Sub-County	III	HC 3
County/Sub-District	IV	HC 4
District	V	District/General Hospital
Regional		Regional Referral
National		National Referral

The Public Healthcare System (2)



- The public pharmaceutical sector follows a similar format, but only 49% of the population accesses medicines through the public system.
- Rural communities are particularly affected because they have to walk long distances to access the services. Therefore, **Public-Private Partnerships** are important and ADS is a step towards such an attempt.
- The ADS project seeks to build capacity of the private for-profit medicine dispensing shops/outlets to appropriately manage diseases that are most prevalent in areas where they are located.



The Medicines Supply System



- Medicine supply system is run by both private and public sectors.
 - National Medical Stores (NMS) provides medicines for public sector.
 - Joint Medical Stores (JMS) is a nonprofit organization that supplies medicines to NGOs, faith-based organizations.
 - **Local manufacturers and wholesalers/importers are major sources for the private pharmacies and Drug Shops.**
- Summary of the medicine supply sources:

■ Large scale manufacturers	5
■ Small scale manufacturers	5
■ Public Sector health facilities	2,939
■ Private Pharmacies	300
■ Drug shops	2600

How do medicines reach the final users?



Levels	Private Sector	Public Sector
International	Suppliers/Manufacturers	Procurement Agencies
National	JMS/Local Manufacturers	NMS
Regional	Wholesalers/Importers	Regional Hospital
District	Wholesale and Retail Pharmacies,	District Hospital
Health Sub-District	ADS, Drug Shops	HC II,HC III,HC IV
Community		Community Medicine
USERS		

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.

Why are ADS needed in Uganda?



- **To improve medicines availability**
 - Essential medicines available in all drug shops
- **To improve care provided in the community**
 - Malaria care
 - Childhood diarrhoea care
 - Wound/burn dressings and treatment
- **To reduce inappropriate practices**
 - Prescribing antibiotics for respiratory, urinary and sexual infections
 - Injecting medicines when tablets are safer and equally effective
 - Poor storage of medicines
 - Untidyness
 - Dumping of expired medicines

Benefits of ADS



- ADS will be allowed to stock medicines and other health-related commodities beyond what is generally allowed by ordinary Class C drug shops.
- This expanded list of drugs covers the most prevalent diseases in the communities.
- Drug sellers and owners will be trained in business management, medicine management and patient care.
- There will be a public awareness campaign so that patients will know that ADS provide good care and are a good place to seek help.
- There will be support supervision and regular monitoring.

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.

Conditions for Licensing a Class C Drug Shop



- The person licensed to carry out the business should have a medical background, e.g., nurses, midwives.
- The applicant must have certification from the local authorities.
- Premises should satisfy the requirements for suitability, such as:
 - Must be a permanent structure.
 - Shall not be shared with any other business.
 - Premises should be built so that medicines are protected against conditions such as sunlight, rain, excessive heat.
- A Class C drug shop must keep proper records of all shop transactions, and will allow inspection by NDA or a police officer.

ADS Accreditation Process



1. Obtain application forms for accreditation (from DADI or PDSA).
2. Submit completed forms (to DADI or PDSA).
3. Wait for NDA Inspection (done by DADI in presence of EADSI).
4. Inspection report is sent to Regional Drug Inspector for NDA approval.
5. Successful applicants will be issued Accreditation Certificates, deeming them fit to operate as ADS.

NB: Accreditation will only be given for business to be carried out in an area that is not sufficiently served by existing retail pharmacies.

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

Regulation of ADS (2)



Role of NDA:

- Handles development and regulation of pharmacies and drug shops in the country
- Approves the national list of essential drugs and revises it as needed
- Estimates medicine needs to ensure the needs are met as economically as possible
- Controls imports, exportation, and sale of pharmaceuticals
- Controls medicine quality
- Promotes local medicine production
- Encourage research and development of herbal medicines
- Promote the rational use of drugs through training

Self Regulation



- PDSA, with the assistance from PSU, will provide the framework for self-monitoring and develop a supervision program that will help the association to monitor its members.
- Self regulation will allow members of the PDSA to manage their own affairs, including managing their own performance.
- A team comprising sub-county health assistants, county health inspectors and representatives from the PDSA shall regularly visit the ADS at least every two months using the checklists developed.

Regular Monitoring and Support Supervision



- The objectives are:
 - To ensure that the ADS sellers and owners perform and conform to the regulatory guidelines , and
 - To provide onsite support and mentoring.
- The team will include:
 - In-charge from a HC III
 - PSU
 - A representative of the PDSA at sub-county level.

This team shall make quarterly supervisions using a standard checklist and will be trained to supervise and write reports.

Procedures for Routine Support Supervision



- The supervision team will:
 - Inform owners and drug sellers about the activity
 - Notify the local authorities about the impending inspection exercise before starting
 - Visit each outlet and assess the premises, stock management and dispensing practices using supervision checklist
 - Share findings with drug sellers and owner
 - Provide on-site practical training, orientation and mentoring

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, counselling 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 offense 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

Relationship of Laws to Ethics



- **Ethical values** and **legal principles** are closely related.
- The law often embodies ethical principles, but laws do not always prohibit actions that would be considered unethical.
 - Lying or betraying the confidence of a friend is not illegal, but most people would consider it unethical.
 - Driving too fast is illegal, but many people do not have an ethical conflict with exceeding the speed limit.

Code of Ethics & Conduct



Professionalism:

Professionalism is what one exhibits in terms of attitudes, behaviour, and skills while performing duties, and responsibilities expected of him or her by the community by virtue of having privileged knowledge and skills acquired through a unique and formal education.

What is expected of a Professional Health Worker?

- Attend to the patient's best interest rather than self interest
- Be accountable to the patient and society
- Commit to regularly updating knowledge
- Be available and respond when called upon
- Be fair, truthful, & straight forward when interacting with the patient
- Be respectful to patients and their families

Example Ethical Violations in Medicines Management



- Fraud
- Theft
- Bribery (Kintukidogo)
- Threats
- Nepotism
- Favoritism
- Lack of transparency

Note that some of these
ETHICAL violations are
also ILLEGAL.

Ethical Decision Making



- In deciding on a course of action, ask yourself:
 - Is it right? Is it legal? Does it reflect professional values?
 - How will I explain my decision to others?
 - How will it look to others?
 - What will the consequences be?
 - Who else will be affected by my decision?



The ADS Personnel Code of Ethics and Conduct



- Honesty and integrity
- Patient care
- Special relationship with patients
- Confidentiality
- Do not condone low quality medical service
- Collaborate with other health workers
- Be responsible for assuring and improving competence
- Owners not to require sellers to act illegally
- Health promotion
- No commercial relation to be allowed

Resources to Review



- Readings:
 - Pharmacy and Drugs Act, 1970
 - National Drug Authority and Policy Act
 - ADS survey/pre-inspection reports
 - ADS accreditation criteria/checklist
 - ADS standard of practice
 - ADS (expanded) list of medicines

Conclusions



- We hope that we have empowered you to provide better health services to our communities, with the elements of the ADS concept in mind.
- We urge you all to abide by the ADS Code of Ethics and Conduct while executing your duties.