# FUNTIONALITY OF THE ADDO REGULATORY SYSTEM

## SITUATIONAL AND OPTIONS ANALYSES

## FINAL REPORT

**SUBMITTED BY: APOTHEKER CONSULTANCY LTD to the Sustainable Drug Seller Initiatives Program**

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# CONTENTS

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Assessment of the Accredited Drug Dispensing Outlet (ADDO) regulatory system and the subsequent options analysis, both conducted by Apotheker Consultancy (T) Limited, were extremely helpful in understanding functionality of the system and identifying potential solutions its various needs. The success of both activities would not have been possible without the support from different stakeholders.

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The contribution of the assessment team to the success of the assignment cannot go unmentioned.

Thank you all.

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# ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ADDO | Accredited Drugs Dispensing Outlet |
| ALAGAT | Association of Local Government Authorities of Tanzania |
| CCHP | Comprehensive Council Health Plan |
| CFDC | Council Food and Drugs Committee |
| CHMT | Council Health Management Team |
| DED | District Executive Director |
| DLDB | *Duka la Dawa Baridi* |
| DHO | District Health Officer |
| DMO | District Medical Officer |
| DP | District Pharmacist |
| LGA | Local Government Authority |
| MSH | Management Sciences for Health |
| PC | Pharmacy Council |
| RAS | Regional Administrative Secretary |
| RFDC | Regional Food and Drug Committees |
| RHMT | Regional Health Management Team |
| RP | Regional Pharmacist |
| SACCOS | Savings and Credit Cooperative Society |
| SEAM | Strategies for Enhancing Access to Medicines |
| TFDA | Tanzania Food and Drugs Authority |
| WEO | Ward Executive officer |
| WHC | Ward Health Committee |

# EXECUTIVE SUMMARY

In June 2012 Management Sciences for Health (MSH) through the Sustainable Drug Seller Initiatives (SDSI) project, commissioned Apotheker Consultancy (T) Ltd to assess the Accredited Drug Dispensing Outlet (ADDO) regulatory system. The main objective was to understand functionality of the system and come up with various options and recommendations for strengthening the system, with a view of enhancing adherence to regulations and standards and promoting sustainable delivery of quality medicines and services to all ADDO users. Specific objectives were to assess effectiveness of the system; explored the need for re-accreditation of ADDOs; and come up with a strategy for strengthening the system.

The assessment was conducted in six selected regions of Tanzania Mainland namely Ruvuma, Mbeya, Singida, Morogoro, Tanga and Pwani. The first region (Ruvuma) was selected on the account of being the ADDO pilot region. The rest of the regions were selected on the basis of duration of the ADDO program implementation (5 years or less) and their geographic representativeness, bearing in mind the different geographic zones in the country. In each region, one district with the highest number of ADDOs was selected to participate in the assessment. The districts were Mbinga (Ruvuma), Mbarali (Mbeya), Morogoro Rural (Morogoro), Korogwe (Tanga) and Kihaba Rural (Pwani). Key informants included members of the Regional Food and Drug Committees (RFDCs), Council Food and Drugs Committees (CFDCs), Ward Health Committees (WHCs), ADDO provider associations, as well as ADDO dispensers. At the national level, senior officials of the Tanzania Food and Drugs Authority (TFDA) based at the head office and zonal centers were also interviewed. Data was collected through key informant interviews, group interviews and observational visits to selected ADDOs, using structured interview guides and a standard information checklist (for the observational visits), and data analyzed using SPSS, a common statistical software.

### MAJOR FINDINGS

Findings from the assessment focus on the following six areas:

- Relevance of the decentralized ADDO regulatory system;
- Functionality of regulatory structures (RFDCs, CFDCs, WHCs);
- Effectiveness of the regulatory system;
- Adherence to regulatory standards;
- Perceptions on the need for re-accreditation; and

- Major challenges to effective functioning of the system.

Analysis and discussion of the findings were based on understanding of TFDA's regulatory mandate prior to enactment of the Pharmacy Act 2011[1].

**(a) Relevance of the Recentralized Regulatory System**

The decentralized regulation system is widely perceived by stakeholders as the most feasible approach to regulatory oversight, considering the vastness of the country and rapidly increasing number of ADDOs expected to reach at least 10,000 by the time national rollout of the program is completed. This perception was reaffirmed by findings from the assessment which showed that TFDA has extremely limited capacity to centrally execute its regulatory oversight mandate. For example, in the fiscal years 2010/2011 and 2011/2012, the agency was able to conduct only two inspections covering about 100 ADDOs.
This represents only 0.33% of the total number of ADDOs registered by June 2012. On the other hand, the assessment revealed that 53% of Ward Health Committees (which do not even have direct funding for regulatory activities) were able to conduct all scheduled inspections in the same period (4 per year), with some of the WHCs reporting 100% coverage drug outlets in their catchment area in a single inspection.
The decentralized system allows regulatory agencies (TFDA and Pharmacy Council) to delegate their mandate and functions to the lower level regulatory structures and also makes it possible to cascade the necessary technical support to each level.

**(b) Functionality of the Regulatory Structures (RFDCs, CFCDs and WHCs)**

The major observation from the assessment was that the regulatory structures established under the decentralized system are functional though their performance is generally week. This situation was attributed to a number of factors including inadequate understanding of the decentralization concept in some areas, leading to weak ownership of the delegated TFDA functions; inadequate financial resources at all levels; weak leadership of some of the committees; inadequate prioritization of regulatory activities due to competing priorities especially at the council level; human resource constraints (some councils do even

[1] Until early 2012, TFDA was still the government agency responsible for overall regulatory oversight for all ADDOs and other facilities providing pharmaceutical services in the country. However, this role has since been transferred to the Pharmacy Council of Tanzania (PC) effective 15th May 2012 (*Ref: CA.51/204/01/61*) following enactment of the Pharmacy Act 2011 by the National Assembly. The Act mandates PC to oversee implementation of the ADDO program nationally including accreditation of drug outlets and regulation of the pharmaceutical practice. However, by the time of the assessment, TFDA had not fully transferred all the regulatory functions to PC as per the new Act.

have qualified pharmacist); shortage of regulatory tools especially at the ward level; and high turnover of trained inspectors more so at the ward level.

Of the three regulatory structures, RFDCs were seen to be the least active. Moreover, two out of the six assessment regions (Mbeya and Tanga) had not established the structure by the time of the assessment. It was learnt that with exception of Pwani RFDC which was able to meet 12 time between July 2010 and June 2012, the rest of the committees in Ruvuma, Morogoro and Singida regions met only once in the same period. The under-performance of RFDCs was mainly attributed to the fact that the ADDO program did not be put emphasis on their establishment from the very beginning of the regulatory decentralization process. However, a closer analysis of the situation indicated that the problem has less to do the program's approach but more to do with a structural weakness in the government's overall approach to implementation of the national policy of decentralization by devolution, which tends to give the councils more responsibility, authority and resources, as the custodians of development programs and social services at the community level. As a government agency, TFDA was obliged to align delegation of its regulatory mandate and functions with the "council-based decentralization". This was associated with the general feeling of marginalization noted at the regional level and the apparent indifference of RFDCs.

On the other hand, the performance of CFDCs was not satisfactory even though a number of them have not been operational for a long time. Apart from Mbinga CFDC established more than 5 years ago, most of the CFDCs which participated in the assessment were established 2-3 years ago. According to ADDO regulations, CFDCs are required to meet quarterly and submit their activity reports four times a year to TFDA and copy RFDC. However, this was not the case in most councils. Scheduled regulatory meetings are an important indicator of vibrancy in the committees and quarterly reports are helpful in knowing how the structures are performing. With regard to inspections, only Kibaha CFDC (Pwani Region) surpassed the number of scheduled inspections in the period under review (between July 2010 and June 2012). The CFDC managed to conduct a total of 12 inspections against 8 scheduled for FY2010/11 and FY2011/12. The rest of the CFDCs (Mbinga, Morogoro Rural, Singida Urban, Korogwe and Mbarali) conducted only 2 inspections each in the same period.

Ward Health Committees showed a much better performance compared with the rest of the regulatory structures. About 74% of the WHCs reported conducting all scheduled meetings in the period under review (July 2010 to June 2012). About 53.1% carried out all scheduled inspections in the same period, with some inspections covering up to 100% of drug outlets in their respective catchment areas. However, WHCs have

much fewer outlets to inspect than other regulatory structures. Most wards have between 1-5 drug outlets, though a few have more than 5. With availability of resources, this number of shops can be covered in one to two days. Furthermore, the assessment demonstrated that with proper planning, the cost of ward inspection should be manageable. Usually, a ward inspector is paid between Tsh.5,000 and Tsh.10,000 as extra-duty allowance per inspection day. There are no additional costs since most inspectors walk or use bicycles to inspection sites. Thus, for the WHC to perform the 4 scheduled inspections a year, it would require between Tsh.40,000 and Tsh.80,000 as extra-duty allowance for two inspectors. Given that the average number of wards per council is about 25, the annual cost of local inspection would be about Tsh.1 million to Tsh.2 million only. Consequently, regulatory agencies (TFDA and the Pharmacy Council) need to carefully evaluate the potential of WHC as a regulatory structure and make a calculated choice on where to invest the available limited resources to strengthen regulatory oversight especially at the grassroots level where ADDO services are delivered.

**(c) Effectiveness of the Regulatory System**

In discussing effectiveness of the system, the assessment paid close attention to coordination and reporting between different regulator structures, accreditation of ADDOs, inspections and enforcement of regulations. It was learnt that coordination between the different regulatory levels (central, regional, council and ward) is generally poor. This was clearly reflected by the weak reporting noted at all levels. According to regulations, WHCs are supposed to send to CFDCs their activity reports quarterly, including inspection reports. However, this was not the case in most areas. Likewise, CFDCs are required to send their quarterly activity reports to TFDA and copy RFDC but this requirement has been largely ignored. Out of the six CFDCs which participated in the assessment, only two submitted a report to the respective RFDC in the two-year period under review (July 2010 – June 2012). Discussions with senior TFDA officials also revealed that activity reports from both RFDCs and CDFCs were not forthcoming. Another pointer to weak coordination was the finding that some CFDCs tend to bypass WHCs in the ADDO accreditation process, contrary to clearly stipulated provisions in the ADDO regulations.

Regarding efficiency of the ADDO accreditation process, it was learnt that the process is extremely slow. Most CFDCs mentioned that it takes them about 6-8 weeks or 8-12 weeks to process applications and forward them to TFDA for further action. On the other hand, it takes TFDA about the same period of time to review and approve the applications. Thus, the accreditation lead-time (from receipt of an application by CFDC to final approval by TFDA) is about 12-16 weeks or 16-24 weeks. This is much longer than the 10 or less days stipulated in TFDA Client Charter. Efficiency of the process mainly depends on the councils

(CFDCs), which are mandated to handle all the preliminary procedures and submit approved applications to TFDA for further review and issuance of the accreditation certificate. The CFDCs are however required to do this in close collaboration with WHCs which receive the applications first, interview drug shop owners and dispensers, visit the proposed business location and submit the applications to the CFDC with comments. The assessment showed that the process suffers adverse delays in the hands of CFDCs, mainly due to lack of a reliable system for training potential ADDO providers (owners and dispenser) wishing to join the program, delays in conducting initial inspection of drugs shops applying to operate as ADDOs, delays in convening CFDC meetings to review and approve the applications, and general lack compliance with the conditions set by TFDA for final approval of the applications. It was learnt that 20% of the applications forward by CFDCs to TFDA are turned back for lack of basic accompanying documents such as a summary of the initial inspection report and minutes of CDFC meeting approving the applications.

Furthermore, the assessment showed that full enforcement of regulations by all the relevant authorities (TFDA, RFDC, CFDC and WHC) was a major challenge despite some inspections taking place albeit intermittently. It was observed that no punitive measures are taken against ADDO providers found with serious regulator violations, rendering the inspections ineffective. While in the field, the assessment team did not come across any written warnings, closure orders, or a single shop closed by the regulatory authorities for gross violation of regulations, yet serious offenses were prevalent in the assessment area. For example, about 14% of the ADDOs visited were managed by untrained dispensers. The situation was worse in Morogoro Rural and Kibaha districts where 32% and 31% of the dispensers found in the shops, respectively, had not attended any ADDO training. Only 53% of the drug shops had the list of authorized ADDO medicines, 45.3% had the ADDO inspection form, 14% had the expired medicines form, and a paltry 10% had the patient complaint form. Moreover, only 33.1% of the ADDOs visited had all the three legal documents for formal operation of the business (accreditation certificate, business permit and dispenser certificate) displayed in the shop as per regulations, 44.6% had an incomplete set of the documents, and 22.3% did not have any of the documents. Considering that the documents define lawful existence of the outlets, their absence should have led to immediate closure of the shops.

**(d) Adherence to Regulatory Standards**

On the other hand, the ADDOs performed considerably well in maintaining physical status of premises and observing the dispenser dressing code. About 91% of the shops visited by the assessment team were rated as clean, 86.6% had medicines properly arranged, 72% had hand-washing facilities, and 61% had strategically placed the ADDO signpost outside the shop for easy identification of the outlet by the

consumers and regulatory authorities. Regarding dispenser dressing code, 54% of the dispensers were formally dressed, 74% had the white dispensing coat with them in the shop though only 31.9% had the coat on while dispensing, and 73% of the coats were clean.

Among the six assessment districts, Mbinga in Ruvuma Region performed remarkably well in most of the indicators. All the dispensers found in ADDOs in the district (100%) had attended ADDO training, 84.6% were dressed formally, 100% had the dispensing coat with them in the shop, all the coats (100%) were clean, and 64.3% of the dispensers were dressed in the coat while dispensing. Regarding status of premises in the district, all shops (100%) were rated as clean, 73% had hand-washing facilities, all outlets (100%) had the ADDO signpost well placed outside the shop, 73% had all the legal documents well displayed in the shop, and all the outlets (100%) had the ADDO patient register. The situation in Mbinga was attributed to the fact that the district, being part of the ADDO pilot area (Ruvuma Region), received adequate attention in terms of training of ADDO providers, follow-up after training and supportive supervision. Experience has shown that these interventions, if well implemented, can have long term impact on business practices of the ADDO providers.

**(e) Perceptions on the Need for Re-accreditation**

The idea of re-accrediting ADDOs received overwhelming support from all stakeholders interviewed. Among ADDO dispensers, 74% gave the idea an affirmative nod. The same was the case with 75% of officials of ADDO provider associations (mainly drug shop owners). However, there were divergent views on the interval for conducting the process. The majority of dispensers (60%) mentioned 1-2 years, most CFDC officials supported 2-3 years, while the majority of ADDO owners (50%) favored 3-4 years. It is instructive to note that dispensers would like see the process conducted most frequently than any other group mainly because they associated re-accreditation with opportunities for re-training and continuous education/career development. However, all the stakeholders were in agreement that re-accreditation offers a unique opportunity to comprehensively revisit the adherence to regulations and standards and promote sustainable delivery of quality medicines and services to the population.

**(f) Major Challenges to the Regulatory System**

In overall, the assessment identified a number of challenges which cut across different functions and needs of the ADDO regulatory system. The challenges include:

- Inadequate financing of regulatory activities at all levels. Currently, the PC has no reliable financing mechanism to support both operational and regulatory activities despite its new enormous

regulatory oversight mandate. At the local level, the main source of funds for regulatory activities is the regulatory fee collected from retail pharmaceutical providers. Forty percent (40%) of the collections is what is retained by the councils for implementation of regulatory activities and 60% sent to TDFA. All the councils reported that the allocation is barely enough to meet financial needs of the delegated functions. It was also learnt most CFDCs face difficulties accessing the money once it is deposited in the general health department account. Moreover, the current system of automatic allocation of the funds to councils is neither activity-driven nor performance-based hence open to abuse.

- Strong resistance to some ADDO regulations especially the distance provision. The provisions allows for establishment of only one ADDO within a radius of 300m. The resistance to the provision is mostly experienced in areas with high concentration of "Part II Poison shops" [commonly known in Kiswahili as *Duka la Dawa Baridi (DLBs)*]. The situation has forced TFDA to relax implementation of the provision so that only new shops which never existed as BLDB before are subjected to the rule.
- A growing demand for expansion of the list of medicines authorized in ADDOs. The push is coming from both ADDO providers and vertical programs at the national level.
- Lack of a reliable system for training of drug shop owners and dispensers in areas already implementing the program. It was learnt that councils take a very long time to organize the short training course for ADDO owners and dispensers, making it difficult for potential ADDO providers to join the program. The situation was widely blamed for the slow process of accreditation, widespread shortage of trained dispensers and operation of some drug shops without trained dispensers.
- Slow process of national roll-out of the ADDO program mainly due to financial constraints and limited human resource capacity at the central level. This has led to continued existence of DLDBs in a number of areas across the country despite the 15th January 2009 deadline set by the government as the last date for renewal of DLDB permits, and revocation of the DLBD regulations by 2011. The situation has made it difficult to enforce the directive and sent a wrong message to stakeholders about the government's capacity to enforce its own directives.
- Sudden transfer of the ADDO program management from TFDA to the Pharmacy Council at a time when national rollout of the program was about to be completed. This was identified as a potential challenge to a smooth transition and effective regulatory oversight by PC in the interim period.
- Poor documentation leading to acute shortage of basic information about ADDOs at all levels (central, regional, council and ward). The situation is made worse by fact that the Pharmacy Council, currently in charge of the ADDO program, does not have a strong monitoring and evaluation (M&E) system yet. Moreover, M&E roles for both PC and TFDA are not yet well defined in light of the

transfer of ADDO program management to PC, and modalities for joint M&E processes remain unexplored.

## RECOMMENDATIONS AND OPTIONS

In view of the above findings, the assessment put forward two sets of recommendations (short and long term) and identified various strategic options as part of the way forward.

### Short Term Recommendations

The short term recommendations underscored the need to strengthen leadership of regulatory committees especially at the council and regional levels; review the system of allocating funds to councils; address immediate training needs of ADDO providers; harmonize TFDA and PC regulatory functions; introduce re-accreditation; and improve quality of inspections to make them more result-oriented. The specific recommendations are as follows:

- In view of the observed inactiveness of regulatory committees, TFDA and the Pharmacy council should review the functional structure of both RFDC and CFDC to give key personnel in the health department more responsibility in management of the committees. Accordingly, RFDC should be chaired by Regional Medical Officer (RMO) assisted by Regional Pharmacist as secretary to the committee. Likewise, CFDC should be chaired by District Medical Officer (DMO) assisted by District Pharmacist (DP) as secretary to the committee. The District Health Officer (DHO) could also be considered as a co-secretary with the DP.
- Considering the challenges experienced in the collection and management of regulatory fees, the Pharmacy Council (PC) in consultation with TFDA, should review the system to give PC direct responsibility for collection and disbursement of the funds to both councils and wards, based on planned activities and performance of the regulatory committees.
- In view of the widespread shortage of ADDO dispensers and high demand for both the dispenser and drug shop owner training courses, the Pharmacy should prioritize this critical need by providing councils with the necessary technical support to conduct the short courses, even as it explores long term solutions to meeting training needs of the ADDO program.
- Following enactment of the Pharmacy Act 2011 and the subsequently transfer of the overall regulatory oversight mandate from TFDA to the Pharmacy Council, both agencies need to move with speed to harmonize their functions at all levels including coordination with the lower level regulatory structures (RFDC, CFDC and WHC) so as to avoid duplication of efforts and ensure optimal utilization of the available limited resources for implementation regulatory activities.

- Bearing in mind the overwhelming support among different stakeholders for introduction of re-accreditation as a strategy for enhancing adherence to regulatory standards and maintaining the quality of ADDO services, the Pharmacy Council should consider initiating a re-accreditation program preferably in a phased manner, starting with the first ADDO regions. This should go hand in with consumer awareness and education to stimulate demand for quality ADDO services.
- In view of the observed infectiveness of ADDO inspections and weak enforcement of regulations, all the responsible regulatory structure (TFDA, PC, RFDCs, CFDCs and WHCs) should work closely together to make inspections more result-oriented and hold inspectors at all levels accountable for any omission or inaction on serious regulatory violations by ADDO providers.

