MINISTRY OF HEALTH

TANZANIA FOOD AND DRUG AUTHORITY

REPORT OF THE ASSESSMENT OF THE EFFECTIVENESS OF THE DUKA LA DAWA MUHIMU (DLDM) REGULATORY SYSTEM AND ACCEPTABILITY OF THE PROGRAMME IN RUVUMA REGION

FEBRUARY, 2005.

TABLE OF CONTENTS

ABBREVIATION

ADDO	Accredited Drug Dispensing Outlet
CHMT	Comprehensive Health Management Team
CPM	Centre for Pharmaceutical Management
DC	District Commissioner
DDTC:	Distric Drug Technical Committee
DLDM:	Duka la Dawa Muhimu
DMO	District Medical Officer
HQ	Headquarters
MoH	Ministry of Health
MSD	Medical Store Department
MSH	Management Science for Health
PORALG	Presidents Office regional Administration and Local Government
RC	Regional Commissioner
RDTC	Regional Drug Technical Committee
RHMT	Regional Health Managent Team
RMO	Regional Medical Officer
TFDA	Tanzania Food and Drugs Authority
USA	United States of America
WHC	Ward Health Committee
WHsC	Ward Health sub-Committee

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EXECUTIVE SUMMARY

The Accredited Drug Dispensing Outlet (ADDO) "Duka la Dawa Muhimu" programme is a pilot project launched in Ruvuma region in 2003 by the Ministry of Health through TFDA in collaboration with the American non-profit organization known as Management Science for Health/ Centre for Pharmaceutical Management (MSH/CPM).

Following completion of the pilot project, MSH has conducted a assessment to evaluate whether the programme has achieved the anticipated goals in line with the previously conducted baseline assessment. However, the assessment did not incorporate areas related to effectiveness of the DLDM regulatory system. In view of this TFDA decided to conduct a parallel assessment to measure the effectiveness of the enforcement system and acceptability of the programme.

The assessment was conducted by personal administration of structured questionnaires to randomly picked 50% of wards, members of the RDTC, DDTC and WHsC. Others respondents were DLDM owners and dispensers. The information gathered from the assessment was consolidated under formulated criteria geared towards assessing the effectiveness of the DLDM regulatory system and acceptability of the programme.

The result of the assessment indicates that between 80-99% of the RDTC, DDTC and WHsC members interviewed were of the opinion that the DLDM regulations were adequate in terms of the suitability of licensing procedures; enforcement set up and decentralized enforcement. On adequacy of composition of the RDTC, members of the RDTC were not in favour of the composition, as they wanted more members to be included. On the other hand majority of the RDTC and DDTC were in favour of the existing composition of the DDTC and WHsC. However for the purpose of checks and balance dropping out of the Regional and Districts Commissioners from the respective Committees was recommended

One hundred percent of all categories of respondents indicated acceptance of the DLDM programme.

Basing on the findings, a number of factors were identified as limiting for efficiency, effective and sustainability of the programme. Such factors include; high cost of running the programme and lack of provisions in the DLDM regulations prohibiting committee members to engage in DLDM business. Another limitation is inability to sustain training of DLDM dispensers to meet ever-increasing demand.

As a result of the successes so far attained, it is recommended that the programme be extended to other parts of Ruvuma region and be rolled out in other regions.

1.0 INTRODUCTION

The Accredited Drug Dispensing Outlet (ADDO) "Duka la Dawa Muhimu (DLDM)" programme is a pilot project launched in Ruvuma region in 2003 by the Ministry of Health through Tanzania Food and Drugs Authority (TFDA) in collaboration with an American non-profit organization known as Management Sciences for Health/Centre for Pharmaceutical Management (MSH/CPM) based in Boston, U.S.A. The main objective of the programme is to improve accessibility by the community to quality, safe, effective and affordable drugs with particular emphasis to the rural and peri-urban population where health service delivery is a problem.

Before embarking to this programme a baseline assessment was conducted in both Ruvuma and Singida regions in 2001 to determine the levels of health services focusing on accessibility by the community to quality, safe, effective and affordable drugs. The assessment involved pharmacies, health centres, dispensaries and part II shops. Among the findings was the existence of about 4,600 part II shops all over the country of which 118 were in Ruvuma region. The contribution of part II shops regarding accessibility to drugs was found to be enormous.

Besides the significant contribution by Part II shops were found to have the following shortfalls:

i. Inadequate qualified staff to dispense drugs
ii. Inadequate assurance to quality, safe and effective drugs at any point in time
iii. Poor dispensing practices
iv. Inadequate assortment of drugs to meet patient needs
v. Stocking of unauthorized drugs.
vi. Uncertainty of the price of drugs
vii. Inadequate regulatory control

Following the above findings a project proposal was developed so as to revamp the scenario. In this regard a net work of DLDMs was established in Ruvuma region on pilot basis. The programme was launched on 11th August 2003 by the Minister for Health, Hon. Anna Abdalah in Songea. Singida region was taken as control sample.

The DLMD programme is being implemented under technical support of MSH/CPM through Strategies for Enhancing Assess to Medicines (SEAM)

Programme. TFDA realized that to a certain extent the above-mentioned shortfalls were largely attributed to weak regulatory system. In this regard the Authority in collaboration with Ruvuma regional authority devised and implemented DLDM regulatory mechanisms.

To date there are 151 DLDMs established in all districts in Ruvuma Region manned by 337 trained dispensers. For better management of the programme, committees have been established at different levels namely Regional Drug Technical Committee (RDTC) which is chaired by the Regional Commissioner, District Drug Technical Committee (DDTC) chaired by the District Commissioner and Ward Health sub-Committee (WHsC). Powers and responsibility of each Committee are provided under the Tanzania Food, Drugs and Cosmetics (Standards and Code of Ethics for Duka la Dawa Muhimu) Regulations, 2004.

2.0 RATIONALE FOR CONDUCTING THE ASSESSMENT.

DLDM programme planning was based on the findings revealed during the baseline assessment carried out in Singida and Ruvuma regions. However, during implementation of the programme it was realized that other enhancing aspects such as marketing, communication skills, financial management and accessibility to credit facility have to be incorporated in the programme. At the stage of evaluating the programme, MSH decided to concentrate on variables identified during the baseline assessment excluding regulatory matters.

Better decision making regarding rolling out of the programme to other regions and thus developing the appropriate strategies, TFDA felt that it was necessary to evaluate the DLDM enforcement system. Enforcement system is a key aspect in assuring the public of quality, safe and effective drugs.

2.1 Specific objectives of the assessment

i. To determine the adequacy of the Tanzania Food, Drugs and Cosmetics (Standards and Code of Ethics for Duka la Dawa Muhimu) Regulations, 2004.

ii. To determine whether the licensing system for DLDM is effective and efficient

iii. To establish whether the set DLDM administrative structure is in line with Local government and Health Sector Reforms

iv. To assess the acceptability of the programme at various levels

3.0 METHODOLOGY

3.1 Data collection instrument

Evaluation was conducted by personal administration of structured questionnaire carried out by eight members of TFDA staff to randomly sampled respondents who are key DLDM stakeholders. Such stakeholders are the RDTC, DDTC and WHsC. Others are DLDM owners and dispensers.

A set of questionnaire was designed for each category of respondents in line with the Terms of Reference for the assessment **(appendix I)**. The respective set of questionnaire are presented as **(appendix II)**

Members of TFDA assessment team developed the questionnaires. The involvement of the team was very important for enhancement of understanding of the questionnaires and hence their uniform administration

3.2 Sampling technique

Four districts were selected for assessment. Districts selected were those having DLDM which were established before June 2004 namely Songea urban, Songea rural, Namtumbo and Mbinga. Fifty percent of the qualified DLDM in each district were sampled. The same was applied to respective DLDM members of Regional, District and Wards Committee.

A list of wards in each district were prepared from which samples was randomly picked by skipping the next candidate in the list. The same procedure was employed in determining the respective DLDMs.

Table showing Districts, wards and DLDMs sampled

Disticts	**wards**	**Number of DLDM**
Songea Urban	Mjini	8
	Mfaranyaki	3
	Mshangano	2
	Ruhuwiko	1
	Ruvuma	1

	Matogoro	1
	Bombambili	4
Sub total		**20**
Songea Rural		
	Gumbiro	2
	Maposeni	3
	Kilagano	1
	Magagula	1
	Litisha	1
	Mpitimbi	1
	Lilambo	1
Sub Total		**10**
Namtumbo		
	Namabengo	1
	Namtumbo	3
	Rwinga	3
Sub total		**7**
Mbinga		
	Mbinga Mjini	8
	Mbambabay	2
	Liuli	3
	Nyoni	1
	Kilosa	1
	Mpepai	1
	Kigonsela	4
Sub-total		**20**
Grand total		**57**

3.3 Method of analysis

The data collected are both quantitative and qualitative. Quantitative data are presented in tabular, frequency, percentages, and histograms for better interpretation of the results.

