FIELD IMPLEMENTATION PROTOCOL FOR ACCREDITED DRUG DISPENSING OUTLET PROGRAM

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 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 Outlet (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 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
Assistant Director
TDFA

ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
CFDC	Council Food and Drugs Committee
CHMT	Council Health Management Team
DLDB	*duka la dawa baridi* (Swahili, private drug shop)
DLDM	Duka la Dawa Muhimu (Swahili, private accredited drug shop)
IMCI	Integrated Management of Childhood Illness
MEO	mtaa executive officer
MoHSW	Ministry of Health and Social Welfare
MSH	Management Sciences for Health
NMCP	National Malaria Control Programme
PMO-RALG	Prime Minister's Office Regional and Local Government
RFDC	Regional Food and Drugs Committee
RHMT	Regional Health Management Team
RMO	Regional Medical Officer
TFDA	Tanzania Food and Drugs Authority
VEO	village executive officer
WEO	ward executive officer

INTRODUCTION

The Ministry of Health and Social Welfare (MoHSW) through the Tanzania Food and Drug Authority (TFDA) in collaboration with Prime Minister's Office Regional Administration and Local Government (PMO-RALG) and Management Sciences for Health (MSH), a nongovernment organization, is implementing the accredited drug dispensing outlet (ADDO) program in Tanzania. This process aims to upgrade and accredit the current *duka la dawa baridis* (DLDBs) to become ADDOs (Duka la Dawa Muhimu [DLDM]). The program's overall purpose is to improve access and availability of quality pharmaceutical services through the outlets in villages and small towns.

Major program components include—

- Sensitizing stakeholders
- Mapping and pre-inspecting DLDBs and new premises
- Training local inspectors, ADDO owners, and dispensers
- Final inspection of DLDBs before accreditation
- Accreditation and certification
- Inspecting and supervising ADDOs (DLDMs)
- Monitoring and evaluation of the program

To date, the ADDO program has been implemented in Ruvuma, Mtwara, Morogoro, and Rukwa regions. One of the major challenges that the MoHSW has faced in implementing this program is the availability of funds. The lack of assured funding sources has slowed the rollout countrywide.

To speed up rollout implementation and make the program sustainable, the MoHSW has agreed with PMO-RALG that the program should be implemented by all councils in the country. The PMO-RALG through its Permanent Secretary has already issued a circular directing all councils in the country to implement various TFDA responsibilities including the ADDO program, through what is called "Delegation of Power to Councils."

The ADDO program field implementation protocol has been prepared to guide program implementers at all levels on how to carry out implementation in line with existing laws and regulations.

PROGRAM IMPLEMENTATION TEAMS

As mentioned earlier, program implementation will be done by council technical staff in collaboration with those from regional secretariat. TFDA will have the responsibility of coordinating and monitoring so as to ascertain adherence to established procedures and standards.

To successfully carry out the ADDO program rollout, there will be different implementation teams at national, regional, and district levels.

- **National Level—**Director of Medicines and Cosmetics, TFDA; ADDO Program Manager; Assistant ADDO Program Coordinators; TFDA accountant, ADDO Program Administrative Officer; Artemisinin-based Combination Therapy (ACT) Coordinator for the National Malaria Control Programme (NMCP), and ADDO program associates from MSH.

- **Regional Level**—Regional Medical Officer (RMO), Regional Pharmacist, regional livestock advisor, regional Integrated Management of Childhood Illness (IMCI) malaria coordinator, and any technical person that the region may appoint based on specific needs.

- **District Level**—District Medical Officer (DMO), District Pharmacist, district livestock officer, district IMCI/malaria coordinator, district treasurer, and any other technical person that the district may appoint based on specific needs.

In addition to these technical implementers, regional and district Council Food and Drugs Committees (CFDC), under the chairmanship of the regional commissioners and the council directors respectively, and regional and district health management teams will have the obligation to see that this program is implemented accordingly.

TFDA will write and circulate a letter to all regional Admistrative Secretaries and Council Directors explaining the type of work that is expected to be done in his/her region or district respectively. It will also point out who will be responsible for the implementation of this program.

Funds for Program Implementation

Funds for program implementation are expected to come from contributions from council budgets, Basket Funding Account, and other sources. Finances from other sources will be used to cover financial deficiences within the council budgets for program implentation. Funding from all the sources will be used to prepare necessary documents and tools for program implementation, sensitization, and awareness building for various stakeholder at all levels (national, regional, district, and ward), and for training of local inspectors, owners, and dispensers. These funding sources will also be used for mapping and inspection of drug outlets,

Food and Drugs Committee meetings, and outlets' supervision at all levels. Furthermore, outlet dispensers and owners will be required to meet some of the training costs. Regional and district medical officers will coordinate availability of transportation resources for implementing various planned activities of the program.

Payments from donors funds will be coordinated by council accountant and TFDA chief accountant. If the donor funds are to be channeled through regional subtreasury, the relevant accountants will collaborate with council accountants to make payments and prepare financial expenditure report.

ADDO PROGRAM IMPLEMENTATION STEPS AND RESPONSIBLE PERSONS

To easily implement all program components, the following steps should be followed.

Program Implementation Sequence

Step	Component	Main Implementers
1.	Building awareness/sensitization of regional implementation team	Director, Drugs and Cosmetics, TFDA; ADDO program manager, ADDO coordinator, assistant ADDO coordinator, MSH senior program associate, ACT coordinator–NMCP
2.	Building awareness/sensitization of regional implementation team	ADDO program manager, assistant ADDO coordinator, regional medical officer (RMO), regional pharmacist, regional livestock advisor, regional IMCI/malaria coordinator
3.	Sensitization of drug outlets owners and ward executive officers (WEO)	ADDO coordinator, district medical officer, district pharmacist, district livestock officer, district IMCI/malaria coordinator
4	Training of local ward inspectors	ADDO coordinator, regional pharmacist, regional livestock advisor, district pharmacist, district livestock officer, ADDO trainer
5.	Mapping and pre-inspection	ADDO program coordinator, regional pharmacist, regional livestock advisor, district pharmacist, district health officer, district livestock officer, ADDO trainer
6.	Dispenser' course candidates interviews and enrollment	Regional pharmacist, regional livestock advisor, regional medical officer, district medical officer, district pharmacist, district livestock officer
7.	Owners' training	ADDO program coordinator, regional pharmacist, regional livestock advisor, district pharmacist, district trade officer, district cooperative officer, district livestock officer, ADDO trainer
8.	Dispensers' training	ADDO coordinator, regional pharmacist, regional livestock advisor, district pharmacist, district livestock officer, zonal training coordinator, regional IMCI/malaria coordinator, ADDO trainer
9.	Final inspection	ADDO program coordinator, regional pharmacist, regional livestock advisor, district pharmacist, district health officer, district livestock officer, ADDO trainer
10.	Accreditation and certification	CFDC and TFDA
11.	Regulatory control of ADDOs	CFDC, local ward inspectors, TFDA, and RFDC
12.	Monitoring and evaluation	TFDA, CFDC, RFDC, Council Health Management Team (CHMT), and Regional Health Management Team (RHMT)

Orientation of Regional Teams on the ADDO Program

The national ADDO program implementation team in close collaboration with the respective regional pharmacists will carry out a one-day orientation seminar for the regional implementation teams. TFDA will discuss when to hold the seminar with the respective RMOs and agree on a date.

