

# Sustainable Drug Seller Initiative Partner Presentations



# Assessment of ADDO Regulatory System in Tanzania

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# Assessment Objectives

- To observe the functionality and effectiveness of the decentralized regulatory system in improving regulatory oversight and recommend further action for future sustainability
- To explore the need for a re-accreditation process as a mechanism for improving quality of care provided by ADDOs and ensuring their compliance to regulatory standards
- Using the assessment results, develop a strategy for future sustainability of the regulatory system



# Methodology (1)

- Assessment Approach
  - This was a comprehensive structured assessment intended to gather information from various levels and individuals or groups.
  - Teams of trained data collectors and experienced interviewers made field visits to the selected regions, districts, and wards.
  - Information was gathered through questionnaires, interviews, and prospective observations.



# Methodology (2)

- Selection of Districts
  - Regions where the program has been in existence for more than 5 years; selected one district with more drug outlets than the rest of the districts in the region
  - Regions where the program has been in existence for 5 years and less
- Selection of wards:
  - The wards were purposely selected to cover a wide coverage of the district
  - Divided the districts into three segments, identified the wards in each segment, and randomly select two wards from each segment



# Assessment Areas

Name of Region	Name of District	Number of Wards	Number of ADDOs
Ruvuma	Mbinga	6	30
Pwani (Coast)	Kibaha Rural	6	30
Morogoro	Morogoro Rural	6	30
Singida	Singida Urban	6	30
Tanga	Korogwe	6	30
Mbeya	Mbalari	6	30
<b>Total</b>		<b>36</b>	<b>180</b>

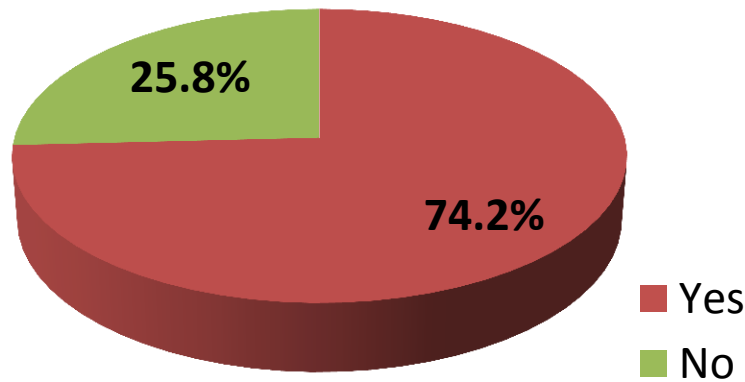


# *Findings*



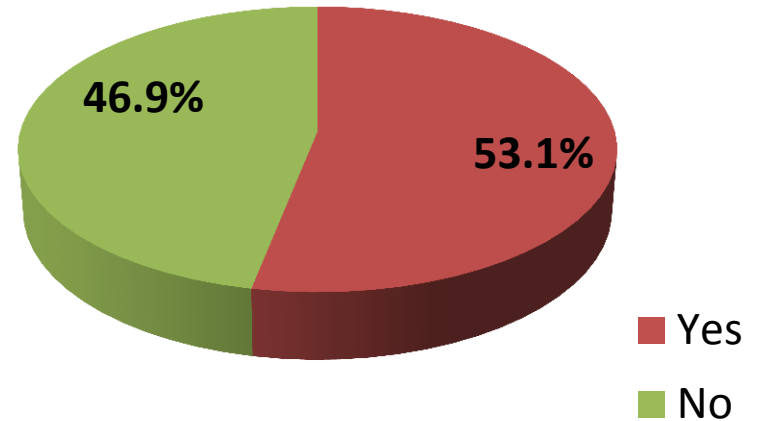
# Functionality of Ward Level Inspection

