# TRAINING MANUAL FOR ACCREDITED DRUG DISPENSING OUTLET INSPECTORS

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## 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.

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## FOREWORD

The Tanzania Food and Drugs Authority (TFDA) came into existence under the Food, Drugs and Cosmetics Act, 2003, with the aim of controlling the quality, security, and effectiveness of food substances, drugs, cosmetics and diagnostics items. The main purpose is to provide good care for the health of the communities. To implement these roles, the TDFA has the responsibility to register all premises which provide and dispense medicines, after fulfilling and abiding to regulations and requirements put forward.

In the process of making sure that the community is getting quality health services, which goes hand in hand with the availability of essential medicines at all times, the authority is also implementing the ADDO program. This aims to upgrade drug shops part II, commonly known as *duka la dawa baridi* (DLDB) into ADDOs to solve many problems which emerge from management of drug shops and livestock shops.

ADDOs and other sites involved in the business of selling human and livestock drugs need to be well managed and closely supervised to ascertain that regulations and Acts are properly followed and adhered to. To realize this, TFDA is collaborating with the local government in inspecting and overseeing drug shops. The inspectors of drug shops are in level of region, districts, and wards.

Inspectors from all levels need training to know how to inspect and control drug selling business outlets. It is therefore expected after this training, all inspectors will acquire an understanding on the Food, Drugs and Cosmetics Act, 2003, regulations for ADDOs, and strategies for inspection.

It's my hope and expectation that the participants of the inspection training course will use this training manual as one of the reference materials during the control of drugs selling business in the country.

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**Director General**
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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.

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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ADDO | accredited drug dispensing outlets |
| CFDC | Council Food and Drugs Committee |
| DLDB | *duka la dawa baridi (*Swahili, private drug shops) |
| DLDM | Duka la Dawa Muhimu (Swahili, private accredited drug shop) |
| MEO | mtaa executive officer |
| MSH | Management Sciences for Health |
| RFDC | Regional Food and Drugs Committee |
| TFDA | Tanzania Food and Drugs Authority |
| VEO | village executive officer |
| WEO | ward executive officer |

# INTRODUCTION

In Tanzania, drug selling services are under the Tanzania Food, Drugs and Cosmetics Act, 2003. This act has empowered the Tanzania Food and Drug Authority (TFDA) to control the quality, safety, and effectiveness of drugs, food materials, cosmetics, and diagnostic equipment. The Act also conforms to the national health policy on access to quality health services which addresses community needs.

The accredited drug dispensing outlet (ADDO) is registered with the TFDA so that it can keep and sell certain medicines that do not need a doctor's prescription and some essential medicines that do require a prescription. These shops need to be under supervision of a dispenser who has received special training in dispensing medicines.

The ADDOs for human and livestock medicines has been established as means of solving the problems discovered with the management and control of drug stores (*duka la dawa baridi*). These problems include—

- Lack of qualified dispensers to provide services in those shops as per drug shops regulations of 1998, including some dispensers not having any knowledge about health science, treatment, and medicines.

- Poor distribution of drug shops with a much higher percentage found in urban than in rural areas defeating the reason for establishment.

- Unregulated and unauthorized selling of part I and part II poison drugs by 72 percent of the shops, a threat to the safety and health of the people and the nation as a whole. By law, the shops are only supposed to sell nonprescription medicines.

- Lack of quality control mechanism for the quality of medicines as some of the drug shops were found to stock and sell expired or unregistered medicines.

- Some of the shops were selling medicines stolen from public health facilities and other vertical health programs.

- Lack of quality standard buildings for the shops selling medicines, leading to substandard medicine quality because of poor storage practices.

- Selling livestock medicines in an unhygienic setting—displaying them on bare ground during animal auctions.

- Unauthorized medicine dispensing without adhering to regulations and guidelines on proper dispensing.

- Insufficient variety of medicines authorized to be sold in the drug shops, therefore not meeting clients' needs

To address these problems, the Ministry of Health and Social Welfare (MoHSW), through the TFDA, has made basic changes in how of human and livestock drug shops should be managed and operated throughout the country. These changes aim to improve dispensers' knowledge, control shops' management of the medicines authorized to be sold from those shops, and improve the buildings (premises) and their drug storage.

The main purpose of these changes is to improve services provided by the drug shops by upgrading them to ADDOs after complying with the standards specified in the regulations for ADDOs.

One of the important concepts in the ADDO program is to involve district and ward levels in inspection and control of these shops.

This manual has been prepared as a training material to be used in training regional and district medicines inspectors and inspectors from ward level. Important areas in this training include understanding the Food, Drugs and Cosmetic Act, 2003; regulation of ADDOs, and strategies for inspection.

# REGULATIONS AND PROCEDURES ON HOW TO ESTABLISH AND RUN ADDOS

## Introduction

The services of selling medicines in Tanzania is under the Tanzania Food, Drugs and Cosmetics Act, 2003,which gives mandate to TFDA to control and supervise all business related to the quality, safety and effectiveness of food stuffs, medicines, cosmetics, and diagnostic apparatus in the country. Drug shops generally have not obeyed the regulations and guidelines concerning the management of drug shops part II poisons in a great deal has not adhered to requirement of the regulation and the Act, which has greatly contributed to the population's poor health.