Seminar participants will include RMO, regional livestock advisor, assistant regional adminstrative secretary–Social Services, regional IMCI/malaria coordinator, regional trade officer, and regional agricultural officer.

Orientation of District Teams on the ADDO Program

The ADDO program manager in collaboration with regional implementation teams will organize a one-day orientation seminar for council program implementation teams. These seminars would be organized per council within the respective regions, and the seminar participants will include—

- District commissioners
- Council directors
- District planning officers
- District medical officers
- District pharmacists
- District health officers
- District livestock officers
- District IMCI/malaria coordinator
- Council accountants
- District legal officers and district trade officers

1. SENSITIZATION OF OUTLET OWNERS AND WARD EXECUTIVE OFFICERS ON ADDO PROGRAM

The respective district implementation teams will organize and carry out the sensitization seminars for outlet owners and WEOs. In addition to these participants, people who would like to operate ADDOs but are not currently operating a DLDB can also attend.

Field Activity Protocol Checklist 1

Objective

To describe the procedure for planning and carrying out orientation and sensitization activity for regional and district stakeholders

Facilitating Teams and Persons

- National ADDO implementing team
- ADDO coordinator and regional implementing team (RMO-Office)
- District ADDO implementing teams (DMO-Office)

Checklist 1. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Standard mobilization and sensitization materials from TFDA		
• Facility equipment; LCD projector, printer, flip charts and stand, computer		
• Stationery—pens, writing pads, marker pens, accounting forms, participants' registration forms and end of activity evaluation forms, and owners' ADDO-application forms		
• Venue with large rooms that are within budget, can accommodate 40-50 trainees, large dining place, other necessary utilities (water, electricity, clean toilets)		
• Public address system*		
• Catering services		
• Guidelines on per diem payment		
Meeting organization		
Responsible persons at any level shall • Identify and send invitation to the participants through their employers 14 days or more before the meeting day.		
• Give all necessary details in the invitation—date, venue, cost reimbursement and per diems, requirements for participation.		
• Identify orientation or sensitization facilitators and work with them to agree on the timetable.		

Checklist 1. Things to do or check for	**Status**	
	Yes	**No**
• Review the standard sensitization materials to fit the participating group.		
• If group work is planned, develop group work materials/questions.		
How to carry out orientation/sensitization		
• Identify and request a high ranking and influential officer to officiate the meeting.		
• Let participants and facilitators introduce themselves.		
• Allow participants to select meeting chairperson and secretariat.		
• Briefly talk about the logistics including related financial issues.		
• The organizer or head facilitator should provide a brief meeting outline and indicate what level of participation is expected, e.g., group discussions.		
• Let facilitators lead the event and observe timing as per timetable.		
• Allow brief questions, discussions, and pass out presentation materials.		
• Provide ample time (30-40 minutes) for group work or discussion after all the topics have been presented.		
• Alert the secretary to note down vital points/issues comments raised during discussions.		
• Evaluate the activity; this may be done by filling in evaluation forms.		
• Distribute any other ADDO-related information, education, and communication materials that are relevant for the group.		
• At the end of the meeting, distribute ADDO application forms to those interested in becoming an ADDO owner. • Provide time for them to complete application forms.		
• Collect all completed ADDO application forms • Inform applicants as to what the next step will be in the application process and when it might occur.		
Activity report		
• Compile the participants' evaluation results, have the participants' secretariat record the results, and note critical issues, in the report. Attach the evaluation report to the main activity report.		
• Using the report format, write an activity report within three days after the meeting and submit as directed.		
Organizer's comments		
Supervising coordinator/officer observations and comments		

Note: Attach a copy of the completed protocol checklist on orientation and sensitization to final activity report.

2. TRAINING LOCAL WARD INSPECTORS

Since the district inspectors were trained during the regional sensitization and capacity building seminars, the districts' program implementation teams will organize and carry out these two-day training course for local inspectors in their respective districts/councils. This training will include all ward health officers, ward extension officers (livestock), health center/dispensary (whichever is within the ward) in-charge.

Field Activity Protocol Checklist 2

Objective

To describe training protocol of local ward inspectors.

Responsibility

- District ADDO program implementation teams (DMO-Office)
- National program coordinators

Checklist 2. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Inspectors' training manuals, guide, and other supportive training materials (from TFDA)		
• Computer (at least one), printer, photocopier		
• Stationery—pens, rulers, writing pads or exercise books (large), flip charts, marker pens, adhesive tape		
• Venue with large rooms that are within budget, can accommodate 40-50 trainees, large dining place, other necessary utilities (water, electricity, clean toilets)		
• A standard training timetable (TFDA copy)		
Preparation for the training		
• DMO-Office (district pharmacist) consults with the training team and agrees on the dates.		
• Fourteen days before the training, inform the inspection trainees about the training, indicating date, venue, and how costs are covered.		
• Also inform the trainees that they should have three passport-size photos in color which they will give to you the first day.		
• The day before the meeting, meet with the training team to work on the timetable, review logistics, and bring up any anticipated problems.		
• Build a team from the start; all team members should have equitable roles and participate equally. If you are also a trainer, your participants should be part of a team, not just trainees.		