## Meetings



Percentage of WHCs which held meetings

## Inspections



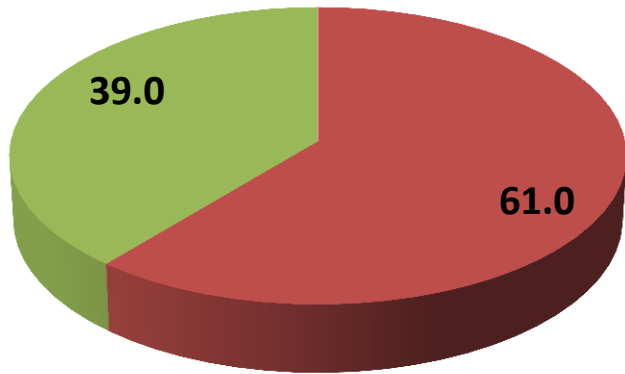
Percentage of WHCs that carried out inspections





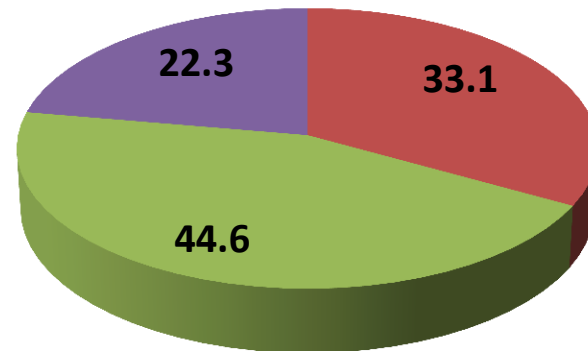
# ***ADDOs Premises and Dispenser Adherence to Standards and Regulations***

**Availability of ADDO Signage Post (%)**



- Post available
- Not Available

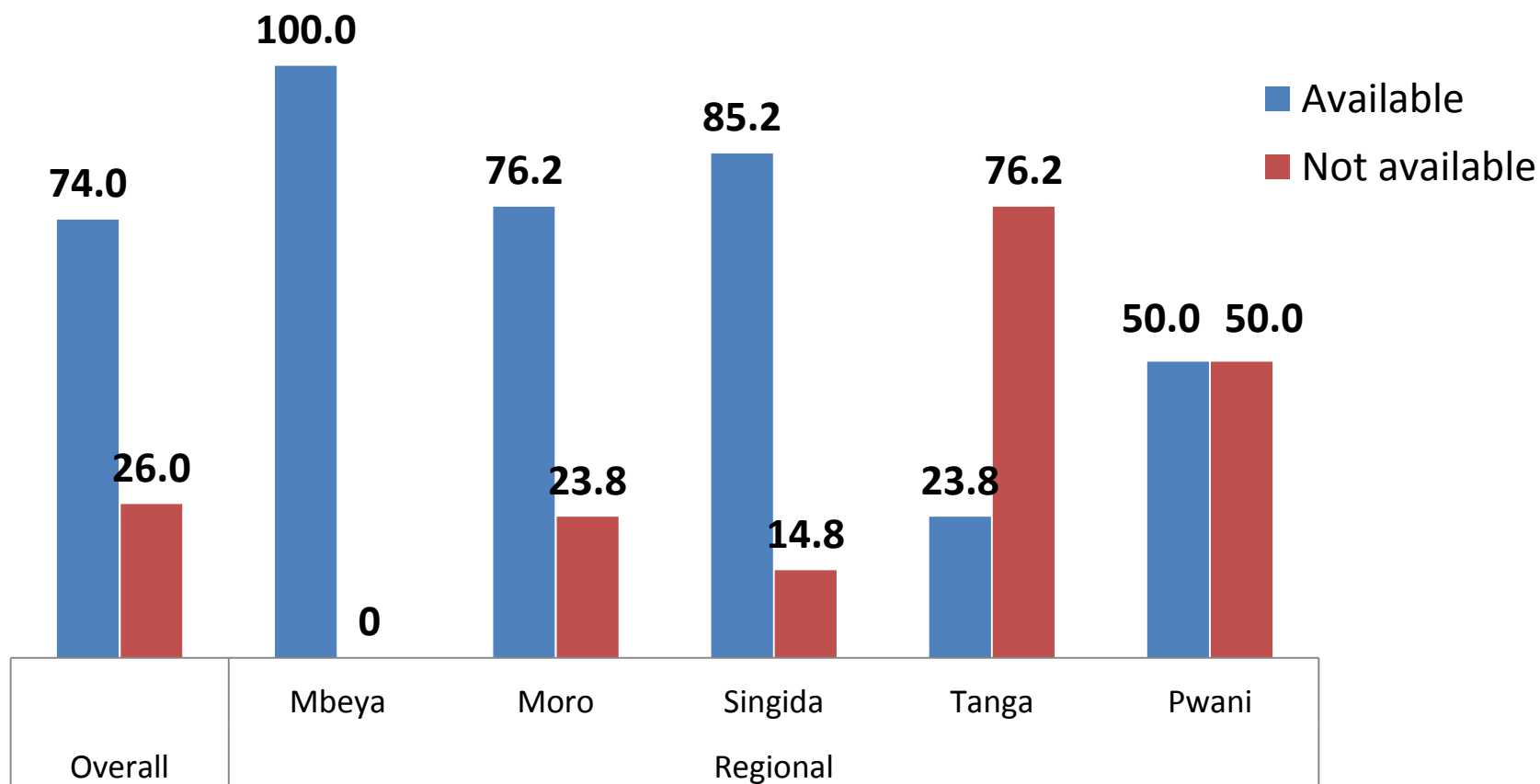
**Overall Availability of Legal Certificates (%)**