This section will discuss important issues of the regulations that ADDO inspectors are expected to know. At the end of this section, participants will be able to describe—

- Sections of the Food, Drugs and Cosmetics Act, 2003, relating to the business of selling medicines
- Regulations of ADDOs
- Guidelines on operating ADDOs

How ADDOs operate needs to be managed through the Act, requirements, and specified regulations. Therefore, it is important for ADDO inspectors to understand the Act.

## The Act and Controlling Drugs Business in Tanzania

Under the Act, TFDA was given the following powers concerning drug supervision—

- Sections 18 to 21 pertain to registering premises and issuing permits to run drug businesses
- Section 26 gives TFDA the mandate to provide special permits to other cadres apart from pharmacists to dispense medicines
- Section 51 involves registration of a drug after ascertaining its quality, safety, and effectiveness
- Section 105 gives mandate to the TFDA to nominate ADDO inspectors
- Section 106 gives ADDO inspectors the mandate to take action when there is violation of said Act. They have the power to take samples of medicines for investigation purposes.

## Regulations for ADDOs

The regulations for ADDOs have been derived from Act, section 122 (h) which encompasses supervising, guiding, and controlling establishment and operation of ADDOs for purposes of improving availability of essential medicines and services for the benefit of village and small town communities. These regulations are divided into seven main areas—

1. Definition of terms and aims of establishing ADDOs
2. Selection/establishment of ADDOs supervisory committee
3. Procedure for requesting permit to run ADDOs
4. Standards and regulations for operation
5. Inspection
6. Ethics for operation
7. Offenses and penalties

In addition, there are other important regulations which need to be adhered to when supervising ADDOs. These regulations are—

- Regulations for fees and charges, 2005—This describes fees and charges for variety of services given by TFDA, such as the permit for operating ADDOs.

- Regulations for delegating authority and responsibilities of TFDA to city councils, municipals, town councils, and districts.

## Guidelines

The guidelines for establishing and operating ADDOs explain in simple terms what to follow in implementing the Act and regulations for ADDOs. Following are explanations of the different regulations.

### *Procedures and Roles of Different Levels in Establishing ADDOs*

The request for establishing ADDOs will be processed through these levels—

- Village executive officer (VEO)
- Ward executive officer (WEO)
- Council Food and Drugs Committee (CFDC)
- Regional Food and Drugs Committee (RFDC)
- TFDA

The following are the roles of different levels/players in establishing ADDOs—

### *ADDO Applicant*

- Learns the guidelines, criteria, and procedures for establishing and operating ADDOs, and where they should be located and built.
- Obtains ADDO application form from village/ward executive officer.
- Completes section A of the application form and gives it to village or ward executive officer with the dispenser certificates attached. The application then goes through the following levels—district (CFDC) or regional (RFDC) secretary, zonal offices, and TFDA headquarters.

### *Village/Ward Executive Officer*

- Provides application forms for establishing ADDOs
- Receives, reviews, and provides opinion related to the application (officer provides in Section B of the form)
- To interview the applicant and the possible dispensers in conformity to instructions found in the application form.
- Presents already filled application form on section A and B to the ward executive officer.
- Assists inspectors from all levels with their duties in the village
- Carries out any duty as instructed from high authority

### *Ward Health Committee*

The ward health committee includes the following—

- The WEO— chairperson
- Health facility in-charge— secretary
- Ward health officer
- Ward extension officer for livestock services

When the applicant presents his/her application to village or ward government, the village executive officer and the ward executive officer will interview the applicant to provide the following information to CFDC—

- The importance of the service in their area
- The behavior of the applicant and his/her relationship with the community
- Nationality
- The physical address of the applicant
- The current or previous business of the applicant
- Additional information from the applicant about the site where he/she wants to open ADDO.

In addition, the officers will—

- Visit the proposed ADDO site to enable them to provide constructive advice
- During the process of advising the applicant, follow criteria for establishing ADDOs as stipulated by the authority

TFDA will then receive reports from CFDC and check if set criteria are adhered to.

The committee is responsible for the following—

- To provide application forms for establishing ADDOs
- To receive and scrutinize application forms from the village or ward executive officer
- To request for ward inspectors to inspect the premise after being certified with information in section A and B of the application form
- To give their opinion related to the application by filling out form section C
- To present completed application forms with relevant premise inspection information to CDFC secretary
- To support ADDO inspectors from all levels when on duty to their respective wards
- To carry out other duties as instructed by higher authorities

### *CFDC*

The CDFC has the following members—

- District executive director—chairperson
- District medical officer—secretary
- District pharmacists
- District trade officer
- District health officer
- District livestock officer
- District agriculture officer
- District treasurer

Other members may be added if their expertise is required

***Note:*** *The secretary to council food and drugs committee is the district medical officer who will be assisted by the district pharmacist or district officer, depending on the purposes of the meeting.*

The roles of the committee will be as follows—

- To provide application forms for establishing or renew of permits.
- To receive application forms and inspections reports for establishing ADDOs from ward level and make decisions.
- To inspect ADDOs which have presented their applications to CFDC

- To accept or reject applications on behalf of TFDA by adhering to the criteria for providing permits for establishment of ADDO

- To submit reports on decisions for ADDOs establishment and operation to TFDA (copied to the secretary of RFDC). The meeting minutes should be attached to the reports.