4.0 FINDINGS AND DISCUSSIONS

Basing on information gathered, criteria for assessment of the effectiveness of the DLDM regulatory system and the acceptability of the programme by various stakeholders were prepared. The data collected are summarized, analyzed and presented under (**appendix III).** The findings for each criterion are presented and discussed as follows:

4.1(a) Clear understanding of responsibilities

All categories of respondents were asked to check whether they clearly understood their responsibilities. Understanding of one responsibility is the key factor towards effective and efficient implementation of DLDM programme. All respondents were able to state clearly their basic roles. Such finding indicates that the training given as part of DLDM programme was adequate and probably has contributed to the success so far achieved.

4.1(b) Feeling on increase in responsibilities

Before launching of the DLDM programme, enforcement of the DLDB was centralized at Regional level; members of the RDTC were therefore asked whether such changes resulted in increased responsibilities. Majority of the respondents (80%) indicated increase in responsibilities despite the fact that many of the responsibilities have been delegated to lower level. This is partly due to more stringent requirements under the current system which requires regular meetings and follow up in implementation of the programme.

4.1(c) Preference of DLDM to DLDB

Members of the RDTC were asked whether they preferred the DLDM to DLDB, in order to gauge if the programme was achieving its anticipated goals. All respondents indicated preference to the DLDM system as it has within a short time improved accessibility to quality, safe and effective drugs.

4.2. Adequacy of composition for DLDM Committees

4.2.1 Regional Drug Technical Committee

Among the members of the RDTC interviewed 40% were in favour of the current composition of the RDTC while 60% were not, where as for DDTC, 46% were in favour of the current composition while 54% were not. Those who were not in favour of the current composition proposed that in addition to the current composition, the following were recommended to be members

of RDTC; Regional Administrative Secretary (RAS), Regional Security Officer (RSO), Regional Crime Officer (RCO), officer responsible for community welfare, representative of DLDM owners' association and a representative of NGO dealing with community development.

Another recommendation is dropping out of the RC on the reasons that all development activities are done by technocrats through him and not by him. This arrangement is meant to enable him oversee all development activities in the region. Furthermore the RC is supposed to be the appellant body in case of dispute. The other reasons put forward are that the RC has a lot of responsibilities which makes it difficult to hold DLDM meetings as scheduled and that his presence in the meeting creates undue influence among his subordinates.

4.2.2 District Drug Technical Committee

Among the members of the RDTC interviewed 80% were in favour of the current composition of the DDTC while 20% were not, where as for DDTC, 50% were in favour of the current composition while 50% were not. Those who were not in favour of the current composition proposed that in addition to the current composition, the following were recommended to be members of DDTC; Member of Parliament, Officer Commanding District (OCD), Town Medical Officer, Officer responsible for community welfare, representative of DLDM owners' association and District Security Officer. However Town Medical Officer is a member of DDTC as provided under the DLDM regulations.

Another recommendation is dropping of the District Commissioner (DC) on the reasons that basically all development activities are done by technocrats through him and not by him. This arrangement is meant for him to oversee all development activities in the district. Furthermore the DC is supposed to be the appellant body in case of dispute.

4.2.3 Ward Health Sub-Committee (WHsC)

All members of the RDTC interviewed 100% were in favour of the current composition of the WHsC, where as for DDTC, 54% were in favour of the current composition while 46% were not. Among the WHsC members 67% were in favour of the current composition while 33% were not. Those who are not in favour of the current composition proposed that in addition to the current composition, the following were recommended to be members of the WHsC; Ward Education Officer and Councilor.

Other recommendations made are co-opting of members who have expertise in health/drug matters or any other person for the reasons that in some

wards there is shortage of members stipulated under the DLDM regulations, some members do serve more than one ward and it may be difficult for the committee to be technically self sufficient.

4.3 Suitability of the licensing procedure

Under DLDM regulations, licensing procedure involve committees at the ward, district and region level as opposed to DLDB system where application is made direct to the region level. All interviewed RDTC, DDTC, WHsC, were in favour of the DLDM licensing procedure except one member of the WHsC.

Among interviewed owners 65% were in favour of the DLDM licensing procedure while 35% were not. Some of the owners perceived the system to be beauracratic and might provide loophole for corruption. This observations entails that efficiency is required at all levels.

4.4 Suitability of the enforcement set up

Performance of the DLDM programme is greatly influenced by the set up of the enforcement as this enhances better inspection and monitoring of the DLDM.

DLDM enforcement functions are carried out by RDTC, DDTC and WHsC committees. Member of the committee were asked on the suitability of the existing enforcement setup. Among the respondents, 97.2% were satisfied with the setup because it delegates the responsibility up to ward level. Such setup improve effectiveness of inspection and monitoring of DLDM. Some respondents were of the opinion that:

a) The ADDO system runs parallel to that of the Ministry of Health. The MoH setup is made up of MoH-RMO-RHMT-DMO-CHMT- DHSB-WHC whereas the ADDO system is made up of MoH-TFDA-RDTC-DDTC-WHsC. In this regard there is no harmonization of committees and their functions therefore such situation does not give health officials adequate opportunity to play an active role in the enforcement of the DLDM programme and hence this can affect day-to-day enforcement activity and thus sustainability of the Programme.
b) Responsibilities are not adequately delegated to lower level to enhance effective enforcement as currently enforcers at ward level play an advisory role.
c) There is no clear chain of command between TFDA and other levels

d) There is limited feedback from higher to lower level leading to delayed decision making.

4.5 Adequacy of the approved DLDM drug list

Under DLDM Regulations a range of prescription drugs have been allowed for sale in DLDM as compared to the DLDB system where such drugs were prohibited to be sold. In view of this, all categories of respondents were asked to give their view on whether the approved list meets the expectations of the consumer.

It was observed that 53.9% of the respondents felt that the list is not adequate hence does not meet the expectation of the consumers. The reasons cited out was that pharmacies are not available in rural areas and some dispensaries/ health centre do not have such drugs.

In view of the fact that most pharmacies are located in urban and peri-urban areas, and the fact that the objectives of the programme is to enhance accessibility of consumer to drugs, it may be necessary to revisit the list so that other drugs are included but institute a system that will prevent abuse and misuse of drugs. The list of drugs proposed for inclusion in the approved list is indicated in the **appendix III.**

4.6 Suitability of the requirement of two dispensers for each DLDM

Under the existing setup, Each DLDM is required to have a minimum of two dispensers. The assessment for suitability of having two dispensers per DLDM indicated that 83.8% of all categories of respondent were in favour of the arrangement

The rest of the respondent were of the opinion that in rural areas and in places where business turn over is very small one dispenser is adequate.

4.7. Adequacy of DLDM regulations

Members of the DDTC and WHsC were asked to give their views on the adequacy of the DLDM regulations because they are involved in a day-to-day enforcement of the same and thus are in better position to give practical experience on problem encountered due to inadequacy of the regulations. Among the interviewed members of the DDTC, 83.3% and 95.7% members of WHsC were of the opinion that the regulations are adequate
The main deficiency observed is lack of a provision in the regulations barring members of the respective committees to own DLDM. This scenario creates conflict of interest, which invites partiality.

4.8 Violation of DLDM regulations by owners and dispensers

The assessment also looked at the extent of adherence to code of conduct by owners and dispensers.
Members of Regional, District and Ward DLDM committees were asked if there were reports on violation of code of conduct committed by owners and dispensers. Among the respondents 35.2 % indicated that they received complaints regarding violation of code of conduct. However most of them were referring to same case, which may be misleading regarding the magnitude of the problem. Common violations reported include;

a) Re-labeling of drugs.
b) Repacking of drugs
c) Sale of Government drugs (MSD drugs)
d) Sale of expired drugs
e) Improper record keeping.

The same observations were confirmed during inspections carried out by DDTC and WHsC and the following measures were taken:

a) Confiscation of unauthorized drugs
b) Advise to rectify anomalies observed
c) Closure of shop for habitual defaulters

It is perceived that inspections coupled with provision of education need to be strengthened to improve the adherence to regulations and awareness among owners and dispensers

4.9. Weakness of the regulatory system

Members of RDTC, DDTC, and WHsC. were asked to comment on the weakness of the system. The findings of this assessment were as follows

4.9.1 Weakness inherent in DLDM regulations

a) More powers are centralized to higher levels
b) Lack of provision in DLDM regulations prohibiting Committee members to engage themselves in DLDM business.
c) No clear chain of command, which leads to, delayed implementation i.e it is not clear whether day-to-day correspondence from HQ regarding day-to-day operations of DLDM should be channeled to the chairman or sent direct to secretary of the respective committees.
d) Regional and District Commissioners being member of the respective committees is not appropriate as development activities are done

through them and not by them. Equally true this arrangement limits appeal by complainant to a Regional and District levels respectively.