- Accreditation, TFDA license, Dispensers'
- Not complete
- None

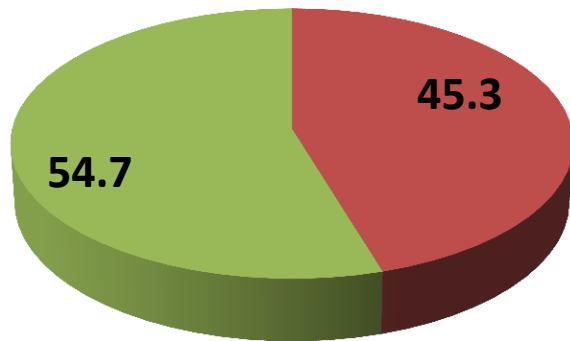


# ***% Availability of Drug Registers***



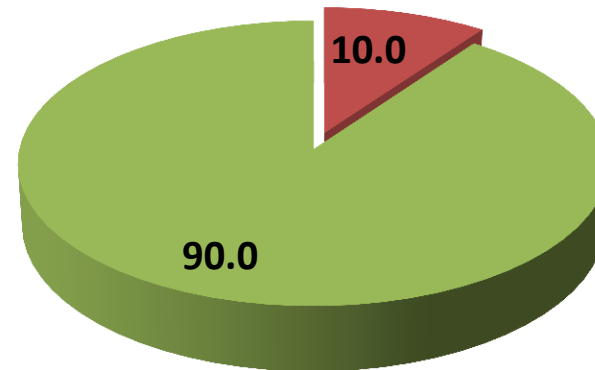
# Availability of Other Standard Documents (%)

## Inspection Forms Booklets



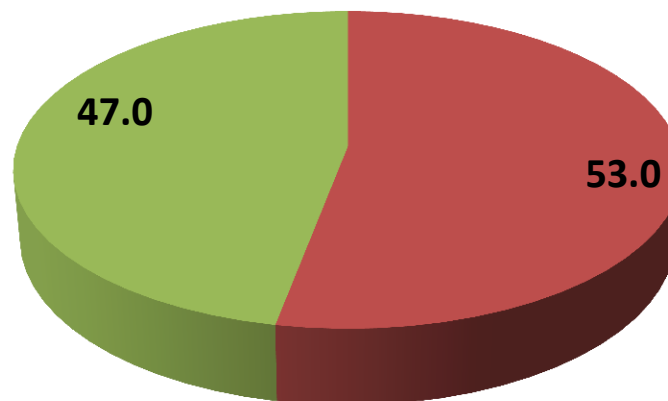
- Booklet available
- Book not available