**Long Term Recommendations**

- Considering the widespread shortage of ADDO dispensers nationally, coupled with the declining number of nurse assistants who are the main candidates for the council-based short dispenser training course, the Pharmacy Council needs to fast-track the on-going efforts to institutionalize a one-year dispenser training course that to open doors for other potential candidates including form-four leavers who have passed in science subjects, to become dispensers. The one-year training program is also expected to support development of a clear career path for successful candidates and ensure steady supply of qualified dispensers in the market.
- In view of the financial constraints widely reported by RFDCs, CFDCs and WHCs as a major obstacle to effective functioning of the regulatory system, the Pharmacy Council in collaboration other stakeholders, should develop a strategy for sustainable financing of regulatory activities at all levels. The strategy should among other things, prioritize improving collection, disbursement and utilization of regulatory fees; cutting down expenditure at central level and channeling more resources to the grassroots where regulatory efforts are needed most; and increasing utilization of other existing opportunities including those at the council level such as the Health Sector Basket Fund accessible through integration of regulatory activities in the Comprehensive Council Health Plan (CCHP).
- Considering the acute shortage of basic data about the ADDO program at all levels (central, regional, council and ward), the Pharmacy Council should develop a sound monitoring and evaluation system capable addressing various documentation and information needs of the levels. Establishment of a national database routinely updated and easily accessible by all levels, will go a long way to support crucial regulatory functions and facilitate effective planning, implementation, as well as monitoring and evaluation of ADDO activities. The system should also clearly define monitoring and evaluation roles for both PC and TFDA in light of the transfer of ADDO program management to PC, and create

a mechanism for joint M&E between both agencies to cater for specific interests of different program components which fall under each agency's mandate.

## STRATEGIES FOR THE FUTURE

Apart from putting forward the above sets of recommendations, the assessment identified various strategies for strengthening the regulatory system and ensuring effective delivery of quality of ADDO services in a sustainable manner. The strategies focus on two key areas: (i) strengthening operations of regulatory structure, and (ii) enhancing sustainability of the ADDO program.

### Strategies for Strengthening Operations of Regulatory Structure

- Strengthening human resource capacity of the Pharmacy Council (PC) to enable it to execute its regulatory oversight mandate effectively;
- Developing a comprehensive financing strategy to help increase access to financial resources for regulatory activities at all levels;
- Re-orientation to RFDCs to make them more conversant with the decentralized regulatory functions;
- Regular production and timely distribution of regulatory tools to minimize shortages at all levels;
- Strengthening coordination and reporting between PC/TFDA and lower level regulatory structures;
- Establishing a performance-based financing for all regulatory activities;
- Centralizing collection and management of the regulatory fees;
- Improving planning and budgeting for efficient utilization of resources;
- Restructuring and repositioning CDFC to make them more responsive to technical needs of the ADDO program;
- Integrating RFDCs in the Regional Health Management Team (RHMT) to increase its visibility and access to resources;
- Integrating CFDC and WHC regulatory activities in the Comprehensive Council Health Plan (CCHP);

### Strategies for Enhancing Sustainability of the ADDO Program

- Institutionalizing long term dispenser training current being developed, to ensuring sustainable production and supply of qualified dispensers in the market.
- Promoting public private partnership in addressing both short and long term training needs of the ADDO program.
- Strengthening institutional capacity of regulatory structure to enhance enforcement of regulations;

- Introducing re- accreditation to promote adherence to regulatory standards;
- Supporting establishment of ADDO provider associations to empower the providers economically and promote private sector participation in sustaining the ADDO program.

### STAKEHOLER RECOMMENDATIONS

In September 2012, the findings and recommendations from the assessment were dissented at a national conference organized by MSH in collaboration with the Pharmacy Council and TFDA. Part of the conference's brief was to review the findings and recommendations from the assessment, and come up with priority interventions. The following were the interventions agreed on for immediate implementation:

- Reviewing ADDO regulations to reflect the transfer of the overall regulatory oversight mandate from TFDA to the Pharmacy Council;
- Reviewing the system for collecting regulatory fees and disbursement of the collections to councils to make it more performance-based;
- Integrating regulatory activities in the Comprehensive Council Health Plan to promote utilization of councils' own resources, increase ownership of the delegated regulatory functions and enhance sustainability;
- Introducing re-accreditation to enhance adherence to regulations and standard;
- Repositioning and re-structuring the leadership of CFCDs in line with the recommendations from the assessment;
- Developing a mechanisms to strengthen coordination between the central and local levels on all regulatory issues;
- Strengthening the ADDO monitoring and evaluation (M&E) system as per recommendations from the assessment;
- Reviewing the ADDO medicines list periodically to accommodate new therapeutic changes and consumer needs.
- Strengthening the capacity of WHCs to carry out effective inspections.

# 1. BACKGROUND

## 1.1 INTRODUCTION

In 2002, the Tanzania Government received a grant from Bill & Melinda Gates Foundation through the MSH Strategies for Enhancing Access to Medicines (SEAM) Program, to pilot the Accredited Drug Dispensing Outlets (ADDO) Program in Ruvuma Region. The goal was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural and peri-urban areas where there are a few or no registered pharmacies.

To achieve this goal, the SEAM Program took a holistic approach that combined changing the behavior and expectations of individuals and groups that use, own, regulate, or work in retail drug shops. For shop owners and dispensing staff, this was achieved through training, provision of incentives, supportive supervision, monitoring, and enforcement of regulations, as well as consumer education to raise awareness about ADDOs and stimulate demand for quality products and services.

Results of the pilot showed significant improvements in access to quality medicines and pharmaceutical services. By the end of the pilot process, Tanzania Food and Drugs Authority (TFDA) had accredited over 200 shops in Ruvuma Region. A year later, the Ministry of Health and Social Welfare approved a plan to roll out the program to other regions in Tanzania Mainland.

Prior to inception of the ADDO program, the Pharmacy and Poisons Act (1978) did not provide any legal mandate to local authorities to take responsibility for regulatory oversight to drug outlets. The regulatory system was centrally managed by the then Pharmacy Board (currently TFDA and Pharmacy Council), without a clear definition of roles of the lower administrative structures. This was one of the major regulatory weaknesses observed during the 2001 review of Tanzania's pharmaceutical sector conducted by the SEAM program in collaboration with the Pharmacy Board.

Moreover, given the high number of Part II poison shops [commonly known in Kiswahili as *Duka la Dawa Baridi (DLD*)] at the time (over 6,000 shops), and scarcity of human resources to perform various regulatory activities, the existing system was unable to effectively regulate the drug outlets and health facilities providing pharmaceutical services through a centralized approach. As a result, inspection

activities were rarely conducted and opening of new outlets was not well regulated. Most drug shops were operating without set procedures and trained personnel.

Consequently, the ADDO program came up with a strategy to improve regulatory oversight at the local levels by empowering councils to regulate the services provided by drug outlets and health facilities in their respective areas. These efforts led to establishment of the decentralized regulatory system.

## 1.2 DESCRIPTION OF THE DECENTRALIZED REGULATORY SYSTEM

The Government of Tanzania approved the proposal to decentralize TFDA regulatory functions in 2006 through the "Tanzania Food and Cosmetics Delegation of Powers Order 2006 (GN 162)". In 2008, the Ministry of Health and Social Welfare through TFDA signed a memorandum of understanding with the Prime Minister's Office - Regional Administration and Local Government (PMO-RALG) to facilitate effective delegation of some of the TFDA powers and functions to local government authorities (councils), in line with the "*Tanzania, Food and Cosmetics Delegation of Powers Order 2006 amended by the Delegation of Powers (amendment) Order of 2007 (GN 165)".* Subsequently, PMO-RALG issued a circular to councils regarding implementation of TFDA activities, leading to establishment of an elaborate regulatory framework consisting of the following key structures:

- Central level establishment (consisting of TFDA headquarters and zonal offices) closely supporting regions and districts to carry out regulatory activities;
- Regional Food and Drugs Committee (RFDC) which coordinates regulatory functions at the regional level and provides technical support to councils;
- Council Food and Drug Committee (CFDC) responsible for all regulatory issues within the council. The committee has a legal mandate to inspect, approve or reject applications to establish ADDOs, and advises TFDA on related matters;
- Ward Health Committee (WHC) mandated to carry out regular inspections of all facilities providing pharmaceutical services within the ward, and conducts preliminary inspection of new drug shops wishing to operate as ADDOs. The committee consists of 3 members trained as local (ward) inspectors.

The following are the specific roles and responsibilities of the regulatory structures:

**(a) TFDA Central Level Establishment**

- Conducts routine and audit inspections;
- Approves or rejects new ADDO application i.e. can overrule decisions made by the CFDC and RFDC regarding new ADDO establishment;
- Provides regulatory oversight for all pharmaceutical services in the country;
- Supports the councils and regions to execute the delegated regulatory functions.

**(b) Regional Food and Drugs Committee**

- Provides technical support to councils by offering guidance and advice on management of ADDOs and other pharmaceutical services;
- Receives and reviews inspection reports from CFDCs, as well as appeals from complainants, and takes appropriate action;
- Conducts audit inspections of all outlets providing pharmaceutical services in the region;
- Monitors performance of CFDCs by following up on actions taken by the committees as shown in their quarterly reports;
- Carries out any other task assigned by TFDA and reports back accordingly.

**(c) Council Food and Drugs Committee**

- Receives and reviews comments submitted by Ward Health Committees (WHC) on new ADDO applications;
- Receives inspection reports from WHC and acts as appropriate;
- Inspects all outlets that provide pharmaceutical services in the district;
- Approves or rejects new ADDO applications on behalf of TFDA;
- Carries out overall regulation of all pharmaceutical services in the district;
- Collects annual accreditation fees from drug outlets in the council on behalf of TFDA and submits the approved portion (currently 60%) to TFDA head office;
- Coordinates any other activities assigned to the council by TFDA;
- Prepares and submits quarterly activity reports to TFDA and RFDC.

**(d) Ward Health Committee**

## 1.3 STATUS OF THE REGULATORY SYSTEM

It has been observed from routine monitoring of the ADDO program that the decentralized regulatory system is, to a large extent, functional. However, no systematic assessment has been conducted since inception of the program nine years ago, to critically look at effectiveness of the regulatory system, in light of the rapidly increasing number of ADDOs, following national rollout of the program. It was against this backdrop that MSH, through the Sustainable Drug Seller Initiatives (SDSI) Project, commissioned a detailed assessment of the ADDO regulatory system as part of a wider scheme to maintain implementation quality of the program and enhance its sustainability in the long term.

## 1.4 OBJECTIVES OF THE ASSESSMENT

The main objective was to understand functionality of the regulatory system and come up various options and recommendations for strengthening the system, with a view of enhancing adherence to ADDO regulations and standards and promoting sustainable delivery of quality medicines and services to all ADDO users.

Specific objectives were as follows:

(i) To observe the functionality and effectiveness of the decentralized regulatory system in improving regulatory oversight and recommend further action for future sustainability;
(ii) To explore the need for re-accreditation of ADDOs as a mechanism for improving quality of care provided by the ADDOs and ensuring their compliance to regulatory standards;
(iii) To come up with a strategy for future sustainability of the regulatory system, based on results of the assessment.

# 2. METHODOLOGY

## 2.1 THE ASSESSMENT AREA

The assessment was carried out at the national, regional, council and ward levels. At the national level, TFDA head office and zonal offices in Dar es Salaam, Mbeya and Dodoma were involved in the study. At the regional level, 6 regions namely Ruvuma, Pwani, Morogoro, Singida, Tanga and Mbeya, were selected on the basis of implementation period of the ADDO program and geographic location of the regions. Priority was given to one region (Ruvuma) where the program had been in existence for more than 5 years. For the rest of the regions where the program had been in existence for 5 years or less, consideration was given to their geographic representativeness, taking into consideration the various zones in the country. Thus, the regions were scattered as widely as possible, with Mbeya representing the Southern Highlands Zone, Morogoro (Eastern Zone), Pwani (Coastal Zone), Tanga (Northern Zone) and Singida (Central Zone).

From each of the 6 regions, one district with the highest number of ADDOs was selected to participate in the assessment. The districts were divided into 3 divisions each, out of which 2 wards were selected randomly. Thus, a total of 30 wards (6 wards per district) participated in the assessment. The initial plan was to cover 10 wards in each district but due to the short duration of the assessment, the number was reduced to 6 wards. From each of the 30 wards, 30 ADDOs were randomly identified to participate in the assessment. *Table 1* below highlights the geographic coverage of the assessment.

***Table 1: Assessment area***

| Region | District | Number of Wards | Number of ADDOs |
|---|---|---|---|
| Ruvuma | Mbinga | 6 | 30 |
| Pwani | Kibaha Rural | 6 | 30 |
| Morogoro | Morogoro Rural | 6 | 30 |
| Singida | Singida Urban | 6 | 30 |
| Tanga | Korogwe | 6 | 30 |
| Mbeya | Mbalari | 6 | 30 |
| **Total** | **6** | **36** | **180** |

## 2.2 THE PARTICIPANTS

Various ADDO stakeholders participated in the assessment at the national, regional, council and wards levels. They included TFDA staff, regional teams including selected members of the RFDC, technical staff at the council level including selected members of the CFDC, key personnel at the ward level including selected members of the WHC, representatives of ADDO provider associations, and dispensers working in different ADDOs across the assessment area. Table 2 below highlights the list of participants.

***Table 2: Participants in the assessment***

| SN | Level | Participants |
|---|---|---|
| 1 | National | TFDA staff (ADDO program manager and zonal inspectors). |
| 2 | Regional | Regional pharmacist and 2 members of the Regional Food and Drugs Committee. |
| 3 | District/Council | District medical officer, district pharmacist, and 2 members of the Council Food and Drugs Committee. |
| 4 | Ward | Ward executive officer, 2 members of the Ward Health Committee, officials of ADDO provider associations, and ADDO dispensers found in the drug shops during observation visits. |
| | | |

## 2.3 DATA COLLECTION METHOD

Primary data was collected through key informant interviews, group interviews, and observational visits to selected drug shops. The key informant interviews were conducted using structured questionnaires, and observational visits using a standard checklist to assess the condition of premises and adherence to basic regulatory standards. On the other hand, secondary data was collected through desk review of relevant documents including TFDA/CFDC minutes and inspection reports. The assessment focused on the following aspects of the ADDO regulatory system:

- TFDA regulatory oversight;
- Inspection activities at different levels;
- Functionality of different regulatory structures in the decentralized framework;
- ADDO accreditation procedures and practicability;
- Reporting systems and availability of feedback;
- Compliance with ADDO regulations;

- Status of the drug shops and adherence to basic regulatory requirements;
- Stakeholders' views on emerging regulatory issues (such as the need for re-accreditation of ADDOS, use of the patient register, and the role of ADDO provider associations).

### 2.4 DATA COLLECTION TOOLS

The following sets of tools were developed to facilitate primary data collection:

- Questionnaires for interview with TFDA staff at the head office and zonal offices;
- Questionnaire for interview with the selected Regional Food and Drugs Committee members;
- Questionnaire for interview with the selected Council Food and Drug Committee members;
- Questionnaires for interview with Ward Executive Officers and selected ward level inspectors;
- Questionnaire for interview with ADDO dispensers found in the shops during observation visits;
- Information checklist for assessing the physical status of the drug shops and adherence to basic requirements.

### 2.5 DATA COLLECTION TEAM

Apotheker Consultancy (T) Ltd deployed an experienced team of technical experts to collect the necessary information from the assessment area. Prior to deployment of the team, a short training was organized to enlighten the members of the team about the ADDO program including the decentralized regulatory system, and acquaint them with the data collection tools. The training was also helpful in getting feedback from the team on some of the data collection tools.

### 2.6 DATA PROCESSING AND ANALYSIS

Given the wide scope of the assessment, large volumes of both qualitative and quantitative data were generated from the process. Since this situation was expected, electronic templates for data entry were developed in advance to facilitate prompt processing of the information. Thus, at the end of each fieldwork day, data collectors were assigned to transfer the information they had recorded in hard form, to the electronic templates. The electronic data was then sent to a data clerk for further processing. The cumulative data set was processed and analyzed using SPSS (statistical software for managing both qualitative and qualitative information). The final data set was organized in different formats (mainly graphs and tables) for easy interpretation and analysis.

# 3. THE FINDINGS

Until early 2012, TFDA was still the government agency responsible for overall regulatory oversight for all ADDOs and other facilities providing pharmaceutical services in the country. However, this role has since been transferred to the Pharmacy Council of Tanzania (PC) effective 15th May 2012 (*Ref: CA.51/204/01/61*) following enactment of the Pharmacy Act 2011 by the National Assembly. The Act mandates PC to oversee implementation of the ADDO program nationally including accreditation of drug outlets and regulation of the pharmaceutical practice.

However, by the time of the assessment, TFDA had not fully transferred all the regulatory functions to PC as per the new Act. Thus, findings from the assessment are based on understanding of the TFDA regulatory mandate prior to enactment of the Pharmacy Act 2011. The findings pay particular attention to the following key areas:

- Roles and functions TFDA in the decentralized regulatory system;
- Functionality of Regional Food and Drugs Committees;
- Functionality of Council Food and Drugs Committees;
- Functionality of Ward Health Committee; and
- Adherence to ADDO regulations and standards by the drug shops and need for re-accreditation.

## 3.1 TFDA ROLES AND FUNCTIONS

In assessing the roles and functions of TFDA, efforts were made to understand perception of senior TFDA staff regarding the decentralized regulatory system and effectiveness of the TFDA mandate in terms of overall regulatory oversight, coordination with lower level regulatory structures, accreditation of ADDOs and financial support to the regional and council food and drugs committees.

### 3.1.1 TFDA Perception of Decentralization

The general opinion among senior TFDA staff who participated in the assessment was that the major regulatory restructuring which came along with implementation of the ADDO program and the subsequent decentralization of some of the TFDA powers and functions, is a positive development. Part of the transformation was the 2009 review of the ADDO Regulations (2004) to accommodate new developments in implementation of the program. However, the whole process of decentralization and enforcement of the ADDO regulations has not been without challenges.

Among the challenges mentioned during consultations with the TFDA staff, were:

- Widespread resistance to the distance provision in ADDO regulations. The provisions allow establishment of only one ADDO within a radius of 300m. Resistance to the provision is mostly experienced in areas with high concentration of DLBs. The situation has forced TFDA to relax implementation of the provision so that only new shops which never existed as BLDB before are subjected to the rule.
- A growing demand for expansion of the list of medicines authorized in ADDOs. The push is coming from both ADDO providers and vertical programs at the national level.
- Lack of a reliable system for training of drug shop owners and dispensers in areas already implementing the program. It was learnt that councils take a very long time to organize the basic training course for ADDO owners and dispensers, making it difficult for potential ADDO providers to join the program. The situation was widely blamed for the slow process of accreditation, widespread shortage of trained dispensers and operation of some drug shops without a trained dispenser.
- Weak enforcement of regulations by council authorities mainly due to human resource shortage, limited technical capacity (some councils still do not have qualified pharmacists), competing priorities, financial constraints and general complacency by regulatory authorities at the lower levels.
- Slow process of national roll-out of the ADDO program mainly due to financial constraints and limited human resource capacity. This has led to continued existence of DLDBs in a number of districts countrywide despite the January 15 2009 deadline set by the government as the last date for renewal of DLDB permits and revocation of the DLBD regulations by 2011.
  The situation has made it difficult to enforce the directive and sent a wrong message to stakeholders about the government's capacity to execute its own directives.
- Sudden transfer of the ADDO program management from TFDA to the Pharmacy Council at a time when national rollout of the program was about to be completed. This was identified as a potential challenge to a smooth transition and effective regulatory oversight by PC in the interim period. Concerns were also voiced on monitoring and evaluation of ADDO regulatory activities in light of the transfer of TFDA functions to PC.

*"I have some concerns regarding monitoring and evaluation in light of the on-going transfer of ADDO program management to the Pharmacy Council. The M&E involves among other things, market surveillance for several products other than the medicines authorized for ADDOs. It is not yet clear whether the M&E function will also be shifted to the Pharmacy Council. I think there is a need for a clear-cut description of the M&E roles between TFDA and the Pharmacy Council considering the importance of this component",* TFDA ADDO Program Manager.

### 3.1.2 Coordination with Other Regulatory Structures

Effective coordination between TFDA and other regulatory structures at the lower levels (RFDCs, CFDCs and WHCs) is critical to efficient functioning of the decentralized system. The assessment wanted to determine existence and functionality of such a coordination mechanism.

During discussions with TFDA zonal officers in the Eastern and Southern Highlands zones, it was reported that zonal inspectors do hold meetings with CFDCs and RFDCs whenever they visit regions and councils/districts for audit inspections. Nevertheless, in both areas, no minutes of such meetings were available, putting into doubt occurrence of the reported meetings in a structured manner. Experience has shown that most inspectors tend to interact more with individual members of the regulatory committees found on site during inspections visits, than engaging with wider membership of the committees through structured meetings.