### *The Regional Food and Drugs Committee*

The RFDC has the following members—

- Regional commissioner—chairperson
- Regional medical officer—secretary
- Regional pharmacist
- Regional health officer
- Regional agriculture officer
- Regional livestock officer
- Regional trade officer

This committee shall have the following roles—

- To receive and work on all reports and appeals from district level

- To conduct audit inspection to ADDOs and on other areas providing medicine services when necessary

- To guide and give advice on operation of drug business in the region

- To collaborate with ADDO inspectors from all levels while working in the region

- To advise TFDA on better ways to operationalize ADDOs

- To carry out other responsibilities related to control of food, medicines, cosmetics, and medical devices as instructed by TFDA

### *TDFA*

- To receive and work on suggestions and advice from CFDC on applications to open ADDOs and provide decisions

- To issue permits and certificates of registration for those who have complied with requirements for opening ADDOs

- To explain and give advice on operations activities for drug business in the region.

- To receive and work on reports, appeals, and complaints from the districts and regions.

- To produce and disseminate guidelines and different forms to CFDC and RFDC

- To select ADDO inspectors and to provide inspection training

Permits for ADDOs expire on June 30 of each year. Each ADDO owner has to renew the permit by paying the annual fees and make sure that he or she is operating the ADDO according to the established criteria. If the owner wishes to open another outlet, he or she must follow the procedures for registering premise and should not use the permit of the previous shop.
*The permit cannot be transferred from one ADDO to another or from one area to another area.*

The owner must apply for permit to operate ADDO from the district he/she wishes to transfer the services and follow all described procedures in opening an ADDO. If ADDO owner decides to close the business, he or she must inform the CFDC secretary and return the permit. The CFDC is the only entity that can give permission for changes in ownership of or dispensers for ADDOs or other changes to the registered building.

**Key**

→ = Flow of recommendation/decision reports

⇢ = Feedback (positive or negative)

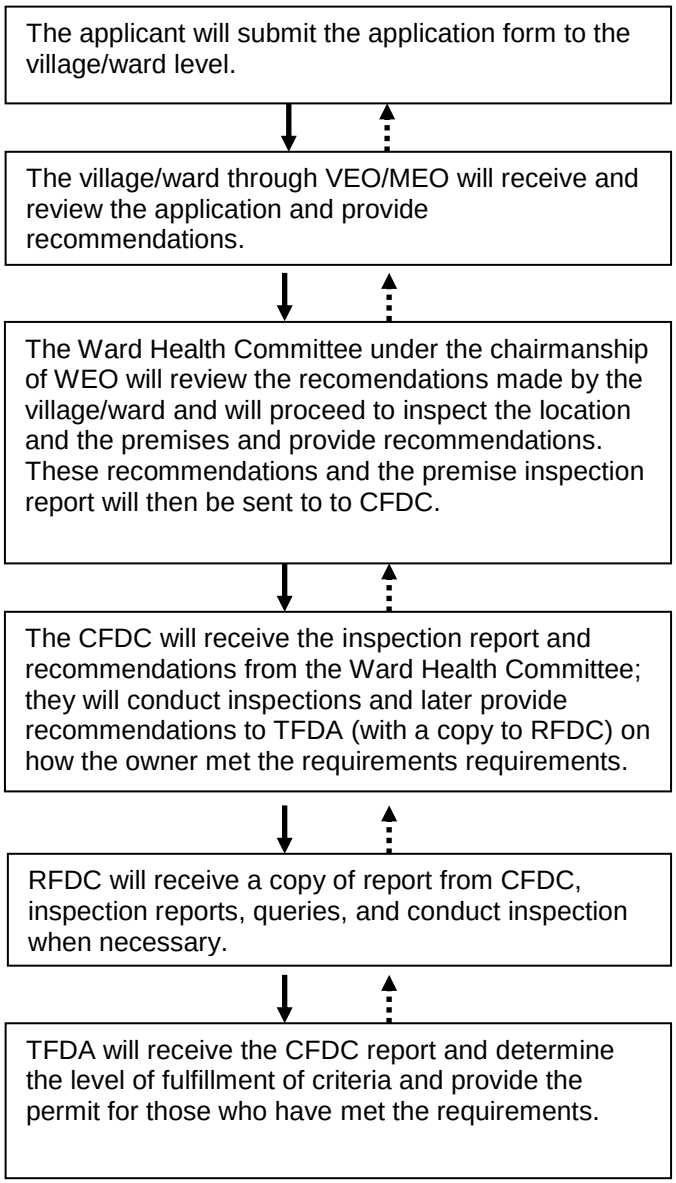


**Figure 1. Flow of permit application process to establish ADDO**

## Criteria for Establishing an ADDO

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

### *ADDO Owner Qualifications*

- Must be a Tanzanian citizen above 18 years of age and of sound mental health
- Must undergo training on regulations and Act for operating ADDOs and business entrepreneurship training

### *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 livestock ADDOs, the dispenser must be—

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

### *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 at least 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 livestock 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.

### *The ADDO Building (premises)*

- Should be well-constructed and permanent
- Should have a sturdy, leak-proof roof
- Should have cement floor or tiles that are easy to clean
- Should have solid walls that are painted white and easy to clean
- Floors should be easy to clean
- Should be sealed against rodents and insects
- Must have a water source for washing hands
- The premise should have two rooms, one for dispensing and one for storage
- The dispensing room should measure 3.04 meters in length(10 feet) by 2.74 meters wide (9 feet) and 2.43 meters high (8 feet)
- The store room should have sufficient space and pallets/shelves for medicine storage
- The building premises should not be accessible from other facilities such as laboratories or any other business not related to selling medicines.
- A **NO SMOKING** sign should be displayed inside the dispensing section and no smoking allowed in the entire premises.
- Premise should have two doors, a strong outer door for security and an inner glass door to protect the premise against dust, rodents, and insects.
- The premise should have a window in each room to allow air to circulate
- The ADDO logo shown below should be displayed

# INSPECTION FOR DRUG BUSINESS

## Introduction

This chapter will discuss medicine inspections issues and provision of services and drug storage. The chapter will also describe what has to be inspected, different types of inspection, what inspectors will and will not do, and what will go into their reports. Therefore, every inspector needs to read and understand this chapter before conducting inspections.

