GUIDELINE FOR ESTABLISHING AND OPERATING ACCREDITED DRUG DISPENSING OUTLETS

AUGUST 2009

Tanzania Food and Drugs Authority
P.O. Box 77150, Mabibo, Mandela Road,
Dar es Salaam, Tanzania
Tel: +255 22 2450 512/ 2450 751/2452108
Fax: +255 22 2450 793
Website: www.tfda.or.tz
Email: info@tfda.or.tz

This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Recommended Citation

Tanzania Food and Drugs Authority. 2010. *Training Manual for Accredited Drug Dispensing Outlet Owners on Regulations.* Arlington, VA: Management Sciences for Health.

Strengthening Pharmaceutical Systems
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org
Web: www.msh.org/sps

CONTENTS

FOREWORD

The Tanzania Food and Drugs Authority (TFDA) was constituted under the Food, Drugs and Cosmetics Act, 2003, to ensure the the quality, safety, and effectiveness of the food products, medicines, cosmetics, and medical devices in order to protect the health of the general community. In executing this role, TFDA has the responsibility to register all facilities which provide medicine services and ensure that medicines are available.

TFDA is implementing the Accredited Drug Dispensing Outlets (ADDO) Program in the country with the aim of improving Duka La Dawa Baridi (DLDB) and upgrading them to ADDOs with the intention of minimizing the problems encountered in the operation of DLDBs both for human beings and livestock. To facilitate the establishment and operation of the ADDOs according to the established regulations and procedures, TFDA has prepared this guideline.

This guideline is an important tool to be used by every ADDO owner, dispenser, supervisor, and inspector of food, drugs, and cosmetics. In addition, this guideline aims at sensitizing various partners on ADDOs.

It is my hope that all those who are responsible with implementing the ADDO Program will read this guideline and ultimately be able to execute their respective responsibilities effectively and efficiently within the program.

M. Ndomondo-Sigonda
Director General,
Tanzania Food and Drug Authority

The TDFA would like to encourage you—as stakeholders in the TFDA—to give us your opinion of these materials and guidelines. Please write us at the following address and let us know your opinions and recommendations.

Director General
Tanzania Food and Drugs Authority
P.O. Box 77150
Dar es Salaam, Tanzania
E-mail: Info@tdfa.or.tz
Fax: 022.2450793

ACKNOWLEDGMENT

The completion of these materials for accredited drug dispensing outlets (ADDOs) inspectors is the result of much work of implementers from the Tanzania Food and Drugs Authority (TFDA) in collaboration with Management Sciences for Health (MSH), a nongovernmental organization, and the Prime Minister's Office Regional Administration and Local Government in the implementation of ADDO program. These experts used their experiences and those of various stakeholders to prepare these materials.

TFDA would like to thank all partners in the ADDO program implementation, particularly Management Sciences for Health (MSH), which through support from U.S. Agency for International development and the Bill & Melinda Gates Foundation, has assisted in preparing this guideline. TFDA would also like to sincerely thank the Danish International Development Agency for the financial support rendered in preparing this guideline.

Furthermore, TFDA is grateful to all individuals who actively participated in in the preparation of this guideline. They include the following: Emmanuel Alphonce, Iskari C. Fute, Dr. Sadi Kajuna, Akida Khea, Bryceson Kibassa, Suleiman Kimatta, Ollympia Kowero, Jafary Liana, Bundala Maganga, David Maganga, Dr. Cliffson Maro, Dr. Romuald Mbwasi, Mshindo Msule, Zera Msuya, Ngoyako Mtenga Mwemezi Ngemera, Dr. Sikubwabo S. Ngendabanka, Boniface Nobeji, Amani Phillip, Elizabeth Shekalaghe, Grace M. Shimwela, and Richard Valimba. In addition, thanks are extended to TFDA management team under the leadership of the Director General for their technical contribution. Special thanks go to the support staff of Ms. Mary Mbwambo and Ms. Johari Mirambo who helped produce this guideline.

Hiiti B. Silo
Director, Medicine and Cosmetics
TDFA

ACRONYMS AND ABBREVIATIONS

Act	Food, Drugs and Cosmetics Act, 2003
ADDO	accredited drug dispensing outlet
ARW	ADDO Restricted Wholesale
CFDC	Council Food and Drugs Committee
DLDB	*duka la dawa baridi* (Swahili, private drug shop)
DLDM	Duka la Dawa Muhimu (Swahili, private accredited drug shop)
MEO	mtaa executive officer
MoHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
RFDC	Region Food and Drug Committee
TFDA	Tanzania Food and Drugs Authority
VEO	village executive officer
WEO	ward executive officer

INTRODUCTION

In Tanzania, pharmaceutical services are under the Food, Drugs and Cosmetics Act, 2003. This Act gives power to Tanzania Food and Drugs Authority (TFDA) to regulate the quality, safety, and effectivenes of medicines, food, cosmetics, and medical devices. Furthermore, this Act is in line with National Health Policy which emphasizes availability of quality health services to all Tanzanians.

The accredited drug dispensing outlet (ADDO), popularly known in Swahili as Duka la Dawa Muhimu (DLDM), is the drug outlet registered by the TDFA to store and sell medicines that do not need prescriptions and some essential medicines that need prescriptions. These outlets must be operated by a dispenser who has undergone basic training in dispensing medicines.

These medicine outlets for human beings and livestock have been established to resolve the problems encountered in the Part II Poison shops popularly known as *duka la dawa baridi* (DLDB). The problems encountered in the DLDBs include the following—

- Drug sellers with no qualifications dispense medicines that are not permitted under the Guideline for Operating Part II Poison Shops, 1998.

- Most DLDBs are located in the urban area instead of rural areas, and this is not in line with the aim of establishing them.

- Most DLDBs (72 percent) have been found to stock and sell both prescription and nonprescription medicines. This is a threat to the safety of general public's health. According to the Act, DLDBs are supposed to stock and sell non-prescription medicines only.

- Medicine quality is not assured because most DLDBs have been found to sell expired and/or unregistered medicines.

- Some of the DLDBs sell medicines stolen from public health facilities and from other health-related projects.

- The premises of DLDB are not maintained adequately for proper storage of medicines. This in turn lowers the quality of medicines available in these shops.

- Livestock medicines have been sold in the open market.

- Medicines are sold without following proper guidelines for good dispensing practices.

- The range of medicines authorized to be sold in the DLDBs does not meet the health demand of the customers.

To solve this problem, the Ministry of Health and Social Welfare (MoHSW) through the TFDA has made some essential amendments to DLDB operations. These amendments are targeting the knowledge and the skills of the dispensers, supportive supervision of these outlets, the quantity and type of medicines that are allowed to be stocked in the outlet, improvement of the quality of the premises, and conditions for keeping and storing medicines.

The objective of these changes is to improve the services rendered by DLDBs through accrediting and upgrading them to become ADDOs (Duka la Dawa Muhimu) after meeting criteria as established by ADDO regulations.

To assist individuals who want to establish an ADDO, and also to help program implementers to understand the procedures for establishing and operating these outlets, TFDA has prepared a Guideline for Establishing and Operating ADDOs. This guideline, which covers both people and livestock ADDOs, identifies areas that the owners and the dispensers need to abide by.

The owners, dispensers, and overseers of the Act should use always this guideline as a reference book when establishing and operating or when supervising and inspecting these outlets. All partners dealing with the ADDOs are encouraged to understand the Food, Drugs and Cosmetics Act, 2003; the ADDO regulations of 2004, and its 2008 amendments.