At the central level, TFDA head office acknowledged that apart from the Association of Local Government Authorities of Tanzania (ALAGAT) Annual Conference, there is no other national forum bringing together the central, regional and council authorities on a regular basis. It was learnt that TFDA usually sponsors a day at the ALAGAT conference to discuss regulatory issues. Consequently, a suggestion was made that a similar conference should be organized routinely to discuss regulatory issues, get feedback from the regions and councils, and strengthen coordination with the regulatory structures.

*"If resources were available it would be a good idea for TFDA to convene annual meetings with council representatives especially the DEDs (who are the CFDC chairpersons) and the District Pharmacist (technical focal point), the same way the National Malaria Control Program used to conduct annual national meetings for Malaria and IMCI Focal Persons. Such forums can help to assess the performance*

*of councils and improve reporting by asking the councils to bring the necessary reports to such meetings",* TFDA ADDO Program Manager.

### 3.1.3 Accreditation by TFDA

According to the ADDO regulations, CFDCs are mandated to receive, evaluate and approve ADDO applications and forward their recommendations to TFDA Head Office for final review and issuing of the accreditation certificate. TFDA zonal offices are only responsible for approving applications by ADDO Restricted Wholesales (ARW) if submitted by the CFDCs. Part of the focus of the assessment was to find out how this process is handled by TFDA.

It was explained that accreditation is a continuous process. As soon as TFDA completes ADDO program rollout in a particular council, the council takes over all the preliminary procedures for accreditation of drug outlets. However, TFDA acknowledges that the process is not without challenges:-

- Many CFDCs do not carry out routine inspection, leave alone inspection of drug shops wishing to operate as ADDOs;
- Many CFDCs do not conduct scheduled meetings as per regulations. The meetings are critical to the accreditation process since they are the ones that review all ADDO applications at the council level;
- Some CFDCs do send to TFDA incomplete accreditation applications in that they lack the necessary accompanying documentation such as summary of inspection reports and minutes of CFDC meetings approving the applications.
- Councils take a long period of time to organize trainings for new ADDO providers.

These shortcomings contribute significantly to delays in accreditation of new shops. According to the TFDA Client Charter, the process should not take more than 10 days but in practice it takes about 12 weeks mainly due to the above mentioned problems. The trend has major implications on compliance with ADDO regulations. According to the regulations, all unsuccessful applicants should close their shops within 90 days of rejection of the application. Enforcement of this provision has been a major challenge due to the accreditation delays. This partly explains the continued existence of DLDBs in some areas already implementing the ADDO program.

### 3.1.4 TFDA Regulatory Oversight

Regarding the overall regulatory oversight, the assessment wanted to find out how TFDA is executing this mandate in collaboration with RFDCs and CFDCs. Thus, the assessment focused on functions that are directly carried out by TFDA and those that are executed through CFDCs with support from RFDCs. Among the things the assessment paid attention to were:-

- Number of inspections carried out by TFDA in the last two years (FY2010/11 – FY2011/12)
- Proportion of drug outlets inspected in the last two years (FY2010/11 – FY2011/12)
- Proportion of outlets closed by TFDA in the last two years (FY2010/11 – FY2011/12) due to serious regulatory violations; and
- Proportion or outlets given warnings due to any other regulatory violations in the last two years (FY2010/11 – FY2011/12).

It was learnt that TFDA carried out two inspections in the fiscal years 2010/11 and 2011/2012, covering about 100 ADDOs (50 per inspection). This represents only 0.33% of the number of ADDOs accredited by the end of FY2011/12. Among the violations observed during both inspections were: dispense of medicines not authorized in ADDOs, stocking of medicines not registered by TFDA, operation of the drug shops without a trained dispenser, selling of prescription medicines without prescription, poor documentation by the outlets, and operation of the shops without permits. Even though most of these violations are serious offenses, no closure orders were issued to any of the ADDO providers. Instead, verbal warnings were given to those found culpable. Nonetheless, inspection forms reviewed during the assessment showed that most of the violations were not widespread.

Regarding execution of TFDA functions delegated to other regulatory structures (RFDC and CDFC), the assessment considered the following two indicators:

- Proportion of ADDOs that have renewed their licenses and received TFDA accreditation certificate or business permit in the last two years;
- Proportion ADDOs with expired accreditation certificates or business permit.

Both indicators have been discussed under Section 3.2 on functionality of CFDCs.

### 3.1.5 Financial Support to Regulatory Committees

One of the important factors for smooth functioning of the committees is the availability of funds to cover cost of meetings and inspection activities by CFDCs and WHCs. The two main sources of funds for implementation of regulatory activities at the council level are council's own resources allocated through the Comprehensive Council Health Plan (CCHP), and the 40% retention of local TFDA collections. According to a survey conducted by TFDA in 2011, 39 out of 42 councils (93%) had included TFDA related activities in their budgets, with the Basket Fund being the main funding source.

Between FY2008/2009 and FY2010/2011, the average allocation ranged from TZS 770,000 - 25,000,000, which was a substantial amount for implementation of basic regulatory functions delegated to the councils. However, the assessment found out that many of the surveyed councils did not have any specific budgets to cover ADDO related activities including inspections.

Regarding TFDA allocations, it is worth noting that the agency does directly provide funds to the councils. Instead it authorizes the councils to collect accreditation and business permit fees from drug outlets in their respective areas and retain 40% of the collections. However, a TFDA Survey Report (2011) showed that councils are not performing very well in making the collections. For example, in the fiscal years 2007/08, 2008/09 and 2009/10, only 14 out of the 42 councils survey collected the regulatory fees from drug outlets and only 9 out of the 42 councils remitted 60% of the collections to TFDA as per regulations. Commenting on the collections, TFDA ADDO Program Manager had this to say,

> *"My general opinion is that the 40% of regulatory fees allocated to the councils is not enough. For example, assuming that a district has 50 ADDOs and each pays Tsh.30, 000 to renew a permit. The total collection would amount to Tsh.1, 500,000 only per year, out of which the council retains Tsh.600, 000 and remits Ths.900, 000 to TFDA. I wonder what they can do with such amount of money. Secondly, I am not sure if all councils retire the funds timely."*

Consequently, TFDA has been continuously advocating to councils to include TFDA regulatory activities in the CCHP for more resource allocation through the Basket Fund. Such allocations would support major regulatory activities by the council. On the other hand, the 40% of collections retained by the councils could support ward level inspection activities which is relatively cheaper. For example, the daily allowance for two ward inspectors does not exceed Tsh.10,000. Experience has shown that ward inspectors need only one day to cover all shops within the ward although there could be a few exemptions.,

### 3.1.6 Major Observations

- TFDA remains conscious of its overall regulatory oversight role in spite of decentralization of some of its powers and functions.
- The general perception of TFDA officials is that councils do not have sufficient capacity to effectively implement the decentralized regulatory functions.
- Coordination between TFDA and CFDCS is generally weak, with routine meetings to discuss operational issues including performance taking place in an ad-hoc manner.
- ADDO accreditation lead-time (from application by drug shop owners to issuance of accreditation certificates by TFDA) is extremely long (16-24 weeks). It was learnt that it takes CFDCs between 8-12 weeks to process and forward applications to TFDA, and it takes about the same period of time for TFDA to review and issue accreditation certificates to successful applicants.
- Inspections conducted by TFDA (central and zonal levels) cover less than 1% of ADDOs. This is a clear indication that centralized inspection is unlikely to be effective, more so as the number of ADDOs increase nationally. On the other hand, findings from the assessment demonstrated the significance of RFDCs and CFDCs in carrying out TFDA regulatory functions. Consequently there is a need to for the central level (TFDA and Pharmacy Council) to support both committees as well as ward inspectorate teams, both technically and financially, to be able to conduct inspections more routinely and effectively than they currently do.
- No punitive measures are taken giants ADDO providers who violate regulations. Instead verbal warnings are given to the violators. The trend generally encourages non-compliance with the set regulations and standards.
- All regulatory committees at different levels are poorly financed, a situation which jeopardizes performance of the committees. Considering the limited coverage of the central level inspections, TFDA and PC should devise a strategy to support the lower level regulatory structures directly to enable them to effectively perform the decentralized regulatory functions including inspections, routine meetings and reporting. Direct financial support and technical assistance through training, follow-up and supportive supervision, would go a long way to strengthen capacity of the regulatory committees for optimal performance.

## 3.2 FUNCTIONALITY OF THE REGIONAL FOOD AND DRUG COMMITTEE (RFDC)

### 3.2.1 RFDC Description

The Regional Food and Drugs Committee is important regulatory structure. The committee is chaired by the Regional Administrative Secretary, assisted by Regional Medical Officers as the committee's secretary. Other members of the committee are Regional Pharmacist, Regional Veterinary Officer, Regional Trade officer, Regional Health Officer. The committee has three basic functions: (i) it serves as the appeal body for ADDO providers who feel aggrieved by CFDC decisions, (ii) Carries out audit inspections in collaboration with TFDA and CFDC and (iii) supervises and reviews performance of CFDCs in the region. The committee is expected to meet quarterly to discuss operational issues and review its performance.

Consequently, in assessing functionality of RFDC, the study focused on knowledge about RFDC functions, status of establishment, and the committee's effectiveness in terms of:-

- Number of RFDC meetings held in the last 2 years (FY2010/11 and FY2011/12);
- Availability of minutes of the meetings;
- Number of inspections conducted by RFDC (with or without CFDCs direct involvement) in the last two years (FY2010/11 and FY2011/2012);
- Proportion of drug outlets inspected by RFDC (with or without CFDCs direct involvement) in last two years (FY2010/2011 and FY2011/2012).

### 3.2.2 Knowledge about RFCD Functions and Status of Establishment

Not all RFDC members interviewed were aware of the committee's functions including its supervisory role to CFDCs. Nevertheless, they had a favorable view of decentralization of TFDA regulatory functions despite the implementation challenges.

> *"Decentralization has improved regulatory oversight especially in the case of inspections. However, the inspections seem to be more effective in urban councils like Songea than in rural councils,"* one member observed.

It was learnt during the assessment that out of the six assessment regions, four (Ruvuma, Pwani, Morogoro and Singida) had established the committee but with minimal support from the central level. It was reported that the central level only sensitized the regions to establish the committees without further facilitation of the process. Most RFDC members voiced concern over the limited authority of the

committee especially in accreditation of drug outlets. A number of respondents indicated that they would be happier with the RFDCs having a major say in the ADDO accreditation process.

### 3.2.3 RFDC Effectiveness

**(a) Frequency of Meetings**

The assessment revealed that most of the committees are largely inactive. For example, over the past two years (between July 2010 and June 2012) all the committees with exception of Pwani Region met only once. This represents 1/8 of the number of meetings they ought to have conducted as required by ADDO regulations. Moreover minutes of the said meetings were largely unavailable. However in Pwani Region, the RFDC managed to meet 12 times, effectively setting it apart as the most active RFDC in the assessment area.

**(b) Coordination with TFDA and CFDCs**

It was learnt that there is no proper system for formal engagement of RFDCs in regulatory activities conducted by TFDA in the regions. It was reported that whenever TFDA is in the regions for routine inspection activities, it occasionally involves one or two RFCD members (mostly regional pharmacist) in an individual capacity, not as a committee. Because of the ad-hoc nature of this engagement, there are no formal records of such activities in the regions. Likewise, the relationship between RFDCs and CFDCs is characterized by similar informality. The practice makes some of the RFDCs ignorant of the situation in the councils, even as they complain of marginalization through the council-based decentralization.

**(c) Inspection Activities**

In all the four regions where RFDC has been established, it was learnt that each of the committees conducted at least one inspection in the last two years (FY2010/11 and FY2011/12). However, this information could not be verified by the assessment team since none of the RFDCs had inspection reports. When the assessment team inquired further on how the inspections were carried out, it became evident that most of the reported inspections were neither initiated nor planned by the RFDCs as such, but rather the result of the ad hoc involvement on individual RFDC members in routine inspections conducted by TFDA. That partly explains why the RFDCs did not have reports from the inspection activities.

When asked to describe the most common violations observed during the inspections, the respondents mentioned stocking of medicines not allowed in ADDO, provision of services by untrained ADDO dispenser and selling of prescription medicines without prescription.

The assessment team further wanted to know what actions were taken by the RFDCs against those found to have violated ADDO regulations. Among the actions mentioned were:

- Gave warning (verbal since there was no evidence of written warnings)
- Reported to the respective CFDC (perhaps verbal)
- Recorded in the inspection form ( however no such records were seen)
- Ordered the closure of the premises ( again perhaps it was verbal)

The assessment team was however not able to verify through a written document, any of the said actions taken by the RFDCs. In the absence of systematic meetings for most of the RFDCs, it was unlikely that such steps were ever taken as claimed by the respondents.

On financial resources, all RFDCs complained that they did not have funds to conduct inspections and this was cited as a major reason for the observed under-performance by the committees. Consequently some RFDC members suggested that that part of the 40% of TFDA collections retained by councils should be shared with RFDCs for such activities.

When asked about their opinion on the proposal to re-accredit all ADDOs after a given period of time, there was consensus that re-accreditation is a necessary measure to promoting regulatory adherence, improve quality of services and upholding standards.

**(d) Discussion of the Findings**

Before official launch of the ADDO program in a given region, TFDA in collaboration with MSH conducted sensitization meetings to key members of the Regional Secretariat headed by the Regional Commissioner, as the guest of honor, flanked by Regional Administrative Secretary and heads of different departments. During the sensitization meetings the regulatory system was explained in detail including roles and responsibilities of the regions. Regional pharmacists were the main organizers and facilitators. It is instructive to note that some regions are yet to establish RFDCs and some key decision-makers seem to be unaware of basic functions and responsibilities of the committee.

Furthermore, in the absence of effective inspections carried out by the RFDCs it is not clear whether the reported regulatory violations by ADDO providers are based on practical field observation or are just historical memories from the past experiences or anecdotal statements. In the event that the observations are true, the fact that none of the RFDCs took any disciplinary action against outlets found with serious violations calls their credibility to question. Consequently the consultant would like to take the feedback from RFCDs cautiously since no tangible evidence was found to support them.

While there are no doubts that shortage of funds is a major constraint to effective functioning of the RFDCs, the constraint cannot be entirely blamed for the widespread under-performance of the committees, considering that each region has a budget line for the Regional Health Management Team (RHMT) whose activities cover the entire health sector including ADDO services. Part of the funds allocated to the RHMT could be used to conduct ADDO inspections and supervise CFDCs within the region. Moreover, there are certain operational issues which RDFCs could easily address without necessarily having a specific budget line, such as requesting DMOs to include ADDO issues in the council health department quarterly and annual reports.

Lastly, the observed under-performance by RFDCs can also be attributed to inadequate support by the central level. The ADDO program did not put enough emphasis on establishment of RFDCs from the very onset of the decentralization process. The regions have largely been left on their own with minimal supervision by the national level. Thus, in the regions that have managed to establish the committee and conducted some basic regulatory activities deserve credit.

## 3.3 FUNCTIONALITY OF COUNCIL FOOD AND DRUGS COMMITTEES

### 3.3.1 Description of the Committee

The Council Food and Drugs Committee is a crucial organ in the decentralized regulatory system. The committee has the following major roles and responsibilities:

- Regulating pharmaceutical services in the council;
- Processing applications for establishment of ADDOs;
- Conducting quarterly meetings to address operational issues including performance review;
- Reporting to TFDA and RFDC on a quarterly basis;
- Supervising ward inspection teams and reviewing their quarterly activity reports;

- Collecting accreditation and licensing fees from all drug outlets in the council and remitting 60% of the collections to TFDA annually.

In assessing functionality of the committees, the study focused on their formation/establishment status, perceptions of TFDA regarding the committees, regulatory activities of the committees, coordination with the central and regional levels (TFDA and RFDCs), and appeals against decisions taken by the committees.

### 3.3.2 Status of Establishment

Apart from Mbinga CFDC established more than 5 years ago, most of the CFDCs which participated in the assessment were established 2-3 years ago. The majority of the committee members interviewed were well conversant with the roles and responsibilities of the committees. It was learnt from discussions with TFDA officials that all councils had been fully sensitized on decentralization of TFDA regulatory mandate and functions. Nevertheless, most CFDC members who took part in the assessment indicated that the committees have not been as effective as envisaged due to various constraints and challenges including:-

- Human resources shortage, leading to heavy workload on the few available personnel;
- Inadequate integration of ADDO activities with other council health programs;
- Weak reporting;
- High staff mobility especially at the ward level where those already familiar with the ADDO program and trained in regulatory issues are replaced by new staff without any prior training or knowledge about the program;
- Overdependence on the district pharmacist as the main technical person for pharmaceutical services in the council. Moreover, many councils do not even have qualified pharmacists, and where they are available, they are overburdened;
- Lack of commitment by some district pharmacists;
- Slow decision making due to structural weaknesses and bureaucracy. For example, going by the reporting structure in the councils, the District Pharmacist reports to District Medical Officer who in turn reports to the District Executive Director (DED). Getting DED to act on certain proposals/decisions at times takes a long time due to competing priorities;
- Inadequate motivation of key personnel, especially in councils where the authorities feel that the 40% of TFDA collections retained by the councils is not enough to carry out the regulatory functions delegated by TFDA;

- Inadequate understanding of the TFDA regulatory responsibilities by some council authorities, despite continuous sensitization by TFDA in collaboration with the Local Government and Health Ministries; and
- Competing priorities in the councils, given the enormous responsibility of the councils as the custodian of all development activities at the community level.
- Financial constraints due to poor budgeting, inadequate resource mobilization and lack of accountability by some council officials.

### 3.3.3 TFDA Perceptions

The general opinion of TFDA officials is that the regulatory system has realized considerable improvements following establishment of CFDCs as a regulatory structure. However, most of the committees are not yet to performing optimally as per TFDA's expectations. One of the officials had this to say regarding relevance of the committees,

> *"CFDC is very important structure in as far as regulation of pharmaceutical services is concerned. For example given the vastness of the country and the large number of districts (135) it would be impossible for TFDA to execute its regulatory functions nationally through a centralized approach."*

> Another TFDA staff commenting on the same issues said, *"Having a regulatory system up to the grass roots level is in itself, an important step. It is interesting to see an inspector at ward level who feels obliged to regulate the pharmaceutical business, something which never existed before. In other words, the regulatory system has brought some sense of ownership and accountability. However, what is lacking is a clear mechanism to strengthen and streamline the regulatory changes with the existing system at the lower level."*

Discussions with the TFDA officials underscored the need to address the various constraints and challenges which impede effective functioning of CFDCs. Among the proposed measures were continued sensation of the councils on the decentralized TFDA functions; capacity development through training, follow-up, and supportive supervision; and provision of the necessary financial support and other incentives to encourage good performance. These views were captured well in the comments below by TFDA ADDO Program Manager.

*"If the CFDCs are well sensitized and capacitated technically and financially, they should be able to effectively oversee implementation of TFDA regulatory functions at the council level. We need to put in place an effective incentive mechanism to motivate the CFDCs to perform. In my opinion, the proportion of local collections which the councils retain should be reversed so that they keep 60% and retire 40% to the central level."*

### 3.3.4 Regulatory Activities

The assessment of CFDC regulatory activities paid particular attention to frequency of regulatory meetings including recording keeping, inspection of drug outlets, disciplinary measures against violators of laws and regulations, accreditation and re-accreditation of ADDOs, and complaints against decisions taken by the committees. Consequently, the assessment focused on the following performance indicators:

- Number of CFDC meetings conducted in the past two years
- Availability of minutes of CFDC meetings
- Number of inspections conducted by CFDCs in the past two years
- Number of drug outlets inspected in the past two years
- Number of illegal sources/outlets identified to be dealing with medicines
- Number of outlets closed or given warnings due to serious or tolerable regulatory violations
- Number of days it takes CFDCs to approve new ADDO applications

**(a) Routine Regulatory Meetings**

According to ADDO regulations, CFDCs are required to meet quarterly and submit their activity reports four times a year to TFDA and copy RFDC. However, the assessment noted some laxity in certain councils in conducting the meetings. For example between July 2010 and June 2012, Morogoro and Korogwe CFDCs conducted only one meeting each (perhaps that was during the program establishment); while Mbinga and Mbarali CFDCs conducted two meetings each. However, Singida and Kibaha managed to hold at least six meetings each. By mid-2012, both councils had convened two CFDC meetings each.

