UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA FOOD AND DRUGS AUTHORITY

TRAINING MANUAL FOR DRUG INSPECTORS

FACILITATION GUIDE

Second Edition

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WORKSHOP SCHEDULE

TIME	ACTIVITY	RESPONSIBLE
DAY 1		
8:30-9:00	**Registration**	
9:00-10:30	Trend-Setting Activities • Welcome note • Arrival of Guest of Honour • Self introductions • Opening speech • Overview of workshop logistics, goals, objectives, methodology, assessment/evaluation • Ice-breaking exercise • Group norms	Organizing Committee/ Trainers/Facilitators/Sponsors
10:30-11:00	**Health Break**	
11:00-12:00	Definitions	Trainers/Facilitators
12:00-1:00	Port of Entry (POE) Consignment Inspection Flowchart	Trainers/Facilitators
1:00-2:00	**Lunch Break**	
2:00-4:00	SOP for Inspection of Pharmaceutical Consignments at POEs	Trainers/Facilitators
4:00-4:30	**Health Break**	
4:30-5:30	POE Consignment Inspection Form	Trainers/Facilitators
5:30-5:35	Review Exercise/Assignment	Trainers/Facilitators
DAY 2		
8:30-10:30	Practical Exercise on POE Consignment Inspection	Trainers/Facilitators
10:30-11:00	**Health Break**	
11:00-12:00	Practical Exercise on POE Consignment Inspection (continued)	Trainers/Facilitators
12:00-1:00	SOP on Physical Examination of Pharmaceutical Products	Trainers/Facilitators

1:00-2:00	**Lunch Break**	
2:00-3:00	SOP on Physical Examination of Pharmaceutical Products (continued)	Trainers/Facilitators
3:00-4:00	Physical Examination Results Form	Trainers/Facilitators
4:00-4:30	**Health Break**	
4:30-5:30	Illustrations of Drug Defects	Trainers/Facilitators
5:30-5:35	Review Exercise/Assignment	Trainers/Facilitators
DAY 3		
8:30-10:30	Practical Exercise on Physical Examination of Pharmaceutical Products	Trainers/Facilitators
10:30-11:00	**Health Break**	
11:00-12:00	Practical Exercise on Physical Examination of Pharmaceutical Products (continued)	Trainers/Facilitators
12:00-1:00	SOP for Drug Quality Surveillance Programme	Trainers/Facilitators
1:00-2:00	**Lunch Break**	
2:00-4:00	Practical Exercise on Drug Quality Surveillance Programme; Illustrations	Trainers/Facilitators
4:00-4:30	**Health Break**	
4:30-5:30	SOP on Suspicious Sample Surveillance Programme	Trainers/Facilitators
5:30-5:35	Review Exercise/Assignment	Trainers/Facilitators
DAY 4		
8:30-10:30	Practical Exercise on Suspicious Sample Surveillance Programme	Trainers/Facilitators
10:30-11:00	**Health Break**	

11:00-1:00	SOP for Chain of Custody, Packing, and Shipping Procedures	
1:00-2:00	**Lunch Break**	
2:00-3:30	SOP for Chain of Custody, Packing, and Shipping Procedures (continued)	Trainers/Facilitators
3:30-4:00	**Health Break**	
4:00-6:00	Practical Exercise on Chain of Custody, Packing, and Shipping	Trainers/Facilitators
DAY 5		
8:30-10:30	SOP on Postmarketing Surveillance Programme (Inspection of Dispensing Outlets)	Trainers/Facilitators
10:30-11:00	**Health Break**	
11:00-1:00	Drug Dispensing Outlets Inspection Forms	Trainers/Facilitators
1:00-2:00	**Lunch Break**	
2:00-4:00	Practical Exercise on Drug Dispensing Outlets Inspection	Trainers/Facilitators
4:00-4:30	**Health Break**	
4:30-5:30	Practical Exercise on Drug Dispensing Outlets Inspection (continued)	Trainers/Facilitators
5:30-5:35	Review Exercise/Assignment	Trainers/Facilitators
DAY 6		
8:30-10:00	Theoretical Assessment	Trainers/Facilitators
10:00-10:30	**Health Break**	
10:30-12:30	Practical Assessment (OSPE)	Trainers/Facilitators
12:30-1:00	Workshop Evaluation	All Participants
1:00-1:30	**Close**	**TFDA and Sponsor(s)**

DESCRIPTION OF TREND-SETTING ACTIVITIES

ACTIVITY 1: Welcoming Activities

Each participant and trainer should have a nametag or name card; they should underline the name they would like to be called during the workshop. Trainers should assist with the nametags or cards. Ask participants to wear their tags or place their cards in front of their seats throughout the workshop.