PROCEDURES FOR ESTABLISHING AN ADDO

Procedures for establishing an ADDO include the following areas—

- Application to establish an ADDO
- Roles and responsibilities of various administrative levels
- Criteria for establishing ADDO

Application to Establish an ADDO

The application to establish an ADDO is done through the following administrative levels—

- Village/mtaa
- Ward
- Council
- Region
- TFDA

An individual applying to establish an ADDO should do the following—

- Read and understand the Guideline for Establishing and Operating an ADDO. Copies of the guideline are available in the offices of Regional and Council Pharmacists, TFDA Zonal Offices, and TFDA headquarters.

- Obtain the application form for permit to establish an ADDO (annex 1) from the executive officer of the village/mtaa/ward, Council for Food and Drugs Committee (CFDC) secretary, regional medical office, TDFA Zonal Offices, or TFDA headquarters.

- Complete section A of the application form and then submit it to village executive officer (VEO)/mtaa executive officer (MEO) together with copies of Certificate of Dispenser and Contract Agreement with the Dispenser.

- Pay the annual fee for the permit after receiving permission to operate an ADDO as specified by TFDA in accordance with the 2005 regulations relating to fees and charges.

Roles of Various Administration Levels in Establishing ADDOs

Application forms for establishing ADDOs have to pass through various administrative levels whose members and their roles are as follows—

Village/Mtaa Level

At this level, the key responsible person is VEO/MEO who is supposed to—

- Provide application forms to the applicants

- Receive, review, and provide opinions related to the submitted application; this requires filling in section B of the form

- Submit the completed form (sections A and B) to the WEO

Ward Level

The Ward Health Committee has the following members—

- WEO—chairperson
- Medical officer in-charge of the nearby health facility—secretary
- Ward health officer
- Ward extension officer dealing with livestock

The Ward Health Committee is responsible for the following—

- To provide the application forms for establishing an ADDO

- To receive and go through completed application forms from VEO/MEO

- To interview applicants together with potential dispensers in accordance with information in application form

- If conditions in the application form sections A and B have been satisfied, the inspectors will inspect the premise for which the permit has been applied in accordance with mapping and pre-inspection forms (Annex 2)

- To provide opinions on the submitted application to the committee by filling in section C of the application form

- To submit completed application form together with results of the premise's inspection to the CFDC secretary

Note: *The applicant is advised to seek opinion from the Ward Health Committee on the expected location of the ADDO before building/renovating the intended ADDO premise.*

Council Level

The CFDC has the following members—

- Executive director—chairperson
- Medical officer—secretary
- Pharmacist
- Trade officer

- Health officer
- Veterinary officer
- Agriculture officer
- Treasurer
- Any other co-opted member whose expertise will be needed by the committee.

Note: *The CFDC secretary is district medical officer supported by the district pharmacist or district livestock officer, depending on the objectives/issues of the meeting.*

The Council is responsible for the following—

- To provide ADDO applications and yearly renewal forms

- To receive the completed application forms for establishing ADDO and inspection forms from ward level and make decision

- Using a team of approved ADDO inspectors, inspect all ADDOs that have submitted application forms to the council

- To accept or reject ADDO applications on behalf of TFDA in accordance with criteria of getting ADDO permit

- To submit reports on decisions relating to establishment and operation of ADDOs to TFDA and a copy to the Region Food and Drug Committee (RFDC)

Note: *Reports submitted from one administrative level to another must be accompanied by the meeting minutes of respective committee.*

Regional Level

The RFDC has the following members—

- Commissioner—chairperson
- Medical officer—secretary
- Pharmacist
- Health officer
- Agriculture officer
- Livestock officer
- Trade officer

The committee is responsible for—

- Receiving a copy of decision made by the council on establishing and operation of ADDOs

- Receiving and acting on appeals from council level

- Seeking further information on steps taken by the council committees with respect to information it has received and take appropriate measures when necessary in collaboration with TFDA

- Providing technical support to CFDC regarding the establishment and operation of ADDO

Tanzania Food and Drug Authority

TFDA is the highest level in issuing the ADDO permit and is responsible in effecting the following—

- To receive and review decisions of establishment of ADDO from CFDC

- To make the final decision related to establishment of ADDO including accepting or revoking decisions made by lower administrative levels for the benefit of the general public

- To issue permits to those who have fulfilled the ADDO requirements

Key

→ = Flow of recommendation/decision reports

⇢ = Feedback (positive or negative)

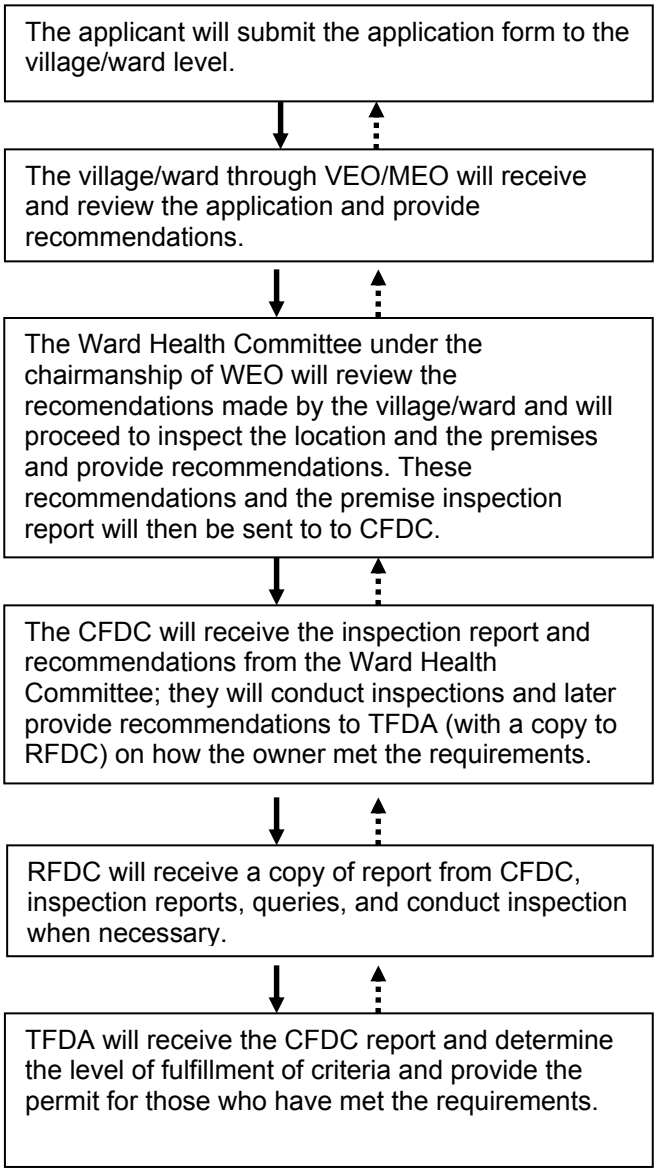


Figure 1. Flow of permit application process to establish ADDO

Criteria for Establishing an ADDO

To be accredited and get a permit, an ADDO and its staff should meet the following criteria.