The meetings are an important indicator of vibrancy of the CFDCs. While a number of CFDCs mentioned lack of funds as the major reason for not conducting meetings as recommended, the councils routinely make collections on behalf of TFDA and retain 40% of the collections to support basic CFDC activities including the meetings. However, some councils misappropriate the funds.

In terms of record keeping, most of the committees, especially those that have met only once since establishment, did not have any minutes of meetings. On the contrary, those that have been meeting more frequently (Kibaha and Singida) had minutes of their meetings.

**(b) Inspection of Drug Outlets**

It was learnt that the committees neither carried out inspections regularly nor followed up with WHC to do so. For example, between July 2010 and June 2012 (FY2010/2011 and FY2011/2012) most of the CFDCs (Mbinga, Morogoro Rural, Singida Urban, Korogwe and Mbarali) had conducted only 2 inspections each, out of the recommended 8 for the two-year period. However, in the first quarter of FY2012/13, Singida Urban conducted an additional inspection.

The only exception is Kibaha District Council which managed to conduct a record 12 inspections between July 2010 and June 2012, and another 4 inspections in the first quarter of FY2012/13. The outstanding performance was attributed to the fact that the council embarked on the ADDO program implementation in that period and was therefore obliged to carry out several inspections as part of the ADDO accreditation procedure. Nevertheless, the fact that the council was able to conduct 4 other inspections in the immediate post-ADDO-rollout period was a clear sign of commitment to enforcing ADDO regulations.

On the other hand, the assessment was interested in knowing the number of drugs outlets covered during the various inspections conducted by different CFDCs. However, this could not be readily established due to lack of records. Most of the CFDCs did not have minutes of regulatory meetings; neither did they have reports from inspection visits.

When the CFDC members were asked about the most common regulatory violations observed during inspections, the following were mentioned: ADDO dispensers not wearing a white coat, service delivery by untrained dispensers, dispensing of prescription medicines without prescription, and untidy premises. However, in Kibaha District only minor violations were reported and dispensers were said to be performing generally well. None of the six CFCDs assessed reported existence of any illegal sources of medicines in their areas.

**(c) Enforcement of Regulations**

With regard to enforcement of regulations, the assessment wanted to identify disciplinary measures taken against drug outs operating in contravention of set regulations and standards, such as issuance of written warning or closure of shops due to gross violation of regulations and standards. Even though CFDC members interviewed claimed that the necessary disciplinary measures were taken culprits, such claims could not be verified by the assessment team due to lack of documentary evidence. According to regulations, whenever a closure order is issued to any outlet, the order has to be in writing and a copy filed with the responsible CFDC and TFDA. While in the field, the assessment team did not come across any such orders, nor any shop closed through CFCD's directive, despite prevalence of regulatory violations across the assessment area.

Consequently, the assessment concluded that enforcement of regulations is generally weak in most councils; a situation largely blamed on the tendency by individual inspectors, CFDCs and even TFDA to refrain from taking stern measures against serious violations. The tendency defeats the purpose of conducting inspections, especially when there are no serious consequences to regulatory violations.

**(d) Accreditation and Re-Accreditation of ADDOs**

According to the ADDO regulations, CFDCs have a mandate to handle all preliminary ADDO accreditation procedures and submit approved applications to TFDA for further review and issuance of accreditation certificates. The CFDCs are required to do this in close collaboration with WHCs which receive the applications first, interview drug shop owners and dispensers, visit the proposed business location and submit the applications to the CFDC with comments.

The assessment found out that although CFDCs were carrying out this activity, most of them allowed applicants to bypass the WHC by submitting applications directly to the CFDC. It was also learnt that about 20% of applications forwarded by CFDCs to TFDA for final approval are rejected mainly due to lack of supporting documents including minutes of CFDC meetings approving the applications.

Moreover, the assessment found out that the ADDO accreditation process is considerably slow. Most CFDCs mentioned that it takes them about 6-8 weeks to process applications and forward them to TFDA for further action. On the other hand, it takes TFDA about the same period of time to review and approve the applications. Thus, the accreditation lead-time (from receipt of an application by CFDC to final approval by TFDA) is about 12-16 weeks. While there could be other reasons for the slow process of accreditation, the following three major factors determine efficiency of the process: (i) frequency of

CFDC meetings, (ii) availability of funds for the meetings, and (iii) compliance with accreditation requirements.

According ADDO regulations, CFDCs are supposed to meet at least once every quarter. However, the assessment revealed that most of the committees are not meeting regularly mainly due to lack of funds. Assuming that the meetings took place as scheduled, it would take the CFDC up to 12 weeks to review ADDO applications and forward them to TFDA for further action. Moreover, the assessment revealed that about 20% of applications submitted to TFDA by CFDCs are rejected mainly due inadequate documentation (e.g. minutes of CFDC meeting approving the applications). This often delays the accreditation process and increases the waiting time.

Given the above factors, it is unlikely that CFDCs would process applications in 6-8 weeks as mentioned by most of the CFDC members interviewed, unless special meetings are called to deal with the applications or approvals done by individuals on behalf of the committee. Considering that some of the applications have been turned back before by TFDA due to lack of minutes of CFDC meetings approving the applications, it is possible that some of the approvals at the council level are done by individuals, not the committee.

The slow process of accreditation has major consequences on enforcement of regulations and overall growth of the ADDO enterprise. It defeats the very purpose of the program which aims to improve access of essential medicines in underserved areas. Moreover, the slow process of accreditation encourages illegal operation of drug shops especially those whose owners have rented premises, invested heavily and can no longer afford to wait because of the potential losses. Thus, there is a need to review the accreditation process to make it more efficient and business friendly.

Regarding re-accreditation ADDOs, the majority of CFDC officials who volunteered their views on the issue were in agreement that it would enhance adherence to regulations and standards and sustain quality of ADDO services. Most of them identified 2-3 years as a reasonable timeframe for re-accreditation.

### 3.3.5 Coordination with Key Stakeholders

The assessment found out that CFDCs were generally aware of their coordination functions with key ADDO stakeholders including TFDA, RFDC, WHC and ADDO provider associations. However, in practice, coordination with these stakeholders was seen to be weak in most areas. For example, while the preliminary process of accreditation of drug shops requires participation of the WHC, in most CFDCs, the WHC was bypassed and ADDO applications delivered directly to the CFDC. In some CFDCs, only summaries of applications were received from WHCs but not detailed activity reports especially from inspection activities. Furthermore, many CFDCs had no linkage with the RFDCs yet regulations require that they copy RFDCs, all quarterly activity reports to TFDA. Out of the six CFDCs assessed, only two submitted a report each to RFDC between July 2010 and June 2012. In overall, reporting to TFDA and RFDC was found to be very weak in the six councils.

### 3.3.6 Utilization of the Existing Financing Opportunities

Shortage of funds was identified as a major constraint to effective functioning of CFDCs. Among the major sources of funds to the committees are the 40% of TFDA collections retained by the councils, and the Basket Fund accessed through the Comprehensive Council Health Plan (CCHP). However, utilization of the retained TFDA collections is constrained by Local Government Authorities (LGAs) financial regulations which require the money to be deposited in the council's health department account (Account No. 6). Once the money is in the account, many CFDCs experience difficulties in accessing the funds due to the existing bureaucratic procedures. Some councils such as Morogoro Rural have tried the option of sending all the collections to TFDA and requesting for disbursement whenever needed by the CFDC, just to avoid the Account No. 6 route.

On the other hand, utilization of the Basket Fund for CFDC activities is hampered in most councils by lack of budgeting and integration of CFDC's priorities in the CCHP. However, Kibaha CFDC has been able to utilize the Basket Funds to implement its activities. The CFDC had its own budget of about Tsh.900,000/- in the CCHP, which was made available to the committee as planned. The committee also received funds from other council own sources allocated to the health department.

### 3.3.7 Immediate ADDO Priorities to Councils

The following issues emerged from discussions with the council officials, as the immediate priorities in strengthening functionality of CDFCs and implementation of the ADDO program:

- Training of ADDO dispensers to reduce the widespread shortage experienced in many areas;
- Changing signatories and account for depositing the 40% retention from TFDA collections so that the money can be easily accessible for implementation of ADDO related activities;
- Reviewing the proportion of the TFDA collections retained by the councils, so that 40% goes to TFDA and 60% remains in the council;
- Strengthening coordination by improving communication between TFDA and CFDCs;
- Providing identity cards (IDs) to ward inspectors so as to increase credibility of inspections at the local level.

## 3.4 ESTABLISHMENT AND FUNCTIONALITY OF WARD HEALTH COMMITTEES

Ward Health Committee (WHC) is one of the local government structures at the grassroots level. The committee is primarily responsible for coordinating all health activities in the ward. The committee is chaired by the Ward Executive Officer (WEO) and is answerable to the Ward Development Committee which oversees all development activities in the ward, health included.

Following decentralization of TFDA functions down to the ward level, the WHC is mandated to:-

- Conduct preliminary inspection and interviews to drugs outlets wishing to operate as ADDO;
- Receive, process and submit to CFDC, applications by drug outlets wishing to operate as ADDOs;
- Carry out regular inspection of all outlets providing pharmaceutical services in the ward including ADDOs, at least once in every quarter;
- Collect annual fees from drug outlets and remit the collections to the council health account; and
- Prepare and submit activity reports to CFDC on a quarterly basis;

### 3.4.1 The Situation of WHCs

During the ADDO Program rollout, at least three people were trained in each ward as local drug shop inspectors. Those trained included health facility in charge, ward health officer and an extension officer with animal science background. Ward executive officer was also trained and attended sensitization seminars on the program. All the three local inspectors were given identity cards by TFDA.

During the assessment, it was learnt that most of the ward inspectors have since been replaced by new service providers, many of whom have not been trained in the ADDO program including inspection services. Moreover, most of the local inspectors did not have basic tools such as inspection guide and identity cards. The situation is made worse in most areas by lack of funds to carry out inspection activities.

### 3.4.2 The Performance of WHCs

In analyzing performance of the WHCs, the assessment considered the following key indicators:

- Proportion of WHCs which conducted routine meetings in the past two years (July 2010 to June 2012);
- Proportion of WHCs which carried out scheduled inspections in the past two years (July 2010 to June 2012)
- Frequency of scheduled inspections by WHCs in the past two years (July 2010 to June 2012);
- Coverage of drug outlets during routine inspections by the WHC in the past two years (July 2010 to June 2012).

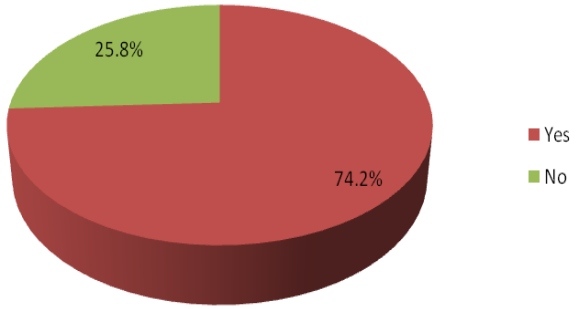
**(a) Routine WHC Meetings**

The assessment showed that WHCs meet more frequently than CFCDs despite the fact that the wards do not receive direct financial support from TFDA. Nevertheless, the meetings are not necessarily related to ADDO activities given that the WHC is structurally required to meet at least once every quarter before routine WDC meeting. However, considering that the meetings are all about health, they offer a good opportunity to discuss ADDO related issues, as correctly confirmed by WHC members who participated in the assessment. *Table 3* below highlights the proportion of WHCs which reported meeting routinely to discuss various health issues including ADDO related activities. *Figure 1* below provides an overall picture in the study area. According to the WHCs, among the ADDO issues which featured strongly in the agendas of the WHC meetings were: lack of funds and basic tools for inspection activities including inspection checklists and IDs for local inspectors; and need for training of new ward inspectors.

***Table 3: Proportion of WHCs conducting routine meetings (by region)***

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Pwani | Tanga | Singida | Morogoro | Ruvuma | Mbeya |
| Yes | 74.2% | 60.0% | 57.1% | 40.0% | 100.0% | 100.0% | 100.0% |
| No | 25.8% | 40.0% | 42.9% | 60.0% | 0.0% | 0.0% | 0.0% |
| **Total number (n)** | **31** | **5** | **7** | **5** | **6** | **5** | **3** |

*Figure 1: Proportion of WHCs conducting routine meetings (overall picture)*




### (b) Inspection Activities

With regard to inspection activities, the assessment focused on the following three indicators:

- Proportion of WHCs which carried out scheduled inspections in the past two years;
- Frequency of scheduled inspections by WHCs in the past two years;
- Coverage of drug outlets by WHCs during routine inspection

*Table 4: Proportion of WHCs conducting scheduled inspections (by region)*

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Pwani | Tanga | Singida | Morogoro | Ruvuma | Mbeya |
| Yes | 53.1% | 60.0% | 14.3% | 33.3% | 50.0% | 100.0% | 100.0% |
| No | 46.9% | 40.0% | 85.7% | 66.7% | 50.0% | 0.0% | 0.0% |
| **Total number (n)** | **32** | **5** | **7** | **6** | **6** | **5** | **3** |

*Figure 2: Proportion of WHCs conducting scheduled inspections (overall picture)*

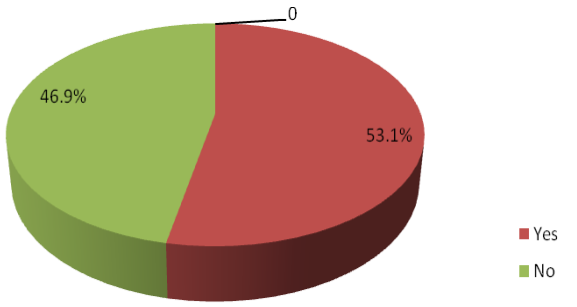


***Figure 3: Frequency of scheduled inspections by WHC in the past two years***

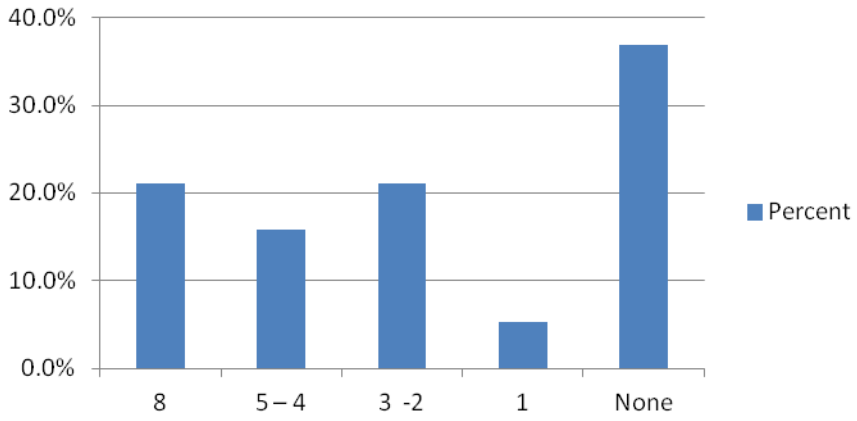
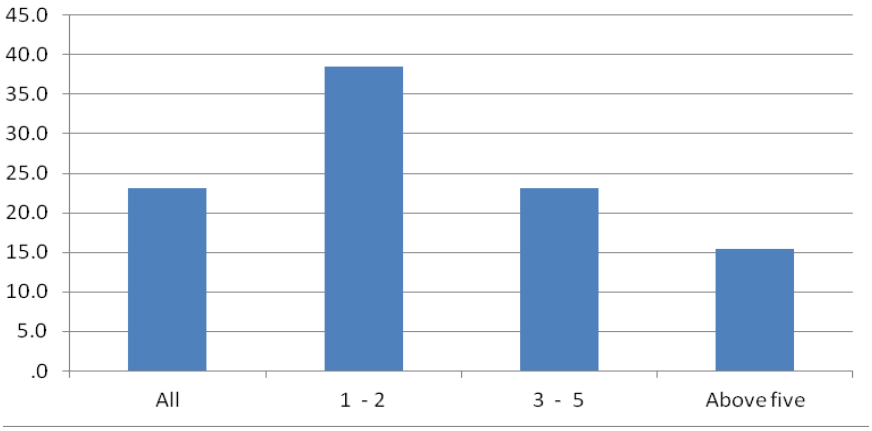



***Figure 4: Coverage of drug outlets during routine inspections conducted by WHCs in the past two years***




**(c) Important conclusions regarding WHC performance**

The following conclusions were made by the assessment regarding performance of WHCs:

- Although WHCs have no specific funding for regulatory activities, they seem to utilize financial opportunities at their disposal better than CFDCs to implement ADDO related activities. The trend projects the WHC as a more promising regulatory structure to invest in for improved regulatory oversight at the grassroots level.
- WHCs have the potential to cover a significant proportion of drug outlets during routine inspection. The assessment showed that some WHCs have been able to cover up to 100% of drug outlets in their areas despite various operational challenges including financial constraints, personnel turnover and lack of basic working tools including inspector IDs. Usually a ward has between 1-5 drug outlets, though a few have more than 5. With availability of resources, this number of shops can be covered in one to two days.

- With proper planning, the cost of local level inspection should be manageable. Usually, ward inspectors are paid between Tsh.5,000 – 10,000 as extra-duty allowance each inspection day. There are no additional costs since most inspectors walk or use bicycles to inspection sites. Thus, for the WHC to perform the 4 scheduled inspections each year, it would require between Tsh.40,000 – 80,000 as extra-duty allowance for two inspectors. Given that the average number of wards per council is about 25, the annual cost of local inspection would be about Tsh.1 -2 million only. Moreover, ward meetings need no extra funding since they are scheduled.
- In view of the above observations, regulatory agencies (TFDA/Pharmacy Council) need to carefully evaluate where to invest the available limited resources in order to strengthen regulatory oversight at the grassroots level and improve quality of pharmaceutical services to the population.

### 3.5 ADHERENCE TO REGULATORY STANDARDS

Considering that ADDO accreditation is a onetime process, the assessment wanted to determine the current physical, organizational and professional status of the ADDO enterprise several years after the outlets were accredited. A special observation form was developed that contained most of the basic regulatory requirements for an ADDO. The exercise covered a total of 128 ADDOs in the six assessment regions as shown in Table 5 below.

***Table 5: Regional distribution of ADDOs observed for regulatory adherence***

| SN | Region | District | No. of ADDOs Observed |
|---|---|---|---|
| 1. | Mbeya | Mbarali | 27 |
| 2. | Morogoro | Morogoro Rural | 22 |
| 3. | Pwani | Kibaha Rural | 16 |
| 4. | Ruvuma | Mbinga | 15 |
| 5. | Singida | Singida Urban | 27 |
| 6. | Tanga | Korogwe | 21 |
| **Total** | | | **128** |

Among the things observed were:

- Adherence to dispenser dressing code;

- Physical conditions of premises including general cleanliness, availability of hand-washing facilities, arrangement of medicines in the drug shop and availability of ADDO signpost;
- Availability of legal documents (accreditation certificate, business permit and dispenser certificate);
- Availability of regulatory tools including patient registers, inspection form/booklet, patient complaint form/booklet, expired medicines form/booklet, and approved medicines list; and
- The person who dispenses medicines in the drug shop.

During the observational visit, the assessment also took advantage of the opportunity to get dispensers' views on various regulatory issues including use of the patient register and the proposal to reintroduce re-accreditation of ADDOs.

### 3.5.1 Adherence to Dispenser Dressing Code

ADDO dispensers have a dressing code which requires them to be formally dressed at all times. This includes putting on a white coat during the whole period of stay/service delivery in the drug shop. Considering that most dispensers have been trained through a decentralized approach at the district level, the assessment wanted to find out the following, with regard to the dressing code:

- If the dispensers were formally dressed and appeared neat;
- If the dispensers had received or bought the white dispensing coat by the end of the dispenser training course; and
- If dispensers with the coat were putting it on while dispensing, and the coat was clean.