Checklist 2. Things to do or check for	**Status**	
	Yes	**No**
During training		
• This is a three-day training course.		
• ADDO district coordinator should be always available at the training site.		
• Have trainees meet with trainers and use this meeting to advise the trainees to select their own leadership during the course.		
• Coordinator is responsible for all the logistics at the site. In addition, if is not part of the training team, he or she should periodically sit in classes to follow the training.		
• At the end of the training day, coordinator holds a 20-30 minute meeting for trainers' feedback, exchange of experiences, and agreement on next steps to improve performance.		
• During the meeting, trainers should bring up any logistics problems which then can be resolved as soon as possible.		
• As often as possible, meet with trainees' leadership to hear their issues. Try to understand their issues and provide explanations to the issues raised. Remember, these are professionals and should be acknowledged and respected.		
• Food has always been the major cause for complaints. The ADDO coordinator must follow up to make sure that food is prepared according to the agreement. He or she should be fair and ensure that the quality of food provided is consistent.		
Training process		
• The first two days are for intensive theoretical training.		
• During these two days, trainees should be divided in discussion groups and plenary sessions to describe major inspection areas.		
• Give trainees time to provide examples of practical experiences they have had as government officials and provide scenarios to be used during plenary discussions for trainees to build consensus.		
• In preparation for the practical on the third day, divide the trainees into groups of 2-3 and allocate them to drug outlets for practical inspection		
• During the third day, distribute the necessary inspection tools and guides, and provide sufficient time for the inspectors to carry out inspections in at least 2-3 outlets per group.		
• At the end of the exercise, trainees should be given time to write their inspection report/group work notes.		
• Provide time for each group to present their report in a plenary and let other participants comment on it.		
• At the end of the plenary, make final comments emphasizing on the importance of inspection and inspectors' roles.		
• Each ward inspectors' group should develop an implementation plan for local inspection that they will begin when they return to work; trainers should go through these plans and assist the trainees as needed		
• At the end of the course, trainees should be awarded attendance certificates.		
• To make the training meaningful, trained inspectors should be given all necessary job aids, including inspectors' identification, at the end of the training or no later than 14 days after the training.		
• Request trainees to put the photos they brought and a piece of paper with his/her signature on it into an envelope. The trainee's full (official) name should be written in capital letters on the envelope; make sure that all trainees have submitted their photos		

Checklist 2. Things to do or check for	**Status**	
	Yes	**No**
and signatures.		
• Submit the photos and trainee information—name, address, phone, organization, and title—to TFDA together with the training report.		
Activity report		
• Using the format provided (see implementation guidelines), write a report for the training activity within three days after the course.		
• Attach the necessary appendixes to the report and submit as required.		
Training team comments		
Supervising pharmacist and or coordinator observations and comments		

Note: Attach a copy of the completed protocol checklist to the final activity report.

3. MAPPING AND PRE-INSPECTION OF DRUG OUTLETS

The district teams in collaboration with ward inspectors will carry out mapping and preliminary inspection of all existing DLDBs and any new premises of existing or newly applying owners. ADDO program coordinator(s) and regional implementation teams will provide technical assistance whenever it is required.

The objective of this activity is to identify, map, and provide detailed guidance on how to improve the premises to meet ADDO standards as provided in the ADDO regulations.

Field Activity Protocol Checklist 3

Objective

To describe the process for mapping and preliminary inspection of DLDB or new premises before accreditation.

Responsibility

- District ADDO implementing teams (DMO-Office—district pharmacists and other inspectors)
- RMO-Office (regional pharmacists–regional inspectors/inspectors trainers)
- ADDO coordinators

Checklist 3. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Standard mapping tools/forms and preliminary inspection checklist (TFDA)		
• Two experienced senior inspectors		
• At least two district inspectors and respective ward inspectors		
• Stationery—pens, writing pads, marker pens, accounting forms, completed ADDO owners application forms, measuring tapes		
• Regulatory materials (ADDO/DLDB regulatory documents)		
• Standard sketches (drawings) of a typical DLDM		
• List of operating DLDBs as given by the district		
• Vehicles and drivers (RMO and DMO)		
• Copies of ADDO Regulation and Guidelines (TFDA)		
• Guidelines on per diem payment (TFDA)		

Checklist 3. Things to do or check for	**Status**	
	Yes	**No**
How to proceed		
• Prepare the itinerary of the activity and send it to the WEOs at least 10 days before the activity begins; instruct WEOs to inform all outlet owners in WEO's ward.		
• Give all necessary details of the activity to WEOs in your letter and emphasize the importance for all owners to be notified and to attend.		
• Follow up 3-5 days before the activity to check if information has been delivered or if there are problems to be addressed. Probe by directly calling some owners that you know.		
• Work on the completed owners application forms and list all applicants per division and ward. Compare with the official list from the district.		
• The day before, organize a meeting with all mapping team members and agree on the itinerary and routes. Form the groups (at least two).		
• During this meeting, one of the two senior inspectors should briefly explain the upcoming work, identify controversial areas, and provide direction on how to solve them.		
Upon arriving at the ward		
• The team should pay a courtesy call to the WEO at the ward office.		
• Explain the objective of the activity and the extent to which the ward will be involved; ask for one or two ward inspectors to accompany your team.		
• Using the mapping tool for WEO, interview him/her (do this before sharing with him/her the applicants list and the official district list).		
• After the interview, share both lists with the WEO and compare the information from the interview you have just had with the WEO.		
Mapping		
• Using the lists of owners you have and the ward inspectors' guidance, start mapping.		
• Use the mapping tools/form, interview VEOs, owners, and drug sellers of the shops you map.		
• Also, using the applicants list you made, identify new applicants within this ward and map out the locations being suggested.		
• The exercise you have just finished has provided you with basic information that you will use in the next activity—preliminary inspection.		
• Extract the following data from the mapping exercise for each shop; legal status, establishment year, and distance from the nearest drug outlet.		
Carrying out preliminary inspection		
• Strictly follow the TFDA ADDO standards, but also use your judgment.		
• Review the standards before starting the inspection.		
• Using the preliminary inspection checklist, carefully and chronologically go through the entire form.		
• While filling in the form, carefully examine the item subject to the area you are about to fill out. As you do the inspection, tell the owner or representative what you are doing and why. Explain what is required, and if the conditions observed do not meet ADDO premise/location requirements, explain why.		
• Always be polite and helpful while carrying out preliminary inspections but do		