## What is Inspection

Inspection is the process of scrutinizing or looking closely at something to find out if it conforms to set criteria and standards. Drug inspection involves examining factors/criteria that contribute to total quality of medicines to ascertain safety, effectiveness, and quality.

## Purposes of Inspection

Inspection aims at achieving the following—

- To identify if drug selling business is carried out in accordance to set regulations and procedures, and take steps if there is a problem
- To follow-up on the quality of medicines and medical appliances in the market
- To educate dispensers on the importance of adhering to the Tanzania Food, Drugs and Cosmetics Act, 2003, and regulation requirements for operating the drug business

Generally the main purpose for conducting inspection is to "Protect user safety by ascertaining quality and safety of drugs and medical appliances."

Therefore, inspection does not only mean looking for problems and shortcomings, but also includes building collaboration between service providers and government inspectors by educating everyone on how to correct deficiencies and provide quality services to the communities.

## Types of Inspection

- Preliminary inspection—Conducted for the first time on new premises; also conducted when the business is being transferred to provide instructions to what improvements are needed, if any, to ensure that the building meets ADDO criteria

- Routine inspection—Performed to identify if the drug business is carried out in accordance with the Act and set regulations or take actions where necessary.

- Follow-up inspection—Carried out as a follow-up to whether suggestions given during previous inspection has been implemented.

- Investigative inspection—Conducted following reports or complaints on violation of regulations and Act

## Areas for Inspection

For purposes of ensuring quality of medicines and medical appliances brought in the country and sold to communities, the following sites involved in drug services must be inspected frequently.

- The borders through which medicines enter the country

- Drugs shops (wholesale and retail pharmacies, and ADDOs)

- Health facilities, like dispensaries, health centers, hospitals, and other areas involved with storing and operating drug businesses

- Any other suspected area including shops selling non-pharmaceutical items that are also involved in selling medicines

## Inspectors

### *Selection*

The inspectors for ADDOs will be nominated by TFDA in accordance to section 105 of Tanzania Food, Drugs and Cosmetics Act, 2003, after being given special inspection training. They will also be given equipment for conducting inspection, like identity cards and inspection forms.

Ward inspectors will include—

- One clinician from a public dispensary or health center in the respective ward
- Extension livestock officer
- Ward health officer

District inspectors will include—

- District medical officer
- District pharmacist

- District livestock officer
- District health officer

All ADDO inspectors and others will be nominated by TFDA as noted by the Act.

### *Inspector Authority*

- To inspect ADDOs in his/her prescribed area involved in selling medicines. The inspection will only be carried out by an accredited ADDO inspector.

- To make a follow-up visit or collect sample for investigation.

- To remove from market medicines which are not suitable for human consumption.

- To make a follow-up visit to recheck the quality and safety of medicines in the ADDO.

- To carry out inspections and make follow-up inspections in areas involved in unlawful selling of medicines

- To carry out inspection on documents related to the business control of medicines to ascertain their legitimacy, i.e., permits, registers, sales receipts

- To confiscate medicines that are suspected to be of questionable quality

- To close ADDOs and other shops involved in drug business if there is violation of regulations/Act and take appropriate steps as instructed by the Act.

### *Limitation of Inspectors' Powers*

To enhance effectiveness of inspectors' decisions, their powers will be limited as noted—

- The inspector will pass suggestions on to authorities at a higher level regarding the magnitude of violated regulations and Act leading to cessation or closure of service.

- The inspector may temporarily close the premise while waiting for decisions from higher authority. If the authorities believe that people's lives are endangered, they may make the closure permanent by revoking the ADDO.

- The inspector may report to the police when the violation of regulations warrants doing so, for example, if stolen, government, or counterfeit medicines are being sold.

- Any action taken by the inspector must be reported or sent to the committee which will review it and send a report to TFDA

### *TFDA Authority over Inspectors*

TFDA has the powers and authority to revoke any inspector's nomination. The powers of any ADDO inspector will cease immediately when the nomination of the inspector is nullified.

### *Inspectors' Ethics*

To ensure good performance of inspectors for food, drugs, and cosmetics, those who have been nominated will have to adhere to the following ethics—

- To carry out his/her duties by following regulations and procedures set by the country Act.
- To protect his/her professional image, not associate persons involved in illegal activities or with a criminal record, or behave in a manner that will be detrimental to carrying out his/her responsibilities commissioned by Act.
- Not to make inspection decisions based on tribalism, favoritism, business structure and competition, or political patriotism, all of which is illegal.
- To speak openly to TFDA about any additional relationship and ownership of a medicine, food, and cosmetics businesses, or similar business interests of family members.
- To be aware of and not accept duties which might influence decisions that inspectors make in their role as an agent of the TDFA
- Not to use information from his/her duties as an inspector for individual, family or any other person's gains.
- Not to use abusive language, threats, or ridicule, that would affect an individual's ability to carry out his or her duties.
- Not allowed to receive presents, favors, bribes, or any kind of payments, but only when this is permitted by Act.
- Must have and wear his/her inspection identity card and be ethical during inspection so that his/her actions should reflect favorably the good image of TFDA.