## Patients Complaints Forms



- Form available
- Form not available

## Approved Medicines List

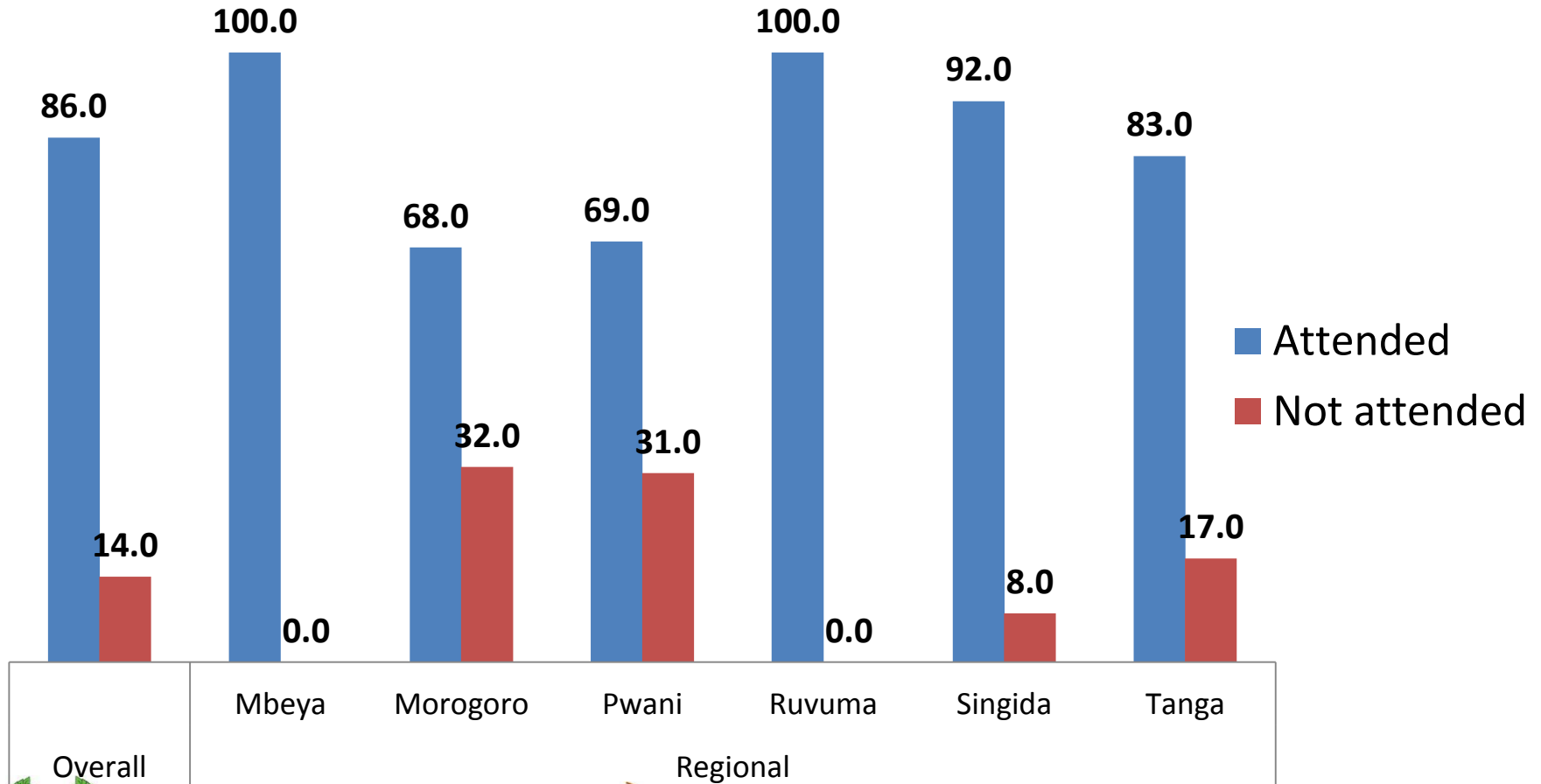


- List available
- Not Available



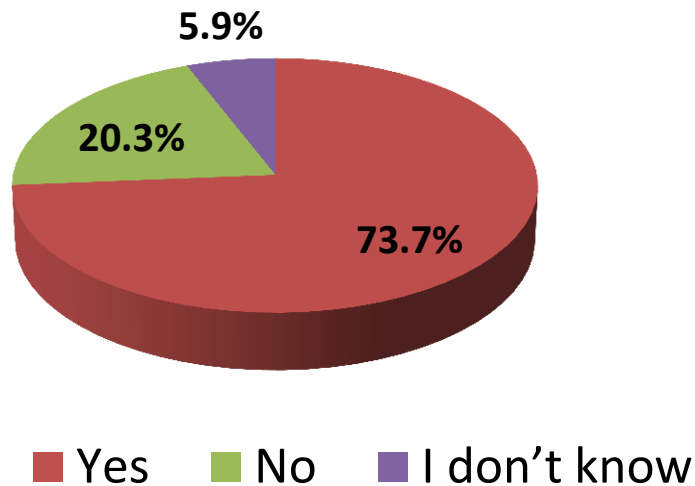
# Who Dispenses in ADDOs?

Percent of outlet dispensers who attended ADDO training

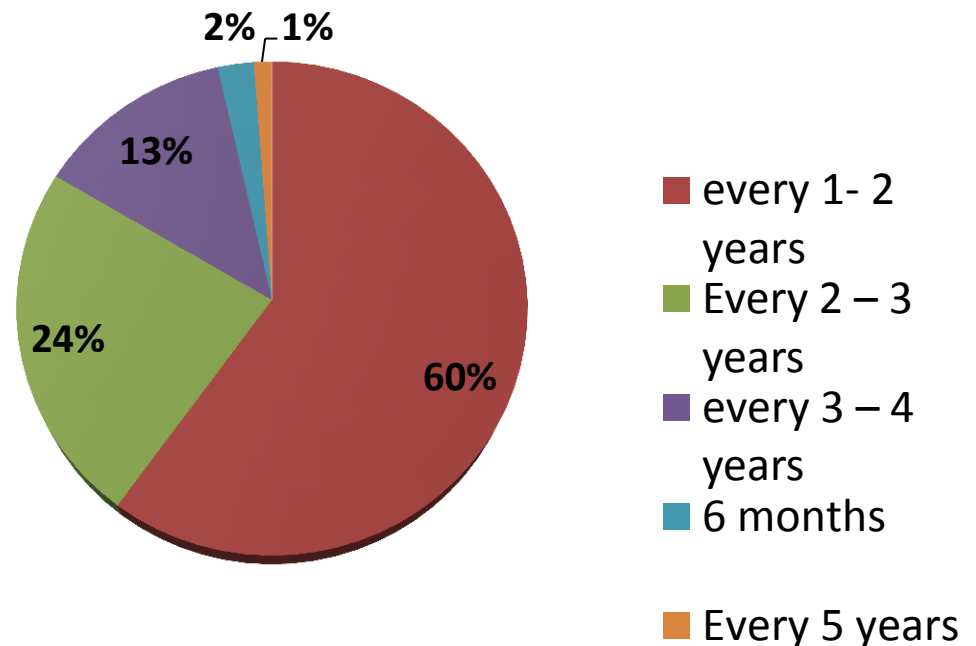


# ADDOS' Recommendation for Reaccreditation

## Percentage of Dispensers who Favored Reaccreditation



## Overall Recommendation for Reaccreditation Interval



# Findings (1)

## Coordination and challenges of implementing decentralized regulatory system:

- No planned joint meetings between TFDA, regional, and council committees have taken place
- Although TFDA understands decentralized regulatory system of some of its mandate to the councils as necessary and correct undertaking, TFDA acknowledges that the practical implementation of this process faces constraints
- The waiting time for the accreditation certificate was found to be very long ( 16–24 weeks) even for those who sufficiently met the criteria