Ask the participants to introduce themselves using the following guide:

- Name
- Designation
- Duty station
- Years in service
- Main interest(s)

Also introduce the administrators and any other support staff.

ACTIVITY 2: Workshop Logistics (5 minutes)

Explain the following to the participants:

- Daily schedule (agree on timing of activities)
- Practical matters (breaks, lunch, accommodations, health care, etc.)
- Location of toilets/washrooms, telephone, transport, etc.
- Duration of the workshop
- Evaluation/assessment
- Certificate of attendance by the TFDA upon successful completion of the training

ACTIVITY 3: Introduce Workshop Goals and Objectives (5 minutes)

Goals of the Workshop

Review the workshop goals, which have been written on a flipchart beforehand. Explain the significance of the workshop as an effort to strengthen and improve the drug inspection system. Point out that after the workshop, participants are expected to immediately put into action what they have learned at the stations of their deployment under the Directorate of Inspections and Surveillance.

Objectives of the Workshop

Review the workshop objectives, which have been written on a flipchart beforehand. (These are the broad objectives described in this guide under the Facilitation Notes for each module.)

ACTIVITY 4: Introduce the Methodologies of Delivery

Methodologies of delivery of the training may include:

- Lecture-discussions
- Group discussions
- Simulations
- Practical exercises
- Brainstorming
- Demonstrations
- Role plays

ACTIVITY 5: Evaluation/Assessment Methods

Tell the participants that:

- Continuous assessment of their training will be done through the assignments and review exercises

- A summary assessment will done through a written theoretical paper (40%) and an Objective Structured Practical Examination (OSPE) (60%) on the sixth (last) day of the workshop

- Evaluation of the workshop will be done immediately after the OSPE

ACTIVITY 6: Group Norms (5 minutes)

Introduce this activity by explaining that because participants will be working closely together for about six days, it is important to establish a common working understanding they all can agree upon and follow. As an idea is presented, a trainer should quickly check with everyone to be sure that the majority agree to it; if they do, add it to the list of norms. Write the norms on a flipchart and post them on the wall, where they should remain throughout the workshop. An example of a norm would be: “Observe punctuality.”

All participants and trainers/facilitators should follow these norms.

ACTIVITY 7: Ice-Breaking Exercise (15 minutes)

- Tell participants that they will now play a short game designed to be fun and provide a learning experience as well
- Explain the rules of the game
- Ask them to clear their tables and wait until all tables have been cleared before proceeding
- Divide participants into small but convenient groups

An example of an ice-breaking exercise is explained below.

"The Untold Story"

Explain that each group will be given an envelope that contains 12 sorted diagrams that do not bear explanations. Explain that the rule of the game is very simple: to arrange the diagrams in a sequence so that they tell a story. Emphasise that the diagrams must be appropriately arranged to depict a sequence of events that make a complete story. Explain further that the group members will work together and that no talking will be allowed while the group is working. If any group member speaks, the group will be disqualified. They will have 10 minutes to arrange the diagrams in sequence.

When everyone is ready, distribute the envelopes to the groups and tell them to open the envelopes and start working. Allow about 5 minutes. Trainers should carefully observe that no one is talking. At the end of the first 5 minutes, stop the groups and explain that you are now changing one of the rules of the game. Now they are allowed to talk. There are no further restrictions on communicating. Allow them another 5 minutes, then stop all groups.

Use the following questions to process the group work:

- Was any group able to arrange the diagrams in a sequence that tells a story?
- If so, how did you accomplish this?
- What ways did you use to communicate during the first five minutes?
- When you were allowed to talk, did you share ideas on how to accomplish the task?
- Did members of the group willingly listen to each other's ideas? How did this help the group's progress?
- Did your group have a leader? More than one leader? How did this help the group's progress?
- Did everyone participate equally in the group task? If not, how did the nonparticipation of any group member hinder the group's progress?