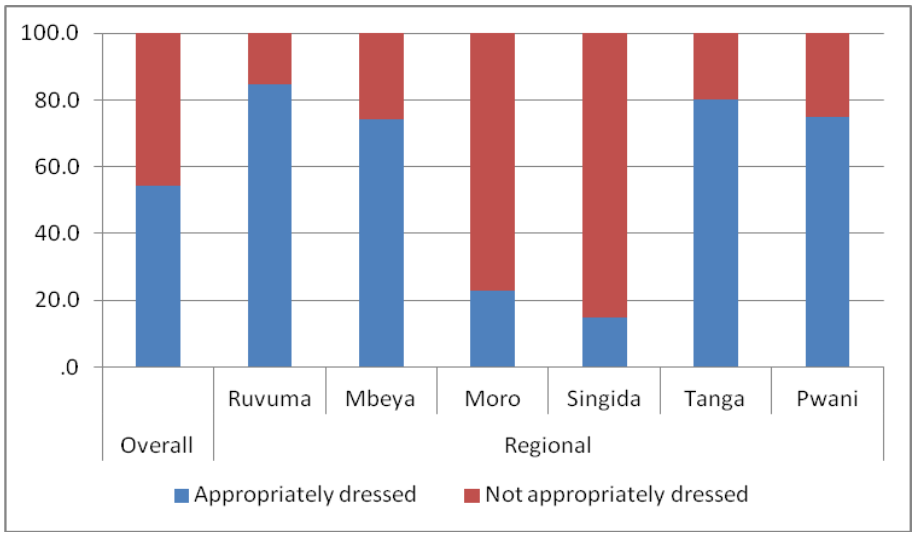
**(a) Formal Dressing**

It was observed that not all dispensers adhere to the dressing code. Only 54% of the dispensers were found formally dressed during the assessment. However, there was a significant variance between districts/regions, with dispensers in Mbinga (Ruvuma Region) posting the best performance at 84.6%, followed by Korogwe-Tanga (80%), Kibaha-Pwani (75%) and Mbarali-Mbeya (74.1%), among the good performers. On the other hand, the appearance of dispensers in Morogoro Rural (Morogoro Region) and Singida Urban (Singida Regions) was far from satisfactory, as only 22.7% and 14.8%, respectively, were formally dressed at the time of the assessment.

*Table 6: Proportion of ADDO dispensers dressing formally (by region)*

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Formally dressed | 54.4 | 84.6 | 74.1 | 22.7 | 14.8 | 80.0 | 75.0 |
| Not formally dressed | 45.6 | 15.4 | 25.9 | 77.3 | 85.2 | 20.0 | 25.0 |
| **Total** | **125** | **13** | **27** | **22** | **27** | **20** | **16** |

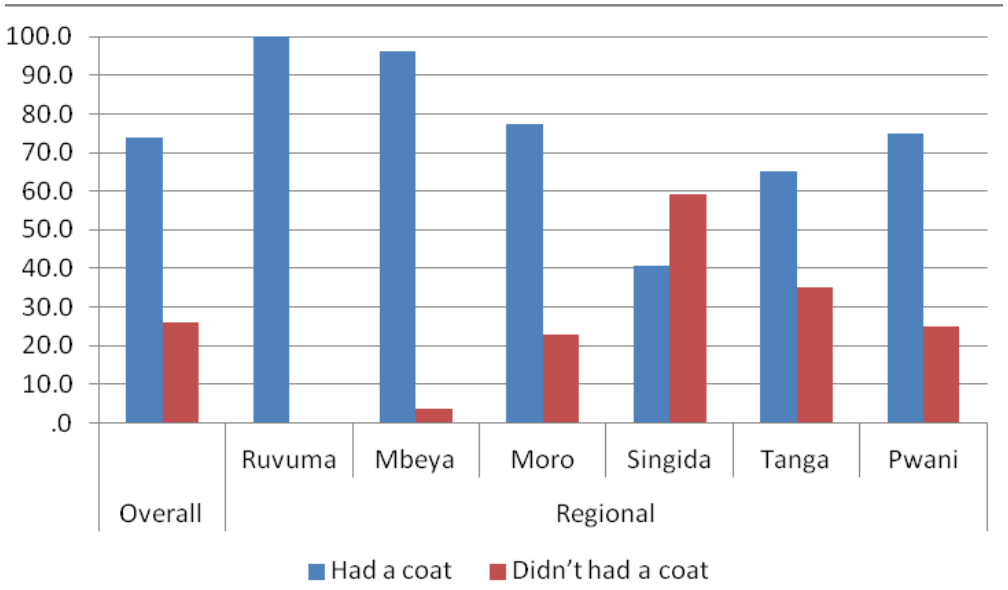
*Figure 5: Proportion of ADDO dispensers dressing formally (overall picture)*




**(b) Availability of the Dispensing Coat**

The assessment also wanted to find out if all dispensers had the dispensing coat with them in the drug shop, even if they were not putting it on at the time of the assessment. All dispensers in Ruvuma Region (100%) were found with the white coat in the shop, followed by dispenser is Mbeya (96.3%), Morogoro (77.3%), Pwani (75%), and Singida (40.7%). In overall, 74% of all ADDO dispensers had the dispensing coat with them in the drug shop at the time of the assessment.

*Figure 6: Proportion of dispensers with the dispensing coat*



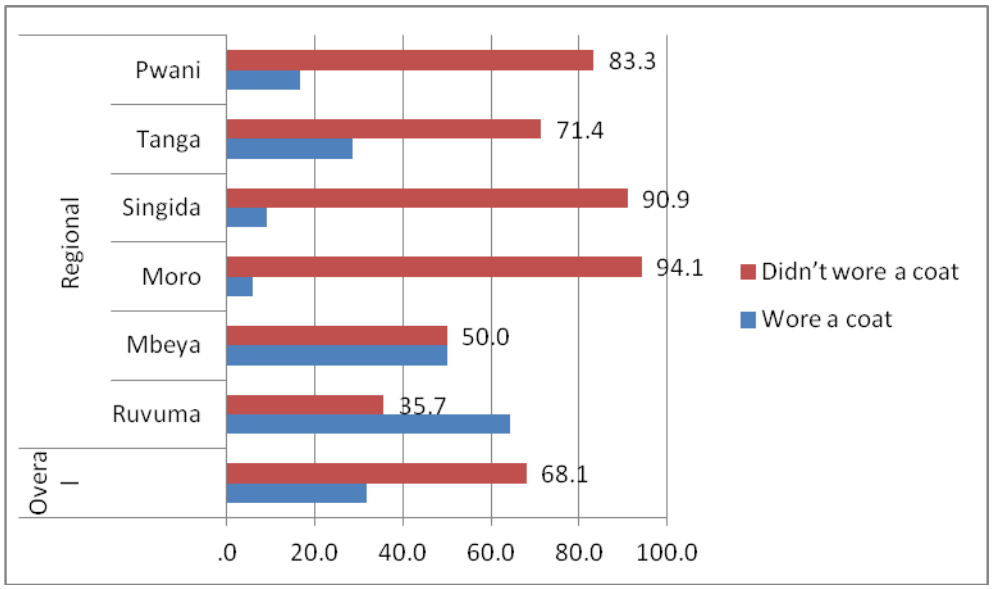

**(c) Appropriate Use of the Dispensing Coat**

Even though 74% of ADDO dispensers had the dispensing coat with them in the drug shop at the time of the assessment, only 31.9% were dressed in the coat while dispensing. However, situation was relatively better in Mbinga-Ruvuma where 64.3% of dispensers were in the coat while dispensing, but worst in Morogoro Region where a paltry 10% had it on while dispensing. Table 7 below shows the trend in the assessment area.

*Table 7: Proportion of ADDO dispensers dressed in the white coat while dispensing (by region)*

| Practice | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Morogoro | Singida | Tanga | Pwani |
| Dressed in the dispensing coat | 31.9 | 64.3 | 50.0 | 5.9 | 9.1 | 28.6 | 16.7 |
| Not dressed in the dispensing coat | 68.1 | 35.7 | 50.0 | 94.1 | 90.9 | 71.4 | 83.3 |
| **Total number (n)** | **94** | **14** | **26** | **17** | **11** | **14** | **12** |

***Figure 7: Regional pattern of the dispensing coat use by ADDO dispensers***




Asked why they were not using the dispensing coat as recommended, the most common reason given by the dispensers was that they had forgotten to do so. The assessment attributed the poor adherence such basic ADDO standards to lack of regular inspection and corrective measure to blatant violation of regulations and standards.

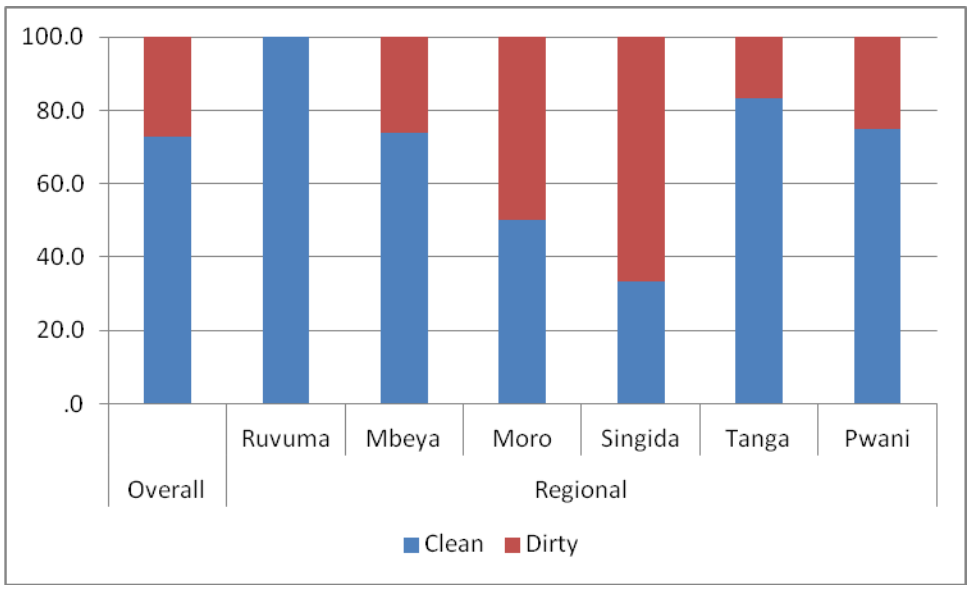
**(c) Condition of the Dispensing Coat**

The ADDO standards require that the dispensing coat must always be clean. The assessment wanted to find out the level of adherence to this requirement. About 73% of ADDO dispensers were found in a clean coat. Adherence to the standard was most impressive in Mbinga (Ruvuma Region) where all dispensers in possession of the white coat (100%) had kept it clean. However the situation was far from impressive in Singida Urban (Singida Region) where only 33.3% of the dispensers had a clean coat. The figures below highlight the trend in other districts/regions in the assessment area.

*Table 8: Proportion of ADDO dispensers with a clean dispensing coat*

| Condition of the dispensing coat | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Clean | 72.9 | 100.0 | 73.9 | 50.0 | 33.3 | 83.3 | 75.0 |
| Not clean | 27.1 | 0 | 26.1 | 50.0 | 66.7 | 16.7 | 25.0 |
| **Total number (n)** | **59** | **12** | **23** | **8** | **6** | **6** | **4** |

*Figure 8: Regional representation of ADDO dispensers with a clean dispensing coat*




### 3.5.2 Status of Premises

ADDO regulations provide minimum standards which must be maintained at all times by drug outlets. These include general cleanliness of the business premise; proper arrangement of medicines in the dispensing room, under the counters and in storage areas; availability of hand-washing facilities including water; and proper display of an ADDO signpost outside the premise to direct users to the drug shop. The following were the observations made in different areas regarding adherence to the standards.

### (a) General Cleanliness

***Figure 9: Proportion of premises regarded as generally clean (overall picture)***

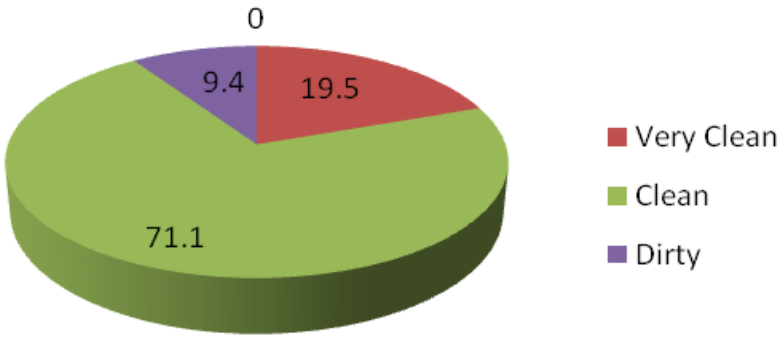



***Table 9: Proportion of ADDOs with a clean floor, walls, ceiling and shelves (by region)***

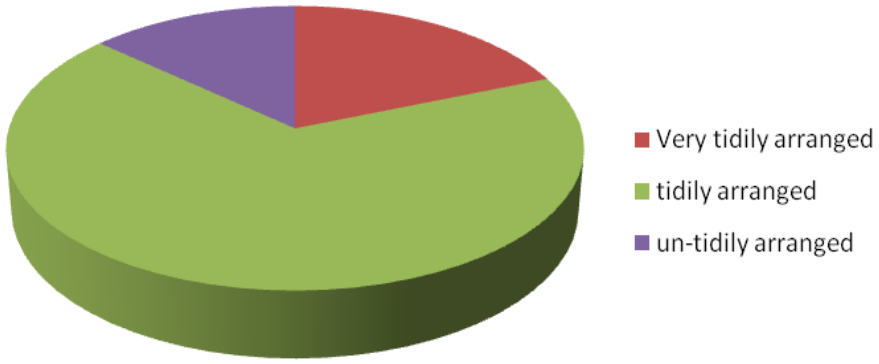
| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Very Clean | 19.5 | 33.3 | 29.6 | 9.1 | 11.1 | 4.8 | 37.5 |
| Clean | 71.1 | 66.7 | 70.4 | 68.2 | 70.4 | 90.5 | 56.3 |
| Dirty | 9.4 | 0 | 0 | 22.7 | 18.5 | 4.8 | 6.3 |
| **Total number (n)** | **128.0** | **15** | **27** | **22.0** | **27.0** | **21.0** | **16.0** |

### (b) Proper Arrangement of Medicines

***Table 10: Proportion of ADDOs with medicines properly arranged (by region)***

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Very tidily arranged | 18.9 | 26.7 | 25.9 | 13.6 | 18.5 | 10.0 | 18.8 |
| tidily arranged | 67.7 | 66.7 | 70.4 | 40.9 | 74.1 | 85.0 | 68.8 |
| un-tidily arranged | 13.4 | 6.6 | 3.7 | 45.5 | 7.4 | 5.0 | 12.5 |
| **Total number (n)** | **127.0** | **15.0** | **27.0** | **22.0** | **27.0** | **20.0** | **16.0** |

*Figure 10: Proportion of outlets with proper arrangement of medicines on shelves and under the counter (overall picture)*

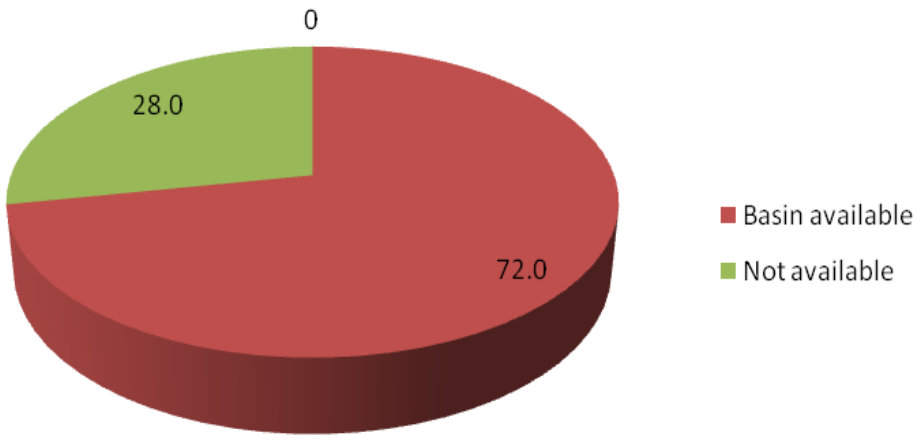



### (c) Availability of Hand-washing Facilities

*Table 11: Proportion of outlets with a hand washing basin (by region)*

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Basin available | 72.0 | 73.0 | 81.0 | 41.0 | 81.0 | 71.0 | 81.0 |
| Not available | 28.0 | 27.0 | 19.0 | 59.0 | 19.0 | 29.0 | 19.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **16** |

*Figure 11: Proportion of outlets with a hand washing basin (overall picture)*

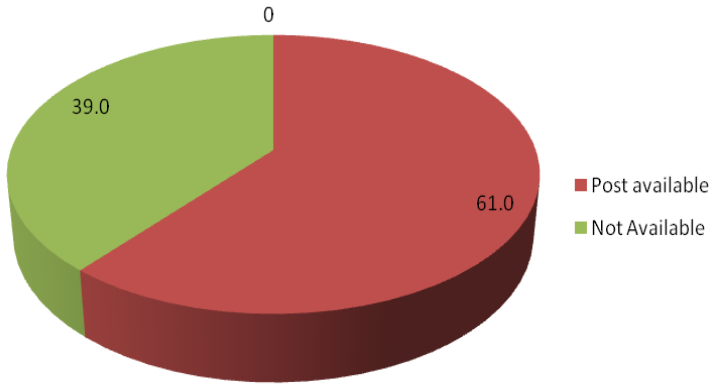


**(d)Availability of ADDO Signpost**

***Table 12: Proportion of outlets with an ADDO signpost fixed outside the shop (by region)***

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Post available | 61.0 | 100.0 | 59.0 | 64.0 | 78.0 | 24.0 | 44.0 |
| Not Available | 39.0 | 0.0 | 41.0 | 36.0 | 22.0 | 76.0 | 56.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **100** |

***Figure 12: Proportion of outlets with an ADDO signpost fixed outside the shop (overall picture)***




Major observations regarding status of premises include the following

- In overall, the assessment noted that there is generally good adherence to the set standards for ADDO premises. About 90.6% of the outlets visited were found to be clean, 86.6% had medicines properly arranged, 72% hand washing facilities, and 61% had displayed ADDO signposts as recommended.
- While most of the councils had performed generally well by adhering to the set standards for ADDO premises, the performance in Mbinga District (Ruvuma Region) was remarkable, followed by Mbarali District in the neighboring Mbeya Region. On the other hand, performance of ADDOs in Morogoro Rural was the least impressive in most of the indicators.

### 3.5.3 Availability of Legal Documents (Accreditation Certificate, Business Permit and Dispenser's Certificate)

The ADDO accreditation certificate, business permit and dispenser's certificate are the three basic legal documents every ADDO is required to have at any given point in time of formal operation. In the initial phase of the program, TFDA used to renew the accreditation certificate annually to all legally

operational ADDOs. With expansion of the program, this procedure became untenable as it meant increased workload to TFDA head office, often occasioning long delays in issuance of the certificate to detriment of the laid down regulations. Consequently, the procedure was reviewed to allow TFDA to issue the certification only once upon successful accreditation of a drug shop and the councils charged with responsibility of issuing and renewing the business permit annually to legally operational ADDOs. The dispenser's certificate is also issued once upon successful completion of the dispenser training course.

According to the ADDO regulations, every drug shop is required to display in the shop, the accreditation certificate, business permit, and a copy of the dispenser certificate. Thus, the assessment wanted to determine adherence to this regulatory requirement. The following were the observations made in the assessment area.

***Figure 13: Proportion of ADDOs with basic legal documents displayed in the shop (overall picture)***

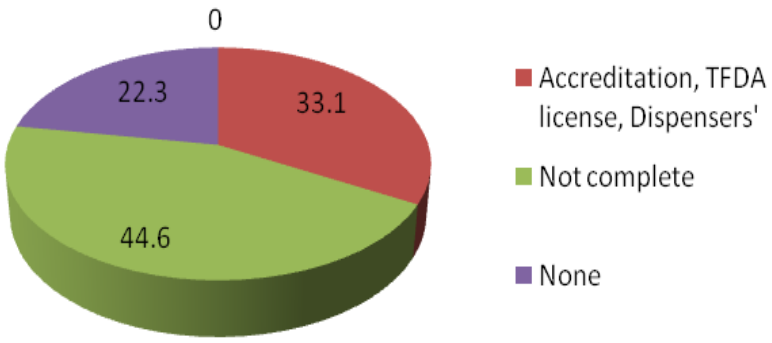



***Table.13: Proportion of ADDOs with basic legal documents displayed in the shop (by region)***

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Accreditation, TFDA Business Permits, Dispensers' Certificates | 33.1 | 73.3 | 44.4 | | 52.0 | 14.3 | 6.3 |
| Not complete | 44.6 | 26.7 | 44.4 | 47.1 | 36.0 | 61.9 | 50.0 |
| None | 22.3 | 0 | 11.1 | 52.9 | 12.0 | 23.8 | 43.8 |
| **Total** | **121** | **15** | **27** | **17** | **25** | **21** | **16** |

As indicated by *Figure 13* above, only 33% of ADDOs in the assessment areas had all the three documents displayed, 44% did not have either of the documents, and 22% did not have any of the documents. Considering that the documents define legitimate existence of the outlets, their absence should lead to closure of the shops. However, none of the shops operating without the documents was closed. When asked why they did not have the documents, some of the dispensers said the shop owner had kept documents at home, others said they had applied and paid for the documents but were yet to receive them, and the rest did not have any excuse for not having the documents.