4.9.2 Administrative weakness

a) Inadequate supervision and inspection budget
b) Delayed payments of inspection allowance to WHsC members
c) Transfer of trained personnel from respective stations leaving untrained ones
d) Failure to convene scheduled meetings
e) Inefficient communication between different levels
f) Shortage of working tools such as stationeries, reference books, uniforms etc
g) Failure of the committees to conduct scheduled meetings and inspections

4.10 Acceptance of DLDM programme

The assessment wanted to know the acceptability of the programme among all stakeholders. All categories of respondents were asked to give their perception regarding the acceptability of DLDM programme in the community. It was observed that 100 % of respondents were of the opinion that the programme is acceptable.

The acceptance of the programme is probably attributed by achievement so far attained under the programme such as; improvement of accessibility to different types of drugs, involvement of various stakeholders in decision-making, improved delivery of services to customers by DLDM and better regulatory mechanism.

4.11. Challenges facing RDTC, DDTC and WHsC in implementing DLDM

According to the assessment, the significant challenges observed by members of the said committees are:

a) Ability of the regional and local governments to support the DLDM programme financially
b) Ability to facilitate establishment of new DLDMs in terms of training of new owners and dispensers
c) Ability to sustain enforcement at all levels in terms of facilities, personnel.
d) Ability to conduct scheduled meeting in view of the tight work schedules
e) Creation of awareness among various stakeholders regarding their roles and responsibilities in the implementation of the programme.

4.12 Sustainability of the programme

The DLDM programme is at present supported by development partners. The sustainability of DLDM programme in Ruvuma region and its replication in other regions is the critical issue at hand after the withdrawal of development partners. In order to sustain and replicate the programme contribution of various stakeholders particularly PORALG remain inevitable.

The assessment conducted under this aspect revealed that the following could be done by the PORALG in order to sustain the programme:

a) Incorporating DLDM activities in the work plan and budget
b) Assigning staff to the enforcement of DLDM regulations
c) Incorporating DLDM programme in Comprehensive Council Health plan (CCHP) especially on supportive supervision and inspection
d) To provide technical advise
e) Facilitate institutional arrangement to ensure smooth and continuous services in terms of people's participation and solicit for donors.

4.13 Strength of DLDM regulatory system

An efficient and effective regulatory system is one of the pillars for the success of the DLDM programme. The assessment was geared towards evaluating the strength of DLDM regulatory system. The respondents cited the following strengths;

a) Presence of Tanzania Food, Drugs and Cosmetic Act, 2003 and Tanzania Food, Drugs and Cosmetic (Standard and Code of Ethics for Duka La Dawa Muhimu) regulations 2004
b) Existence of administrative structure from Ministry Headquarter to ward level
c) Presence of trained personnel at all levels, which enhance effectiveness of the programme.
d) Delegation of power and responsibility to lower level, which enhances better implementation of the programme.
e) Positive political will at all government level

4.14 Number of scheduled and extra ordinary committee meetings conducted

Committee meetings are supposed to be convened to deliberate on a number of issues including discussion of inspection report, consideration for applications of licenses and any other matter as stipulated under the Standard and Code of Ethics Regulations for DLDM. Convening of scheduled and extra – ordinary meeting is important for effective implementation of the programme. Evaluation was conducted to check whether meetings are conducted as scheduled.
The assessment revealed that;

a) The RDTC had not met since its establishment.
b) Among DDTC members, 84.2% indicated to have attended more than two meetings since launching of the DLDM programme. Such level of attendance was considered satisfactory as the scheduled number of meetings is twice a year.
c) Among members of ward level, 58.3% of the respondents attended more than two meetings of the WHsC

Based on the observations above, more meetings were conducted by DDTC than WHsC. This could be attributed to more sensitization at District level than at Ward level. Also it could be that inadequate funding and inadequate advocacy at ward level.

4.15 Suitability of decentralized inspection to ward level

The members of RTDC, DDTC and WHsC were requested to express their views regarding suitability of the decentralized inspection up to ward level as compared to that of DLDB whereby the Regional Drug Technical Advisory Committee was responsible for the licensing and inspection of DLDBs. Among the respondents 99% were in support of the arrangement.

The reasons given in support of the decentralized system include:

a) Inspectors at ward level are closer to DLDM premises and thus can easily detect malpractices of owners and dispensers
b) It provides empowerment and ownership of the programme at all levels
c) It reduces the cost of conducting inspections by the districts and Head quarters.
d) It improves transparency and accountability at all levels of inspection

4.16 Adequacy of training

The DLDM programme conducted training for dispensers, owners and member of WHsC so that they can be able to execute their duty as provided under the DLDM regulations. The motive of the assessment was to gauge

whether they were able to comprehend the training given. The results of the assessment showed that 75.9% of the respondents were of the opinion that the training was adequate. However 24.1% of the respondents commented that the training was inadequate giving the following reasons:

a) The time allocated for the training was too short to cover all lessons.
b) The information provided during the training was too technical to be comprehended by those with little medical background.

When interviewed on the training needs, the Ward Health sub-Committee requested for additional training on inspection techniques and DLDM regulations while owners and dispensers requested for retraining because the previous training period was not adequate.

4.17 Involvement in establishing DLDM programme

During the establishment of DLDM programme, involvement of DLDM owners was considered as one of the strategies to enhance its effective implementation. Therefore as part of the evaluation, owners were asked whether they were involved in the establishment of the programme.

The assessment indicated that 100% of the respondents were involvement in the establishment of the programme, particularly during training of DLDM owners. However, their opinion was not sought during the development of the DLDM regulations.

4.18 Awareness of DLDM owners on enforcement set up

In the implementation of the DLDM programme, it was thought that knowledge on the enforcement setup by owners could help them in following appropriate channels while applying for licenses or making appeals.

In view of this, owners were asked if they knew about the enforcement set up. Out of all respondents, 81.3% indicated that they knew the enforcement set up. The initial training provided before licensing might have attributed to this level of awareness. On the other hand, the remaining respondents were not aware of the existing set up because at the initial stage of the pilot programme the existing licensing procedure was not followed.

4.19 Effectiveness of inspection system

The effectiveness of the inspection system was gauged by determining the number of inspections conducted at DLDMs, inspectors involved, behaviour of inspectors and usefulness of the inspections as perceived by owners and dispensers. Among owners interviewed 3% indicated that their DLDM have never been inspected, 29% indicated that their DLDM have been inspected 1

to 2 times, 55% were inspected 3 to 4 times and 13% were inspected more than 5 times. On the other hand, 51% of the interviewed dispensers revealed that their DLDM were inspected 1 to 2 times, 40% were inspected 3-4 times and 9% were inspected more than 5 times. The inspections were conducted by WHsC, DDTC, TFDA or jointly.

The variation on the number of inspection reported by owners and dispensers may be attributed to the fact that dispensers are in better position to give correct number of inspections conducted because they spend more time at the DLDM than owners

In all inspections conducted, only 6.5% of owners considered the inspectors to be harsh while the rest perceived them as diplomatic and educators. On further enquiry, it was revealed that the two owners were found in contravention of the DLDM regulations by conducting clinical services and selling unauthorized drugs.

Regarding perception on the usefulness of the inspections, 94% of owners found the inspections useful where as 98% of dispensers found the inspections useful. The observations clearly indicated that inspections are essential for improving the performance of DLDM.

4.20 Satisfaction by DLDM owners with technical skills of the dispensers

Before Launching of ADDO programme, DLDM dispensers were provided with one month dispensing training to enable them carry out the dispensing duties at the DLDM.

Among the owners interviewed 90.6% were satisfied with the technical skills of the dispensers. The respondents recommended the retraining.

4.21 Perception on sustainability of the DLDM by owners

In order to roll out the programme, sustainability of the DLDM business is one of the criteria to be taken into consideration. The evaluation looked at this aspect by asking owners if they think the DLDM business is sustainable. Among the respondents, 93.8% indicated that the business is sustainable based on the reason that there is a high demand for the service and an elaborate enforcement system. The remaining respondents indicated that the business is not sustainable because of high costs of operation relative to the turn over, particularly in rural areas.

4.22 Problems affecting the DLDM business

Owners interviewed on this aspect indicated the following factors affecting their business:

a) Low Purchasing power among the population
b) Low level of awareness
c) Shortage of source of drugs supplies
d) Inability to meet the cost of two dispensers
e) Limited list of authorized drugs
f) Normal shops Selling unauthorized drugs
g) Theft
h) Limited capital
i) Defaulting of dispensers

The following are the recommendations of DLDM owners as possible solution to the above mentioned problems:

a) Regular inspections to be conducted on all suspected illegal drug dealers
b) Intensive advocacy should be done to sensitize the public on the role of DLDM
c) Regular training of new dispensers to meet demand

4.23 Proposed minimum entry qualifications for DLDM dispensers

Dispensers who are skilled are important for ensuring Good Dispensing Practices. For a dispenser to be able to grasp the necessary skills he/she must have minimum qualifications; therefore the assessment was geared towards getting an opinion on the minimum qualifications for DLDM dispensers course.

The assessment revealed that among the dispensers interviewed 56.6%, were of the opinion that the minimum qualifications for DLDM dispenser to be nursing assistants, 39.6% form four and 3.8% Diploma in Nursing.