Checklist 3. Things to do or check for	**Status**	
	Yes	**No**
not compromise standards.		
• Working as a team, it is considered ethical to avoid private discussions with owners during or after preliminary inspection. Issues that arise should be discussed by the team and the decision should be that of the team's.		
• If, using your best judgment, a decision has been made that is contrary to the prescribed standards, the reason for doing that should be clearly stated, agreed on by the team, and included in your activity report. Remember, TFDA cannot provide directives for all field conditions that you might come across with in practice; collective thinking is sometimes needed to solve field problems.		
• After completing the preliminary inspection questionnaire, carefully and clearly fill the preliminary inspection result form in duplicate.		
• Give the original copy to the owner/representative, and carefully and pleasantly explain to him/her what needs to be done to meet standards for accreditation. Remind the owners in a professional way that the ADDO standards cannot be compromised.		
• Provide a tentative date for final inspection (not exceeding three months) prior to accreditation and briefly explain what the objective of that inspection will be.		
• Shake hands with the owner/seller and wish him or her good luck. Move to the next shop.		
• At the end of the activity in the ward, debrief the WEO if possible and thank him or her for the cooperation given.		
Activity report		
• Go through the mapping interviews, records, and preliminary inspection result forms and note major issues		
• Using the report format, write an activity report within three days of completing the activity, incorporating major findings and submit it to TFDA, RMO, and CFDC as directed.		
• Attach copies of the inspection result forms as appendixes to your report.		
Mapping and pre-inspection team comments		
Supervising senior inspector's observations and comments		

Note: Attach a copy of the completed protocol checklist to the final activity report.

4. INTERVIEW AND ENROLLMENT OF ADDO DISPENSERS' COURSE CANDIDATES

Candidates for the ADDO dispenser's course need to be interviewed to ascertain their knowledge and skills with respect to medicines and related services. Before being interviewed, candidates must take and pass the regional/district written examination.

Field Activity Protocol Checklist 4

Objective

To describe the process for selecting candidates for the dispensers' course.

Responsibility

- District ADDO coordinator or district pharmacists–district inspectors
- RMO-Office (Registered pharmacist, registered nursing officers)
- TFDA ADDO coordinator

Checklist 4. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Screening examination made under the regional medical officer's supervision		
• Two experienced senior nursing and pharmacy staff		
• Stationery—pens, examination papers, rulers, standard interview protocol, writing pads		
• Venue with rooms large enough to provide isolated seating for each candidate during examination to prevent cheating. Each candidate must sit separately and apart from other candidates.		
Preparing and carrying out the activity		
• In collaboration with the RMO, the regional pharmacist should take the lead in this activity.		
• The regional pharmacist should work closely with a senior nursing officer, preferable a trainer, to develop a one-hour examination paper .		
• The paper should mostly test on nursing skills as the majority of applicants are nurse assistants (testing on dispensing skills is not a determinant because although some persons have not had basic medical related training, they have practical experience from working in DLDB and are able to pass through with forged nursing certificates).		
• Compile the list of candidates (this information found from the mapping and pre-inspection).		
• Prepare standard answers to the examination and marking scheme.		
• Send an invitation through the owners to all selected candidates from the shops that		

Checklist 4. Things to do or check for	**Status**	
	Yes	**No**
you have just mapped and pre-inspected at least 10 days before the examination. day. Let other candidates outside the mapped outlets know that they can also come for this examination (this is important as students from outside the mapped area can fill in for those students who fail the examination).		
• Take other initiatives to make sure that all candidates have received information early enough before the examination day.		
• Inform the candidates that they will have to pay an examination fee (current TZH 5,000) at registration before sitting for the exam.		
• Set realistic starting time for the exam, taking into account transportation problems. You should hold several exam sessions, but be aware that leakages are possible through doing these multiple sessions.		
• Strictly stick to the time set for the examination period.		
• Have all candidates registered before going into the hall for the examination.		
• The regional pharmacist leading the activity should identify two to four nurses/pharmacists, depending on the number of candidates that sit for the exam, to correct the papers as soon as possible but within seven days from the examination date. Use standard answers previously prepared.		
• During the registration time, candidates must present original copies of their certificates. The regional pharmacist must check the authenticity of the document (check for forged documents). Explain the seriousness of the offense if forgeries are found.		
• Suspect certificates and other testimonials should be copied (the originals returned to the student) and later checked with the training institutions before giving out the results.		
• Before correction work starts, the regional pharmacist should briefly orient the correction team on the marking scheme and answer any related questions, and then closely follow the process.		
• The regional pharmacist should randomly check some of the corrected papers, especially those with very high passing marks and very low passing marks.		
• Compile the results and make them available to the candidates. Candidates who have been verified as presenting forged documents should be disqualified and results should say “candidate disqualified.”		
• Compare the compiled results list with the registration list you made on the examination day. Check for any discrepancies and deal with them.		
• Display the results on the public notice board and also send them to the respective districts and TFDA. All this should be completed within seven days after examination.		
Enrollment interview		
• This should be done at the respective district.		
• Seven days before the interview date, the district pharmacist should send information to all the candidates that have passed the regional examination.		
• Candidates or their owners should be informed that they will cover all the costs related to the interview, e.g., transportation, food, and accommodation. The information also should say candidates should come with copies of their original certificates.		
• On the interview day, all participating candidates must register first with necessary details.		

Checklist 4. Things to do or check for	**Status**	
	Yes	**No**
• Follow the interview guide step by step.		
• Provide the interview results to the candidate immediately after the interview and the information about the next steps.		
• The interviewing team should meet at the end of the activity to compile all the results.		
Activity report		
• Using all the data you collected and the report format provided (see implementation guidelines), write a report for the enrollment activity within three days after the interviews.		
• Attach the necessary appendixes to the report and submit to RMO, TFDA, and DMO as required.		
Interview team comments		
Supervising pharmacist observations and comments		

Note: Attach a copy of the completed activity protocol checklist to the final activity report.

5. TRAINING OF OWNERS

Approved applicants for ADDO ownership will undergo a six-day training course on medicines and cosmetics related law, ADDO regulation, ADDO guidelines, and basics on entrepreneurship. Training on regulatory matters will be conducted by regional and district pharmacists and ADDO trainers; entrepreneurship training will be handled by trade and cooperative officers. Where the course cost becomes high and infrastructures do not support carrying out the training in a particular district, the RMO's office in collaboration with districts' medical officers will determine the possibility of combining the courses for more than one district.

All course trainees will meet costs for attending this course that will include transportation to and from the course, accommodations, and evening meals. The entire course will run six days—four days for entrepreneurship (given first) and then two days for training on regulatory matters.

Field Activity Protocol Checklist 5

Objective

To describe the ADDO owners' business management training protocol that should be followed during training.