# Findings (2)

## Coordination and challenges of implementing decentralized regulatory system (cont.):

- Many CFDCs do not carry out inspections regularly, which is problematic for new applicants
- Many CFDCs do not hold meetings as required by ADDO regulations, a vital process for approval of new applications
- Many CFDCs approved and submitted incomplete applications to TFDA for accreditation in that they lack necessary accompanying documentations
- Councils take long to organize trainings for new ADDO applicants and dispensers



# Findings (3)

## Audit Inspections:

The 2010/2011 TFDA audit inspection covered no more than 1% of the total number of ADDOs in the country.

## Inspection Consequences:

There are limited or no repercussions for ADDOs found committing serious violations.





# Findings (4)

- TFDA Financial support to the Council Food and Drug Committees:

Most council fee collections from drug outlets is inefficient; in most cases it is unpredictable whether the required 60% of the collected fees are submitted to TFDA



The 40% of the total collected fees that remains with the councils is generally not used for the purpose of improving performance of the CFDC



# Findings (5)

## Inspections

- Over the past 2 years, at least four of the RFDCs carried out single inspections each
- These covered hardly half the drug outlets in the region

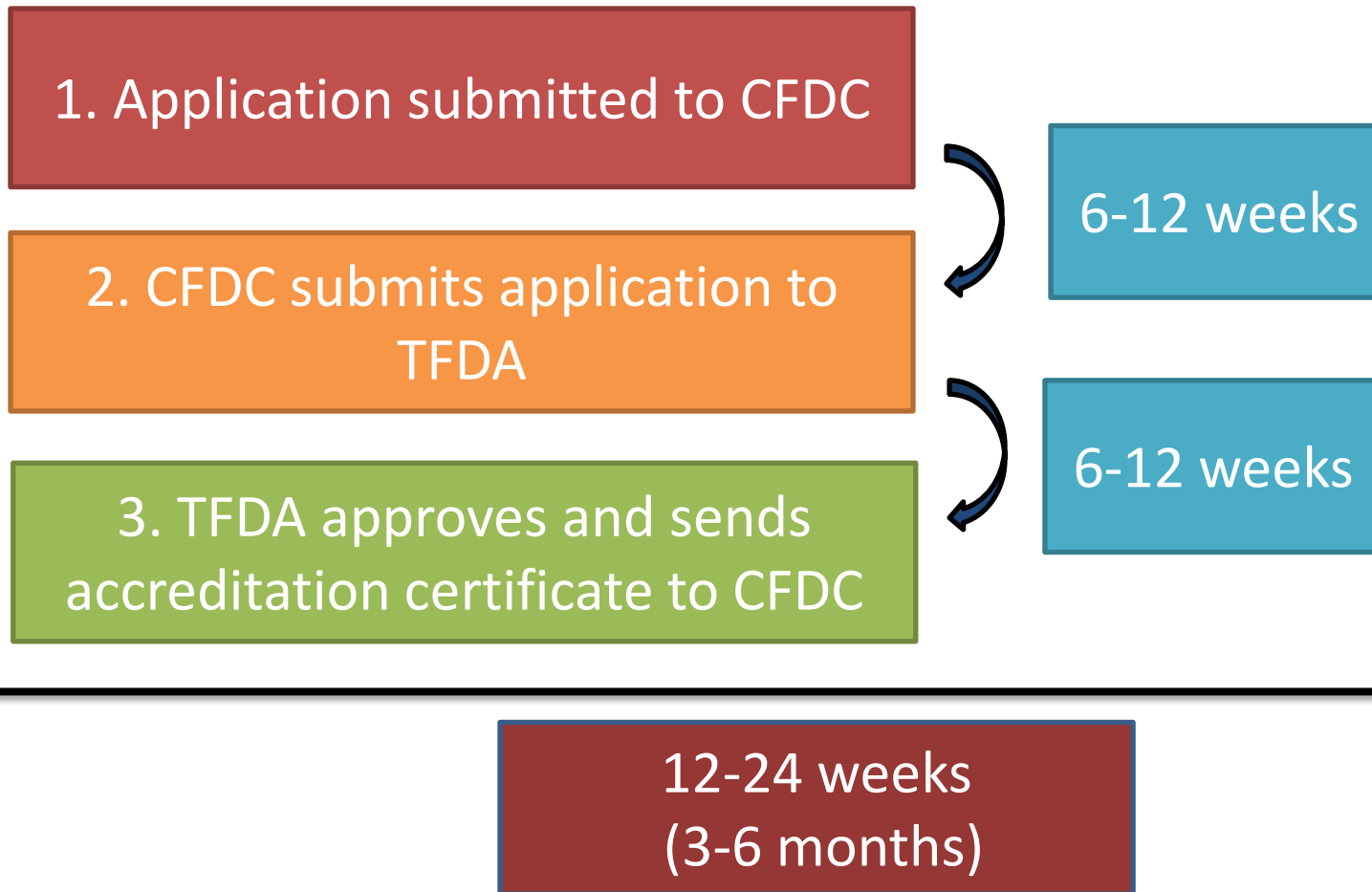
- CFDCs have not conducted quarterly meetings as required
- Inspection frequency varies greatly across districts