The majority of the respondents indicated nursing assistants as the minimum requirement. This could be attributed to the fact that significant proportion of DLDMs dispensers are Nursing Assistants and logically they were defending their position.

4.24 Perception of dispensers on being protected by DLDM regulations

In order to make the DLDM effective, there is a need of having regulations, which are useful to dispensers in terms of working condition, employment security and good relationship with owners. Dispensers were asked if they are satisfied with ADDO regulations regarding the above issues. Among the

respondents 94.2% showed that the regulations have adequately addressed the above issues.

4.25 Demand for prescription drugs without prescription

Under the existing DLDM regulations, DLDMs are allowed to sell selected prescription drugs with prescription. Dispensers were interviewed to determine whether the demand of prescription drugs without prescription is a common problem. The assessment indicated that 94.3% of dispensers interviewed admitted the existence of the problem

Reasons cited for demand for prescription drugs without prescriptions were:

a) Inability to meet medical consultation fee
b) Habit acquired from DLDB malpractices
c) Long distance to health facilities
d) Avoidance of queuing at health facilities
e) Need for secrecy
f) Ignorance of the consequences of using drugs without prescriptions/instructions
g) Lack of awareness of the required procedures to obtain prescription drugs

4.26 General comments on the DLDM programme.

The general comments made by members of the RDTC, DDTC, WHsC, owners and dispensers are summarized as follows:

a) Regional experts should be involved in the training of owners and dispensers in order to have more insight of the programme as at the end they are responsible for supervision of the programme
b) The Regional pharmacist attends RDTC and DDTC meetings creates inefficiency and lack of checks and balance
c) The Programme is very useful in terms of accessibility to quality, safe and effective drugs
d) The programme has significantly improved the income of both owners and dispensers
e) Entrepreneurs should be encouraged to establish pharmaceutical wholesale shops in Ruvuma region
f) There should be DLDM for veterinary drugs
g) The programme should be extended to other parts of Ruvuma region and other regions
h) There should be regular inspections to improve compliance
i) There is an improvement in dispensing practices as compared to DLDB
j) Before rolling out the programme to other regions, there must be adequate sensitization campaigns to all stakeholders to make them perceive the ownership of the programme as compared to the current situation where by DLDM programme is felt to be owned by TFDA and MSH by some stakeholders. This is one of the reasons for failure of some committees to conduct scheduled meeting and inspections in the event that respective allowances are not made available by TFDA and MSH.
k) There should be regular training of dispensers to improve their dispensing skills
l) There is a need to train more owner and dispensers so as to sustain the programme in terms of human resources.
m) Introduce cost sharing for training of owners and dispensers

5.0 STRENGTH, WEAKNESSES, OPPORTUNITIES AND THREATS (SWOT) ANALYSIS

Performance and sustainability of the DLDM programme partly depends on how strategies are made to control both internal and external factors that can have influence on effectiveness of the DLDM programme. The analysis of Strength, Weakness, Opportunities and Threats related to the DLDM programme are indicated below:

5.1. Strength

(a) Presence of legislation

Presence of the Tanzania Food, Drugs and Cosmetics (Standard and code of ethics for Duka la Dawa Muhimu) regulations, 2004 forms the basis upon which the DLDM programme is regulated to enable availability of quality, safe and effective drugs.

(b) Administrative structure

Existence of administrative structure from Ministry Headquarter to ward level enables delegation of powers and responsibilities at various levels therefore enhances better implementation of the programme.

(c) Presence of trained personnel

Under ADDO programme, various stakeholders at different levels have been trained to enable them perform their responsibilities efficiently and effectively.

(d) Positive political will

There is a positive will among political and government leaders in supporting the implementation of the DLDM programme as enforcement of the regulation is undertaken at Regional, District and Ward levels by the respective committees.

(e) Acceptance of the DLDM programme by various stakeholders

The DLDM programme has attained significant achievements since its inception as indicated by improved availability of quality, safe and effective drugs and delivery of services. This has resulted into acceptance of the programme by majority of the stakeholders as evidenced by 100% of the interviewed respondents.

(f) Involvement of stakeholders

Participation of various stakeholders in decision making of issues pertaining to regulation of the DLDM. This enhances effective implementation of the programme.

5.2 Weaknesses

(a) The cost of running the pilot programme was relatively high to the extent that it may be difficult to roll out the programme in the same manner without depending on external funding.
(b) Regional and Districts Commissioners being chairpersons of the respective committees is not appropriate as development activities are done through them and not by them.
(c) Lack of provision in the DLDM regulations, prohibiting committee members to engage in DLDM business.

5.3 Opportunities

(a) Existence of market for drugs because of high incidences of diseases
(b) The programme provides employment and business opportunities
(c) Increased awareness among the people in quality, safety and effectiveness and rational use of drugs provides assurance on demand for DLDM services
(d) Existences of DLDMS have created needs for training of dispensers.

5.4 Threats

(a) Donor dependency: Notion by some government officials that such programme cannot be sustained without donor's support
(b) Inability to finance implementation of the DLDM programme by regional and local governments
(c) Adequate stocking of Drugs in hospitals, health centers and dispensaries creates competition with DLDM.
(d) Lack of ability to train adequate number of dispensers to meet the demand of DLDMs.
(e) Limited access to credit facilities by owners of the DLDM makes them unable to run the business in a sustainable manner.
(f) Low purchasing power by the majority of the rural and peri – urban population
(g) Limited number of wholesale pharmacies to support establishment of DLDMs particularly in remote areas

6.0 CONCLUSIONS

Based on the findings made during the assessment, it was observed that the Tanzania Food, Drugs and Cosmetics (Standards and Codes of Ethics for Duka la Dawa Muhimu) regulations, 2004 are quite adequate. However, there is a need for revision of the regulations to include provisions such as dropping of the RC and DC out of the RDTC and DDTC respectively. The other improvement is inclusion of a provision prohibiting members of DLDM committees from engaging in DLDM business. The existing procedures for application for DLDM license were found to be quite useful and elaborate. This is because it provides for empowerment at different levels and fair playing field for all applicants. However, there is a great need for improvement of the effectiveness and efficiency of the system to avoid chances of delays in processing of applications at different levels.

The DLDM administration structure is in line with the local government and the Ministry of Health reforms because there is delegation and empowerment of ward, district, regional, TFDA and Ministry of Health. Basically, while the Ministry of Health is responsible for policy matters, TFDA is charged with provision of guidelines while the regional, district and wards are responsible for day-to-day implementation of DLDM programme.

The involvement of various experts in the RDTC, DDTC and WHsC is meant to enrich such committees and is in line with the nature of the programme as it touches various segments of the community.

The programme is well accepted by all segments of Ruvuma community, as 100% of interviewed respondents were of the opinion that the programme is acceptable. The big challenge ahead of the government is extension of the programme in other parts of Ruvuma region, its replication to other regions and sustainability.

Replication and sustainability of the programme is very possible provided that there is adequate involvement and ownership of the programme by all stakeholders. Cost of implementing the programme should be met by all involved parties including owners, dispensers, local authorities, TFDA and Ministry of Health and development partners.

7.0 RECOMMENDATIONS

Basing on the findings, discussions and Terms of Reference it is recommended that:

1. The DLDM programme be extended to other parts of Ruvuma region and be rolled out to other regions in phases depending on resources availability
2. For the purpose of checks and balance the Regional and District Commissioners be dropped out from the respective DLDM committees.
3. The regional Administrative Secretary (RAS) be included in the RDTC and take over the chairmanship of the committee.
4. The District Executive Director be the chairperson of the DDTC
5. A representative of the DLDM owners' association in each district be incorporated in the respective DDTC
6. The post of Vice-chairperson be dropped and in his/her absence the committee members should appoint a chairperson for that particular meeting
7. All committees should be able to co-opt any other member when discussing specific matters of which it finds that person resourceful
8. Matters related to day-to-day operations of DLDM should be directed to the Secretaries of the respective committees in order to facilitate communication and implementation of directives
9. A technical committee need to be established to revisit the list of approved DLDM prescription drugs
10. There should be consideration to revise the requirement for two dispensers for each DLDM in rural areas
11. Members of the respective DLDM committees should not be allowed to own DLDM.
12. Members of WHsC should not demand payment of allowances when conducting inspections and attending meetings related to DLDM activities in their respective duty station within normal working hours.
13. For the districts where there are no pharmacists, the Pharmaceutical Technicians in-charge should be co-opted into the DDTC
14. TFDA and the regional authority should agree on the minimum working tools and the modalities of acquiring and making them available to the respective committees in time
15. Regional and Local governments should incorporate supervision and promotion of DLDM programme into their work plan and budget

16. Ministry of Health and TFDA should provide supportive role in terms of audit inspections and facilities to the regional and local governments regarding implementation of DLDMs
17. All the licensing fee collected should be spent for facilitating implementation of DLDM programme in respective areas
18. Ministry of Health zonal training centers should be used to train DLDM dispensers and owners
19. Owners and dispensers should be asked to contribute towards the costs of their training
20. More time should be dedicated during training dispensers, owners and members of WHsC as most of them do not have adequate medical background
21. There should be periodic re-training of dispensers to update their dispensing skills
22. Consideration should be made to develop tailor made DLDM dispensing course for form four leavers with passes in Biology and Chemistry
23. While training dispensers and owners, respective regional and district experts should be included among the trainers so as to improve ownership of the programme.
24. The head of dispensary or health center as member of WHsC should be replaced with the head of public dispensary or health center.