The situation reflects laxity in enforcement of regulations by regulatory agencies at all levels and calls for more stringent action against drug shops operating without the vital legal documents. The regulatory agencies also need to attach due importance to the documents by increasing efficiency in their processing so as to seal any associated loopholes that might compromise adherence to regulations and standards. Regulatory violations such as the absence of dispenser's certificate should never be tolerated because it would give room to untrained dispensers to provide services in the drug shops.

### 3.5.4 Availability of ADDO Documentation Tools

ADDO regulations require drug outlets to have a set of documentation tools including the patient register, inspection form, patient complaint form and expired medicines' form. In addition, the outlets are required to keep with them a complete list of ADDO authorized medicines.

Apart from the patient register which is sold to ADDO providers, the rest of the tools are distributed to the providers free of charge by TFDA via CFDC. The patient register is used for recording details about clients/patients receiving care at the drug shop, including type of medicine(s) dispensed and/or services received. Copies of the patient register are printed by TFDA and distributed to district pharmacists who sells them to ADDO owners at Tsh.5,000 – 6,000 per copy.

Given the significance of the documentation tools to formal operation of ADDOs, the assessment wanted to establish their availability and use in the drug outlets. The following were the observations made by the assessment.

### (a) Availability of the Patient Register

***Figure 14: Proportion of ADDOs with the patient register (overall picture)***

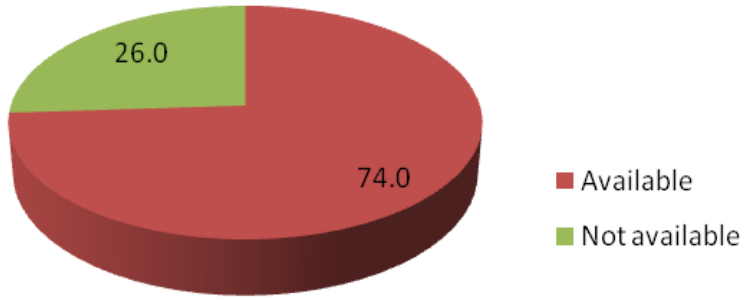
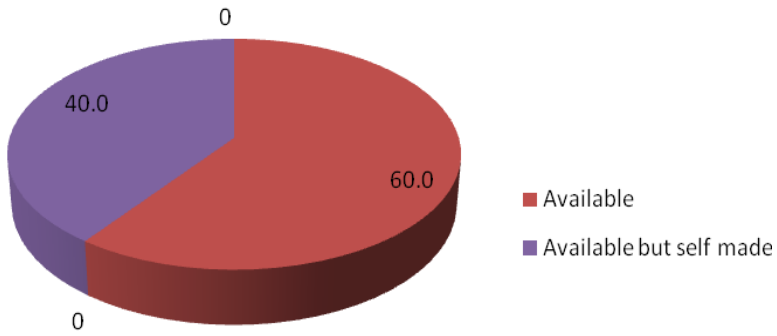



***Table 14: Proportion of ADDOs with the patient register (by region)***

| Availability of the register | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Morogoro | Singida | Tanga | Pwani |
| Available | 74.0 | 100.0 | 100.0 | 76.2 | 85.2 | 23.8 | 50.0 |
| Not available | 26.0 | 0 | 0 | 23.8 | 14.8 | 76.2 | 50.0 |
| **Total number** | **127** | **15** | **27** | **21** | **27** | **21** | **16** |

It is instructive to note that in Mbinga (Ruvuma) and Mbarali (Mbeya), all ADDOs had the patient register. However, in Mbinga it was learnt about 40% of the available registers were reproduced locally to bridge supply gap from the central level (see Figure 15 below).

***Figure 15: Proportion of ADDOs in Mbinga District with the patient register***



### (b) Use of the Patient Register

*Table 15: Proportion of ADDOs using the patient register (by region)*

| Response | Overall | Region | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| Yes | 75.8% | 81.5% | 41.2% | 100.0% | 93.3% | 73.9% | 80.0% |
| No | 24.2% | 18.5% | 58.8% | 0.0% | 6.7% | 26.1% | 20.0% |
| **Total number (n)** | **95** | **27** | **17** | **8** | **15** | **23** | **5** |

*Figure 16: Proportion of ADDOs using the patient register (overall picture)*

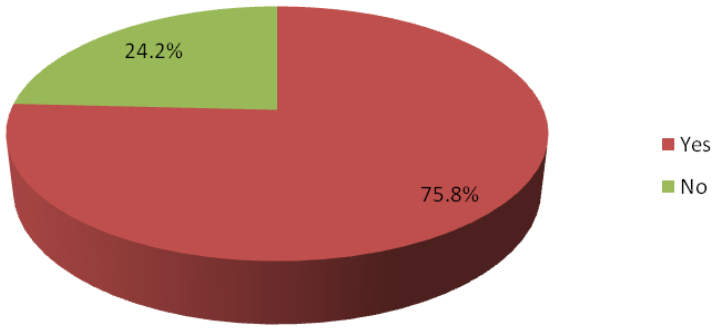
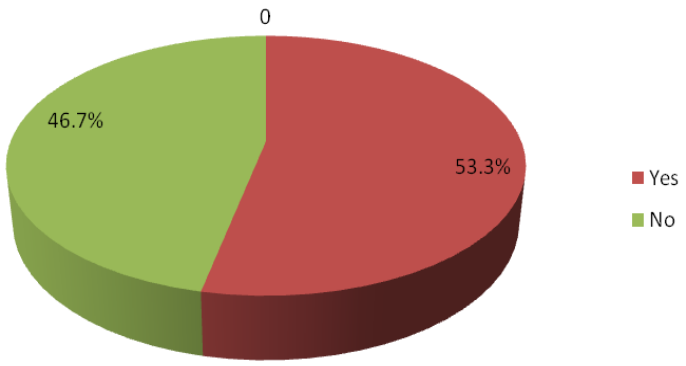



*Table 16: Proportion of ADDOs with the patient register filled out correctly (by region)*

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| Yes | 53.3% | 53.8% | 7.1% | 87.5% | 92.9% | 39.1% | 80.0% |
| No | 46.7% | 46.2% | 92.9% | 12.5% | 7.1% | 60.9% | 20.0% |
| **Total number (n)** | **90** | **26** | **14** | **8** | **14** | **23** | **5** |

*Figure 17: Proportion of ADDOs with the patient register filled out correctly (overall picture)*

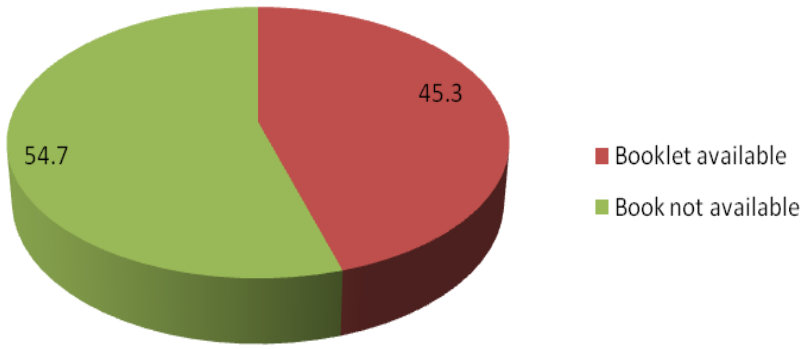


### (c) Availability of the Inspection Form

*Table 17: Proportion of ADDOs with the inspection form booklet (by region)*

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Booklet available | 45.3 | 87.0 | 74.0 | 27.0 | 52.0 | 5.0 | 25.0 |
| Book not available | 54.7 | 13.0 | 26.0 | 73.0 | 48.0 | 95.0 | 75.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **16** |

*Figure 18: Proportion of ADDOs with the inspection form booklet (overall picture)*

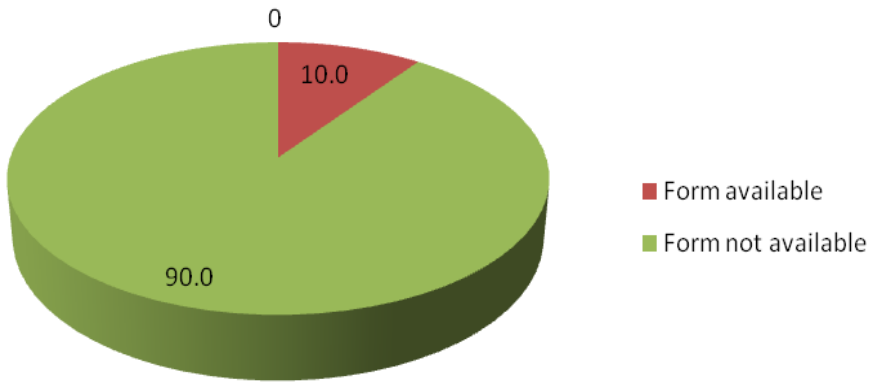



### (d) Availability of the Patient Complaint Form

*Table 18: Proportion of ADDOs with the patient complaint form booklet (by region)*

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Form available | 10.0 | 67.0 | 4.0 | 9.0 | 0.0 | 0.0 | 0.0 |
| Form not available | 90.0 | 33.0 | 96.0 | 91.0 | 100.0 | 100.0 | 100.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **16** |

*Figure 19: Proportion of ADDOs with the patient complaint form booklet (overall picture)*

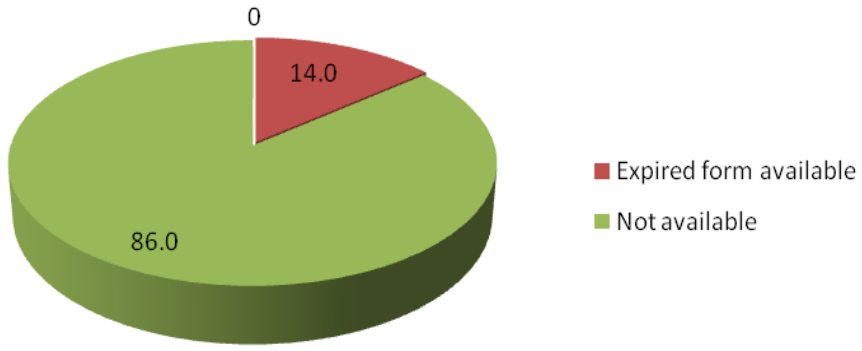



## (e) Availability of the Expired Medicines' Form

*Table 19: Proportion of ADDOs with the expired medicines form booklet (by region)*

| Description | Overall | | Regional | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| Expired form available | 14.0 | 67.0 | 7.0 | 18.0 | 4.0 | 5.0 | 0.0 |
| Not available | 86.0 | 33.0 | 93.0 | 82.0 | 96.0 | 95.0 | 100.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **16** |

*Figure 20: Proportion ADDOs with the expired medicines form booklet (overall picture)*

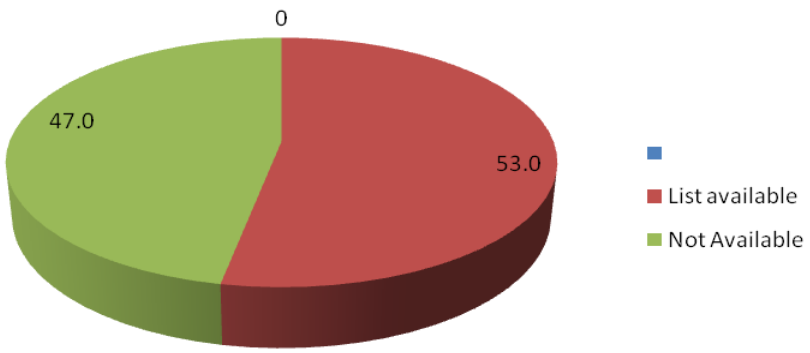


### (f) Availability of the Approved Medicines List

***Table 20: Proportion of ADDOs with the approved medicines list (by region)***

| Description | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ruvuma | Mbeya | Moro | Singida | Tanga | Pwani |
| List available | 53.0 | 93.0 | 96.0 | 27.0 | 59.0 | 19.0 | 13.0 |
| Not Available | 47.0 | 7.0 | 4.0 | 73.0 | 41.0 | 81.0 | 88.0 |
| **Total number (n)** | **128** | **15** | **27** | **22** | **27** | **21** | **16** |

***Figure 21: Proportion of ADDOs with the approved medicines list (overall picture)***




Major observations on availability of ADDO documentation tools include the following:

- Apart from the patient register found in 74% of drug outlets in the assessment area, availability of the rest of ADDO documentation tools was significantly low. Only 45.3% of the drug shops had the ADDO inspection form, 14% had the expired medicines form, and a paltry 10% had the patient complaint form. About 53% of the outlets had the list of approved ADDO medicines, which is an import document to the drug shops though not used as a documentation tool.
- Most of the tools were however available in Mbinga District (Ruvuma Region) where all ADDOs (100%) had the patient registers, 93% had the approved medicines list, the inspection form was available in 87% of the outlets, and 67% had the patient complaint form and expired medicines form.
- Mbarali District (Mbeya Region) also performed fairly well on availability of the patient register (100%), approved list of ADDO medicines (96%) and inspection form (74%); but poorly on the expired medicines form (7%) and patient complaint form (4%).

- The rest of the assessment districts in Morogoro, Singida, Tanga and Pwani performed dismally in all the indicators, with the patient complaint form completely missing in all ADDOs in Tanga, Singida and Pwani even though it was found in 9% of ADDOs in Morogoro. The expired medicines form was also missing in all ADDOs visited in Kibaha (Pwani Region).
- All the ADDO documentation tools including the list of approved ADDO medicines are produced centrally by TFDA and distributed through the councils. It was learnt that TFDA had enough stock of the tools at the time of the assessment, thus their shortage at the point of use was mainly as a result of inefficiencies in the distribution system. The distribution system is modeled on a "pull approach" whereby the district pharmacist orders and collects the tools from TFDA headquarters in Dar es Salaam and sells them to ADDO providers in the district based on demand. However, this system can only work if the pharmacist is pushed by high demand for the tools by ADDO provider; which is not always the case because most of the providers (dispensers and owners) are not fond of using them. Thus, without a strong push, even the pharmacists would not feel obliged to place orders or travel to TFDA offices to collect the tools for distribution to ADDO providers.

The observed weaknesses in distribution of the ADDO documentation tools have major implications on adherence to regulations and standards. Thus, a review of the entire system (from production to distribution) should be considered to allow the councils to play a more active role by producing the tools locally and distributing them through more efficient channels. Distributing the tools through ADDO provider associations could be a better option to relying on district pharmacists whose hands are already full with several technical responsibilities. This option could also be a good source of revenue to the associations, more so if they were to be allowed to put a certain mark-up on the buying price of the tools from the council.

### 3.5.5 Who Dispenses in ADDO?

The majority of ADDO dispensers are holders of primary school education certificate with one year of training at a regional or mission hospital as nurse assistant. A few of them have also been trained by private hospitals or private auxiliary medical schools. There are, however, dispensers who have higher medical training qualifications such as full nursing officers, clinical or retired medical personnel. All such cadres undergo a five-week training to qualify as an ADDO dispenser recognized by regulatory authorities. Any other person who has not successfully undergone the five weeks dispenser training course does not qualify to work in ADDO.

Informed by this understanding of a legitimate ADDO dispenser, the assessment wanted to find out who actually dispenses in practice. It was learnt that 14% of ADDOs did not have a trained dispenser (see Figure 22 below). The situation was worse in Morogoro Rural and Kibaha districts where 32% and 31% of the dispensers, respectively had not attended the ADDO training; but slightly better in Korogwe and Singida Urban where only 17% and 8% of the dispensers, respectively, had not been trained. However, in Mbarali and Mbinga districts, all the ADDOs visited had a trained dispenser (see Table 22 below).

***Figure 22: Proportion of dispensers who attended ADDO training (overall picture)***

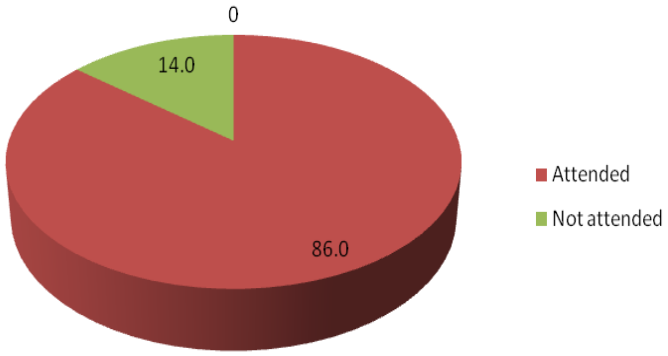



***Table 21: Proportion of dispensers who attended ADDO training (by region)***

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| Attended | 86.0 | 100.0 | 68.0 | 69.0 | 100.0 | 92.0 | 83.0 |
| Not attended | 14.0 | 0.0 | 32.0 | 31.0 | 0.0 | 8.0 | 17.0 |
| **Total number (n)** | **121** | **25** | **22** | **16** | **14** | **26** | **18** |

Availability of ADDO trained dispenser is critical to promoting adherence to regulations and standards, and maintaining quality of services. It is also a major requirement for accreditation. Thus, provision of ADDO services by untrained dispensers is a clear indication of inefficiency in the inspectorate system. It is instructive to note that Morogoro Rural which performed poorly in most indicators including inspections had the highest proportion of untrained dispensers providing services in ADDOs (31%). Ironically even Kibaha Rural which carried out inspections regularly, also had an equally high proportion of untrained dispensers (31%) working in ADDOs, an indication that the inspections are not effective.

The inefficiencies in the inspectorate system and the observed violation of regulations cannot be blamed on the councils alone but TFDA as well, since neither of the regulatory actors is committed to taking stern measures against those found violating regulations. On the other hand, the widespread presence of untrained dispensers in ADDOs underscores the need for training of more dispensers in the affected areas to minimize shortage of the personnel and enhance adherence to regulations and standards.

### 3.5.6 ADDO Dispensers' Opinions on Emerging Regulatory Issues

There have been discussions at various levels on the need for re-accreditation of ADDOs a strategy for enhancing adherence to regulations and standards and maintaining implementation quality of the ADDO program. Before an outlet is accredited as an ADDO, it is subjected to several regulatory procedures to ensure that it has the necessary capacity to provide quality products and services to the population. The original idea of the program was that accreditation status of the drug outlets would be reviewed periodically to ensure adherence to the set regulations and standards. However, due to operational challenges, the procedure was reviewed, giving way to a "one-time" accreditation by TFDA and annual renewal of the ADDO business permit by the local government authority (council).

Nevertheless, observations made from various field visits including this assessment indicate that adherence to regulations and standards has been slowly going down, largely because of inadequate regulatory oversight at various levels, and partly because the stringent conditions under which the drug outlets got accreditation no longer apply in issuing the annual business permit. Consequently, proponents of re-accreditation think that the process of accreditation should be repeated periodically to allow regulatory authorities to ascertain that outlets have adhered to regulations and maintained implementations standards, before giving them clearance to continue with the business.
The other emerging issue is the on-going contentious debate by different stakeholders on relevance of the ADDO patient register and whether its continued use as a regulatory tool is feasible. The register captures basic information about ADDO clients including name, age, type of medicine or supply bought, prescription source ( if it is a prescription medicine), as well as dosage instruction and quantity given. It also records the price at which a particular product was sold to the client and shows the signature of the dispenser who provided the services.

However, several field observations have shown that most dispensers are not using the register as recommended. This was confirmed by this assessment which revealed that only 53.3% of ADDOs filled

out the register correctly. Moreover, not all patients/customers served are recorded in the register, for different reasons. Lack of cooperation by clients has been widely documented. Some of the clients refuse to provide their names and addresses for undisclosed reasons. On the other hand, some ADDO owners discourage their dispensers from recording all visits and sales due to tax implications. Furthermore, some dispensers avoid using the tool since the process is time consuming and increasing waiting for clients attending the shop.

In view of the situation, questioned have been raised by different stakeholders at the programming level about usefulness of the system considering that the information collected through the patient register, is, in most cases, incomplete, inaccurate and does not reflect frequency of client visits as well as sales volumes. Moreover, there is no reliable system for processing the data beyond the point of collection and the end-user of the information is not clearly defined.

