REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

REVISED MASTER PLAN

FOR

THE PHARMACEUTICAL SECTOR

2005 - 2010
Acknowledgements/Disclaimer

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## 1. ABBREVIATIONS

- **CE** - Continuing Education
- **CEC** - Continuing Education Committee
- **CEU** - Continuing Education Unit
- **CHS** - College of Health Science
- **CHN** - Community Health Nurse
- **CMS** - Central Medical Store
- **DANIDA** - Danish International Development Assistance
- **DHMT** - District Health Management Team
- **DMU** - Drug Management Unit
- **DSU** - Drug and Supplies Unit
- **DTC** - Drug and Therapeutic Committee
- **EDL** - Essential Drug List
- **HF** - Hospital Formulary
- **HSR** - Health Sector Reform
- **HTC** - Hospital Therapeutic Committee
- **INN** - International Non – Proprietary Name
- **MoF** - Ministry of Finance
- **MoHSW** - Ministry of Health and Social Welfare
- **MO** - Medical Officer
- **NDP** - National Drug Policy
- **NGO** - Non – Governmental Organisation
- **PB** - Pharmacy Board
- **PHC** - Primary Health Care
- **PHCC** - Primary Health Care Centre
- **PHCU** - Primary Health Care Unit
- **PSU** - Pharmaceuticals and Supplies Unit
- **STG** - Standard Treatment Guidelines
- **TM** - Traditional Medicine
- **TRIPS** - Trade Related Aspect on International Property Rights.
- **ZFDB** - Zanzibar Food, Drug and Cosmetic Board
2. INTRODUCTION

The revised master plan for the pharmaceutical sector 2005 – 2010 is an implementation plan for the National Policy and it is also a continuation of the previous Master Plan in as far as the implementation of the previous plan 1995 – 1998 fell short of achieving its goals and objectives.

The preparation of this plan has been made possible by contributions of personals who play important roles in the pharmaceutical sector and health sector in general and other interested parties under the sponsorship and guidance of WHO.

The plan covers all the important areas of the Pharmaceutical Sector, setting goals, objectives, activities, indicators and anticipated risk against successful implementation.

Most of the failures in the achievement of the objectives and goals set in the previous plans were mainly caused by lack of sufficient funds and other implementation facilities like trained personnel.

Though the economic situation has not improved much, and may still pose an implementation risk, it is yet expected that some improvement will be made and some goals may be reached through proper utilization of what ever is available in resources. Managerial capacity has improved within the few years, the fact which makes it possible to enhance the implementation of the plan.

The goals and objectives of the NDP are in agreement with Health Sector reform targets and the objectives of the Health Policy. This will necessitate intersectoral cooperation in the implementation of the Master Plan as well as the HSR plan of action.
3. DRUG AND THERAPEUTIC COMMITTEES

Situation Analysis

The Zanzibar health sector reform document 2002/3 – 2006/7 did not mention the importance and the role of Drug and Therapeutic Committee. It does not mean that they have no importance.

The function of such committee were mentioned in the previous Zanzibar Pharmaceutical Master Plan document, they have been established at various Hospitals but nowhere were active in fulfilling their role.

Likewise therapeutic committee is in existence but not functioning as required due to financial constrains.

Goal

- Appropriate selection, adequate procurement and rational management and use of essential drugs at Hospitals within their budget limitations.

Objectives

- To ensure that therapeutic committees exist and are active at Hospitals, PHCs and within the MoHSW structure at Zonal and National levels.
- To ensure that all therapeutic committees fully understand their roles, functions and responsibilities.
- To review the functioning of the committees at National levels every two years

Activities

- By September 2005 DMU will request DSU, Ministry of Health Dar-es-Salaam for copies of the training manuals used for training HTC in order to harmonize the training.
- DMU will prepare a comprehensive information bulletin on the role and functions of HTCs and distribute copies at all Hospitals, PHCs, ZMO, and TU, together with copies of the NDP, STGs and ZEDL.
- In the last quarter of 2005, DMU will prepare one training program for key members of therapeutic committees in cooperation with the TU (training unit).
- Zonal therapeutic committees (considered equal to HTCs ) will function under the responsibility the two ZMOs as instrument to discuss drug availability, ZEML, STGs and RUD at PHCU levels at least two times per year.
- In September 2005 each ZMO will appoint a Zonal therapeutic committees consisting of 8 members, representing the various types of health care workers involved in prescribing and dispensing drugs.
- At the end of every calendar year the Secretaries of the respective HTCs will send to DMU their annual report on performed activities.
- DMU will circulate copies of each annual report in January to all HTCs.
Every second year the DHS will call the Chairman and the secretaries of the HTC for the evaluation of their activities in cooperation with the Drug committee.