***Note****: Not complying with Act requirements, regulations, and instructions given above is an offense which may lead to disciplinary action.*

## Preparation before Inspection

Before conducting any type of inspection, it is important for the inspector to prepare the following items—

- The inspection timetable which all those who will participate in the inspection need to know
- The list of all shops which will be inspected with their specific information such as permit number, dispenser's name, and locality.
- Forms and checklists for conducting inspection and collecting drug samples
- Forms for confiscating/preventing illegal medicines and items not permitted by the Act.
- A diary for recording daily inspection dates, activities
- Act and regulations books
- List of drugs registered and allowed to be sold at ADDOs.

## The Procedure during Inspection

The inspector must adhere to the following procedure when he/she enters into the area for conducting inspection—

- To inform the leadership of the village or ward immediately upon arrival in the area.
- When in the inspection area, explain the purpose of the inspection and show the inspector's identity card.
- Be polite and diplomatic to enable you to collect relevant inspection information; don't use threats (intimidation).
- If the owner of the premise refuses to be inspected or give required information on operating the ADDO, he or she should be told that it's a criminal offense under section 106(3) of the Food, Drugs and Cosmetics Act of 2003 and the police will need to be informed to take legal actions.
- To conduct inspection step by step as indicated in the inspection form. Questions should be asked one at a time—asking multiple questions at once may confuse the respondent.
- Fill in inspection forms while conducting inspection. It's not allowed to fill the forms after inspection.
- List the types of medicines, records (documents, accounts books, receipts, etc.) or equipment (medical appliances and diagnostic items, used syringes, scissors, etc.) which you took on the confiscation/seizure form.

- Include all observations in your report. Cheating or false additions to add to the weight of the report is not allowed.

## *How to Inspect an ADDO*

Use the guideline/forms for inspection (*inspection checklist)* for purpose of conducting step by step inspection. The inspection form is divided into the following sections: permit, dispensers, premise, medicine storage, medicine records, and reference books.

These are important steps which need to be adhered to for both new and old ADDOs. The new ADDO owners need to be given information on medicines, records, and reference books that they will be required to have in the shop after being given permit.

For effective inspection the following steps need to be followed—

### *Section One: Shop Records*

- Record on the inspection form the name of the shop, shop owner, owner's home address, and address of the shop.

- For the operating shop, check on the ADDO permit, which include name of the owner, address, and date of expiration. Make sure the information collected is correct and that the permit has not been transferred from another shop.

- Fill in the date of inspection and of the last inspection conducted at that shop

### *Section Two: Dispensers*

- Record information of dispensers (names, experience, and if they have a dispensing permit)

- Check to see if dispensers' certificates (photocopies) are hanging in the shop

- Check to see if dispenser is wearing a white coat with TFDA identity card

- Check to see if dispenser is sober, clean, and dressed appropriately

***Note:*** *If it is a new ADDO, verify if the permit applicant has qualified and if they have TFDA permit for dispensing*

### *Section Three: Premise/Building*

Inspect all criteria of the premise as indicated in the inspection form. Things to observe—

- Area of the building (distance from another ADDO, in the village/small town/urban setting)

- Number of the rooms (two rooms required)
- Quality, soundness, and cleanliness of the building (roof, ceiling, walls, doors, windows, and floor) and surroundings
- Lighting and enough air circulation in the premise—check if there is a fan or air condition where needed
- Facility for washing hands

### *Section Four: Medicine Storage*

Check the room for dispensing and storage to determine arrangement of the medicines, including the following—

- Shelves for keeping medicines (they should never be kept on the floor)
- Check the medicine display counter and if there is a movable section of counter to allow access to shop.
- Check arrangement of drugs on the counter

### *Section Five: Medicines and Other Items in the Shop*

Inspect medicines found in the shop to see if there are medicines which should not be there such as—

- Medicines which are not registered by TFDA. Drugs registered by TFDA has registration number which starts with the letters TAN; Use the registration book for reference.
- Medicines which are not in the list of the drugs allowed in the ADDO.
- Medicines found outside their containers or label that has been tampered with. This is not allowed.
- Government medicines (all government medicines are marked with MSD [Medical Stores Department] or letter G)
- Expired medicines
- Medicines that look suspicious or of poor quality—change of color, smell, shape of the tablet/capsule. Also check on the container seals.
- Check the quality of the language used on the drug labels—should be either English or Swahili

### *Section Six: Filling and Keeping Records in the ADDO*

Every ADDO has to keep records for all medicines sold to clients. These records include—

- *Drug Register*—This is the book where all ADDO dispensers need to record medicine dispensed to patients. Check if all sections have been correctly filled.

- *Purchase receipts*—Check the purchase receipts and invoices for buying and selling medicine.

- *Register for expired medicine*—Every ADDO is required to have a special register for expired medicine. Check if the register is correctly filled out and these medicines are sealed in a container and labeled in red, "Expired drugs–should not be sold." *Note: The ADDO owner is required to produce and send to the CDFC every three month the list of expired drugs, for which the CDFC will send back a permit for and instructions on how to destroy them.*

- *Forms for reporting drug reactions*—Check if these forms are correctly filled out and sent to the secretary of the CFDC and TFDA

### *Section Seven: Reference Books*

The ADDO is required to have a variety of reference books that are readily available to the dispenser. Every shop is required to have the following reference books—

- ADDO regulations
- Guidelines for establishing and operating ADDOs
- Guideline for correct dispensing of drugs.
- List of prescription-only medicine allowed in the ADDO
- Training manual for ADDO dispensers.