8.0 APPENDICES

Appendix i

TERMS OF REFERENCE FOR ASSESSMENT OF THE EFFECTIVENESS OF ACCREDITED DRUG DISPENSING OUTLET (ADDO) SYSTEM IN RUVUMA

BACKGROUND:

Accredited Drug Dispensing Outlet (ADDO) project is a result of an assessment of pharmaceutical sector in Tanzania that was conducted in April – May 2001 by two parties namely; the Ministry of Health (MOH) through Tanzania Food and Drugs Authority (TFDA) and a non – profit organisation namely "MSH/CPM" based in Boston, U. S. A. The assessment targeted to address quality, affordability, acceptability and geographical drug access especially to rural and peri- urban population where delivery of health service for long time in this country has remained a problem. Different health care facilities were involved in the assessment namely; pharmacies, part II poisons shops, health centres and dispensaries.

Among the findings, the assessment revealed that there were more than 4,600 part II poisons shops "Duka la Dawa Baridi (DLDB)" spread all over the country which offer services and dispense drugs to the public. Out of these, 118 were located in Ruvuma region.

The assessment also revealed that, DLDBs play a vital role in providing access to essential drugs for a significant proportion of the population. However, these outlets were found with the following major bottlenecks:

- Lack of qualified personnel to dispense drugs
- Lack of assurance to drug quality at any time
- Poor dispensing practices
- Insufficient variety of drugs to meet patients needs
- Stocking of unauthorised drugs to be used in the country
- Presence of medicines not allowed to be sold in DLDBs
- Price uncertainties
- Inadequate regulatory mechanism

As a result of these findings, a proposal to establish a network of ADDOs, also known as 'DUKA LA DAWA MUHIMU' was developed and implementation is being undertaken under technical support; by MSH/CPM through its Strategies for Enhancing Access to Medicines (SEAM). The project was piloted in Ruvuma and was officially launched on 11th August

2003 by the Minister for Health. To date there are 151 DLDM established in all Ruvuma districts and 337 trained dispensers for DLDMs. In each district a Distict Drugs Technical Committee composed of 10 members has been established, while at each ward level, an Inspection Committee composed of 5 members has been formed. These committees perform their legal duties as prescribed under ADDO regulations established under the Tanzania Food, Drugs and Cosmetics Act, 2003

OBJECTIVES FOR ASSESSING THE EFFECTIVENESS OF THE ADDO SYSTEMS.

During the course of implementation of the pilot project in Ruvuma region, various enhancing and modifying parameters were considered useful to be included in the implementation of the pilot project in line with the Health Sector Reforms. However, these parameters were not assessed during the baseline survey. It is now felt that the assessment of these parameters is necessary to enable the Ministry of Health through Tanzania Food and Drugs Authority to decide on the appropriate strategies during the roll out of the program once found successful.

TFDA has therefore decided to appoint, a Team of eight among its employees to undertake the assessment of effectiveness of the ADDO system as per Terms of Reference (ToR) indicated hereunder and tools for evaluation that shall be provided.

TERMS OF REFERENCE (ToR)

i) Assess the effectiveness of regulatory performance of ADDO system in terms of:

a) Adequacy of The Tanzania Food, Drugs and Cosmetics (Standards and Code of Ethics for Duka la Dawa Muhimu) Regulations, 2004.

b) Licensing procedures for establishing DLDM

c) Established administration structures at Ward, District,
Regional, TFDA and Ministry of Health in line with Health Sector and Local Government Reforms.

ii) **Assess the acceptability of the program by various stakeholders including:-**

a. Leaders at various government levels,
b. Service providers (dispensers and owners) and
c. The community in general.

iii) Assess the usefulness and effectiveness of: -

Supportive supervision in both Communication and Good

Dispensing practices skills that are periodically provided to dispensers towards delivery of quality services.

DATA COLLECTION

The specific responsibilities of the evaluating team will include to:

1. Determine whether the objectives of the program have been achieved in line with the ToR and provide recommendations on the way forward.

2. Submit a report on the evaluation to TFDA Management before 19/02/2003

4. The team is expected to work closely with Regional and District Authorities in Ruvuma Region.

LEVEL OF EFFORT

The estimated level of effort is 32 man-days

EXPECTED OUTPUT

a) ADDO program evaluation report based on the above ToRs including:
   - Executive summary
   - Introduction
   - Findings that shall include the SWOT analysis
   - Discussion
   - Recommendation on the strategies for rolling out ADDO program to other regions
   - Appendix showing:
     - Data collected and analysis,
     - Data collection instruments and
     - References
   - The Team is also expected to prepare a Power Point presentation of the findings and recommendations to TFDA Management.

Appendix ii

QUESTIONNAIRES

QUESTIONNAIRE FOR ASSESSMENT OF DLDM REGULATORY SYSTEM IN RUVUMA REGION

Category of Respondent: RDTC Member

Name of Interviewer: ……

Date:……

Introduction

"Thank you for agreeing to meet with me today. My name is _____ and I am working with the team reviewing experience with the DLDM regulatory system. The objective of this review is to better understand how the new regulatory system introduced in the ADDO program has been working to meet the needs of effective enforcement, challenges to implementation, and where it needs to go in the future. We are interviewing various stakeholders and participants to capture opinions and ideas. We will keep this interview information confidential and anonymous by pooling it together and using it without attribution. Eventually all notes will be destroyed. Please feel free to share what you think but if there is anything that I ask today that you would prefer not to answer, please let me know, and we'll go on to the next question."

1. You have been a member of former Regional Technical Advisory Committee for DLDB and now a member for the RDTC.

   (a) Do you see any significant change of your responsibilities between then and now? (Yes/No). If yes, what are such changes?
   ……

   (b) Between the two, which system do you prefer and why?

   ……

2. (a) In view of the ADDO regulations, RDTC is composed of:- Regional Commissioner, Regional Pharmacist, Officers of the Regional

Secretariat responsible for: Health, Livestock or Veterinary, Agriculture and trade matters. Do you consider this composition adequate? (Yes or No). If No, what member(s) do you think should be added or omitted and why?

……

(b) DDTC is composed of:- District Commissioner, DED, DAS, DMO, District Trade Officer, District Agriculture and Livestock Development Officer, District Veterinary Officer, one person representing the community and another representing NGOs dealing with health matters. Do you consider this composition adequate? (Yes or No). If No, what member(s) do you think should be added or omitted and why?

……

c) Ward Health Sub-committee is composed of:- Ward executive officer (WEO) In charge of dispensary/health centre, ward health officer, Community development officer Ward extension officer. Do you consider this composition adequate? (Yes or No). If No, what member(s) do you think should be added or omitted and why?

……

3. In view of the ADDO regulations, an application for DLDM licence has to go through Village, Ward and District level for approval as opposed to DLDB whereby an application used to be submitted directly to Regional Technical Advisory Committee. Do you find this system efficient and effective? (Yes or No). If No, give reasons?

   ……

4. In view of the ADDO regulations, inspection is decentralized down to ward level as compared to the DLDB system where it was to regional level. Do you find this system advantageous? Yes or No. If No give reasons?

   ……

5. (a) DLDM have been authorized to sell a range of part I poisons as opposed to DLDB,

   Do you think the list of drugs meet the expectation of the consumers?. Yes or No

(b) Have you ever received any application from owners/dispensers for inclusion or omission of some drugs? Yes or No. If yes mention such drugs ……

6. It is a requirement that each DLDM must have a minimum of two dispensers. Do you find this arrangement appropriate (Yes/No).

   If no, give reason

   ……

7. Do you find the set ADDO standards in terms of premises, personnel, and record keeping appropriate? (Yes/No). If no, what should be improved?

   ……

8. Have you ever received any complaints regarding breach of code of conduct for DLDM by the DLDM owners/dispensers? (Yes/No). If Yes can you mention any?

   ……

9. (a) What do you consider to be the weaknesses of ADDO regulatory system?

……

(b) What kind of improvements do you propose to the observed deficiencies?

……

10. What do you consider to be the strengths of ADDO regulatory system?

……

11. What is your opinion regarding the usefulness of DLDM as part of the health service delivery system? Tick accordingly

(a) very useful
(b) Useful
(c) Not useful

12. (a) As a member of the RDTC what challenges / problems are you facing in the course of implementing the DLDM Program?

……

(b) What are your strategies to resolve such challenges /Problems?

……

13. Sustainability of the DLDM needs supports and involvement of various stakeholders. In view of the fact that MSH support to the program ends in June 2005, how best do you think the regional and local government can contribute towards sustainability of the program?