At least once every year HTC will evaluate the ZEDL and STGs with staff members in their Hospitals and prepare suggestions on improvement for the Drug Committee.

Those Pharmaceutical In charge of Hospital and ZMO should ensure appropriate membership and full occupation of their HTCs at all times.

**Indicators**
- HTCs appointed and active in all Hospitals and Zones.
- Annual reports available from all HTCs with DMU and circulated.
- Every two years, meeting of HTCs held with Drug Committee of MoHSW.

4. DRUG MANAGEMENT UNIT [DMU]

**Situation Analysis**
There is established a Drug Management Unit since 1995
The Unit is responsible for all drug policy matters and their implementation. The unit is headed by the Chief Pharmacist. It functions under the Directorate of curative services.

Other responsibilities are as follows:-
- Implementation and monitoring of the NDP of Zanzibar.
- Secretarial to the ministerial Drug and Therapeutic Committee and as such responsible for the implementation of:-
  - Zanzibar Essential medicine list.
  - National Drug Formulary of Zanzibar.
  - Standard Treatment Guidelines for Zanzibar.
  - Rational use of Drugs.
  - Curricula review
  - Supervision and support of Therapeutic committees.

- Adequate drug management at public health facilities and institutions.
  - Development of standards to be implemented.
  - Quality of premises.
  - Quality of personnel.
  - Quality of inventory.
  - Training and supervision activities.

- Quantification of National Drug requirements.
  - To support the procurement decisions of CMS.
  - To support Financial Planning for drugs.

- Training of pharmaceutical manpower.
- Support to the Planning Unit in the coordination of donor support to the pharmaceutical sector.

- Annual reporting on the drug situation in Zanzibar.

Earlier advice to prepare comprehensive descriptions of the functions of the DMU has been followed up and was combined with job descriptions for all staff employed in DMU. Part of the function of supervising pharmaceutical and kit use an activity has been transferred to the DHMTs. DMU could thus concentrate more on technical matters.

**Goal**
- To provide pharmaceutical services of sufficient quality in a planned and consistent manner in accordance with the NDP through both public and private health sectors.

**Objective**
- To ensure that Drug and Therapeutic Committee responsible for selection of drugs is revised and strengthened as soon as possible.

**Activities**
- The chief pharmacist will communicate, at least every quarter, with the Chief Pharmacist Mainland on issues of common interest in the area of drug management and coordinate combined implementation of activities, wherever feasible.
- By December of each year, DMU should prepare a report on the drug situation on Zanzibar detailing DMU and DTC activities, drug availability and affordability, compliance with NDP and Act, RUD training activities, supervision and support activities carried out, studies done, drug quantification activities for national and kit requirements, drug budget and the pharmaceutical staff situation.
- By December of each year, DMU should prepare training requirements for pharmaceutical Staffs with full and adequate justification and with the specific purpose to improve management skills in the pharmaceutical sector and hand them over to the Training Unit.
- Whenever requested by DHMTS, DMU should be prepared to cooperate with supervision activities in both zones in the areas of drug management and RUD.
- As a continuous process, DMU will involve itself in the development of feasible standards for drug management at health facilities (storage, dispensing, cleanliness, compounding, staffing etc) in order to ensure appropriate Pharmaceutical services at health facilities.
- DMU to ensure NDP, ZEML, STG and HF are reviewed accordingly.
- The chief Pharmacist will be made responsible by the Ps.

**Indictors**
- Joint activities with PSU mainland.
- Annual report from DMU on Zanzibar Drug situation.
- Drug budgets prepared adequately and in timely manner.
- Training activities carried out and Pharmaceutical staff trained.
- Clear Job description for DMU Staffs.
- Close relation between DMU and PB

**Possible Impediments**
- Insufficient management and technical capacities available in DMU.
- Insufficient resources allocated to DMU to fulfill its tasks.
- Cooperation with PSU mainland unfeasible.