Summarise the exercise by emphasizing that the task depicts clearly how groups work together to achieve a common goal. To ensure effectiveness and achieve the goal, members must find ways to communicate, share their ideas, be willing to listen to the ideas of others, accept or follow leadership, and participate actively and equally.

COURSE SUMMARY

Module No.	Module Name	Theory Hours	Practical Hours	Total Hours
I	Preparatory Module	2	0	2
II	POE Consignment Inspection	3	16	19
III	Physical Examination of Pharmaceutical Products	2.5	4.5	7
IV	Antimalarial, Antibiotic, and Antiretroviral Drug Quality Surveillance Programme	6	48	54
V	Suspicious Sample Surveillance Programme	1	2	3
VI	Chain of Custody, Packing, and Shipping Procedures	2.5	2.5	5
VII	Postmarketing Surveillance Programme: Drug Dispensing Outlets Inspection	3	24	27
TOTAL HOURS		**20**	**97**	**117**

FACILITATION NOTES FOR MODULE I: PREPARATORY MODULE

TIME: 2 hours

CLIMATE SETTING
- Greet participants
- Open up the discussion by asking the participants (trainees) to brainstorm on some general aspects of drug inspection; for example:
  - What is drug inspection?
  - What is the purpose of drug inspection?
  - What needs to be inspected?

BROAD OBJECTIVE
To familiarise participants with terminology used in drug inspection and with the flow of activities during inspection at ports of entry (POEs)

SPECIFIC OBJECTIVES
Display a flipchart with prewritten objectives, which should read:
- Describe the terminology used in drug inspection
- Depict the steps involved in drug inspection and testing at POEs

CONTENTS
- Definitions
- POE consignment inspection flowchart

METHODOLOGY
Lecture-discussion, group discussion

TASK 1
- Make a presentation of the glossary list, explaining each term with examples
- In the course of the presentation, occasionally ask the trainees to give their experiences with the terminology
- Allow questions from the trainees and clarify the application of the terms in drug inspection

TASK 2
- Show the POE consignment inspection flowchart
- Explain each step involved in the flowchart
- Emphasise the key areas/steps
- Allow the trainees to ask questions; clarify the most difficult steps
- Emphasise that each step will become clearer as the subsequent modules (especially Module II) are completed

TASK 3
- Give a review activity (an assignment) on the areas covered

RESOURCES
Flipchart, markers/pens, glossary list, POE consignment inspection flowchart

OUTPUT
Trainee drug inspectors should be familiar with the terminology used in drug inspection and the key steps involved in POE consignment inspection.

FACILITATION NOTES FOR MODULE II: POE CONSIGNMENT INSPECTION

TIME: 7 hours

CLIMATE SETTING
- Greet participants
- Reflect on the major lessons learned from Module I and give feedback on the review exercise

BROAD OBJECTIVE
- To conduct comprehensive drug inspection and screening at ports of entry

SPECIFIC OBJECTIVES
Display a flipchart with following prewritten objectives:
- Describe the SOP that must be followed by drug inspectors when conducting inspection of pharmaceuticals entering the country
- Request for/obtain the consignment to be inspected (if necessary) from the Tanzania Revenue Authority, Customs and Excise (TRA/C&E) Department
- Record correct information in the POE Consignment Inspection Form according to instructions outlined in the SOP
- Make appropriate use of all other forms that are part of the SOP, namely:
  - Rejection/Detention Form
  - Sample Receipt Form
  - Suspicious Sample Surveillance Programme (SPD 02-00)
  - Drug Quality Surveillance Programme: Antimalarials (SPD 02-01)
  - Drug Quality Surveillance Programme: Antibiotics (SPD 03-01)
  - Drug Quality Surveillance Programme: Antiretrovirals (SPD 05-01)

CONTENTS
- SOP for Inspection of Pharmaceutical Consignments at Ports of Entry
- POE Consignment Inspection Form
- POE Physical Examination Form
- POE Screening Certificate
- Rejection/Detention Form
- Sample Receipt Form
- Suspicious Sample Surveillance Programme (SOP 02-00)
- Drug Quality Surveillance Programme: Antimalarials (SPD 02-01)
- Drug Quality Surveillance Programme: Antibiotics (SPD 03-01)
- Drug Quality Surveillance Programme: Antiretrovirals (SPD 05-01)