    ……

14. Do you have any other comments?

……

……

Thank you for your time and thoughtful input.

QUESTIONNAIRE FOR ASSESSMENT OF DLDM REGULATORY SYSTEM IN RUVUMA REGION

Category of Respondent: DDTC

Name of Interviewer:……

Date:……

Introduction

"Thank you for agreeing to meet with me today. My name is _____ and I am working with the team reviewing experience with the DLDM regulatory system. The objective of this review is to better understand how the new regulatory system introduced in the ADDO program has been working to meet the needs of effective enforcement, challenges to implementation, and where it needs to go in the future. We are interviewing various stakeholders and participants to capture opinions and ideas. We will keep this interview information confidential and anonymous by pooling it together and using it without attribution. Eventually all notes will be destroyed. Please feel free to share what you think but if there is anything that I ask today that you would prefer not to answer, please let me know, and we'll go on to the next question."

1. Being a member of DDTC, what are your responsibilities in implementation of ADDO Program?

   ……

2 (a) How many ordinary or extraordinary meetings have been conducted in your districts since launching of ADDO program?

   ……

   b) Are the minutes of the respective meetings available? Yes or No. If no, give reasons

   ……

3 (a) How many inspection(s) of DLDM have been conducted by DDTC in your district since launching of DLDM program?

……

(b) What significant violations were observed during inspections?

……

(c.) What measures were taken against violators?

……

(d) Have the respective inspection report(s) been submitted to RDTC and TFDA? (Yes or No). If no, give reasons?

……

4 a) Have you ever participated in discussion of ward DLDM inspection reports? (Yes or No). If no, Give reasons

……

b) What is your opinion in relation to the performance of DLDM inspectors at ward level in line with responsibility and powers given under DLDM regulations in terms of;

i Number of inspection

…… ……

ii Quality of report

……

iii Recommendation made

……

5 Do you find ADDO regulations adequate? (Yes or No). If no, give reasons

……

6 In view of the ADDO regulations, inspection is decentralized down to ward level as compared to the DLDB system where it was to regional level. Do you find the new system advantageous? (Yes or No). If no, Give reasons

……

7 Do you consider the current enforcement setup appropriate? (Yes or No). If no, give reasons

……

8 (a) In view of the ADDO regulations, RDTC is composed of:- Regional Commissioner, Regional Pharmacist, Officers of Regional Secretariat responsible for: Health, Livestock or Veterinary, Agriculture and Trade matters. Do you consider this composition adequate? (Yes or No). If no, what member(s) do you think should be added or omitted and why?

……

(b) DDTC is composed of:- District Commissioner, DED, DAS, DMO, District Trade officer, District Agriculture and Livestock Development officer, District Veterinary Officer, one person representing the community and another representing NGOs dealing with health matters. Do you consider this composition adequate? (Yes or No). If no, what member(s) do you think should be added or omitted and why?

……

c) Ward Health Sub Committee is composed of:- Ward Executive Officer, In charge of dispensary/health centre, Ward Health Officer, CDO, Ward Extension Officer. Do you consider this composition adequate? (Yes or No). If no, what member(s) do you think should be added or omitted and why?

……

9 In view of the DLDM regulations, an application for DLDM license has to go through Village, Ward and District level for approval as opposed to DLDB whereby an application used to be submitted directly to Regional Technical Advisory Committee. Do you find this system efficient and effective? (Yes or No). If no, give reason

……

10. a) DLDM have been authorized to sell a range of part I poisons as opposed to DLDB. Do you think the list of drugs meet the expectation of the consumers? (Yes or No) . If no, give reason.

……

b) Have you ever received any request from owners/dispensers for inclusion or omission of some drugs? (Yes or No). If no, give reason

……

……

11. It is a requirement that each DLDM must have a minimum of two dispensers. Do you find this arrangement appropriate? (Yes/No). If no, give reason

……

12 Do you find the set ADDO standards in terms of premises, personnel, and record keeping appropriate? (Yes/No). If no, what should be improved?

……

13 Have you ever received any complaints regarding breach of code of conduct for DLDM by the DLDM owner/dispensers? (Yes/No). If yes, can you mention any?

……

14. What do you consider to be the weaknesses of ADDO regulatory system?

……

15. What do you consider to be the strengths of ADDO regulatory system?

……

16 (a) As a member of DDTC what challenges / problems do you think the DDTC is facing in the course of implementing the DLDM Program?

……

b) What strategies do you think are appropriate to resolve such challenges /Problems?

……

(b) What kind of improvements do you propose to the observed deficiencies?

……

17. What is your opinion regarding the usefulness of DLDM as part of the health service delivery system?. Tick accordingly

a) Very useful
b) Useful
c) Not useful

18. Do you find DLDM program sustainable? (Yes or No). Give reason

……

19. Sustainability of the DLDM needs supports and involvement of various stakeholders. In view of the fact that MSH support to the program ends in June 2005, how best do you think the regional and local government can contribute towards sustainability of the program?

……

20. Do you have any other comments?

……

Thank you very much for your time and thoughtful input.

QUESTIONNAIRE FOR ASSESSMENT OF DLDM REGULATORY SYSTEM IN RUVUMA REGION

Category of Respondent: Ward Health Sub-committee

Name of Interviewer:……

Date:……

Introduction

"Thank you for agreeing to meet with me today. My name is _____ and I am working with the team reviewing experience with the DLDM regulatory system. The objective of this review is to better understand how the new regulatory system introduced in the ADDO program has been working to meet the needs of effective enforcement, challenges to implementation, and where it needs to go in the future. We are interviewing various stakeholders and participants to capture opinions and ideas. We will keep this interview information confidential and anonymous by pooling it together and using it without attribution. Eventually all notes will be destroyed. Please feel free to share what you think but if there is anything that I ask today that you would prefer not to answer, please let me know, and we'll go on to the next question."

1. Being a member of Ward Health Subcommittee, what are your responsibilities in implementation of ADDO Program?

   ……

3 (a) How many ordinary or extraordinary meetings have been conducted in your ward since launching of ADDO program?

   ……

   b) Are the minutes of the respective meetings available? (Yes or No). If no, give reason

   ……

3 (a) How many inspection(s) of DLDM have been conducted by your committee in your ward since launching of DLDM program?

   ……

(b) What significant violations were observed during the inspections?

……

(c.) What recommendations were made to DDTC against violators?

……

(d) Have the respective inspection report(s) been submitted to DDTC? (Yes or No). If no, give reasons?

……

4. (a) Was the training given adequate to enable you to carry out your inspection activities confidently? (Yes/ No). If no, give reasons?

……

(b) Which aspects do you think need to be improved to make you perform your work?

……

5. Do you find ADDO regulations adequate? (Yes or No). If no, give reasons?

……

6. In view of the ADDO regulations, inspection is decentralized down to ward level as compared to the DLDB system where it was to regional level. Do you find the new system advantageous? (Yes or No). If no, give reasons?

……

7. Do you consider the current enforcement setup appropriate? (Yes or No). If no, give reason?

……

8 Ward health sub-committee is composed of:- Ward Executive Officer, In charge of dispensary/health centre, Ward Health Officer, CDO, Ward Extension Officer. Do you consider this composition adequate? (Yes or No). If No, what member(s) do you think should be added or omitted and why?

……

9 In view of the DLDM regulations, an application for DLDM license has to go through Village, Ward and District level for approval as opposed to DLDB whereby an application used to be submitted directly to

Regional Technical Advisory Committee. Do you find this system efficient and effective? (Yes or No). If no, give reason?

……

10. DLDM have been authorized to sell a range of part I poisons as opposed to DLDB. Do you think the list of drugs meet the expectations of the consumers? (Yes or No). If no, give reason?

……

11. It is a requirement that each DLDM must have a minimum of two dispensers. Do you find this arrangement appropriate? (Yes/No). If no, give reason

……

12 Do you find the set ADDO standards in terms of premises, personnel, and record keeping appropriate? (Yes/No). If no, what should be improved?

……

13 Have you ever received any complaints regarding breach of code of conduct for DLDM by the DLDM owner/dispensers? (Yes/No). If yes can you mention any?

……

14.(a) What do you consider to be the deficiencies of ADDO regulatory system?

……

(b) What kind of improvement do you propose to the observed deficiencies?

……

15 (a) As a member of Ward health sub-committee what challenges / problems do you think the committee is facing in the course of implementing the DLDM Program?

……

b) What strategies do you think are appropriate to resolve such challenges /Problems?

……

(b) What kind of improvements do you propose to the observed deficiencies?

……

16. What is your opinion regarding the usefulness of DLDM as part of the health service delivery system? Tick accordingly

a) Very useful
b) Useful
b) Not useful

17. Do you have any other comments?

……

Thank you very much for your time and thoughtful input.