In addition, these books are recommended to be kept in the ADDO—

- Tanzania National Formulary
- Livestock Formulary for ADDOs
- Drug list book for medicines registered by TFDA.
- Standard Treatment Guidelines
- Tanzania Food, Drugs and Cosmetics Act, 2003

### *Section Eight: Other Issues*

Describe other observations or issues found during the inspection.

### *Section Nine: Inspection Instructions*

After conducting inspection, the inspector will fill the form of inspection result and give instructions to each observation/issue found. Immediately after inspection, he or she should give feedback of the inspection, starting with the positive things (strengths) observed, and then areas for improvement. Time should be given to check improvement and compliance.

### *Section Ten: Inspection Evidence*

Both the ADDO owner and the inspector have to put their names and inspection date on the inspection form and then sign it as evidence that the inspection was conducted. The owner should also be given a copy of form showing inspection results and any decisions made.

## Drug Sample Collection

The Food, Drugs and Cosmetics Act, 2003, section No. 101, gives inspectors the power to collect/take medicine samples from any drug shop for purposes of investigating the quality when deemed necessary. The investigation/ of any medicine sample from an ADDO or any other shop will follow TFDA procedures as indicated by the Act.

A drug sample is collected for various reasons but the main purpose is to safeguard people's health from poor quality, counterfeit, or illegal medicines such as—

- Medicines suspected of causing reactions like sudden death, or falling sick immediately after using it.
- Ineffective medicine—Medicines suspected of or blamed for not being effective for the prescribed treatment.
- Counterfeit medicines or medicines of poor quality—samples taken that visually appear to be substandard or counterfeit.
- Post-marketing surveillance samples: These are drug samples taken by inspectors during routine inspection, for purposes of checking or approving whether the medicine has the acceptable quality after being in the market.
- The procedure for collecting medicine samples is as follows—
    - Whenever possible, the sample should be taken from a new box which has not yet been opened
    - Take samples for investigation from three batches, labeling them A, B, and C
    - The sample should be tightly sealed and labeled, and the sample name, batch number ,and date of collection should be recorded

- Once collected, divide the medicine samples as follows—
    - Give sample A to the owner to be kept at the shop
    - Take the remaining two samples (B and C) and send them to the laboratory, one for investigation and the other for the record
    - Remember to fill out the forms for collecting the samples which have to be signed by inspectors and owner of the ADDO/dispenser/responsible person
    - The collected samples will have to be paid for as per the price at the shop
    - The inspector must get a receipt for any purchased samples for accountability

**Table 1. Medicines to be Collected**

| Type of medicine | Amount to collect |
|---|---|
| Tablets | Collect with its container–not less than 100 tablets |
| Injections (vials) | Not less than 10 vials |
| Ampoules | Not less than 10 ampoules |
| Syrups (60–100 mLs) | Not less than 10 bottles |
| Syrups (more than 100 mLs) | Not less than 5 bottles |

## Case Study 1

### Offenses and penalties for breaking ADDO regulations

Mr. Mwendapole lives in Nakapanya village. He became interested in establishing an ADDO after visiting his friend Ngonyani who has an ADDO in Mbiga town. Mr. Mwendapole sent his application for establishing ADDO through the required levels. After Mr. Mwendapole and his dispenser attended and successfully completed ADDO training, he was able to open his shop.

Mr. Mwendapole expected that he would make a profit from the ADDO and build a modern house. To ensure reasonable profits, he searched for medicines from different sources to equip his shop, including buying medicine from illegal drug vendors and medicines stolen from mission and government hospitals. He also wanted to maximize his sales by instructing the dispenser to sell medicines to patients regardless of whether they have prescriptions or not and also sell expired medicines. Mr. Mwendapole also thought of reducing the operating cost for his ADDO by firing the dispenser and having his wife who does not know how to read or write take over the role of dispenser.

After six months of running his business, inspectors from the district arrived to inspect ADDOs, including Mr. Mwendapole's shop. After inspecting Mr. Mwendapole's shop, the ADDO inspectors decided to close his shop. After the shop is shut down, Mr. Mwendapole could not finish building his modern house.

### *Questions*

- Why did Mr. Mwendapole fail to finish constructing his house?
- Identify the offenses which might have caused the inspectors to close Mr. Mwendapole's shop.
- What problems could have occurred if Mr. Mwendapole's shop was not closed?

## ANNEX 1. APPLICATION FORM FOR PERMIT TO ESTABLISH AN ACCREDITED DRUG DISPENSING OUTLET (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. REQUEST FORM TO RENEW ADDO PERMIT

**Ministry of Health and Social Welfare**
**Tanzania Food and Drugs Authority**

Prepared under Regulation no. 11 of the *Tanzania Food, Drugs and Cosmetics Regulation, 2004 (Standards and Code of Ethics for DLDM)*

Chairperson,
Council for Food and Drugs Committee

_____

_____

### Section A: To be Completed by Applicant

Name of Applicant _____

Complete address _____

Phone _____

Business premise (ADDO) is located at _____

House/ Plot No _____

Hamlet /Mtaa/Village _____

Ward _____

Division _____

District _____

Region _____

Name of the ADDO _____

Accreditation Certificate No. _____

The dispensers for this ADDO who will be registered by TFDA are as follows—
Name of the dispenser _____
Address _____ Phone number _____
Dispensing certificate number _____ Date of issue _____

Name of the dispenser _____
Address _____ Phone number _____
Dispensing certificate number _____ Date of issue _____

Date on which the request was made _____
Signature of requesting person _____

Remember:
Enclose (1) copies of dispensing certificate, (2) contract agreement between ADDO owner and dispenser, (3) original letter of the dispensers indicating his or her willingness to continue working at this ADDO.