ADDO Dispenser

The potential ADDO dispenser will have to attend and successfully complete special training to dispense in an ADDO. To qualify for training, the potential dispenser must be one of the following—

- Pharmaceutical technician
- Pharmaceutical assistant
- Nursing officer
- Nurse midwife
- Clinical officer
- Clinical assistant
- Nursing assistant
- Any other person seen as capable by the MoHSW after being advised by TFDA

For veterinary ADDOs, the potential dispenser should have the following qualifications—

- Livestock officer
- Assistant livestock officer
- Any other person seen as capable by the MoHSW after being advised by TFDA

ADDO Owner

An ADDO owner should meet the following criteria—

- Should be a Tanzania citizen 18 years old or above and of sound mental health

- Must have undergone a TFDA authorized training on Ethics and Regulations of Operating of ADDO

Contract Agreement between the ADDO Owner and ADDO Dispenser

According to the Regulations of Operating ADDO, the owner and dispenser need to enter into a contractual agreement to facilitate smooth running of the outlet, and assume roles and responsibilities that benefit both parties. The importance of the agreement is as follows—

- To help owner and dispenser to abide to their agreement related to the terms of employment.

- To provide modalities on how to resign or be terminated from work when necessary without causing unnecessary inconvenience to either of the parties

- To be used by legal system to provide fairness to both parties (annex 3)

Location for Establishing an ADDO

ADDOs are to be located in the following areas—

- Rural areas and small towns where the availability of medicines is problematic
- In peripheral areas of big towns or cities where the availability of medicines is erratic
- In the small town with a population of about 3,000 to 5,000, the ADDO must be established at a distance not less than 300 meters in each direction from the nearest ADDO. In rural areas the distance should not be less than 200 meters from the nearest ADDO and not less than 500 meters from a pharmacy. (Distance is not taken into consideration for veterinary ADDOs.)
- ADDOs should not be located in or close by an area where there are open sewage systems, dumping sites, or industries using toxic chemicals.

ADDO Building (Premises)

- Should be a permanent, well-built structure
- Should have a sturdy, leak-proof roof and ceiling
- Should have a solid floor which can be easily cleaned
- Should have sturdy walls painted white which can be easily cleaned
- Should have two front doors—a strong outer door for security and an inner glass door that should be kept closed to protect against dust, insects, and rodents
- Should have at least two rooms; one for dispensing and the other for storage
    - The dispensing room should be the following size: 3.04 meters long (10 feet) by 2.74 meters wide (9 feet) and 2.43 meters in height (8 feet). The dispensing room should be arranged to allow customers to get into the room (figure 2)—dispensing through windows in strictly prohibited.
    - Should have a hand-washing facility in the dispensing room.
    - The medicine storage room should be of adequate size and have shelves or pallets.
    - Every room must have a sturdy window covered with mosquito gauze which allows adequate ventilation and, where possible, the room should have a fan or air conditioner (temperatures should not exceed 30°C).

- There should not be egress to other rooms that are not part of ADDO, such as bedroom or living room.

- Should have a sign prohibiting smoking of any kind while inside the ADDO (NO SMOKING)

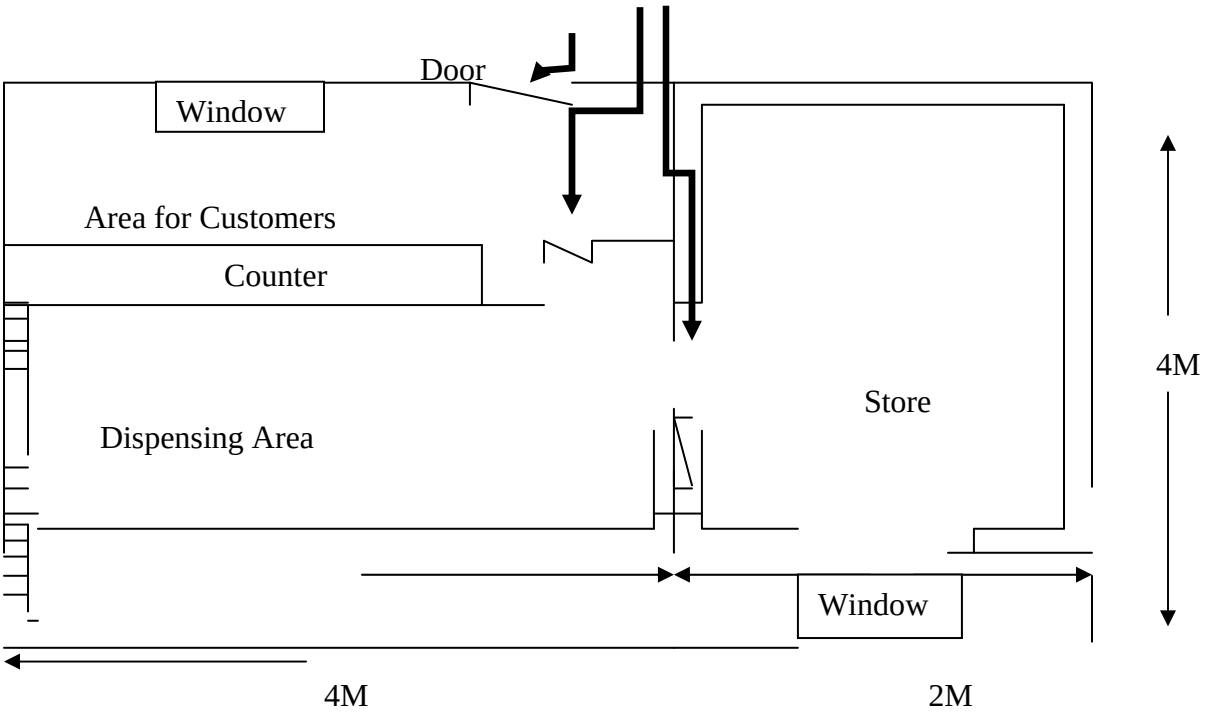
- Should have a glass counter and display case and a movable section of counter to allow access to shop

- Should have sign with an ADDO logo as shown below (to get the sign, the owner should liaise with CFDC)

ADDO Logo

The premise can be constructed according to either of the two drawings (A or B).