QUESTIONNAIRE FOR ASSESSMENT OF DLDM REGULATORY SYSTEM IN RUVUMA REGION

Category of Respondent: DLDM Owner

Name of Interviewer:……

Date:……

Introduction

"Thank you for agreeing to meet with me today. My name is _____ and I am working with the team reviewing experience with the DLDM regulatory system. The objective of this review is to better understand how the new regulatory system introduced in the ADDO program has been working to meet the needs of effective enforcement, challenges to implementation, and where it needs to go in the future. We are interviewing various stakeholders and participants to capture opinions and ideas. We will keep this interview information confidential and anonymous by pooling it together and using it without attribution. Eventually all notes will be destroyed. Please feel free to share what you think but if there is anything that I ask today that you would prefer not to answer, please let me know, and we'll go on to the next question."

1. Being the owner of DLDM, what are your main responsibilities in day-to-day management of your DLDM?

……

2. Were you involved in the process of establishing DLDM system? Yes or No. If yes how?

……

3. Can you mention different committees involved in the regulation of the DLDM

……

3. (a) How many inspections have been conducted at your DLDM ?……

(b) Who conducted the inspection(s)?

……

(c.) What is your opinion on the behavior of the inspectors?

……

(d) Did you find the inspection useful? (Yes or No). Give reasons

……

4. Was the training given adequate to enable you to manage your business confidently? (Yes/ No). If no, give reasons?

……

5. Are you satisfied with your dispenser's technical skills in discharging his /her daily duties?

……

6. DLDM have been authorized to sell a range of part I poisons as opposed to DLDB. Do you think the list of drugs meet the expectations of the consumers? (Yes or No). If no, give reasons and what drug do you proposed to be added?

……

7. It is a requirement that each DLDM must have a minimum of two Dispensers. Do you find this arrangement appropriate? (Yes/No). If no, give reason

……

8. In view of the DLDM regulations, an application for DLDM license has to go through village, ward and District level foe approval as opposed to DLDB whereby an application used to be submitted directly to Regional Technical Advisory Committee. Do you find this system efficient and effective? Yes or No. If no, give reasons

……

9. Do you find the set ADDO standards in terms of premises, personnel, and record keeping appropriate? (Yes/No). If no, what should be improved?

……

10. What is your opinion regarding the usefulness of DLDM as part of the health service delivery system? Tick accordingly

a) Very useful
b) Useful
b) Not useful

11. (a)As owner of DLDM, what problems do you encounter in running your business?

……

(b) How do you resolve such problems?

……

12. Do you find your business sustainable? Yes or No. If no, give reasons.
……

13. Do you have any other comments?
……

Thank you very much for your time and thoughtful input.

QUESTIONNAIRE FOR ASSESSMENT OF DLDM REGULATORY SYSTEM IN RUVUMA REGION

Category of Respondent: DLDM Dispensers

Name of Interviewer:……

Date:……

Introduction

"Thank you for agreeing to meet with me today. My name is _____ and I am working with the team reviewing experience with the DLDM regulatory system. The objective of this review is to better understand how the new regulatory system introduced in the ADDO program has been working to meet the needs of effective enforcement, challenges to implementation, and where it needs to go in the future. We are interviewing various stakeholders and participants to capture opinions and ideas. We will keep this interview information confidential and anonymous by pooling it together and using it without attribution. Eventually all notes will be destroyed. Please feel free to share what you think but if there is anything that I ask today that you would prefer not to answer, please let me know, and we'll go on to the next question."

1. Being the dispenser of DLDM, what are your main responsibilities in day-to-day operation of DLDM?

……

2(a) How many inspections have been conducted at your DLDM in your presence as a dispenser?……

(b) Who conducted the inspection?

……

(c.) What is your opinion on the behavior of the inspectors?

……

(d) Did you find the inspection useful? (Yes or No). Give reasons

……

3. Was the training given adequate to enable you to perform your duties as dispenser confidently? (Yes/ No). If no, give reasons?

……

4. What do you think should be dispenser's minimum qualifications?

……

5. Do you consider the ADDO regulations useful to you as dispenser in terms of working condition, employment security relationship with owner?
……

9. DLDM have been authorized to sell a range of part I poisons as opposed to DLDB. Do you think the list of drugs meet the expectations of the consumers? (Yes or No). If no, give reasons and what drug do you proposed to be added?

……

10. It is a requirement that each DLDM must have a minimum of two dispensers. Do you find this arrangement appropriate? (Yes/No). If no, give reason

……

8. Do you find the set ADDO standards in terms of premises, personnel, and record keeping appropriate? (Yes/No). If no, what should be improved?

……

9. What is your opinion regarding the usefulness of DLDM as part of the health service delivery system? Tick accordingly

a) Very useful
b) Useful
b) Not useful

10. Is the demand for part one drugs without prescription a common problem at your DLDM? (Yes or No). What could be the probable reason(s) and how do you handle such situation?

……

11. What problem do you encounter while carrying out your responsibility as a dispenser?

……

12. Do you have any other comments?

……

Thank you very much for your time and thoughtful input.

Appendix iii

Findings

The response by the different categories of respondents is summarised as follows:

A: Table of quantitative data

S/N	Criterion	RDTC		DDTC		WHsC		Owner		Dispenser		Total		% Acceptance
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	yes	No	
1.	Feeling on increase in responsibilities	4	1	NA	NA	NA	NA	NA	NA	NA	NA	4	1	80
2.	Preference of DLDM to DLDB	5	0	NA	NA	NA	NA	NA	NA	NA	NA	5	0	100
3.	Adequacy of committee composition													
(a)	RDTC	2	3	9	10	NA	NA	NA	NA	NA	NA	11	13	45.8
(b)	DDTC	4	1	9	9	NA	NA	NA	NA	NA	NA	13	10	56.5
(c)	WHsC	5	0	16	3	23	16	NA	NA	NA	NA	44	19	69.8
4.	Suitability of the licensing procedures	4	0	19	0	47	1	20	11	NA	NA	90	12	88.2
5.	Suitability of the enforcement set up	5	0	18	1	47	1	NA	NA	NA	NA	70	2	97.2

S/N	Criterion	RDTC		DDTC		WHsC		Owner		Dispenser		Total		% Acceptance
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	yes	No	
6.	Adequacy of the approved DLDM drug list	2	2	13	5	35	12	6	26	15	38	71	83	46.1
7.	Suitability of the requirement for 2 dispensers for each DLDM	5	0	16	1	40	7	26	6	42	11	129	25	83.8
8.	Adequacy of DLDM regulations	NA	NA	15	3	44	2	NA	NA	NA	NA	59	5	92.2
9.	Report on violation of code of conduct by owners and dispensers	3	2	13	6	9	38	NA	NA	NA	NA	25	46	35.2
10.	Acceptance of the DLDM programme	5	0	19	0	48	0	32	0	53	NA	157	0	100
11.	Suitability of decentralized inspection to ward level	5	0	19	0	47	1	NA	NA	NA	NA	71	1	98.6
12	Adequacy of training	NA	NA	NA	NA	32	16	26	6	43	10	101	32	75.9

S/N	Criterion	RDTC		DDTC		WHsC		Owner		Dispenser		Total		% Acceptance
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	yes	No	
13.	Involvement in establishing DLDM programme	NA	NA	NA	NA	NA	NA	32	0	NA	NA	32	0	100
14.	Awareness on enforcement set up	NA	NA	NA	NA	NA	NA	26	6	NA	NA	26	6	81.3
15	Usefulness inspections	NA	NA	NA	NA	NA	NA	30	2	50	1	80	3	96.4
16.	Satisfaction by DLDM owners with technical skill of the dispensers	NA	NA	NA	NA	NA	NA	29	3	NA	NA	29	3	90.6
17.	Perception on sustainability of DLDM	NA	NA	NA	NA	NA	NA	30	2	NA	NA	30	2	93.8
18.	Perception of dispensers on being protected by DLDM regulations	NA	NA	NA	NA	NA	NA	NA	NA	49	3	49	3	94.2
19.	Demand for prescription drugs without prescription	NA	NA	NA	NA	NA	NA	NA	NA	50	3	50	3	94.3

B: Tables of other quantitative data

1. Number of inspection conducted at particular DLDM

Inspections	0	1-2	3-4	5 and above
Response by Owner	1	9	17	4
Response by dispense	1	27	21	4