In view of the above concerns, the assessment sought to understand ADDO dispensers' perceptions of client register with regard to its relevance, alongside the re-accreditation idea. Consequently, the assessment posed the following two questions to the dispensers on both issues:

- Should ADDOs be subjected to re-accreditation?
- Should the patient register still be used?

### (a) Dispensers' Opinion on Re-accreditation of ADDOs

***Table 22: Proportion of ADDO dispensers who support re-accreditation (by region)***

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| Yes | 73.7% | 68.0% | 68.4% | 62.5% | 64.3% | 84.6% | 88.9% |
| No | 20.3% | 24.0% | 15.8% | 31.3% | 35.7% | 15.4% | 5.6% |
| I don't know | 5.9% | 8.0% | 15.8% | 6.3% | 0.0% | 0.0% | 5.6% |
| **Total number (n)** | **118** | **25** | **19** | **16** | **14** | **26** | **18** |

*Figure 23: Proportion of ADDO dispensers who support re-accreditation (overall picture)*

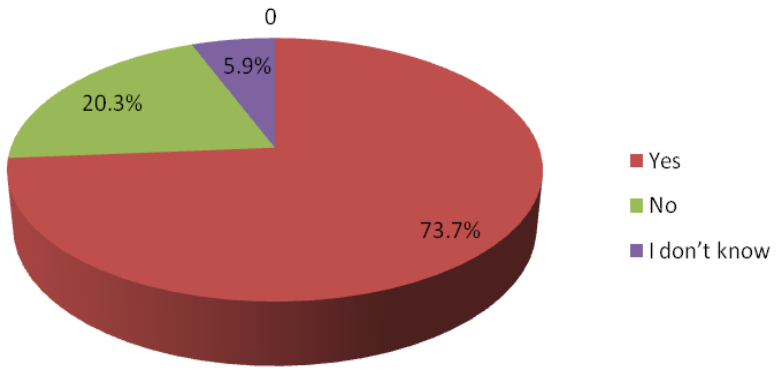
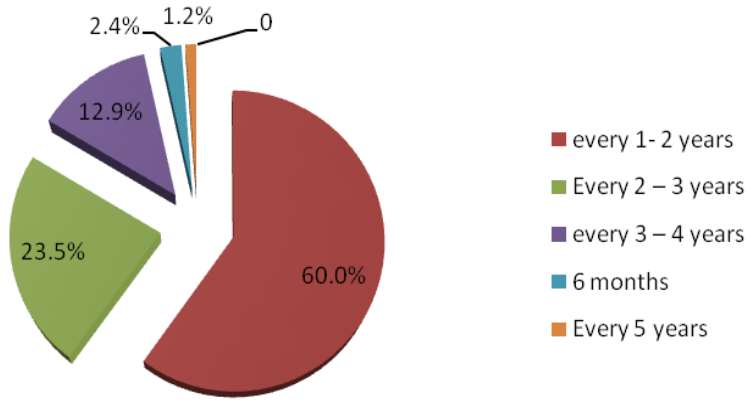



*Table 23: Preferred re-accreditation intervals (by region)*

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| every 1- 2 years | 60.0% | 61.1% | 81.8% | 50.0% | 44.4% | 45.5% | 80.0% |
| Every 2 – 3 years | 23.5% | 38.9% | 9.1% | 40.0% | 33.3% | 18.2% | 6.7% |
| every 3 – 4 years | 12.9% | 0.0% | 9.1% | 10.0% | 0.0% | 31.8% | 13.3% |
| 6 months | 2.4% | 0.0% | 0.0% | 0.0% | 22.2% | 0.0% | 0.0% |
| Every 5 years | 1.2% | 0.0% | 0.0% | 0.0% | 0.0% | 4.5% | 0.0% |
| **Total number (n)** | **85** | **18** | **11** | **10** | **9** | **22** | **15** |

*Figure 24: Preferred re-accreditation intervals (overall picture)*




The results above show that the re-accreditation idea is very popular with ADDO dispensers. About 74% the dispenser approve of the idea, with 60% of the respondents suggesting that it should be carried out at intervals of 1-2year. Of the remaining 40%, about 24% preferred the process to take place every

3-4 year, 13% were in favor of 3-4 years, 2% (6 months) and 1% (5 years). The popular opinion was that re-accreditation would go a long way to enhance compliance with regulations and standards and improve quality of services provided by ADDOs to the population. Some of the ADDO providers (owners and dispensers) mentioned that the process would provide regulatory agencies with an opportunity to flash out illegal outlets including those operating without trained dispensers. Furthermore, most dispensers associate re-accreditation with opportunities for re-training/continuous education and would therefore prefer to have the process carried out as frequently as 1-2 years.

### (d) Dispensers' Opinion on Continued Use of the Patient Register

***Figure 25: Proportion of dispensers who support continued use of the patient register***

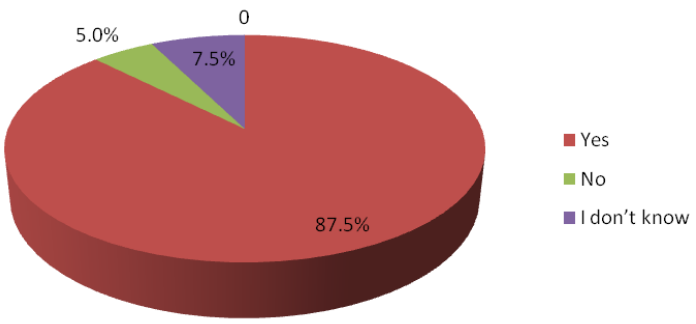



***Table 24: Proportion of dispensers who support continued use of the patient register (by region)***

| Response | Overall | Regional | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mbeya | Morogoro | Pwani | Ruvuma | Singida | Tanga |
| Yes | 87.5% | 100.0% | 71.4% | 68.8% | 100.0% | 92.3% | 88.9% |
| No | 5.0% | 0.0% | 4.8% | 18.8% | 0.0% | 3.8% | 5.6% |
| I don't know | 7.5% | 0.0% | 23.8% | 12.5% | 0.0% | 3.8% | 5.6% |
| **Total number (n)** | **120** | **25** | **21** | **16** | **14** | **26** | **18** |

The findings above show that the majority of dispensers (87.5) prefer continued use of the patient register. In Mbinga and Mbarali districts, virtually all the dispensers interviewed were happy with the register system. When asked if they wanted any modifications in the content, the majority said they were comfortable with the tool in its current form. Those in support of the register system cited its usefulness to both the care-seeker and dispenser. They explained that because the tool documents the

type of medicine given to the client as well as instructions on how to use it, the dispenser can always refer to the records in case the client experiences any problem with the medicine.

Nevertheless, all the respondents were in agreement that the process of completing the register is tedious and time consuming for a busy outlet, delays service delivery and increases client waiting time. Perhaps the regulatory authorities (TFDA and PC) should review the tool to come up with a minimum set of information which can be easily collected by dispensers and put into effective use by relevant stakeholders. Unless the purpose of collecting the information is well understood by ADDO providers (owners and dispensers) and a two-way feedback mechanism established between the providers and regulatory authorities, proper recording of the information would remain a challenge.

### 3.6 ROLE OF ADDO PROVIDER ASSOCIATIONS IN STRENGTHENING THE REGULATORY SYSTEM

Since inception of the ADDO Program, drug shop owners and dispensers have been encouraged to form associations as a platform through which they can speak in one voice on ADDO related issues; empower each other economically; and ensure sustainable delivery of quality medicines and services to the population through the concepts self-regulation and peer supervision.

Informed by this understanding of the associations' role, the assessment wanted to determine contribution of the associations to strengthening the ADDO regulatory system. To achieve this, key informant interviews were conducted with selected association officials to understand their opinion on the following issues:

- Adherence of ADDO providers to regulations and standards;
- Responsibility of the associations in promoting compliance with regulations and standards;
- Impact of the ADDO regulations to the ADDO enterprise;
- Inspection of ADDOs including frequency, coverage and the inspector behavior;
- Enforcement of ADDO laws, regulations and standards by regulatory authorities; and
- Re-accreditation of ADDOs.

About half of the association officials interviewed (50%) believed that ADDO providers were performing well in terms of adherence to regulations, 25% thought they were doing very well, while the remaining 25% had reservations about their performance citing existence of some errant providers who continue to operate in contravention of the laid down laws, regulations and standards, while tarnishing

reputation of the business. Among the common violations widely mentioned were dispensing of medicines by untrained dispensers and selling of expired, stolen and unauthorized medicines.

The respondents acknowledged that associations have a responsibility to support regulatory efforts by educating their members of the importance of complying with regulations and standards, promoting peer supervision, and strengthening collaboration with regulatory authorities in various ADDO activities. It was learnt that some of the associations had already embarked on collaboration efforts by holding meetings with CFDCs periodically to discuss ADDO implementation issues, inviting council officials to major events organized by the associations such as annual general meetings, and advocating for permanent representation of the associations in the CFDC.

Regarding impact of ADDO regulations and standards on the ADDO enterprise, the association officials mentioned that the business has changed for the better, noting that ADDOs enjoy greater trust by consumers than ever before since the business is legally recognized, quality of services has improved and operations of the shops are more transparent compared to the situation before introduction of the ADDO program.

However, the officials acknowledged that the quality of ADDO services can only be maintained through provision of the necessary technical support to ADDO providers, routine inspections and stern action against serious violation of regulations and standards. The officials noted that most inspections conducted by the regulatory agencies are not regular and do not cover all drug outlets, leaving room for errant outlets to continue with business as usual. They further observed that lack of stringent action by regulatory authorities against serious regulatory violations was compromising adherence to regulations and standards.

None of the association officials interviewed confirmed knowledge of any shop in their locality which had been closed for gross violation of regulations, and called to question the commitment of regulatory authorities to full enforce of the ADDO laws and regulations. Concerns were also raised about the conduct of a few inspectors who tend to compromise their integrity by behaving in unethical manner. However, the majority of the respondents (75%) seemed to be happy with the manner in which inspections are conducted.

Regarding re-accreditation ADDOs, 75% of the association officials supported the measure, citing its potential to restore the deteriorating standards of some ADDOs including physical condition of premises

and dispensing practices. About half (50%) of those in support of the re-accreditation idea suggested that process should be conducted at intervals of 3-4 years.

### 3.7 SUMMARY OF FINDINGS AND REFLECTIONS

The decentralized regulation system is widely perceived by stakeholders as the most feasible approach to regulatory oversight, bearing in mind the vastness of the country and rapidly increasing number of ADDOs expected to reach at least 10,000 by the time national rollout of the program is completed. This perception was reaffirmed by findings from the assessment which confirmed that TFDA has extremely limited capacity to centrally execute its regulatory oversight mandate. For example, in the fiscal years 2010/2011 and 2011/2012, the agency was able to conduct only two inspections covering about 100 ADDO (50 per inspection). This represents only 0.33% of the total number of ADDOs registered by June 2012. The decentralized system allows regulatory agencies (TFDA and Pharmacy Council) to delegate their mandate and functions to the lower level regulatory structure and makes it possible to cascade the necessary technical support to each level. The following were the major observations made regarding functionality of the system:

**(i)** The regulatory structures established under the decentralized framework (RFDC, CDFC and WHC) are yet to function optimally partly because of inadequate understanding of the decentralization concept hence weak ownership of the delegated TFDA mandate and functions in some areas; inadequate prioritization and allocation of financial resources for regulatory activities; limited technical capacity of the councils (some councils do not even have qualified pharmacist); and high turnover of trained inspectors especially at the ward levels; among other factors.

**(ii)** Weak ownership of the decentralized TFDA mandate and functions was most noticeable at the regional level. This was mainly associated with a structural weakness in the l government's overall approach to the national policy of decentralization by devolution, which tends to give the councils more responsibility, authority and resources, as the custodians of development programs and social service delivery at the community level. As a government agency, TFDA's approach to decentralization of its powers and functions is aligned to the "council-based decentralization". Consequently, regulatory authorities at the regional level feel somehow marginalized by this structural framework, hence have not been proactive enough in executing their regulatory mandate which includes supervising councils under their watch.

**(iii)** Poor coordination and reporting between regulatory committees was most significant between RFDCs and CFDCs. According to TFDA regulations, CFDCs are required to copy RFDC all their

quarterly activity reports to TFDA. However, the assessment showed that this is not the case in most areas. Out of the six CFDCs assessed, only two submitted a report each to RFDC in the entire period between July 2010 and June 2012. The situation can be attributed to the above-explained structural weakness, as some councils tend to ignore the poorly resourced and somewhat "toothless" RFDCs.

**(iv)** The assessment also showed that although WHCs had no specific funding for regulatory activities, they seemed to utilize the limited financial opportunities at their disposal better than CFDCs and RFDCs to implement ADDO related activities. About 74% of the WHCs reported conducting all scheduled meetings in FY2010/11 and FY2011/12 (i.e. between July 2010 and June 2012), and 53.1% carried out all scheduled inspections in the same period. In some areas, the WHC inspections covered up to 100% of drug shops in their areas, compared to 0.33% of ADDOs covered by TFDA inspections in the same period. At the council level, nearly all the CFDC assessed (5 out of 6) had conducted only 2 inspections each out of the 8 scheduled inspections in the two-year period. Proportion of ADDOs covered during the council inspections could be established due to lack of inspection reports. Consequently, the trend projects WHC as a more promising regulatory structure to invest in to improve regulatory oversight at the grassroots level.

**(v)** The observed poor coordination between regulatory structures coupled with weak reporting, inefficiency in conducting regulatory meetings and inspections, and lack of a reliable system for training potential ADDO providers (new applicants), all have a direct bearing on efficiency of the ADDO accreditation process. The assessment showed that the ADDO accreditation lead-time (from application by a drug shop owner to issuance of accreditation certificates by TFDA) is extremely long. The process takes between 16-24 weeks, yet according to the TFDA Client Charter the process should be completed within 10 days. This is an extremely long waiting time for a serious entrepreneur wishing to invest in the ADDO enterprise. It was learnt that CFDCs contribute further to the delays by sending to TFDA applications without the necessary documentations such as a summary of inspection reports and minutes of CFDC meetings approving the applications. The practice accounts for 20% of applications rejected by TFDA. The process is also characterized by malpractices such as direct submission of applications to CFDCs without involvement WHCs as per regulations. By bypassing WHC in the accreditation process, CFDCs are only weakening ownership of the program at the ward level but eroding authority of the WHC as a regulatory structure. It is therefore incumbent on the Pharmacy Council to intervene to restore order and efficiency in the ADDO accreditation process, as it takes over management of the program from TFDA.

**(vi)** The assessment further showed that full enforcement of regulations by all the relevant authorities (TFDA, RFDC, CFDC and WHC) remains a major challenge despite some inspections taking place,

albeit intermittently. It was observed that no punitive measures are taken against ADDO providers found with serious regulator violations. While in the field, the assessment team did not come across any written warnings, closure orders, or a single shop closed by the regulatory authorities for gross violation of regulations, yet serious offenses were prevalent in the assessment area. For example, about 14% of the ADDOs visited in the assessment area were managed by untrained dispensers. The situation was worse in Morogoro Rural and Kibaha districts where 32% and 31% of dispensers found in the shops, respectively, had not attended any ADDO training. Only 53% of the drug shops had the list of authorized ADDO medicines, 45.3% had the ADDO inspection form, 14% had the expired medicines form, and a paltry 10% had the patient complaint form. Moreover, only 33.1% of the ADDOs visited had all the three legal documents for formal operation of the business (i.e. accreditation certificate, business permit and dispenser certificate) displayed in the shop, 44.6% had an incomplete set of the documents, and 22.3% did not have any of the documents. Considering that the documents define lawful existence of the outlets, their absence should have led to immediate closure of the shops.

**(vii)** On the other hand, the ADDOs performed considerably well in maintaining physical status of premises and observing dispenser dressing code. About 91% of the shops visited during the assessment were rated as clean, 86.6% had medicines properly arranged, 72% had hand-washing facilities, and 61% had strategically placed the ADDO signpost outside the shop for easy identification of the outlet by the consumers and regulatory authorities. Regarding dispenser dressing code, 54% of the dispenser were formally dressed, 74% had the white dispensing coat with them in the shop, even though only 31.9% had the coat on while dispensing. About 73% of the coats were clean.

**(viii)** Among the six assessment districts, Mbinga in Ruvuma Region performed exceptionally well in most of the indicators touching on adherence to ADDO regulatory standards, as indicated in Table 25 below.

***Table 25: Adherence to ADDO regulatory standards***

| SN | Indicator | Overall picture (All six districts) | Situation in Mbinga (Ruvuma Region) |
|---|---|---|---|
| **(a) Availability of a trained dispenser** | | | |
| 1. | Proportion of dispensers who attended ADDO training. | 86% | 100% |
| **(b) Adherence to dispenser dressing code** | | | |
| 2. | Proportion of dispensers dressed formally. | 54% | 84.6% |
| 3. | Proportion of dispensers who kept the white dispensing coat in the drug shop. | 74% | 100% |
| 4. | Proportion of dispensers with a clean dispensing coat. | 73% | 100% |

| SN | Indicator | Overall picture (All six districts) | Situation in Mbinga (Ruvuma Region) |
|---|---|---|---|
| 5. | Proportion of dispensers dressed in the white coat while dispensing. | 31.9% | 64.3% |
| **(c) Status of the ADDO premise** | | | |
| 6. | Proportion of ADDOs rated as generally clean. | 90.6% | 100% |
| 7. | Proportion of ADDOs with medicines properly arranged. | 86.6% | 93.4% |
| 8. | Proportion of ADDOs with hand-washing facilities. | 72% | 73% |
| 9. | Proportion of ADDOs with the ADDO signpost properly placed outside the shop. | 61% | 100% |
| **(d) Availability of legal documents (accreditation certificate, business permit and the dispenser certificate)** | | | |
| 10. | Proportion of ADDOs with all the three legal documents displayed inside the drug shop. | 33.1% | 73.3% |
| 11. | Proportion of ADDOs with an incomplete set of the documents displayed inside the shop. | 44.6% | 26.7% |
| 12. | Proportion of ADDOs with none of the legal documents displayed inside the shop. | 22.3% | 0% |
| **(e) Availability and use of ADDO documentation tools** | | | |
| 13. | Proportion of ADDOs with the patient register. | 74% | 100% |
| 14. | Proportion of ADDOs filling out the patient register. | 75.8% | 81.5% |
| 15. | Proportion of ADDOs filling out the patient register appropriately (as recommended). | 53.3% | 92.9% |
| 16. | Proportion of ADDOs with the inspection form booklet | 45.3% | 87% |
| 17. | Proportion of ADDOs with the patient complaint form booklet. | 10% | 67% |
| 18. | Proportion of ADDOs with the expired medicines form booklet. | 14% | 67% |
| 19. | Proportion of ADDO with the list of approved ADDO medicines. | 53% | 93% |
| | | | |

The outstanding performance in Mbinga could be attributed to the fact that the district, being part of the ADDO pilot area (Ruvuma Region), received adequate attention in terms of training of ADDO providers, follow-up after training, routine supportive supervision and regular inspection visits to ensure adherence to the set regulations and standards. Experience has shown that these interventions, if well implemented, can have long term impact on business practices of ADDO providers.

**(ix)** Regarding re-accreditation of ADDOs, the assessment showed that the idea is popular with the majority of stakeholders at different levels. Among the primary stakeholders (ADDO owners and dispenser), 74% of the dispensers gave the idea an affirmative alongside 75% of ADDO provider association official (mainly drug shop owners). However there were differences among different stakeholder groups on the preferred intervals for the re-accreditation. The majority of dispensers

(60%) mentioned 1-2years, the majority of CFDC officials supported 2-3 years, and the majority of ADDO owners were in favor of 3-4 years. It is instructive to note that dispensers would like see the process conducted most frequently than any other group, mainly because they association re-accreditation with opportunities for re-training and continuous education/career development. However, all the stakeholders were in agreement the process would go a long way to enhance adherence to regulations and standards and promote sustainable delivery of quality medicines and services to the population.

**(x)** Concerning the contentious debate on whether use of the patient register should be continued or discontinued, the assessment showed that 85% of the primary user of the tool (ADDO dispensers), preferred continued use of the tool. Those in support of the tool said it serves as a useful reference to the dispenser incase a client experiences any problem with the medicine dispensed. The register captures the name of the client, age, type of medicine or supply given, prescription source (if it is a prescription medicine), as well as dosage instruction and quantity given. It also records the selling price of a particular product to the client and takes the signature of the dispenser who provided the services. However, all the respondents were in agreement that the process of completing the register is tedious for a busy outlet, delays service delivery and increases client waiting time. Consequently, there is a need for the regulatory agencies (TFDA and PC) to review the tool to come up with a minimum set of information which can be easily collected by dispensers and put into effective use by relevant stakeholders.