Drawing A



Drawing B

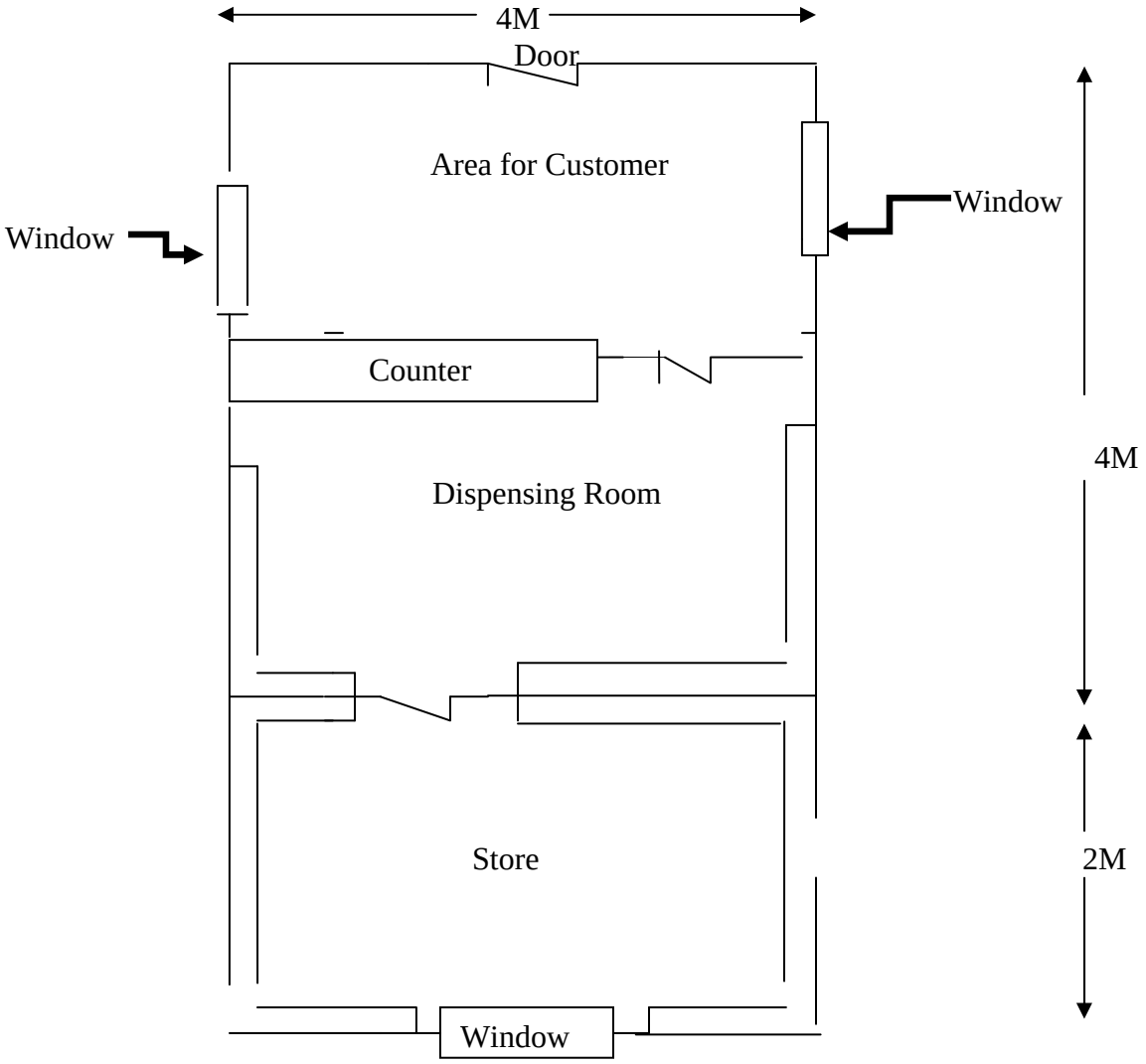


Figure 2. Drawings of the ADDO premises

ADDO Restricted Wholesaler

To improve the availability of registered medicines from authorized sources which are closest to the ADDOs, TFDA has authorized the establishment of an ADDO Restricted Wholesaler (ARW) in every district that does not have a pharmacy. These outlets will be given permission to run a wholesale business for all medicines that are authorized to be sold in the ADDO. This type of outlet is normally registered by TFDA and is supposed to be run by a pharmaceutical technician.

Procedures to Establish ARW

- The applicant will write an application letter for establishing ARW to the TFDA Director General.
- After receiving approval from the TFDA Director General, the applicant will have to complete the application form for establishing the ARW and submit it to the CFDC Secretary.

- CFDC staff will inspect the premises and submit the report together with recommendations to TFDA and a copy to RFDC.

- TFDA will review the recommendations and give decision based on the criteria and procedures for establishing ARW.

- TFDA will provide permit to the respective applicant if he or she has fulfilled requirements and procedures.

Premise Requirements for ADDO Restricted Wholesaler

- Should have three rooms or more; a dispensing room, an office for sales and record keeping, and the other room for storage.

- The premise should have an area of 1,369 square meters (1,497.7 square yards) with a dispensing room that is 78 square meters (256 square feet) in area while the sales office should have an area of 7.62 meters (25 square feet). The storage room should have an area of 78 square meters.

- Other requirements are the same as for retail ADDOs.

OPERATION OF ADDO BUSINESS

ADDOs need to be operated as a collaborative effort between the owner and dispenser according to the Acts, Regulations, and Guidelines.

Roles and Responsibilities of ADDO Owner and Dispenser

The ADDO owner will ensure that—

- There is an accreditation certificate and ADDO permit displayed in the shop at all times
- The ADDO permit is renewed before June 30 each year
- There is a dispenser who is recognized by TFDA and whose dispensing certificate is displayed in the ADDO
- He or she does not interfere with the dispenser's expertise
- He or she stores and sells medicines according to the ADDO list
- He or she refrains from selling public medicines and unregistered, expired, and substandard quality medicines
- The medicines on the ADDO list are available in the ADDO all the time
- There are reference books and other documents for record keeping as stipulated in the ADDO guideline
- ADDO requirements are adhered to at all times

ADDO dispensers will ensure that—

- They handle all the technical duties related to medicine dispensing in the ADDO
- They fill in all the documents correctly for proper record keeping
- The ADDO is kept clean at all times
- They wear the ADDO uniform and carry the identity card all the time while in the ADDO
- They participate in mobilizing and providing health education to the public in relation to the proper use of medicines

Storing and Dispensing Medicines

Storing and dispensing medicine is the major function of ADDOs. Proper storage and dispensing is essential to making sure that medicines reach the customer in appropriate manner so that the intended objectives are achieved.

Medicine Storage

The quality of medicines depends on how they have been stored. Unfavorable temperatures, strong sunlight, high humidity, and dirt can compromise the quality and, therefore, the effectiveness of medicines. Taking this into consideration, the owner and dispenser have responsibilities to ensure that medicines—

- Are stored in clean and dry areas
- Are stored in the original containers
- Are stored on shelves (off the floor)
- Those that can be spoiled by sunlight are stored away from sunlight
- Are kept in a cool place, taking into consideration instructions indicated in the label
- Are arranged according to type and use, for example, topical use medicines should not be kept with those to be ingested (orally)
- Unfit for human use are kept separately and the area should be labeled (in capital letters) **NOT FOR USE**

Dispensing Medicines in ADDO

ADDOs are expected to sell medicines of the highest quality, safety, and effectiveness that are dispensed according to procedures of good dispensing practices. These procedures include—

- Dispensing prescription medicines only when the customer provides a prescription.
- Dispensing nonprescription medicines—these do not require a prescription and should be dispensed according to the information on the disease as provided by the customer

Dispensing medicines in the ADDO will be in accordance with good dispensing practices that are taught during the basic training of ADDO dispensers.

List of Medicines Authorized in the ADDO

The ADDO is supposed to sell the medicines as they are stipulated in the ADDO Regulation amended in 2007. These medicines are divided into two groups: (1) prescription medicines and

(2) non-prescription medicines (over-the counter medicines). The list of these drugs is shown in Annex 4.

Recall of Medicines

If it happens that the ADDO has medicines which have been recalled and have to be removed from the market due to problems with quality, safety, or effectiveness, the ADDO owner and the dispenser ought to offer maximum cooperation to the respective authority to facilitate the recall of such medicines.

Disposal of Medicines Not Fit for Use

Medicines that are not fit for human or livestock should not be dispensed by the ADDO owner and the dispenser. If such medicines are found in the ADDO, the owner should communicate to the district pharmacist or respective authority so that those medicines can be removed and disposed by the proper procedures.

Record Keeping

Every ADDO is supposed to keep correct records with regard to business of medicines. The records are divided into two major groups: (1) sales and expenditure (financial), and (2) medicines and other medical devices.