METHODOLOGY
Lecture-discussion, group discussion, demonstration, practical exercises

TASK 1
- Make a presentation on the SOP for Inspection of Pharmaceutical Consignments at Ports of Entry; emphasise the key points
- Allow trainees to ask questions; clarify as necessary before proceeding to the next topic
- Tell the trainees that their understanding will be enhanced when the POE Consignment Inspection Form is reviewed

TASK 2

- Make a presentation on the POE Consignment Inspection Form, the POE Physical Examination Form, and the POE Screening Certificate; emphasise the key steps
- Allow the trainees to ask questions and clarify as necessary
- Demonstrate how the form is filled out and allow the trainees to practice filling out the form
- Make corrections, if any, to how the forms were filled out

TASK 3

- Present the other forms relevant to the SOP
- Demonstrate how the forms are filled out
- Allow the trainees to practice filling out the forms
- Make corrections, if any

TASK 4

- Summarise the subject by emphasizing the importance of adhering to the instructions outlined in the SOP
- Allow time for more practice

TASK 5

Give a review exercise on the material learned in this module.

RESOURCES

- POE Consignment Inspection Form
- POE Physical Examination Form
- POE Screening Certificate
- Rejection/Detention Form
- Sample Receipt Form

OUTPUT

Drug inspectors should be capable of carrying out successful drug inspection and screening at POEs.

FACILITATION NOTES FOR MODULE III: PHYSICAL EXAMINATION PROCEDURES FOR PHARMACEUTICAL PRODUCTS

TIME: 7 hours

CLIMATE SETTING

- Greet participants
- Start the session by linking the materials presented in the first modules and those contained in this module

BROAD OBJECTIVE

- To monitor the quality of drugs at POEs and during postmarketing surveillance by carrying out visual inspection of different dosage forms to identify gross quality deficiencies

SPECIFIC OBJECTIVES

- Describe the SOP on Physical Examination Procedures for Pharmaceutical Products
- Carry out physical examination of pharmaceutical products
- Identify drug defects
- Identify counterfeit pharmaceutical products
- Record correct information in the POE Physical Examination Results Form
- Make correct decisions congruent with the instructions given in the POE Physical Examination Results Form and other forms relevant to the SOP

CONTENTS

- SOP for Physical Examination Procedures for Pharmaceutical Products
- The following forms:
  - POE Physical Examination Results Form
  - Facility Physical Examination Results Form
  - POE Consignment Inspection Form
  - POE Screening Certificate
  - Facility Screening Certificate
  - Rejection/Detention Form
  - Sample Receipt Form
  - Confiscation/Quarantine Form
  - Suspicious Sample Surveillance Programme (SPD 02-00)
  - Drug Quality Surveillance Programme: Antimalarials (SPD 02-01)
  - Drug Quality Surveillance Programme: Antibiotics (SPD 03-01)
  - Drug Quality Surveillance Programme: Antiretrovirals (SPD 05-01)
- Illustrations of defective drugs
- Illustrations of counterfeit drugs

METHODOLOGY

Lecture-discussion, group discussion, demonstrations, practical exercises (simulations)

TASK 1

- Make a presentation on the SOP for Physical Examination Procedures for Pharmaceutical Products
- Allow questions from participants and clarify as necessary

- Make another presentation on all the forms relevant to this SOP
- Emphasise the key steps and salient features of the forms

TASK 2 – Practical exercise

- Illustrate all the forms relevant to physical examination of pharmaceutical products
- Show the photographs (preferably by using a projector to show colour photos) of defective drugs
- Discuss the information and photographs of counterfeit drugs

TASK 3 – Practical exercise

- Simulate an environment in which the trainee drug inspectors can practice carrying out physical examination of pharmaceutical products and record results correctly in the respective forms relevant to this procedure
- Simulate another environment in which the trainees can practice identifying counterfeit pharmaceutical products

TASK 4

- Summarise the procedure for physical examination of pharmaceutical products
- Outline the difficulties involved when dealing with identification of counterfeit drugs, including:
  - Physical characteristics of the fakes (counterfeit products) are market specific and differ from country to country.
  - There is a tendency to change the characteristics of the fakes within a certain period of time; for instance, the samples of counterfeit products at the TFDA are already outdated

Emphasise that this is a difficult exercise to tackle and requires vigilant inspectors. For further information, refer the trainees to the WHO publication *Counterfeit Drugs*.[1]

TASK 5

- Give a review activity (an assignment) on the areas covered

RESOURCES

Forms, illustration documents (including photos), a projector if available, a room for simulations

OUTPUT

Drug inspectors should be capable of carrying out comprehensive physical examinations of pharmaceutical products and be vigilant enough to identify counterfeit products.