**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)*

Recommendations of CFDC to TFDA

_____

_____

_____

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

a._____

b._____

c._____

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 3. FORM FOR PRE-INSPECTION OF PART II DRUGS OUTLET/ DUKA LA DAWA BARIDI (DLDB)

**Ministry of Health and Social Welfare**
**Tanzania Food and Drugs Authority**

<table>
<tr><td colspan="6">1. INFORMATION OF DLDB OWNER</td></tr>
<tr><td colspan="2">Name of DLDB</td><td>Mtaa/Village</td><td colspan="2">Ward</td><td>District</td></tr>
<tr><td colspan="3">Name of owner</td><td colspan="3" rowspan="3">Level of education<br>□ Primary □ Secondary □ College<br>□ Others<br>Profession ……...</td></tr>
<tr><td colspan="3">Postal address and phone number</td></tr>
<tr><td colspan="2">Sex: □ F □ M</td><td colspan="2">Employment</td></tr>
<tr><td colspan="2">Average working hours per day</td><td colspan="2">Average sales per day</td><td colspan="2">Average number of customers per day</td></tr>
<tr><td colspan="6">2. INFORMATION OF DISPENSER(S)</td></tr>
<tr><td rowspan="4">Number of dispensers<br>----------</td><td colspan="2">Name</td><td>Sex</td><td colspan="2">Level of education and Profession</td></tr>
<tr><td colspan="2">1.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary □ College<br>□ Others, Specify<br>Profession……...</td></tr>
<tr><td colspan="2">2.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary□ College<br>□ Others, specify<br>Profession……</td></tr>
<tr><td colspan="2">3.</td><td>□ F □ M</td><td colspan="2">□ Primary □ Secondary□ College<br>□ Other, Specify<br>Profession……</td></tr>
<tr><td colspan="6">3. REGISTRATION AND LICENSE OF DLDB<br>(Skip this section if the drug outlet is a new one and fill section 4)</td></tr>
<tr><td colspan="2">Is there a TFDA permit?<br>□ Yes □ No<br>If no, is there a receipt of the payment for the permit?<br>□ Yes □ No</td><td colspan="2">Permit no_____<br><br>Number of receipt of the payment for the permit _____</td><td colspan="2">Year of issue of permit_____<br><br>Year of issue of the receipt for the permit _____</td></tr>
<tr><td colspan="6">4. DISTANCES FROM THE NEAREST DLDB, HEALTH FACILITY, AND PHARMACY</td></tr>
<tr><td colspan="2">Distance from nearby DLDB Km----------</td><td colspan="2">Distance from a nearby health facility (hospital, health center, dispensary) Km. ----------</td><td colspan="2">Distance from a nearest pharmacy Km. ----------</td></tr>
<tr><td colspan="6">Note: for the livestock ADDO, there is no criteria for the distance</td></tr>
<tr><td colspan="6">5. GENERAL OBSERVATIONS/OPINIONS WITH REGARDS TO THE CONDITION OF DLDB</td></tr>
<tr><td colspan="6">a. In accordance with criteria of establishment of DLDM, is the location suitable for establishing DLDM?</td></tr>
<tr><td colspan="6">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</td></tr>
</table>

| |
|---|
| |
| c. Give your opinion on the condition of premise of this DLDB in order to effect rehabilitation/renovation of the premise in accordance with criteria of establishing DLDM |

## Pre-Inspection of the Duka La Dawa Baridi Premise

Two copies should be completed; one copy should remain in the premise and the other copy should be kept by ward inspectors for final inspection.

| **CONDITION OF THE PREMISES** | **YES** | **NO** |
|---|---|---|
| Is the size of the dispensing room adequate? | | |
| Is there a store room? | | |
| Is the size of the store room adequate? | | |
| Is the ventilation sufficient? | | |
| Is there a ceiling? | | |
| Is the ceiling in good condition? | | |
| Is the quality of the floor acceptable? | | |
| Is the window in the store room sufficiently protected and secure? | | |
| Is the window in the store room acceptable? | | |
| Is there a front door? | | |
| Is the front door acceptable? | | |
| Is there a front glass door? | | |
| Is the front glass door acceptable? | | |
| Is there interlinkage between ADDO and rooms used for sleeping, laboratory, bar and/or any other rooms? | | |
| Is there any hand washing facility in the ADDO premise? | | |
| Is there any guideline for the establishment of DLDM? | | |
| **STORAGE OF MEDICINES** | **YES** | **NO** |
| Are there sliding glass shelves in the dispensing room? | | |
| Are there shelves in the store room? | | |
| Is there a glass case with a glass countertop in the dispensing room? | | |
| Is there a movable section of counter to allow the dispenser access to shop? | | |

## Results and Recommendations of the Duka La Dawa Baridi Pre-Inspection

Two copies should be completed; one copy to remain in the DLDB; the other goes to the district.