Sales and Expenditure Records (Financial)

These records will be kept using the following documents—

- Invoices and receipts
- Analysis book
- Daily cash sales book

Medicines and Other Medical Devices Records

These records will be kept in the following documents—

- Patient drug register (Annex 5)
- Store ledger
- Bin card
- Inspection report form
- ADR form
- Recall form (Annex 6)
- Any other form as indicated by TFDA

ADDO Reference Materials

To facilitate daily operation, every ADDO should have various reference materials which include—

- *ADDO Regulations*
- *Guidelines for Establishing and Operating ADDOs*
- *Guideline for Good Dispensing Practices*
- List of Authorized Prescription Medicines for ADDO
- *Training Manual for ADDO Dispenser*

ADDOs are also encouraged to have the following reference materials (optional)—

- Tanzania National Formulary
- Veterinary Formulary
- List of TFDA Registered Medicines
- Standard treatment guidelines
- Food, Drugs and Cosmetics Acts, 2003

These books are available in the council offices, Offices of Regional Medical Officers, TFDA Zonal Offices, and TFDA headquarters.

Change in ADDO Operations

Any change in relation to ownership, dispenser, the location of the premise, the ADDO name, or any other change should follow the procedures below—

- The owner should request permission from CFDC in writings.

- The owner will be responsible for returning the accreditation certificate and the permit of ADDO in case he/she intends to reallocate the premise.

- The owner will have to submit a new application for establishing an ADDO in the new area as outlined in this guideline.

Renewal of the ADDO Permit

According to the ADDO Regulations, the ADDO Permit expires on June 30 each year. Each ADDO owner has an obligation to renew the permit before the annual deadline using the application forms for renewal (annex 7). The procedure for renewing the permit is as follows—

- The owner should obtain the application form for the renewal of the permit from the District Pharmacist.

- The owner will fill and return the form to the CFDC together with the binding Contract Agreement with the ADDO dispenser.
- The owner will pay the renewal fee in accordance with the 2005 Regulation of Fees and Charges of TFDA.

- CFDC will go through the application and if requirements have been met, it will present its recommendations to TFDA so that the permit is renewed. The copy of the application form for renewal will be sent to RFDC.

- The owner who delays in renewing his/her permit will have to pay the Permit fee and a fine of 25 percent of the actual permit fee in accordance with Regulation of Fee and Charges of 2005 and its amendments.

Termination of ADDO Business

The owner may terminate his/her business voluntarily. If the owner fails to run his/her business according to the Act, Regulations, and set procedures, he or she can no longer sell medicines that have to be removed within 90 days according to the TFDA, and the owner will have to return the accreditation certificate and the ADDO permit to the CFDC secretary within that period.

Inspection and Supervision of ADDO

For a close follow-up of establishment and operation of ADDOs, TFDA has decentralized the inspection and supervision responsibilities to the ward, district, and regional levels which will collaborate with village/mtaa governments. The routine inspection at the wards and district levels will be conducted every three months using a checklist (annex 8). However, if deemed necessary, inspections can be conducted at any time.

For ADDO inspection and supervision levels—

- Ward level inspection and supervision will be conducted by a team of inspectors as stipulated by the regulation using the inspection form on a quarterly basis. The inspection reports will be sent to the ward development committee which then sends them on to the CFDC secretary for further action.

- Inspection at the district level will be conducted by a team of district inspectors as stipulated in the ADDO regulation on quarterly basis. The inspection report will be sent to the CFDC for action; quarterly reports will then be submitted to the RFDC and TFDA.

- Regional inspectors may inspect ADDOs whenever necessary. The inspection report will be submitted at the RFDC meetings and to the TFDA.

- TFDA will conduct audit inspection to verify if inspections at lower levels are done according to the set procedures.

Penalties Related to Violations of Acts and Regulations

Violations of Acts and Regulations relating to the operation of ADDOs will result in penalties as stipulated in the Food, Drugs and Cosmetics Acts of 2003. Some of the offenses are—

- Operating ADDO business without a permit or using a permit that has already expired which is contrary to sections 18 and 20 of Food, Drugs and Cosmetic Act, 2003
- The ADDO being operated by a dispenser who is not accredited by the TFDA
- Selling medicines that are not in the ADDO list
- Selling fake and substandard medicines contrary to sections 75 and 76 of Food, Drugs and Cosmetics Act, 2003
- To offer medical services in the ADDO

The following are penalties which will be imposed on anyone found to violate the set of procedures of operating ADDO—

- Fines or imprisonment, or both
- Withdrawal of accreditation certificate or withdrawal of dispenser certificate, or both
- Temporarily closure of the ADDO until the owner has corrected the deficiencies identified
- Permanent closure of the ADDO if the criminal offence is related to medicines
- Refusal for renewal of the ADDO permit by the relevant authority

Making Appeals

The ADDO owner or dispenser who feels that the penalties he or she have received are unfair because of any inspection or decision related to the establishment and operation of ADDO can appeal to regional level and TFDA, or the Minister for Health and Social Welfare.

ANNEX 1. APPLICATION FOR PERMIT TO ESTABLISH AN ADDO

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority

Application Form for Permit to Establish an Accredited Drug Dispensing Outlet (ADDO)

Prepared under the *Tanzania Food, Drugs and Cosmetics Regulations, 2004 (Standards and Code of Ethics for DLDM)* with its amendments.

Section A: To Be Completed By Applicant

1. Name of Applicant _____

Address _____

Age _____ Sex (M) ____ (F)____ Phone _____

2. Name of the drug outlet _____

3. Physical location of the outlet:

Region _____ District _____

Ward _____ Village/Street/Mtaa _____

4. (a) Name of dispenser _____

Address _____ Phone _____

Registration number _____ date of issue _____ 20_____

(b) Name of dispenser _____

Address _____ Phone _____

Registration number _____ date of issue _____ 20_____

Date of application _____ **Applicant Signature** _____

Note: *Only dispensers registered by Tanzania Food and Drugs Authority (TFDA) will be permitted to dispense medicines in the ADDOs. Copies of dispenser(s) certificate together with contract agreement should be enclosed with this application form.*

Section B: To Be Completed by Village Executive Officer (Request at the Village Level) or Mtaa Executive Officer (Request at Urban Level) of the Respective Area.

Prepared under the *Tanzania Food, Drugs, and Cosmetics Regulations, 2004* (*Standards and Code of Ethics for DLDM*) and its amendments.

1. Name of Applicant _____

   Citizenship of Applicant _____

2. The general conduct of the applicant in the community he/she lives

_____

_____

3. Brief history of applicant's conduct related to past or present businesses which the applicant has owned in this ward

_____

_____

4. Perceived demand of the ADDO services by the community living in this area. The applicant should justify his/her request with reasons for the need to establish ADDO in this area.

_____

_____

5. Recommendations/opinions on this application

_____

_____

_____

6. The date on which the application forms was received _____

   The date on which the application forms was acted upon _____

_____

Name, Signature, and Stamp of VEO or MEO

Note: *After filling this form, the VEO/MEO should submit it to the WEO who will in turn submit it to the ward inspectors. Neither VEO nor MEO is allowed to make any decision related to the application.*

Section C: To Be Completed by the Ward Inspectors.

Prepared in accordance with the Regulation 13 of the *Tanzania Food, Drugs, and Cosmetics Regulations, 2004 (Standards and Code of Ethics for DLDM)* and its amendment.