[1] World Health Organization (WHO)/Department of Essential Drugs and Other Medicines. 1999. *Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs*. WHO/EDM/QSM/99.1. Geneva: WHO.

FACILITATION NOTES FOR MODULE IV: DRUG QUALITY SURVEILLANCE PROGRAMME FOR ANTIMALARIALS, ANTIBIOTICS, AND ANTIRETROVIRALS

TIME: 3 hours

CLIMATE SETTING

- Greet participants
- Open the discussion by briefly outlining the importance of antimalarial, antibiotic, and antiretroviral drugs in Tanzania and the justification for having a surveillance programme for these drugs

BROAD OBJECTIVE

To closely follow up on the quality of antimalarial, antibiotic, and antiretroviral drugs in current use in order to protect the consumers of these products from using fake or substandard products

SPECIFIC OBJECTIVES

Display a flipchart with the following prewritten objectives:

- Describe the SOPs for the Drug Quality Surveillance Programme for Antimalarials, Antibiotics, and Antiretrovirals
- Carry out POE inspection and screening of the specified antimalarial, antibiotic, and antiretroviral drugs
- Carry out postmarketing surveillance of the specified antimalarial, antibiotic, and antiretroviral drugs
- Identify counterfeit antimalarial, antibiotic, and antiretroviral drug products

CONTENTS

- SOPs on the Drug Quality Surveillance Programme for Antimalarials, Antibiotics, and Antiretrovirals
- The following forms:
  - POE Physical Examination Results Form
  - Facility Physical Examination Results Form
  - POE Consignment Inspection Form
  - POE Screening Certificate
  - Facility Screening Certificate
  - Rejection/Detention Form
  - Sample Receipt Form
  - Confiscation/Quarantine Form
- Illustration(s) of measures for identification of counterfeit drug products

METHODOLOGY

Lecture-discussion, group discussion, practical exercises

TASK 1

- Make a presentation on the SOPs on the Drug Quality Surveillance Programme for Antimalarials, Antibiotics, and Antiretrovirals
- Present all the relevant forms for these SOPs
- Allow for questions from the trainees and clarify as necessary

TASK 2 – Practical exercise

- Conduct a practical exercise on following the instructions given in the SOPs and the forms
- Summarise and emphasise key areas, especially on matters related to the counterfeit drug products

TASK 3

- Give a review activity (an assignment) on the areas covered

RESOURCES

- POE Physical Examination Results Form
- Facility Physical Examination Results Form
- POE Consignment Inspection Form
- POE Screening Certificate
- Facility Screening Certificate
- Rejection/Detention Form
- Sample Receipt Form
- Confiscation/Quarantine Form

OUTPUT

Drug inspectors should be capable of effectively managing the Drug Quality Surveillance Programme for Antimalarials, Antibiotics, and Antiretrovirals.

FACILITATION NOTES FOR MODULE V: SUSPICIOUS SAMPLE SURVEILLANCE PROGRAMME

TIME: 3 hours

CLIMATE SETTING
- Greet participants
- Start by highlighting the importance of the Suspicious Sample Surveillance Programme

BROAD OBJECTIVE
To closely follow up on the pharmaceutical products circulating in the Tanzania market before they reach the consumers

SPECIFIC OBJECTIVES
Display a flipchart with the following prewritten objectives:
- Describe the SOP on Suspicious Sample Surveillance Programme
- Follow up to collect samples that appear suspicious
- Identify counterfeit pharmaceutical products

CONTENTS
- SOP on Suspicious Sample Surveillance Programme
- The following forms:
  - POE Physical Examination Results Form
  - Facility Physical Examination Results Form
  - POE Screening Certificate
  - Facility Screening Certificate
  - Confiscation/Quarantine Form
- Illustrations of counterfeit products