Responsibility

- RMO and DMO offices (regional and district pharmacists)
- ADDO trainers
- Regional and district trade and cooperative officers
- TFDA-ADDO coordinator

Checklist 5. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Owners' training manuals, other supportive training materials, owners regulatory training manuals, owners training guide (TFDA)		
• Computer (at least one), printer, photocopier		
• Stationery—pens, rulers, writing pads, flip charts, marker pens, adhesive tape, cash analysis and cash books		
• Affordable venue with large rooms to accommodate 40-50 trainees, large dining place, catering services, and other necessary utilities (water, electricity, clean toilets)		
• A standard training timetable (TFDA copy)		
Preparation for the training. The responsible team/person shall—		
• Consult with the ADDO entrepreneurship training team and agree on the dates		

Checklist 5. Things to do or check for	**Status**	
	Yes	**No**
• Fourteen days before the training, inform the owners about the training, indicating date, venue, and how costs will be covered.		
• Meet with the training team the day before the meeting to work on the timetable, inform them of the logistics and anticipated problems if any.		
• Build a team from the start; all team members should have equitable roles and participate equally. If you are also a trainer, your participants should be part of a team, not just trainees.		
During training (entrepreneurship)		
• Training coordinator should be available at the training site all the time		
• Have trainees meet with the trainers for introduction and use this meeting to advise trainees to select their own leadership during the course		
• While responsible for all the logistics at the site, if possible, the coordinator should periodically sit in on classes to follow the training.		
• At the end of the training day, coordinator takes 20 to 30 minutes to get trainers' feedback and exchange experiences, and agrees on next steps to improve performance.		
• Trainees have the right during this meeting to raise logistics problems so that they can handled.		
• As often as possible meet with trainees' leadership to hear their issues. Try to be as understanding as possible to their issues and be able to provide explanations to the issues raised. Remember these are professionals and should be acknowledged and respected.		
• Food has always been the major cause for complaints, so ADDO coordinator must follow up to make sure that food is prepared and presented according to the agreement. He/she should be fair, ethical, and persistent on quality of food provided, and not compromising at the disadvantage of the trainees.		
Certification		
• This is a four-day course with no final examination.		
• At the end of the course, the training organization should award certificates of attendance to all participating ADDO owners.		
During training (regulatory)		
• This is a two-day training that immediately follows the business management course.		
• The course should be taught with somebody with solid knowledge and experience in TFDA regulatory issues.		
• To make the training convincing and enjoyable, trainers should encourage group and plenary discussions. Mere regulatory statements are usually monotonous and do not build acceptance because reasons for such enforcements are not understood or not explained convincingly.		
• Threats for punishment due to violations usually do not work. Help the trainers to see the reasons behind all your regulatory protocols.		
• At the end of the two-day training, TFDA should issue an attendance certificate for regulatory matters related to operations of ADDOs.		
Activity report		
• Using the format provided (see implementation guidelines) write a report for the training activity within three days after the course.		

Checklist 5. Things to do or check for	**Status**	
	Yes	**No**
• Attach the necessary appendixes to the report and submit as required.		
Training team comments		
Supervising pharmacist observations and comments		

Note: Attach a completed copy of this activity protocol to the final activity report.

6. TRAINING OF ADDO DISPENSERS

Trainees for the ADDO dispensers' course will undergo a five-week training course; for livestock drug outlets, a four-week course. The course will be conducted by ADDO trainers and coordinated by Zonal Training Coordinators.

Where the course cost becomes high and infrastructures do not support carrying out the training in a particular district, the RMO's office in collaboration with districts' medical officers and livestock will determine the possibility of combining the course for more than one district.

All trainees will be required to cover the following costs; transportation to and from the training, accommodations, and evening meals. All ADDO dispensers' trainees will be evaluated through weekly tests which will count toward 50 percent of the final evaluation while the final examination will also count 50 percent.

Field Activity Protocol Checklist 6

Objective

To describe the dispensers' training protocol that should be followed.

Responsibility

- ADDO trainers
- RMO and DMO Offices (regional and district pharmacists, livestock officers)
- TFDA-ADDO coordinators

Checklist 6. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Dispensers' manual, trainers guide, other supportive training materials		
• Computer (at least one), printer, photocopy*		
• Stationery–pens, rulers, writing pads, flip charts, marker pens, adhesive tape		
• Venue that is within budget, with large rooms that can accommodate 40-50 trainees, large dining place, other necessary utilities (water, electricity, clean toilets)		
• A standard training timetable (TFDA copy)		
Preparing for training dispensers		
• District pharmacist or ADDO coordinator should take the lead in this activity.		
• Using admission list, inform the owners and or the trainees 10-14 days before the training begins.		

Checklist 6. Things to do or check for	**Status**	
	Yes	**No**
• Provide all necessary information to the owners/trainees on which costs will be covered by the program and which costs they will be responsible for—accommodations, transportation to and from training, and evening meals.		
• Include the information that each trainee should come with three color passport size photos. These photos will be used to produce certificates and identification cards.		
• At least seven days before the event, invite one of the leading district figure to inaugurate the training.		
• Visit the training venue to physically check the facility for what you will need during the training. Arrange to discuss with the facility leadership anticipated problems and observed deficiencies. Confirm charges and compare with your budget.		
• If catering services are being provided by other vendor, follow up with the vendor. Be very specific on the, variety, quality, and quantity of food to be provided. Make sure that the food provided is worth the money. Note: insufficient and poor quality of food could cause complaints and affect the training results.		
• In handling issues related to vendors who provide services, be transparent and ethical, involve the team, and do not compromise to the disadvantage of the trainees or quality of the activity product.		
• A day before the training, organize a meeting with all the trainers and work on the following: Review the standard training timetable to fit your situation, divide the trainees into classes of 30-50 (but not more than 50); assign trainers to classes and extra responsibilities, appoint head of the training team clarify his/her responsibilities (should be experienced in dispensers training) and discuss other logistic issues related to the training.		
• Inform the team about all the preparations you have made so far, pending issues to be addressed and assistance needed and invite suggestions or additions to what you have done so far. Work as a team from day one and let everyone be well informed.		
• Explain what is expected from the trainers and inform them about the general educational background of the trainees and the anticipated difficulties in training such a group. Emphasize that patience is needed to get good results.		
Training		
• Have a district authority (district commissioner, district executive director, or DMO) open the training.		
• After inauguration, read out the names of the trainees and their classes, then tell them to go to their respective classes. Make sure that a class list is fixed to the doors or walls of each class so that trainees can easily check to make sure that they are in the correct class.		
• Provide time for the trainees to appoint their class leaders and course leaders. The leaders will be the link between the trainees and the course coordinator and training team. Coordinator should meet periodically with these leaders to find out if there are any problems and complaints. Take their concerns seriously.		
• Trainers should be in their respective classes to meet the trainees. Once assemble, trainers should check the student roster against the class attendees and mark them present or absent. Attendance should be taken every day		