1. The date on which the Ward Inspectors received the application and other documents from the VEO or MEO (Refer to Sections A and B above) _____

2. The date on which the applicant and potential dispenser were interviewed in accordance with information gathered from Sections A and B _____

3. Outcome of the interview

_____

_____

4. Provide information on the correctness of the enclosed documents

_____

_____

Date on which inspection of the premise was done _____

5. The appropriateness of the ADDO location with accordance to the criteria stipulated by Tanzania Food and Drugs Authority

_____

_____

_____

6. Recommendations/opinions of the Ward Inspectors to the Council of Food and Drugs Committee

_____

_____

7. Names and Signatures of Ward Inspectors

Name _____ Signature _____

Name _____ Signature _____

Name _____ Signature _____

8. Date on which the Ward Executive Officer submitted the recommendations and opinions to the Council for Food and Drugs Committee _____

_____

Name, Signature, and Stamp of the Ward Executive Officer (WEO)

Note:

- *Ward Inspectors and WEOs are not allowed to make final decision on any application; instead, they should submit recommendations or opinions to respective meeting of CFDC for decision making.*
- *The inspection should be done according to the TFDA checklist and the report should be submitted to CFDC.*
- *For the ADDOs being established at the urban setting, the distance between one ADDO and the other should not be less than 300 meters from any direction.*
- *For small towns and rural areas, the distance between one ADDO and another should not be less than 200 meters from any direction.*
- *The distance between the ADDO and any pharmacy should not be less than 500 meters.*
- *The criteria for distance are not considered when establishing livestock ADDO.*

Section D: To Be Completed by the Council For Food and Drugs Committee.

Prepared in accordance with Regulation 14 of the *Tanzania Food, Drugs and Cosmetics Regulation, 2004 (Standards and Code of Ethics for DLDM)* and its amendment.

1. The date on which the respective application form was received from the WEO

_____

2. The date on which the CFDC discussed the ADDO application

_____

3. The opinions of the CFDC made from their own observation after conducting inspection or from documents received from WEO. (Explain if there was any need for CFDC to conduct an inspection.)

_____

_____

_____

_____

4. CFDC decisions on the ADDO application

_____

_____

_____

_____

_____

_____

Any specific directives provided to the applicant which should be met before being granted the certificate of accreditation.

_____

_____

_____

_____

_____

_____

_____

_____

_____

Name, Signature, and Stamp of Secretary of CFDC

ANNEX 2. PRE-INSPECTION FORM FOR DLDB

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority (TFDA)

Form for Pre-Inspection of Part II Drugs Outlet/Duka La Dawa Baridi (DLDB). (Two copies should be filled; one copy should remain in the premise and the other copy should be kept by Ward Inspectors for final inspection.)

<table>
<tr><td colspan="5">A.1. DLDB Owner Information</td></tr>
<tr><td>Name of DLDB</td><td colspan="2">Mtaa/Village</td><td>Ward</td><td>District</td></tr>
<tr><td>Name of owner</td><td colspan="2">Postal address and Phone number</td><td colspan="2" rowspan="2">Level of education
□ Primary □ Secondary □ College
□ Others
Profession
……...</td></tr>
<tr><td>Sex: □ F □ M</td><td colspan="2">Employment</td></tr>
<tr><td>Average working hours per day</td><td colspan="2">Average amount of sales per day</td><td colspan="2">Average customers per day</td></tr>
<tr><td colspan="5">A.2. Dispenser(s) Information</td></tr>
<tr><td rowspan="4">Number of dispensers

----------</td><td>Name</td><td>Sex</td><td colspan="2">Level of education and profession</td></tr>
<tr><td>1.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary □ College
□ Other, Specify
Profession……</td></tr>
<tr><td>2.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary □ College
□ Other, specify
Profession……</td></tr>
<tr><td>3.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary □ College
□ Other, Specify
Profession……</td></tr>
<tr><td colspan="5">A.3. Registration and License of DLDB (Skip this section if the drug outlet is a new one and start at section B.1)</td></tr>
<tr><td colspan="2">Is there a TFDA permit? □ Yes □ No

If no, is there a receipt of the payment for the permit?
□ Yes □ No</td><td colspan="2">Permit no._____

Number of receipt of the payment for the permit _____</td><td>Year of issue of permit_____

Year of issue of the receipt for the permit
_____</td></tr>
<tr><td colspan="5">B.1. Distance from nearest DLDB, Health Facility, and Pharmacy</td></tr>
<tr><td colspan="2">Distance from nearby DLDB
Km----------</td><td colspan="2">Distance from nearest health facility (hospital, health center, dispensary)
Km. ----------</td><td>Distance from nearest pharmacy
Km. ----------</td></tr>
<tr><td colspan="5">Note: for livestock ADDO, there is no criteria for the distance</td></tr>
<tr><td colspan="5">B.2. General Observations/Opinions Regarding DLDB Condition</td></tr>
<tr><td colspan="5">a. In accordance with criteria of establishment of DLDM, is the location suitable for establishing DLDM?</td></tr>
</table>

b. Give your opinion on the distance that exist between this DLDB and the nearby DLDB taking into consideration the criteria of distance in establishing the DLDM

c. Give your opinion on the condition of this DLDB premise to determine level of effort needed to rehabilitate or renovate the premise in accordance with criteria of establishing DLDM

C.1. DLDB That Needs to be Relocated

New location of the DLDB
Hamlet/Street _____ Mtaa/Village _____
Distance to the nearby DLDB .....(meters) Pharmacy ……(meters)

C. 2. Inspection of DLDB Which Is Being Upgraded to/Accredited as Duka La Dawa Muhimu

	Condition of the Premises	**YES**	**NO**
a.	Is the size of the dispensing room adequate?		
b.	Is there a storeroom?		
c.	Is the size of the storeroom adequate?		
d.	Is the ventilation sufficient?		
e.	Is there a ceiling?		
f.	Is a ceiling in good condition?		
g.	Is the quality of the floor acceptable?		
h.	Is the window in the storeroom sufficiently protected and secure?		
i.	Is the window in the storeroom acceptable?		
j.	Is there a front door?		
k.	Is the front door acceptable?		
l.	Is there a glass front door?		
m.	Is the glass front door acceptable?		
n.	Is there direct access between DLDB and rooms used for sleeping, laboratory, bar, and/or any other rooms?		
o.	Is there any hand washing facility in the DLDB premise?		
	Medicines Storage	**YES**	**NO**
a.	Are there sliding glass shelves in the dispensing room?		
b.	Are there shelves in the storeroom?		
c.	Is there a glass counter in the dispensing room?		
d.	Is there a door flap at the counter?		

D.1. Results and Recommendations of the Pre-Inspection Of DLDB (Two copies should be filled in; one copy to remain in the DLDB)	
Name of DLDB: …………………………………………………… Name of the Owner………………………………………………… Mtaa/Village…..………………………… Ward…………………District……………………..……… Address………………………………………………………………Phone number…………….....……	
Observation of pre-inspection	Recommendation
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	…………………………………………………………
…………………………………………………………	………………………………………………………
Name of inspectors: Signature 1………………………. …………………. 2………………………. …………………. 3………………………. ………………….	Name of owner: Signature 1……………… …………………. 2……………… ………………….