METHODOLOGY
Lecture-discussion, group discussion, practical exercises

TASK 1
- Make a presentation on the SOP for Suspicious Sample Surveillance Programme
- Further present all the forms relevant to this SOP
- Allow the trainees to ask questions and clarify as necessary

TASK 2
- Conduct a practical exercise following the instructions given in the SOP and the forms
- Summarise the discussion by noting the key areas; make further comments on counterfeit drug matters

RESOURCES
- POE Physical Examination Results Form
- Facility Physical Examination Results Form
- POE Screening Certificate
- Facility Screening Certificate
- Confiscation/Quarantine Form

OUTPUT
Drug inspectors should be capable of effectively managing the Suspicious Products Surveillance Programme.

FACILITATION NOTES FOR MODULE VI: CHAIN OF CUSTODY, PACKING, AND SHIPPING PROCEDURES

TIME: 6 hours

CLIMATE SETTING

- Greet participants
- Start the session by explaining the importance of establishing chain of custody and proper packing and shipping (transporting) of samples for examination

BROAD OBJECTIVE

To establish chain of custody and proper packing and shipping/transporting of samples for examination

SPECIFIC OBJECTIVES

Display a flipchart with the following prewritten objectives:

- Describe the SOP on Chain of Custody, Packing, and Shipping Procedures
- Record correct information in the forms relevant to this SOP
- Maintain strict chain of custody in order to protect the legal integrity of the sample(s)

CONTENT

- SOP on Chain of Custody, Packing, and Shipping Procedures
- The following forms:
  - Chain of Custody Form
  - POE Consignment Inspection Form
  - Rejection/Detention Form
  - Sample Receipt Form

METHODOLOGY

Lecture-discussion, group discussion, demonstrations, practical exercises

TASK 1

- Make a presentation on the SOP for Chain of Custody, Packing, and Shipping Procedures
- Demonstrate how to enter information on the forms
- Have the trainees practice the whole procedure
- Make corrections as necessary

TASK 2

- Give a review activity (an assignment) on the areas covered

RESOURCES

- Chain of Custody Form
- POE Consignment Inspection Form
- Rejection/Detention Form
- Sample Receipt Form

OUTPUT

Drug inspectors should be capable of establishing and maintaining chain of custody and properly packing and shipping samples for examination.

FACILITATION NOTES FOR MODULE VII: POSTMARKETING SURVEILLANCE PROGRAMME: DRUG DISPENSING OUTLETS INSPECTION

TIME: 8 hours

CLIMATE SETTING
- Greet participants
- Start the session by elaborating on the importance of carrying out inspections at the drug dispensing outlet level

BROAD OBJECTIVE
To carry out comprehensive postmarketing surveillance of the drug dispensing outlets

SPECIFIC OBJECTIVES
- Describe the SOP for Postmarketing Surveillance Programme: Drug Dispensing Outlets Inspection
- Carry out inspection of drug dispensing outlets (retailer pharmacies, wholesalers, Duka la Dawa Baridi and Muhimu, hospitals, health centres, and dispensaries)
- Record correct information in the appropriate Drug Dispensing Outlets Inspection Form
- Identify counterfeit products

CONTENT
- SOP on Postmarketing Surveillance Programme: Drug Dispensing Outlets Inspection
- The following forms:
  - Drug Dispensing Outlet Inspection Forms
  - Sample Receipt Form
  - Confiscation/Quarantine Form
- Illustration documents

METHODOLOGY
Lecture-discussion, group discussion, demonstrations, practical exercises

TASK 1
- Make a presentation on the SOP for Postmarketing Surveillance Programme
- Make another presentation on the forms relevant to the SOP
- Let the trainees ask questions and respond accordingly

TASK 2
- Demonstrate how the information is entered on the forms
- Allow the trainees to practice the procedure

TASK 3
- Give a review activity (an assignment) on the areas covered

RESOURCES
- Drug Dispensing Outlet Inspection Forms
- Sample Receipt Form
- Confiscation/Quarantine Form

OUTPUT
Drug inspectors should be capable of appropriately and effectively managing the Postmarketing Surveillance Programme and performing structured inspections of drug dispensing outlets.