**(xi)** Lastly, the assessment demonstrated potential role of ADDO provider associations in strengthening the regulatory system by educating their members of the importance of complying with regulations and standards, promoting peer supervision, and strengthening collaboration with regulatory authorities in various ADDO activities. It was learnt that some ADDO associations had already embarked on collaboration efforts by periodically holding joint meetings with CFDCs to discuss ADDO implementation issues, inviting council officials to major events organized by the associations (e.g. annual general meeting) and advocating for permanent representation of the associations in CFDCs.

# 4. RECOMMENDATIONS AND OPTIONS

In view of the findings from the assessment, two sets of recommendations (short and long term) were put forward and various strategic options identified as part of the way forward.

**(a) Short term recommendations**: Those envisaged to have immediate impact on implementation of the ADDO program and are unlikely to be resource intensive in terms of technical and financial input, and can thus be considered for immediate implementation by relevant institutions/ authorities.

**(b) Long term recommendations**: Those envisaged to have long-term impact on implementation and sustainability of the ADDO program, are potentially resource intensive in terms of technical and financial input, and may thus require wider consultations and careful planning toward successful implementation.

## 4.1 SHORT TERM RECOMMENDATIONS

The short term recommendations underscore the need to strengthen leadership of regulatory committees at the regional and council levels (RFDC and CFDC) in order to make them more effective, improving management of the 40% allocation of TFDA collections to the councils for efficient utilization of the funds, addressing immediate training needs of ADDO providers, harmonizing TFDA and PC regulatory functions in order to improve coordination with regulatory structures at the lower levels, introducing re-accreditation of ADDO to enhance adherence to regulations and standards, and improving the quality of inspections by making them more result-oriented. The specific recommendations were as follows:

**(i)** In view of the observed inactiveness of regulatory committees, TFDA and the Pharmacy council should review the functional structure of both RFDC and CFDC to give key personnel in the health department more responsibility in management of the committees. Accordingly, RFDC should be chaired by Regional Medical Officer (RMO) assisted by Regional Pharmacist as secretary to the committee. Likewise, CFDC should be chaired by District Medical Officer (DMO) assisted by District Pharmacist (DP) as secretary to the committee. The District Health Officer (DHO) could also be considered as a co-secretary with the DP.

**(ii)** Considering the challenges experienced in the collection and management of regulatory fees, the Pharmacy Council (PC) in consultation with TFDA, should review the system to give PC direct

responsibility for collection and disbursement of the funds to both councils and wards, based on planned activities and performance of the regulatory committees.

**(iii)** In view of the widespread shortage of ADDO dispensers and high demand for both the dispenser and drug shop owner training courses, the Pharmacy should prioritize this critical need by providing councils with the necessary technical support to conduct the short courses, even as it explores long term solutions to meeting training needs of the ADDO program.

**(iv)** Following enactment of the Pharmacy Act 2011 and the subsequently transfer of the overall regulatory oversight mandate from TFDA to the Pharmacy Council, both agencies need to move with speed to harmonize their functions at all levels including coordination with the lower level regulatory structures (RFDC, CFDC and WHC) so as to avoid duplication of efforts and ensure optimal utilization of the available limited resources for implementation regulatory activities.

**(v)** Bearing in mind the overwhelming support among different stakeholders for introduction of re-accreditation as a strategy for enhancing adherence to regulatory standards and maintaining the quality of ADDO services, the Pharmacy Council should consider initiating a re-accreditation program preferably in a phased manner, starting with the first ADDO regions. This should go hand in with consumer awareness and education to stimulate demand for quality ADDO services.

**(vi)** In view of the observed infectiveness of ADDO inspections and weak enforcement of regulations, all the responsible regulatory structure (TFDA, PC, RFDCs, CFDCs and WHCs) should work closely together to make inspections more result-oriented and hold inspectors at all levels accountable for any omission or inaction on serious regulatory violations by ADDO providers.

### 4.2 LONG TERM RECOMMENDATIONS

Three major long term recommendations came up from the assessment. The recommendations focus on the need for a long term solution the chronic shortage of trained ADDO dispensers, sustainable financing of regulatory activities at all levels, and effective documentation, monitoring and evaluation of ADDO activities.

**(i)** Considering the widespread shortage of ADDO dispensers nationally, coupled with the declining number of nurse assistants who are the main candidates for the council-based short dispenser training course, the Pharmacy Council needs to fast-track the on-going efforts to institutionalize a one-year dispenser training course that to open doors for other potential candidates including form-four leavers who have passed in science subjects, to become dispensers. The one-year

training program is also expected to support development of a clear career path for successful candidates and ensure steady supply of qualified dispensers in the market.

**(ii)** In view of the financial constraints widely reported by RFDCs, CFDCs and WHCs as a major obstacle to effective functioning of the regulatory system, the Pharmacy Council in collaboration other stakeholders, should develop a strategy for sustainable financing of regulatory activities at all levels. The strategy should among other things, prioritize improving collection, disbursement and utilization of regulatory fees; cutting down expenditure at central level and channeling more resources to the grassroots where regulatory efforts are needed most; and increasing utilization of other existing opportunities including those at the council level such as the Health Sector Basket Fund accessible through integration of regulatory activities in the Comprehensive Council Health Plan (CCHP).

**(iii)** Considering the acute shortage of basic data about the ADDO program at all levels (central, regional, council and ward), the Pharmacy Council should develop a sound monitoring and evaluation system capable addressing various documentation and information needs of the levels. Establishment of a national database routinely updated and easily accessible by all levels, will go a long way to support crucial regulatory functions and facilitate effective planning, implementation, as well as monitoring and evaluation of ADDO activities. The system should also clearly define monitoring and evaluation roles for both PC and TFDA in light of the transfer of ADDO program management to PC, and create a mechanism for joint M&E between both agencies to cater for specific interests of different program components which fall under each agency's mandate.

## 4.3 STRATEGIES FOR THE FUTURE

Apart from putting forward the two sets of recommendations discussed in sections 4.1 and 4.2 above, the assessment identified various strategies for strengthening the regulatory system and ensuring sustainable delivery quality of ADDO services. The strategies focus on two key areas:

(a) Strengthening operations of regulatory structures at all levels to improve regulatory oversight; and

(b) Enhancing sustainability of the ADDO program by addressing major operational needs of the ADDO enterprise.

### 4.3.1 Strengthening Operations of Regulatory Structures

The assessment showed that most regulatory structures are not functioning optimally. Regulatory meetings are not taking place as scheduled, inspections are irregular and ineffective, coordination is

generally weak, financial accountability is inadequate, and documentation and reporting are insufficient. Consequently, the assessment identified various strategies to be deployed by the national and local levels, to address the observed functional inefficiencies of regulatory structures and improve regulatory oversight at all levels (*see Tables 26 below*).

***Table 26: Strategies for strengthening functionality of regulatory structures***

| SN | Strategy | Context /Rationale |
|---|---|---|
| **(a) National Level** | | |
| 1. | Strengthening human resource capacity of the Pharmacy Council (PC) to enable it to effectively execute its regulatory oversight mandate. | The enactment of the Pharmacy Act 2011 and the subsequently transfer of overall regulatory oversight mandate for all pharmaceutical services in the country including the ADDO program management, from TFDA to PC, has major implications on institutional capacity of the PC. Thus, investment in human resource needs of the PC, to match up its technical capacity with the new mandate, is inevitable. |
| 2. | Developing a comprehensive financing strategy to enable PC to execute its new regulatory mandate effectively. | Availability of reliable financing is critical to effective implementation of regulatory functions. Currently, the PC has no reliable financial support to support both operational and regulatory activities at any level. As an immediate measure, the PC should work towards getting government budgetary support through the treasury to enable it execute its new enormous regulatory oversight mandate, other than relying on the current "hand out" style of financing from the MOHSW through the block budget for councils operating under the ministry. As a long term measure the PC needs to develop a comprehensive financing strategy which explores all possible options. |
| 3. | Re-orientation of RFDCs to make them more conversant with their regulatory roles. | The assessment showed that members of some RFDCs were not well conversant with the regulatory mandate and responsibilities of the committee mainly because they were new and had not received the necessary orientation. The situation was partly blamed for weak performance of the affected committees. |
| 4. | Regular production and timely distribution of regulatory tools to all levels. | Shortage of essentials regulatory stools (e.g. inspection form & checklist, inspector IDs and patient registers, among others) were reported in a number of areas during the assessment. The shortages were mainly attributed to irregular production (especially of IDs) and inefficient distribution of the materials. |
| 5. | Strengthening coordination between PC/TFDA and lower level regulatory structures. | Weak coordination between regulatory structures was noted as a major problem at all levels. At the national level, the transfer of the overall regulatory oversight mandate from TFDA to PC means that both agencies must coordinate even more closely to ensure a smooth transition and an uninterrupted flow of services. Weak reporting to the central level by RFDCs and CFDCs also calls for closer coordination with the lower level structures. |
| 6. | Establishing a performance-based | The central level has an obligation to monitor performance of the lower level regulatory structures on all indicators including utilization of financial |

| SN | Strategy | Context /Rationale |
|---|---|---|
| | financing for regulatory activities. | resources on regulatory activities. The assessment showed that financial accountability is a major problem in most councils largely because the current system of resource allocation through automatic deduction of regulatory fee collections (40%) is not based on planned activities and performance of the councils. Furthermore, the system does not recognize the contribution of the ward level to the regulatory system. Consequently, the proposed system should include a mechanism to ensure that every regulatory fully accounts for funds provided for specified regulatory activities. The system should also include the ward level. |
| 7. | Centralizing collection and management of regulatory fees. | Collection and timely remittance of regulatory fees to TFDA by councils was noted as a major challenge. The proposed strategy envisages that the centralized system will boost collections by allowing ADDO providers to pay directly through PC bank account or use a designated m-Money platform or an equivalent electronic money transfer system to make payment. The proposed system would also enable PC to disburse funds to RFDCs, CFDCs and WHCs, based on planned activities and performance of each committee. |
| 8. | Improving planning and budgeting for efficient utilization of resources. | It was observed that the central level has a tendency of allocating itself more funds to support even less effective activities such as the central level inspections which hardly cover 1% of ADDOs, at the expense of essential regulatory activities at the grassroots level such as ward level inspections. This is a pointer to the need for a result-based planning and budgeting to ensure optimal use of the available limited resources. |
| **(b) Local Level** | | |
| 1. | Restructuring and repositioning CDFC to give DMO, DP and DHO more responsibility in management of the committee. | CFDC is currently chaired by the District Executive Director (DED) who is a senior manager with several responsibilities for all departments. Experience has shown that most DEDs hardly find time for CFDC activities, given their busy schedules. This adversely affects functioning of the committees. Thus, shifting the committee's leadership from the office of DED and putting it directly under the health department in the hands of District Medical Officer (DMO) as the chairperson, District Pharmacist (DP) as the secretary and District Health Officer (DHO) as the co-secretary, is expected the give the committee a new impetus especially in addressing technical issues concerning the ADDO program. |
| 2. | Integrating RFDCs in the Regional Health Management Team (RHMT) to increase its visibility and access to resources. | The assessment indicated that RFDCs are the least active of all the regulatory committees and their role is not well recognized at the regional level. Because of the limited visibility, most RFCDs do not receive due attention from key decision at the regional level and are mostly starved of resources to carry out basic regulatory activities. Positioning RFDC as a sub-committee of RHMT is envisaged to give it the much needed visibility and enable it gain access to funds allocated to RHMT. |
| 3. | Integrating CFDC and WHC regulatory activities in the Comprehensive Council Health Plan (CCHP) | All CFDCs which participated in the assessment reported that the 40% of regulatory fee collections retained by the councils is barely enough to meet financial demands of the delegated regulatory activities. Integration of the regulatory activities in the CCHP is seen an opportunity to make use other financing opportunities within the council such as the Health Sector Basket Fund accessible through the CCHP. |

| SN | Strategy | Context /Rationale |
|---|---|---|
| 4. | Strengthening coordination and reporting between regulatory structures at all levels | Coordination and reporting were noted during the assessment as two major areas of weakness in the decentralized regulatory system. It was learnt that WHCs are not sending their activity reports to CFDCs as recommended, CFDCs are sidestepping WHCs in the ADDO accreditation process, RFDCs are not following up regulatory activities of CFDCs, and CFDCs are not copying RFDCs quarterly activity reports to the central level as recommended. Holding meetings and joint planning are some of the approaches which could be employed to strengthen coordination between regulatory structures at all levels. |

### 4.3.2 Enhancing Sustainability of the ADDO Program

Strategies for enhancing sustainable of the ADDO program focus on the following three major operational needs of ADDOs, considered critical to sustainable delivery of quality medicines and services to the population:

- Availability of trained dispensers;
- Adherence to ADDO regulations and standards; and
- Financial security of the enterprise.

Table 27 below highlights the specific strategies.

***Table 27: Strategies for enhancing sustainability of the ADDO Program***

| SN | Strategy | Context /Rationale |
|---|---|---|
| 1. | Institutionalizing long term dispenser training to ensuring sustainable production and supply of qualified dispensers in the market. | The district-based short dispenser training has been the sole system for producing ADDO dispensers. However, the system has not been able to meet all the training needs of the program. Moreover, the short course is currently faced with a major of shortage of nurse assistants (the main candidates) following the decision by the government to phase out the cadre. While continuation of the short term training is inevitable as an intervening measure to meeting immediate dispenser needs, a longer institutionalized course with more flexible entry requirements is seen as a more feasible option to sustainable production of the dispensers. A training curriculum for a one-year dispenser course has been developed and awaits approval by the Ministry of Health and Social Welfare (MoHSW). Accelerating implement of the program will require that Pharmacy Council closely follows up approval of the curriculum and makes deliberate efforts to interest relevant public and private training institutions to take up the course. On the other hand, continuation of the short district-based short dispenser course will require PC to explore other acceptable entry qualifications as directed by ADDO regulations, in order to avert a potential dispenser shortage crisis. |
| 2. | Promoting public private partnership | Public private partnership (PPP) is a major national policy for development and a key strategy in health promotion. The design of the ADDO program is |

| SN | Strategy | Context /Rationale |
|---|---|---|
| | in addressing both short and long term training needs of the ADDO program. | premised on this policy, and its deployment as a strategy has seen ADDO providers contribute significant amount of funds through a cost-sharing mechanism towards training of both drug shop owners and dispensers. Introduction of the long term dispenser training course offers a unique opportunity to expand the partnership by involving private training institutions in delivery of the course. |
| 3. | Strengthening institutional capacity of regulatory structures to enhance enforcement of regulations. | The assessment showed that enforcement of regulations is weak in most areas as inspections are ineffective and no stringent actions are taken against serious regulatory violations. The weakness was mainly attributed inadequate capacity of regulatory structures to conduct effective inspections and lack of accountability on the part of regulatory authorities. Section 4.3.1 above offers rich insights on how to strengthen operations of the regulatory structures towards improved regulatory oversight. |
| 4. | Introducing a re- accreditation program to promote adherence to regulatory standards. | The assessment revealed overwhelming support among various ADDO stakeholders, with the majority of dispensers suggesting that it should be conducted every 1-2 years. Other suggested intervals were 2-3 (by the majority of TFDA and CFDC officials) and 3-4 years (by the majority of ADDO owners. All the stakeholders were in agreement that the strategy will enhance adherence to regulations and standards, and promote sustainable delivery of quality medicines and services to the populations in ADDO catchment areas. |
| 5. | Supporting establishment of ADDO provider associations to empower the providers economically and promote private sector participation in sustaining the ADDO program. | The role of ADDO provider associations has been discussed since inception of the ADDO program. The associations offer a unique opportunity to empower the members economically through establishment of self-help Savings and Credit Cooperatives (SACCOs); engagement in other income generating activities and networking with local financial institution for flexible loan facilities to expand the ADDO business. Experience from the assessment showed that the associations also offer a unique platform for collaboration with other stakeholders in the ADDO program. It was leant that some associations in the assessment areas have already started holding routine meetings with council authorities to address various operational needs of the ADDO program, and their potential to bolster the private sector participation in long term sustainability of the program is getting noticed. |
| | | |

# 5. STAKEHOLDERS' RECOMMENDATIONS

In September 2012, the findings and recommendations from the assessment were dissented at a national conference organized by MSH in collaboration with the Pharmacy Council and TFDA. The conference took place in Tanga and brought together stakeholders from all levels in the country. The purpose of was to update the stakeholders on implementation status of the ADDO and share the findings and recommendations from a number of studies conducted by different contractors on various components of the program.

Part of the conference's brief was to review the contractors' findings and recommendations, and come up with priority interventions with the potential to improve implementation quality of the program and enhance its long term sustainability. Table 28 below highlights the identified interventions for strengthening the ADDO regulatory systems and the implementation plan.

***Table 28: Priority Interventions toward strengthening the ADDO regulatory system***

| Intervention | Activities | Feasibility Ranking | Responsible Institution | Time Frame |
|---|---|---|---|---|
| 1. Reviewing ADDO regulations to reflect the transfer of the overall regulatory oversight mandate from TFDA to PC. | • Constitute a small technical team consisting of representative from PC, TFDA, MoHSW and MSH to initiate the review process and come up with a zero draft by November 2012.<br>• Convene a larger stakeholders' meeting to review the draft and build consensus on contentious issues by December 2012.<br>• Disseminate the revised draft and initiate the subsequent legal steps. | High Effort/ High Impact | MOHSW, PC , TFDA, MSH | 6 - 12 months |
| 2. Reviewing the system for collecting the regulatory fees and disbursement of the collections to councils. | • Coordinate collection of the business permit fee from the central level. | Low Effort/ High Impact | PC, MSH | Within 6 months |
| | • Disbursement of the funds based on planned activities. | | PC, TFDA | To start in 1year |
| | • Review the amount paid by ADDO to determine its adequacy. | | PC, ADDO Associations | Immediately |
| 3. Integrating regulatory activities in the Comprehensive Council Health Plan. | • Lobby and advocate to councils to include ADDO regulatory activities in the CCHP. | Low Effort/ High Impact | PC | Continuous/Long term |
| 4. Periodic re-accreditation of | • Initiate the process in the first regions (Ruvuma, Morogoro, Rukwa, Mtwara). | High Effort/ | PC , CFDC | Annually |

| Intervention | Activities | Feasibility Ranking | Responsible Institution | Time Frame |
|---|---|---|---|---|
| ADDOs | | High Impact | | |
| | • Issue business permits in other regions based on annual inspection reports. | ‘’ | PC, CFDC | Annually |
| 5. Reinforcing the leadership and management of CFDCs. | • Review the composition and leadership structure of the committee. | High Effort/ High Impact | PC, TFDA, LGAs, and other relevant partners | Within 1 year |
| 6. Strengthening coordination between the central level and local government authorities. | • Utilize the quarterly TFDA zonal meetings to get feedback from the lower levels. | Low Effort/ High Impact | TFDA, PC, LGAs | Quarterly |
| | • Participate regularly in the Association of Local Government Authorities in Tanzania (ALGAT) Annual Conference | ‘’ | TFDA, PC, LGAs | Annually |
| 7. Strengthening the ADDO monitoring and evaluation (M&E) system. | • Review the existing M&E framework to determine specific TFDA and PC roles, as well as joint roles. | Low Effort/ High Impact | PC, TFDA and other partners | Within 1 year |
| | • Implement the redesigned M&E framework | ‘’ | ‘’ | ‘’ |
| 8. Reviewing the ADDO medicines list periodically to accommodate new therapeutic changes and consumer needs. | • Establish mechanism for periodic review of the ADDO Medicines List | HE/HI | PC, MOHSW, LGA and Other relevant Partners | Within 1 Year |
| 9. Strengthening the capacity of WHCs to carry out effective inspections. | • Conduct inspection trainings to ward inspectors. | High Effort/ High Impact | PC, LGAs, Partners | Within 3 years |
| | • Provide essential inspection tools to ward inspectors (ID cards, guidelines, checklists and inspection forms). | ‘’ | PC, TFDA | Within 1 year |
| | • Develop a mechanism for funding ward inspections. | Low Effort/ High Impact | PC, TFDA, LGAs and Partners | Within 1 year |
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