Checklist 6. Things to do or check for	Status	
	Yes	**No**
during the morning and afternoon sessions.		
• Trainers should explain how the training will proceed and what is expected from the trainees.		
• For effective time management, 10 o'clock tea/coffee and lunch must be served within the training compound and therefore organized by the training coordinators.		
• Classes should begin at 8 a.m. and end at 5 p.m. with breaks in between– follow STD-TFDA training timetable.		
• During training, both trainers (two per class) must be present. While one is training, the other will sit at back of classroom and takes notes on issues that are worthy discussing with his/her colleague later. The note taker can observe trainees' reactions and comprehension during the session, and can also observe the other's training tactics.		
• Trainers should adhere to the trainers' guide. Trainers should also actively move around when trainees are working in groups. Trainers should not just sit and read the manual.		
• The head of the training team (one with experience in training dispensers) should occasionally sit in different classes and observe the whole training session for all new trainers. He/she should take note and discuss with trainers later to improve quality of training.		
• If, after several discussions, the trainer does not improve, the training team head should provide direct support by taking some sessions together with the new trainer.		
• At the end of the training day, head of trainers should call a 15 to 30 minutes debriefing meeting. Trainers will exchange experiences, problems encountered, and the way forward. Specific issues related to some trainers noted by the head can be politely discussed here too for the benefit of all, but avoid names.		
• Every Saturday, trainees will take a test on the modules covered so far. These tests are mandatory; the trainees' test scores are combined and averaged, and count for 50 percent of the final evaluation. There should not be less than three such weekly tests for the whole course period.		
• At the end of the course, trainees will do final examination as per TFDA timetable. Fifty percent of the average score from this examination will be added to the 50 percent average score from the weekly tests.		
• Average final lowest pass mark for the dispensers' course is 50 percent.		
• Each trainer will come up with questions related to his/her topics and submit them to the trainers' team leader.		
• The team leader and the coordinator will select questions from different trainers and compile them into final examination papers.		
• The final examination papers are confidential and shall be kept under the control of the team leader or coordinator. Note: limiting access to the final examination papers to only those persons who need to see them is important to control possible leakages.		
• All final papers should be put in double envelopes and securely sealed and be opened in the presence of the candidates during examination.		
• All necessary steps be taken to prevent any leakage, and trainers are		

Checklist 6. Things to do or check for	**Status**	
	Yes	**No**
expected to be ethical and not to compromise in any way.		
• Examinations will be done within two days.		
• Trainers are given two days to correct the examinations and compile results.		
• Compiled results can be disclosed to the candidates in classes by their trainers. If there are candidates who have failed to reach the minimum average pass, they should be called first separately and counseled before revealing their results.		
• Certificates can be awarded officially on the following day.		
Preparation of certificates		
• Within the first week after the course start, collect three passport-size photos in color from each trainee.		
• Put two photos in one envelope and ask the trainees to clearly write (in capital letters) their full name as they want it to appear in their certificates on the envelope. Seal this envelope and mark for certificates.		
• Put the other one photo into another envelope and request the trainee to write her/his full name as for the previous envelope. Also provide small plain white paper (4-6 cm long and 2 cm wide) and instruct the trainees to sign at the center of this paper using a thick pen (not marker pen). This signature will be transformed on to their ID cards. Label the envelope “photo for ID card.”		
• Send or hand both envelopes over to TFDA-ADDO manager/coordinator to process the documents. Make sure that all trainees have handed over the two envelopes with the right contents. Check again to be sure that there is no confusion and nothing missing.		
Preparation and delivery of ADDO materials		
• Halfway through the course, enquire about availability of the following materials from TFDA: white coats, ADDO logo, patient registers and other related materials, ID cards, and certificates.		
• Follow up with TFDA and make sure that goods arrive at the training site earlier before the graduation day.		
Graduation Day		
• If you have the goods from TFDA, distribute them (except certificates) to the qualified candidates (based on TFDA instructions) a day before the graduation ceremony.		
• You should invite a high level official from the district to hand over the certificates.		
Activity report		
• Using the format provided (see implementation guidelines), write a report for the training activity within three days after the course.		
• Attach the necessary appendixes to the report and submit as required.		
Training team comments		
Supervising pharmacist observations and comments		

Note: Attach a completed copy of this activity protocol checklist to the final activity.

7. FINAL PREMISE INSPECTION

The district/council implementation teams in collaboration with local ward inspectors will carry out final inspections. The teams will ascertain that all instructions provided to premise applicants during the preliminary inspection activity have been followed and fully implemented. ADDO program coordinator(s) and regional implementation teams will provide technical assistance whenever it is required. The goal of this activity is to see that all premises previously inspected have met all requirements for ADDO as per ADDO regulation and guidelines.

Field Activity Protocol Checklist 7

Objective

- To describe the procedure for carrying out final pre-accreditation inspections for DLDB or new premises.

Responsibility

- District /Council ADDO Implementing Teams
- RMO-Office (regional inspectors)
- TFDA-ADDO Coordinators

Checklist 7. Compliance areas for final premise inspections	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Standard final pre-accreditation inspection checklist		
• Two senior experienced inspectors		
• At least two district inspectors and respective ward inspectors		
• Stationery—pens, writing pads, marker pens, accounting forms, list of preliminarily inspected outlets for accreditation, measuring tapes, copies of forms completed during mapping and preliminary inspection activity		
• Regulatory materials (ADDO/DLDB regulatory documents)		
• Standard sketches (drawings) of a typical DLDM		
• List of operating DLDBs as given by the district		
• Vehicles and drivers		
• Guidelines on per diem payment		
How to proceed		
• Prepare the itinerary of the activity and send it to the WEOs at least 14 days before the activity begins. Instruct WEOs to inform all outlet owners in the respective ward.		
• Give all necessary details of the activity to WEOs in your letter and emphasize the importance for all owners to be informed. Insist on owner's presence during this inspection.		