- Kibaha conducted 12 inspections within the last 2 years
- Singida Urban had 6 inspections in last 2 years
- Remaining CFDCs carried out max. 1 inspection per year



# Findings (6)

Long timeline for accreditation approval in all districts



# Findings (7)

## Local Ward Inspectors:

- High turn over results in new untrained inspectors
  - Inspectors did not have tools such as inspection guide, identity cards, and funds to carry out their activities.
- Ward Inspectors met frequently to address issues related to ADDO activities. In addition, ADDO related issues were discussed during regular WHC meetings.



# Key Recommendations and Options (1)

## Immediate-to-Short Term:

1. As the ADDO program regulatory oversight responsibility becomes Pharmacy Council responsibility, TFDA and the PC should review the CFDC structures

Decide how to effectively engage district technical staff—DMO and Pharmacist—for ADDO program oversight



# Key Recommendations and Options (2)

## Immediate-to-Short Term:

### 2. Review revenue collection, retention, and allocation mechanism:

Directly deposit collected fees at central PC/TFDA level

Service such as M-PESA can facilitate direct deposit

CFDC secretaries to issue business permits immediately upon payment

With improved financial resources, PC can better support CFDCs and utilize performance based financing



# Key Recommendations and Options (3)

## Immediate-to-Short Term:

3. Ward level inspection strengthening should be a priority; to improve inspector performance first focus on providing training, ID, and reporting tools
4. Institutionalize short term training to prevent non-trained dispensers from running ADDOs; take firm action against those found operating ADDOs with untrained dispensers
5. TFDA and PC to discuss the coordination & joint roles within their mandates in establishing regulatory structure at the lower level



# Key Recommendations and Options (4)

## Immediate-to-Short Term:

5. Using technology (mobile and GIS), establish central-level comprehensive ADDO data base that would be regularly updated and accessible to districts as part of a comprehensive monitoring and evaluation system for ADDO program

6. Initiate the re-accreditation process for the first ADDO regions and start consumer awareness program on what, how, why, and who provides services at the ADDO outlets. The consumer can be a strong driving force towards sustainable quality services





# Key Recommendations and Options (5)

## Long Term:

1. PC and TFDA should develop a common strategy on how to commonly and directly fund regulatory activities at the lower level by using the existing structure

2. PC and TFDA should establish a performance-based financing for inspection activities by district that makes any inspection result oriented.

- Officers should be held accountable for failing to take the right action for offences
- Verbal warnings and confiscations have proven that they are not effective deterrents

3. Engage ADDO associations in peer-to-peer supervision



*Thank You!*