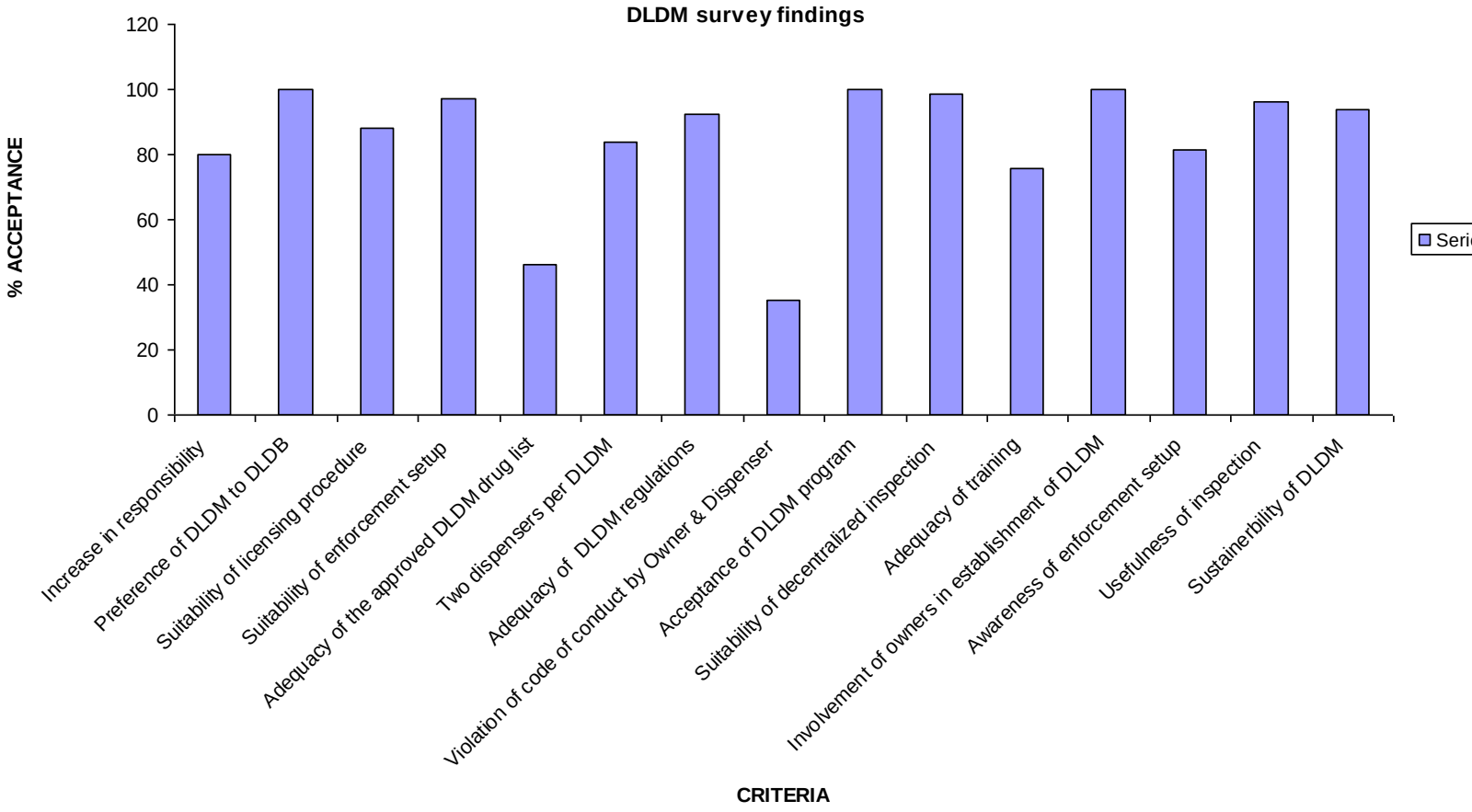
2. Proposed minimum qualifications of DLDM dispensers

Respondents	Frequency	Percentage
Nursing assistant	30	56.61
Form IV	21	39.6
Diploma in Nursing	2	3.8

3. Number committee meetings conducted

Number of meeting		0	1	2 and above
Response by:	RDTC	0	0	0
	DDTC	-	3	16
	WHsC	3	17	28

Histogram of summary of the findings



C: Table of qualitative data

S/N	Criterion	Response
1.	Clear understanding of responsibilities	All stakeholders stated clearly their respective basic roles.
2	Weaknesses of the DLDM regulatory system	A) Regulatory system 1. More powers are centralized to higher levels 2. Lack of requirement for declaration of conflict of interest to members of respective committees 3. The current chain of communication is inefficient as it delays implementation of instructions 4. Regional and District Commissioners being member of the respective committees is a misnomer as development works have to done through him and not by him. Equally true this arrangement denies appeal by complainants B). Administratively 1. Lack supervision and inspection budget 2. Transfer of trained personnel from respective stations leaving untrained ones 3. Failure to convene scheduled meetings 4. Lack of clear job description for members of respective committees 5. Inefficient communication between different levels 6. Shortage of working tools such as stationeries, reference books, uniforms etc 7. Failure of the committees to conduct scheduled meetings and inspections

S/N	Criterion	Response
3.	Challenges for implementing the DLDM programme	1. Ability to sustain enforcement all levels including inspections, conducting of meetings 2. Ability to facilitate establishment of new DLDM by training owners and dispensers 3. Creation of awareness among various stakeholders 4. Ability of the Regional and Local government to support the programme financially
4.	Contribution of PORALG I in sustaining DLDM programme	1. Incorporating DLDM activities in the work plan and budget 2. Assigning staff to the enforcement of DLDM regulation 3. Incorporating DLDM programme in comprehensive council health plan (CCHP) especially on supportive supervision and inspection 4. To provide technical advise 5. Facilitate institutional arrangement to ensure smooth and continuous services in terms of budget, peoples participation and solicit for donors
5.	Strength of the DLDM regulatory system	1. Presence of Act and regulations 2. Existence of administrative structure 3. Presence of trained personnel at all levels 4. Empowerment of the community through the ward leadership and representative of the community 5. Positive political will
6.	Significant common violations observed and collective measures	**Violations** 1. Selling of none unauthorized drugs such as unregistered drugs, government drugs, drugs not included in DLDM list 2. Selling of unregistered drugs 3. Tempering with labels 4. Absence of register **Measures** 1. Confiscation of unauthorized drugs 2. Advise to rectify anomalies observed 3. Closure of shop for habitual defaulters

S/N	Criterion	Response
7	Why inadequate training and training needs (responded by WHsC, owners & dispensers)	**Why inadequate** 1. Time was too short to cover all the lessons **Training needs** WHsC 1. Inspection techniques 2. DLDM regulations Owners and dispensers 3. Retraining
8	Who conducted the inspections at DLDM	TFDA, DDTC & WHsC
9	Opinion on behaviour of inspectors (Owners)	Inspectors were perceived to be diplomatic and educators, only two owners considered them too harsh.
10 (a)	Problems affecting the business (Owners)	1. Poverty patients can not afford the drugs 2. Low level of awareness 3. Shortage of source of supplies 4. Inability to meet the cost of two dispensers 5. Limited list of authorized drugs 6. Presence of illegal dealers 7. Burglary 8. Limited access to capital 9. Defaulting of dispensers 10. Demand for part I drugs without prescription
(b)	Solutions to problems affecting the business	1. Regular inspections to both DLDM and general shops. 2. Intensive advocacy should be done to sensitive the public on the roll of DLDM 3. Regular training of new dispenser to meet the demand.

S/N	Criterion	Response
11.	Reasons for demand for prescription drugs without prescription	1. Inability to meet medical consultation fee 2. Habit acquired from DLDB malpractices 3. Long distance to health facility 4. Avoidance from queuing at health facility 5. Need for secrecy 6. Ignorance from the consequence of effect of using drugs without proper instruction 10. Lack of awareness of the required procedures
12	General comment	1. Regional experts should be involved in the training of owners and dispensers in to have more insight of the programme 2. The is very useful in terms of accessibility to quality, safe and effective drugs 3. The programme has significantly improved the income of both owners and dispenser 4. There should be encouragement for establishment of more pharmaceutical wholesalers in Ruvuma region 5. There should be DLDM for veterinary drugs 6. The programme should be extended to other part of Ruvuma and other regions 7. There should be regular inspections 8. There is an improvement to good dispensing practices 9. While rolling out the programme to other regions, the ownership of the programme by the respective authorities and the community must be spelled out first 10. There should be regular training of dispensers to maintain availability of such carder 11. Introduce cost sharing for training owners and dispensers

D: List of drugs proposed for inclusion in DLDM approved list

1. STI drugs
2. Griseofulvin tablets
3. Ketoconazole tablets
4. Artesunate tablets
5. Cloxacillin capsule
6. Ciproflaxalin tablets
7. Chloromphenicol capsules, eye and ear drops
8. Prednisolone tablets
9. Acyclovir tablets
10. Betamethasone ointment
11. Spironolactone tablets
12. Cimetidine tablets
13. Gentamycine Injection
14. DNS
15. Ringers Lactate
16. Doxycycline Caps
17. Bethazine Injection
18. Quinine tablets
19. Frusemide tablets
20. Tetracycline capsules
21. Cephalexin capsules
22. Ampiclox capsules and syrup
23. Gentrisone cream
24. Diazepam tablets
25. Ephedrine tablets
26. Penicillin tablets
27. Diclofenac injection

9.0 REFERENCES

1. The United Republic of Tanzania, (2003). The Tanzania Food Drugs and Cosmetics Act, 2003, Government printers, Dar es Salaam
2. The United Republic of Tanzania, (2004). The Tanzania Food Drugs and Cosmetics (Standards and Code of Ethics for Duka la Dawa Muhimu) Regulations 2004. Government printers, Dar es Salaam