Checklist 7. Compliance areas for final premise inspections	**Status**	
	Yes	**No**
• Follow up three to five days before the activity to check if information has been delivered or there are problems. Probe by directly calling some owners that you know.		
• A day before, start organizes a meeting with all inspection team members and agrees on the itinerary and routes. Form the groups (at least two).		
• During this meeting one of the two senior inspectors provide a brief explanations on the work ahead, identifying conflicting issues and providing guiding approach to solve them.		
On arrival at the ward		
• The team should report and pay a courtesy call to the WEO at the ward office.		
• Explain the objective of the activity and the extent the ward will be involved and ask for one or two ward inspectors to accompany your team.		
• Using the mapping and preliminary inspection details you have and the final inspection checklist, proceed to the activity.		
Carrying out final pre-accreditation inspection		
• Strictly follow the TFDA ADDO standards (see implementation guideline) but also use your reasonable judgment.		
• Go through the standards to remind yourself before starting the inspection.		
• Using the final inspection checklist, chronologically go through the form that you had used for this outlet during preliminary inspection. You will find areas which the owner was required to carry out to meet prescribed ADDO standards—acknowledge accomplishments and correctly met standards by checking then off.		
• While reviewing this form, carefully and critically examine the item or area you are reviewing, such as walls, shelves, or counters. If you and the team are satisfied with the accomplishment, you write “OK,” if not satisfied, explain what else needs to be done and mark “NSA” (Not satisfactorily accomplished). If done incorrectly or not done at all, write “ND” (Not Done).		
• Once you have gone through the whole pre-inspection form, it should be a team effort to evaluate the compliance level and whether the outlet has met all basic requirements for accreditation. Remember, you should use reasonable judgment when making your final decision. Minor problems should not be the reason for accreditation denial as this may be finalized within a very short time.		
• Be polite and helpful (this is not a practice and legal compliance inspection) all the time while carrying out inspection, but do not compromise on major standards.		
• Work as a team, observe ethics, and avoid private discussions with owners during inspections or after inspection. Any issues that come up should be discussed and decided on by the team		
• If, using your best judgment, a decision has been made that is contrary to the prescribed standards, the reason for doing that should be clearly stated, agreed on by the team, and included in your activity report. Remember, TFDA cannot provide directives for all field conditions that you might come across with in practice; collective thinking is sometimes needed to solve field problems.		
• After completing the final inspection checklist, carefully and clearly fill the final inspection result form in duplicate.		
• Giving the original copy to the owner/representative, clearly explain what needs to be done to meet standards if not yet met; if owner has accomplished and met all standards for accreditation, go over what the next step is.		
• Provide a tentative date for re-inspection for those who have only few requirements to		

Checklist 7. Compliance areas for final premise inspections	**Status**	
	Yes	**No**
accomplish prior to accreditation.		
• Shake hands with the owner/seller and wish him/her good luck. Move to the next shop and consistently follow the same process.		
• At the end of the activity in the ward, debrief the WEO if possible and thank him or her for the cooperation given.		
Activity report		
• Go through the final inspection records and, using a spreadsheet, compile all the inspection results. The following columns should be included: serial number of outlets, name of the outlet, name of owner, name(s) of trained or trainee dispenser(s), location of the shop by district/ward and village, status of accomplishment—if accomplished, write met standards; if not met, provide details of current status of implementation—and finally team recommendations.		
• Using the report format, write an activity report within three days after the activity incorporating major findings and submit as directed.		
• Make a summary of your report for the CFDC and attach the spreadsheet as reference.		
• Attach the spreadsheet to the major final inspection report as appendixes to your report and submit to TFDA.		
Final inspection team comments		
Supervising senior inspector(s) observations and comments		

Note: Attach copy of a completed compliance form to final activity report

8. ACCREDITATION AND CERTIFICATION

The CFDC will receive and read the final inspection report and make decisions on the recommendations put forward by the inspectorate team. The committee will approve accreditation of all outlets that have met all ADDO requirements if they agree with the inspectors recommendations. The committee will then submit the meeting minutes and the decisions to accredit outlets that have met all requirements to TFDA with a copy being sent to RMO. The TFDA will make the final decision on accreditation and will provide the necessary certification for accreditation.

Field Activity Protocol Checklist 8

Objective

- To describe the procedure for carrying out approvals for accreditation.

Responsibility

- DMO-Office (district pharmacist and livestock officer)
- CFDC
- TFDA Director General, TFDA-ADDO coordinator

Checklist 8. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved detailed budget		
• Summary and attached spreadsheet of final Inspection report and recommendations		
• Senior representative of the inspection team		
• Members of the CFDC		
• Stationery—pens, writing pads		
• Regulatory materials (ADDO/DLDB regulatory documents and other reference materials)		
• Venue		
How to proceed		
• The CFDC secretary should make sure that the final inspection report is finalized and agreed on by all inspection team members. No personal feelings should go into the report without team agreement.		
• Beforehand, meet with the chairperson and briefly inform him or her about the inspection you have just finalized. Then discuss and agree on the CFDC approval meeting date.		
• Once the meeting date is determined, write an invitation letter at least a week before		

Checklist 8. Things to do or check for	**Status**	
	Yes	**No**
to all CFDC members giving the necessary details, and attach the meeting agenda and other necessary meeting documents.		
• Also send an invitation letter to TFDA asking if they wish to attend meeting. (Note that the meeting can go ahead even if TFDA is not able to participate).		
• Make all other necessary preparations for a smooth meeting. Be sure of the venue and catering services.		
• During this meeting, some or all the inspection team should be present to provide further explanations when necessary.		
• The inspection team has no legal mandate in any of the decisions of the CFDC. They are not members of the CFDC but a technical team.		
During the meeting		
• The meeting should be headed by the chairperson or his/her deputy. The quorum should be observed.		
• The CFDC secretary should lead the members through the documents and provide explanation on how the process was carried out and the results of the activity. The secretary should also explain the recommendations put forward by the inspection team.		
• Members should be given time to express their opinions and comment on the recommendations provided. Notes should be taken of all the proceedings and record the CFDC approvals for accreditation.		
• Separate out all the outlets that the CFDC has approved for accreditation and form approval list.		
• Also list outlets that have minor issues to address before getting approval and finally a list of those who still have major standards to address or have not started implementation.		
• After the meeting is over, write the meeting minutes within three days and share them with the chairperson for dissemination approval.		
• Once approved by the chairperson, write an official letter to TFDA requesting accreditation consent and certification for the approved outlets and attach the minutes and the lists accordingly.		
Feedback to outlets		
• So that the outlets can receive feedback on the approvals after the CFDC meeting, the TFDA should provide consent on the CFDC approvals within 14 days after receiving the request for accreditation of outlets as approved by the CFDC.		
• The TFDA should also indicate when it will be possible have all accreditation certificates for the approved outlets sent to the CFDC secretary. This should be done within one month from the time when the final inspection was done.		
• After receiving the consent and certification from TFDA, the CFDC secretary should inform all outlets owners' on their approval status. The letter should also say when accreditation certificates can be expected for collection from the CFDC secretary.		