ANNEX 3. SAMPLE OF CONTRACT AGREEMENT BETWEEN ADDO OWNER AND DISPENSER

Contract Agreement to Operate a Business of Duka La Dawa Muhimu: Second Schedule—Made Under Section 18

THIS AGREEMENT is made this_____day of_____ between

on the one part,_____(**Hereinafter referred to as**

"**PROPRIETOR"**), and _____ of _____

(**hereinafter referred to as "DUKA LA DAWA MUHIMU DISPENSER**") of the other part:

WHEREAS the parties intends to carry on business as provided under section _____ the business shall be under the supervision of the **DUKA LA DAWA MUHIMU DISPENSER** who shall not act in a similar capacity for any other body corporate.

NOW THEREFORE the **PROPRIETOR** and the **DUKA LA DAWA MUHIMU DISPENSER** agrees to run the business of **DUKA LA DAW MUHIMU** under the terms and conditions herein set:

1. Upon signing of this Agreement the **PROPRIETOR** and the **DUKA LA DAWA MUHIMU DISPENSER** shall together run and operate an establishment and business known as _____

2. At a salary or emolument stipulated in clause 3 of this agreement, the **DUKA LA DAWA MUHIMU DISPENSER** shall, with all speed and knowledge so acquired, take the necessary steps to establish and efficiently run the said **DUKA LA DAWA MUHIMU**, dealing, in **"DRUGS APPROVED ONLY FOR DUKA LA DAWA MUHIMU."** The "necessary steps" shall include obtaining from the **TANZANIA FOOD, DRUGS AND COSMETICS AUTHORITY** and other appropriate authorities the requisite licences, permits and authorisation and keeping the **DUKA LA DAWA MUHIMU** within the standards, conditions and manner as contained in any written law for the time being in force governing the management regulation control of the business of **DUKA LA DAWA MUHIMU.**

3. Unless the **PROPRIETOR** is able to meet its expenses from funds generated by the **DUKA LA DAWA MUHIMU**, the **PROPRIETOR** shall supply adequate funds to meet the following expenses:

a) Monthly salary/emoluments of TZS_____ payable monthly to the **DUKALA DAWA MUHIMU DISPENSER** in discharging functions as per clause 2 above.

The salary/emoluments shall be net of any applicable taxes and/or deductible employment benefits and shall be paid no later than the 1st day of the month following.

b) The cost of rehabilitating or modifying the present premises and maintaining of the same as **DUKA LA DAWA MUHIMU.**

c) All other costs necessary or incidental to the running and maintaining the **DUKA LA DAWA MUHIMU.**

4. All technical undertaking shall be under the control management of the **DISPENSER**. However, the power to hire and fire as well as disciplining employees shall lie in the **PROPRIETOR.**

5. All personnel of the **PROPRIETOR** shall be under the control of the **DISPENSER** in their day to day functions. However, the power to hire and fire as well as disciplining employees shall lie in the **PROPRIETOR.**

6. The contract agreement shall be for a period of twelve (12) months, and thereafter it shall run on a year to year basis unless one of the parties gives notice of not less that three (3) months to the other of his intention to remove himself the business of **DUKA LA DAWA MUHIMU** when the current twelve (12) month period lapses and has to report to **COUNCIL FOOD AND DRUG COMMITTEE (CFDC).**

7. In the event the **PROPRIETOR** wishes to terminate the business of the **DISPENSER** before the period of twelve (12) months lapses, he shall issue a notice of three months to the **DISPENSER** or pay the equivalent salary for that period and the DDTC shall be notified accordingly.

8. The **DISPENSER** shall not terminate the contract of the business of **DUKA LA DAWA MUHIMU** before the current period of 12 months unless he has given three months prior notice to the **PROPRIETOR**.

9. **PROPRIETOR** shall meet the cost of drawing up this Agreement.

10. The DDTC will accept addition without changing this basic content of this contract.

IN WITNESS WHEREOF the **PROPRIETOR** and the **DISPENSER** have executed this Agreement on the date and in the manner hereinafter appearing:

SIGNED by the said _____
And **DELIVERED**
this _____ day of _____
Before me _____

_____ _____

PROPRIETOR **ADVOCATE**

SIGNED by the said _____
And **DELIVERED**
this _____ day of _____
Before me _____

_____ _____

DUKA LA DAWA
MUHIMU DISPENSER **ADVOCATE**

ANNEX 4. PRESCRIPTION MEDICINES AUTHORIZED FOR SALE IN ADDO

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority

List of Prescription Medicines Authorized to Stock and Sell in ADDOs[a]

TYPE OF MEDICINE	STRENGTH
Medicines for Asthma	
Aminophylline injection (ampoules)	25 mg/mL in 10 mL
Antibiotics	
Amoxycillin trihydrate capsules	250 mg, 500 mg
Amoxycillin trihydrate oral suspension	125 mg/5 mL, 250 mg/mL
Benzyl penicillin powder for injection	3 gm (500,000 IU) in vial
Co-trimoxazole suspension	240 mg/5 mL in 100 mL bottle
Co-trimoxazole tablets	480 mg
Doxycycline capsules/tablets	100 mg
Erythromycin oral suspension	125 mg/5 mL, 250 mg/5 mL
Erythromycin tablets	250 mg, 500 mg
Metronidazole tablets	200 mg, 250 mg, 400 mg
Metronidazole suspension	200 mg/5 mL in 100mL
Metronidazole injection	
Nitrofurantoin tablets	50 mg, 100 mg
Oxytetracycline hydrochloride eye ointment	5% (w/v), 10% (w/v)
Phenoxymethyl penicillin suspension	125 mg/5 mL 250 mg/5 mL in 100mL
Phenoxymethyl penicillin tablets	250 mg
Procaine penicillin Fortified	4 g (400,000 IU) – 4 MU
Silver sulfadiazine cream	10 mg
Chloramphenicol eyedrops/ointment	
Anti-Inflammatory/analgesics	
Diclofenac sodium Tablets	25 mg, 50 mg
Indomethacin capsules	25 mg
Hydrocortisone ointment/cream	1%, 0.5%
Annusol suppositories	
Anesthetics, local	
Lignocaine injection	1% in 10 mL vial, 2% in 30 mL vial
Anti-Fungal	
Nystatin oral suspension	100,000 IU/mL in 30 mL bottle
Nystatin pessaries	100,000 IU
Nystatin skin ointment	100,000 IU/gm
Nystatin tablets	500,000 IU

TYPE OF MEDICINE	STRENGTH
Ketoconazole tablets	
Antimalarials	
Quinine tablets (sulphate or bisulphate)	300 mg
Quinine injection (as dihydrochloride)	300 mg/mL in 2mL
Artemether + lumefantrine tablets/ACT	Artemether 20 mg, lumefantrine 120 mg
Cardiovascular (Anti-arrhythmic drugs)	
Propranolol tablets (Hydrochloride)	10 mg, 40 mg, 80 mg
Diuretics	
Bendrofluazide tablets	5 mg
Oxytocics	
Ergometrine Injection (maleate)	0.2 mg/mL in 1 mL ampoule, 0.5 mg/mL in 2 mL ampoule
Laxative	
Bisacodyl tablets	5 mg
Antihistamines	
Cetirizine hydrochloride tablets	10 mg
Cetirizine hydrochloride oral solution	5 mg/5 mL
Antispasmodics	
Hyoscine butylobromide tablets	10 mg
Hyoscine butylobromide injection	20 mg/mL
Oral Contraceptives	
Ethinylestradiol (0.03mg) + Novethisterone (0.3mg)	
Ethinylestradiol (0.03mg)+ Levonorgestrel (0.15mg)	
Minerals/vitamins	
Neurobion Forte	
Zinc sulfate tablets	20 mg
Anti-emetic	
Promethazine hydrochloride Injection	25 mg/mL in 2 mL ampoule
Fluids and Electrolytes	
Dextrose	5%
Normal Saline Injection	0.9%
Water for Injection	
Anti-Epileptic	
Phenytoin tablets/capsules (Sodium salt)	50 mg, 100 mg