Name of DLDB: _____

Name of the Owner _____

Mtaa/Village _____Ward _____District_____

Address _____Phone number _____

| Observation of pre-inspection | Recommendation |
|---|---|
| | |

| Name of inspectors: | Signature | Name of inspected owner: | Signature |
|---|---|---|---|
| 1_____ | _____ | 1_____ | _____ |
| 2_____ | _____ | 2_____ | _____ |
| 3_____ | _____ | | |

## ANNEX 4. ROUTINE INSPECTION CHECKLIST/FORM FOR ADDO

**Ministry of Health and Social Welfare**
**Tanzania Food and Drugs Authority**

### 1. Information on ADDO

| |
|---|
| 1.1 Region in which the ADDO is located |
| 1.2 ADDO Name |
| 1.3 Postal Address<br>_____<br>……..……<br>……..……<br>_____<br><br>Phone number _____ |

| | | |
|---|---|---|
| 1.4 Physical location<br>Mtaa/Village…….....<br>District……<br>Ward……..... | | |
| 1.5 Number of the Permit | 1.6 Is the permit still valid?<br>Yes No | 1.7 Is the permit displayed in the wall??<br>Yes No |
| 1.8 Is this permit the one issued for this ADDO? | | |
| 1.9 Date of inspection | 1.10 Date for which the last inspection was conducted | |
| 1.11 Name of the ADDO Owner | | |

### 2. Information on Dispenser(s)

| | | | |
|---|---|---|---|
| 2.1 Are the dispensers wearing identity cards that show they are registered with TFDA? Yes No | | | |
| 2.2 Write the names and qualifications of each dispenser (check the correctness of the information through the certificate of the dispenser which is supposed to be displayed in the ADDO) | | | |
| | Name | Qualification | Number of certificate of the dispenser |
| a. | | | |
| b. | | | |

## 3. Conditions of Premise

| | Yes | No |
|---|---|---|
| 3.1 Are the surroundings of the premise relatively clean and trash free? | | |
| 3.2 Is the inside premise clean? | | |
| 3.3 Is the floor clean and in good condition? | | |
| 3.4 Are the walls clean and well painted? | | |
| 3.5 Are the ventilation and light sufficient? | | |
| 3.6 Are the doors and windows strong enough and secure to prevent unauthorized entrance of individuals to the premises? | | |
| 3.7 Is there a hand washing facility in dispensing room? | | |
| 3.8 Is the ceiling in good condition? | | |
| 3.9 Any other issues related to the condition of the premise? | If this space is not adequate, please use another blank sheet of paper | |

## 4. Storage of Medicine

| | Yes | No |
|---|---|---|
| 4.1 Are there enough pallets or shelves for storage so that medicines are not kept on the floor? | | |
| 4.2 Is the ventilation adequate—are there fans or air conditioners that will keep the temperature below 30°C? | | |
| 4.3 Are there any expired medicines in storage? | | |
| 4.4 I s the arrangement of medicines appropriate? | | |
| 4.5 If there is any breach of the Act, please explain: | (If this space is not adequate, please use another blank sheet of paper) | |

## 5. Validity of the medicines currently in the ADDO

Conduct inspection of the medicines currently in the premise. If there are unauthorized medicines, confiscate them and give them to the district pharmacist. Unauthorized medicines include medicines that appear to be questionable standard 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 ADDO? | | | |
| 5.2 Are there any unregistered (with TFDA) medicines in the ADDO? | | | |
| 5.3 Are there any public medicines with MSD or G label? | | | |
| 5.4 Are there any medicines that are not included in the ADDO list? | | | |
| 5.5 Are there any expired medicines? | | | |
| 5.6 Are there any medicines of questionable standards or quality/fake? | | | |

## 6. Documentation and record keeping

| | Yes | No |
|---|---|---|
| 6.1 Is there a drug register? | | |
| 6.2 If the drug register is available, is it filled in correctly? | | |
| 6.3 Are purchase records entered into the register? | | |
| 6.4 Are purchasing records correct? | | |
| 6.5 Are the purchasing receipts available? | | |
| 6.6 Are the used prescriptions available? | | |

| | |
|---|---|
| 6.7 Is there any other issue(s) related to documentation and record keeping? Explain. | |

### 7. Reference books

| Are the following reference books available? | Yes | No |
|---|---|---|
| 7.1 Regulations for ADDO | | |
| 7.2 List of medicines authorized to be stocked in the ADDO | | |
| 7.3 Guidelines for Good Dispensing Practices | | |
| 7.4 List of medicines registered with TFDA | | |
| 7.5 Training manual for ADDO dispensers | | |
| 7.6 Guidelines for establishing and managing ADDO | | |
| 7.7 Other reference books (mention) | | |

### 8. Other observations related to inspection of ADDO

Complete two copies of this form; one copy should remain with the ADDO owner and the second copy goes to the district.

## ANNEX 5. SAMPLE COLLECTION FORM

**Ministry of Health and Social Welfare**
**Tanzania Food and Drugs Authority**

Name of the shop where the sample has been collected _____

Address _____

Date of inspection /collecting sample _____

Reason for taking/collecting sample _____

_____

_____

Name and descriptions about collected drugs.

_____

_____

The amount of the drugs from where sample has been taken _____

Name and address of the manufacturer of the drugs _____

_____

_____

Batch No. _____ Date of manufacturing _____

Expiry Date _____

The amount of collected sample

_____

Name and signature of representative from where sample has been taken

_____

(To be completed in duplicate—one copy each to district CDFC and TDFA)

Names and signatures of the officers who collected the sample

_____

_____

_____