Note: ADDO accreditation certificate must be renewed annually by June 30.

9. CONTROL OF ADDOS

After the establishment of ADDOs, the regions, districts/councils, ward/villages will have a joint responsibility to control daily operations of the outlets as indicated below.

RFDC

- To carry out audit inspection of ADDOs
- To provide technical assistance related to the control of ADDOs
- To receive and discuss submitted appeals related to ADDO program
- To ensure that councils submit reports on the control of ADDOs in a timely fashion

CDFC

- To keep and hand out application forms for new drug outlets within the district/council
- To discuss and approve applications for establishing new ADDOs based on the regulation and given guidelines on establishing ADDOs
- To receive, discuss, and make decisions on various inspection reports and eventually report to RFDC and TFDA
- To strengthen communication/linkage on ADDO-related matters with ADDO stakeholdfers
- To ascertain that all outlets renew their accreditation certificates in time
- To hold quarterly meetings to discuss issues and progress of the ADDO program
- To look for and plan resources (human, financial, and tools for implementation of program responsibilities)
- To carry out monitoring
- To receive and discuss different appeals from villages, mtaa, and wards within the district/council and make appropiate decisions

Ward

- To hand out application forms for establishing new outlets

- To receive completed application forms from new applicants wanting to operate drug outlets at village level
- To submit new completed application forms to the CFDC secretary
- To strengthen communication/linkage on ADDO related matters with ADDO stakeholders
- To keep all records related to the implementation of ADDO program and control of ADDO services

Village/Mtaa

- To hand out application forms for establishing new outlets
- To receive completed application forms from new applicants wanting to operate drug outlets
- To submit new completed application form with village/mtaa recommendations to the ward
- To strengthen communication/linkage on ADDO related matters with ADDO stakeholders
- To keep all records related to the implementation of ADDO program and control of ADDO services

Supervision

Supervision of the ADDOs is vital for the sustainability of the program. Supervision aims at assessing day to day work performance of ADDO dispensers with an intention of strengthening capacity and reducing observed shortcomings to improve the quality of services being provided.

Supervision will be done by RHMTs and CHMTs where possible in collaboration with Cascade supervisors within the councils where the system exists.

Field Activity Protocol Checklist 9

Objective

To describe regional and district supervisory bodies' procedures for supervising ADDOs.

Responsibility

- CHMTs and Cascade Teams
- RHMTs

Checklist 9. Things to do or check for	**Status**	
	Yes	**No**
Required resources		
• Approved supervision budget		
• ADDO supervision checklist and or integrated supervision checklist (if available)		
• Itinerary of supervision activity and routes earmarked		
• At least two district inspectors and respective ward inspectors		
• Stationery—pens and writing pads		
• Reports from previous supervisions.		
• List of operating ADDOs and locations		
• Vehicles and drivers (RMO and DMO)		
• Copies of ADDO Regulation and Guidelines (TFDA)		
How to proceed		
• Head of the supervisory team to prepare the activity itinerary and share with the rest of the team for consensus.		
• Share report of the last supervision done for the outlets currently targeted for this activity. Every supervisor has to read this report.		
• Every supervisor must have a copy of the supervision checklist and have thoroughly reviewed its contents.		
While at the outlet		
• For effective supervision, not more than two supervisors are required per outlet. More than two will crowd the small shops and prevent patients from being served, which is part of the practical supervision.		
• Greet the dispenser/owner and introduce yourselves stating the purpose of your visit. Note: you are not carrying out an inspection but only supervising.		
• Create a friendly environment to get maximum cooperation from the supervisees. Explain that you have come to help him/her to do the job better and address his /her technical problems.		
• Let the supervisee briefly inform you about his/her work and describe any problems that he/she has encountered in the process of doing the work. Note down the issues being raised.		
• The supervision checklist should be followed step by step and completed.		
• Observe how the supervisee is providing services to clients and make any note on what you have observed.		
• At the end of the activity (at least not less than 30 minutes per outlet), provide a feedback on what you have observed. Emphasize on serious issues observed and praising him/her for good things that you have observed too.		
• Hand over a copy of the supervision checklist with comments after letting the dispenser or owner sign it.		
• Note: During supervision you may see some violations; take note of them, warn the owner/dispenser, and explain the consequence of the violation. Tell him/her that this will be reported and followed up to make sure that it has been corrected.		
• Thank the supervisee(s) for his or her cooperation during the activity, shake hands, and wish the supervisee good luck.		
Supervision report		
• The head of the supervision team should make sure that a supervision report is		

Checklist 9. Things to do or check for	Status	
	Yes	**No**
completed within three days after the activity and submitted to RHMT, CHMT, CFDC, RFDC, and TFDA.		

Inspection

Drug outlets' inspection is a vital process for ascertaining outlets adherence to law, regulations, and guidelines governing the management of ADDO business and services. These inspections will be done by all levels from ward to national. In carrying out inspections, inspectors will visit every ADDO and inspect it using ADDO inspection forms/checklists available at the outlets. Feedback on the result of inspections at outlet level will be given immediately after inspection to the outlet owner and dispenser(s)

Different Levels of Inspection

- Ward: Ward inspectors will carry out quarterly inspections and submit inspection reports to the CFDC

- District: CFDC will carry out quartery inspections and submit their reports to RFDC and TFDA

- Regional: RFDC will carry out audit inspections and deal with appeals when necessary

- National: TDFA will carry out audit inspection at any given time as a form of inspector quality check. The TDFA is also required to carry out one comprehensive inspection for re-accreditation purposes every three years. The TDFA will also deal with appeals whenever necessary.

10. MONITORING AND EVALUATION

Monitoring and evaluation (M&E) are important to implementing the ADDO program. Monitoring includes evalution of service provision by comparing investment of resources and product outcome because of that investment.

M&E will provide information to all program stakeholders at all levels who can then get a clear/real picture on whether established program goals and indicators are being achieved during the implementation period and beyond. Information gained at each implementation level can be used to address challenges encountered and to plan strategies to improve program implementation performance. M&E will be carried out jointly by TFDA in collaboration with regional and district teams. Evaluation will be done based on established program indicators and set program goals.

The CFDC should make sure that—

- All ADDOs complete monthly report forms and submit them at ward level
- All wards submit monthly report form on ADDO management to the district level
- All monthly and quarterly reports on program implementation are submitted to DMO and TFDA

Monitoring and Evaluation Framework

A separate, detailed M&E framework can be found with the data collection tools and will be made available.