[a] mg = milligram; mL = milliliter, gr = gram, IU = international unit

ANNEX 5. PATIENT DRUG REGISTER

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority

Register for Patients' Medicines

Name of ADDO _____ Page No. _____

Date	Name of Patient	Address	Sex (M/F)	Age	Type of disease	Generic name of medicine	Dosage	Quantity of medicines for the whole course	Name of health facility: Hospital, Health Center, Dispensary	Price for each medicine sold	Signature of dispenser

Register for Livestock Medicines

Name of ADDO _____ Page No. _____

Date	Name of customer	Address	Type of livestock	Age of live-stock	Type of disease	Generic name of medicine	Dosage	Quantity of the whole course	Side effects reported by customers	Price of medicine sold	Dispenser name	Dispenser Sgnature

ANNEX 6. RECALL FORM FOR MEDICINES UNFIT FOR USE

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority (TFDA)

Date of reporting ……

Name and address of ADDO ……

Complete name of ADDO Owner ……

Generic name of the medicine	Batch no.	Reason for retrieving medicine from the ADDO	Date of expiry of medicine	Quantity of each medicine

Signature of reporting person _____

Position _____

ANNEX 7. PERMIT RENEWAL FORM

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority (TDFA)

Request Form to Renew ADDO Permit

Prepared under Regulation 11 of the Tanzania Food, Drugs and Cosmetics Regulation, 2004. (Standards and Code of Ethics for DLDM) [1]

Section A: To Be Completed By Applicant

1. Name of Applicant _____

Address _____

Age _____ Sex (M) ____ (F) ____ Phone _____

2. Name of the ADDO _____

3. Physical location of the outlet:

House/Plot no. _____ Region _____ District _____

Ward _____ Village/Street/Mtaa _____

4. (a) Name of dispenser _____

Address _____ Phone _____

Registration number _____ date of issue _____ 20 _____

(b) Name of dispenser _____

Address _____ Phone _____

Dispensing certificate number _____ date of issue _____ 20 _____

Date of application _____ **Applicant Signature** _____

Remember to enclose:

- Copies of dispensing certificate of dispensers
- Contract agreement between ADDO owner and dispenser
- Original letter from dispenser(s) indicating his/her willingness to continue working at this ADDO

[1] To be sent to the Chairperson, Council for Food and Drugs Committee

Section B: To Be Completed by Council for Food and Drugs Committee

To be completed in accordance with Regulation No 14 of the Tanzania Food, Drugs and Cosmetics Regulation, 2004 (Standards and Code of Ethics for DLDM)

1. CFDC Recommendations to TFDA

_____

_____

_____

2. Any specific directives provided to the applicant which need to be met before being granted the renewal permit

_____

_____

_____

3. Number of the receipt of the payment for the renewal of the permit._____

   Date of issue of the receipt……

_____

Name, Signature, and Stamp of Secretary, CFDC

_____

Name, Signature, and Stamp of Chairperson, CFDC

ANNEX 8. ROUTINE INSPECTION CHECKLIST/FORM FOR DLDM

Ministry of Health and Social Welfare
Tanzania Food and Drugs Authority (TFDA)

1. Information on DLDM						
1.1	Location (region) of DLDM					
1.2	DLDM Name ……..					
1.3	Postal Address ……..…… ……..……	1.4 Physical location Mtaa/Village……..... Ward……..... District…….				
1.5	Phone number					
1.6	Number of Permit ……	1.7 Is the permit still valid?	Yes/No	1.8 Is the permit displayed on the wall?	Yes/No	
1.10	Date of inspection _____	1.11	Date last inspection was conducted _____			
1.12	DLDM Owner Name _____					

2. Information on Dispenser(s)	**YES**	**NO**
2.1 Are the dispensers wearing (in plain sight) their Identity cards that show they are registered with TFDA?		

Write the names and qualifications of each dispenser (check the accuracy against the dispenser's certificate which should be displayed in the DLDM)

	Name	Qualification	Certificate number of the dispenser
2.2			
2.3			

3. Condition of the Structure		***YES***	***NO***
3.1	Does the structure meet ADDO standards for sturdiness and cleanliness?		
3.2	Are the surroundings adequately clean?		
3.3	Is the inside of the structure adequately clean?		
3.4	Is the floor clean and without holes?		
3.5	Are the walls clean and well painted?		
3.6	Are the ventilation and light sufficient?		
3.7	Are the doors and windows strong enough and secure to prevent unauthorized entrance of individuals into the premise?		

3.8	Is there a hand washing facility in dispensing room?		
3.9	Is the ceiling in good condition?		
3.10	Is there a No Smoking sign?		
3.11	Is the structure inaccessible from other facilities or unrelated businesses?		
3.10	Any other issues related to the condition of the premise? *(If this space is not adequate, please use another blank sheet of paper)*		

4. *Medicine storage*		***YES***	***NO***
4.1	Are the available medicines stored in good condition?		
4.2	Is there enough shelves to store medicines so that the medicines are not kept on the floor?		
4.2	Is the ventilation adequate, i.e., does the storage room have windows and fans or air conditioners to keep the temperature below 30°C?		
4.3	Are there any expired medicines on the shelves?		
4.4	Is the arrangement of medicines appropriate?		
4.5	If there is any breaches of the law, please explain: *(If this space is not adequate, please use another sheet of paper)*		

5. Quality of the medicines currently in the DLDM Inspect the medicines currently on the premise. If there are unauthorized medicines, confiscate them and give them to the district pharmacist. Unauthorised medicines include medicines that appear to be of questionable standards or fake, expired, not registered with TFDA, and not included in the list allowed to be stocked and sold in the DLDM.		***YES***	***NO***	**Quantity And Batch Confiscated**
5.1	Are there any unauthorized medicines in the DLDM?			
5.2	Are there any unregistered (with TFDA) medicines in the DLDM?			
5.3	Are there any public medicines with MSD or G label?			
5.4	Are there any medicines that are not included on the ADDO list?			
5.5	Are there any expired medicines?			
5.6	Are there any medicines of questionable quality or fake?			

6. Documentation and record keeping		***YES***	***NO***
6.1	Is the quality of documentation and record keeping acceptable?		
6.2	Is there a drug register?		
6.3	If the drug register is available, is it filled correctly?		
6.4	Are purchase records entered into the register?		
6.5	Are purchasing records correct?		
6.6	Are the purchasing receipts available?		
6.7	Are the used prescriptions available?		
6.8	Is there any other issue(s) related to documentation and record keeping? Explain.		

7. Reference books	***YES***	***NO***

7.1	Regulation for DLDM		
7.2.a.	The list of medicines authorized to be stocked in the ADDOs		
7.2.b.	Guidelines for Good Dispensing Practices		
7.3.	List of medicines registered with TFDA		
7.4.	Training mannual for ADDO dispensers		
7.5	Guidelines for establishing and managing ADDO		
7.6	Other reference books (mention)		

Other observations related to inspection of DLDM

Fill out two copies of this form—one copy should remain with the ADDO owner.