### 5. PROCUREMENT

**Situation Analysis**
Procurement of all pharmaceuticals and supplies for the public health sector is handled through CMS. The Pharmacist in charge and the senior supplies officer should play the major role in this process.

The imports of pharmaceutical products for the private sectors are handled by each importer individually. Each importer is supposed to request an import license, which is checked by Pharmacy Board on origin and prices. This is a special budget available for running cost and for activities such as procurement but unfortunately very limited.

The following figures show budgets, which had been approved and disbursed:

<table>
<thead>
<tr>
<th>YEAR</th>
<th>APPROVED T SH</th>
<th>DISBURSED</th>
<th>% OF APPROVED</th>
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<tbody>
<tr>
<td>2000/2001</td>
<td>177,954,000</td>
<td>38,687,910</td>
<td>21.7%</td>
</tr>
<tr>
<td>2001/2002</td>
<td>334,496,000</td>
<td>121,800,000</td>
<td>36.4%</td>
</tr>
<tr>
<td>2002/2003</td>
<td>265,353,000</td>
<td>36,000,000</td>
<td>13.5%</td>
</tr>
<tr>
<td>2003/2004</td>
<td>304,353,000</td>
<td>20,963,500</td>
<td>6.9%</td>
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The disbursement of money is irregular and only facilitates crisis procurement. When money becomes available, no proper process to set priorities according to the National
Drug Policy and Zanzibar Essential Medicine list takes place. Since the publication of Master Plan, no procurement was made according to the process described. Tenders were not floated and no order was placed based on sound involved. This process has not been transparent.

Apart from government budget, the MoHSW benefit some funds from donors. In the year 2001/2002 the MoHSW got a commercial loan from ADB of about Tsh. 84,776,800 for drug procurements. Other sources are NGOs, private sector etc.

Up to the end of financial year 2001/2002 the availability of drugs and medical supplies was not so persuasive. The situation was much worse in peripheral health care centres.

In July 2003, the MOHSW signed a contract of donation of Tsh 600,000,000 from DANIDA, for procurement of drugs and Medical supplies. The money was deposited to Medical Stores Department, Dar es Salaam and procurement is done through CMS by Kit system. The system effectively started from August 2003 and the contract is expected to end by 2009.

Kits have been packed and supplied so far from MSD: They themselves and shipping direct to CMS, Unguja and Pemba. Procurement is made irregularly. Kit system is focused for peripheral health facilities whereas Hospitals get supply through bulk stock.

**Goal**

The goal is to ensure that the drug requirements for the public sector are procured in a cost and quality efficient manner, through a rational, transparent procurement process.

**Objectives:**

- To ensure that sufficient stocks of both kits and bulk supplies are available in Zanzibar through MSD and other sources when needed.
- To develop a budgeting procedure and guaranteed payment process by Ministry of Finance such that financial obligations can be fulfilled in time to safeguard smooth and uninterrupted supply.

**Activities**

- In September every year the DMU will calculate, in close cooperation with CMSs, the value of yearly requirements based on MSD actual price list and will adjust quantities to fit the early budget, giving priority to vital items.
- By the end of September each year, such a costed list will be approved by DMU and presented to MOHSW and not for endorsement.
By October each year, an order will be placed with MSD by CMS Zanzibar, based on requirement as presented in September.

Pharmaceutical items outside of the ZEML will also be handled by CMS. The CMS will include in its yearly order a tentative schedule of distribution. This schedule is binding for MSD to have the requirements ready not later than the date requested.

By November each year, such a schedule, based on the approved budget, will be worked out in close collaboration with MSD staff.

The MOHSW will put efforts into obtaining an interest–free loan or grant from donors, to be deposited with MSD in Dar es salaam in two different CMS accounts; one for the supply of kits and one for the supply of if bulk items. These funds function as a payment guarantee for stocks held at MSD for CMS Zanzibar.

Other options such as commercial loans to procure consumables should not be pursued for the following reason:

- Commercial loans are costly.
- It is difficult to safeguard quality and adherence to ZEML when a supplies offers credit.
- Loans are likely to lie of a size, which would result in supplies reaching expiry date before being consumed. This would result in an enormous misuse of funds
- The present storage and distribution system cannot cope with major imports being supplied in a short period of time due to lack of space and managerial constraints.

**Indicators**

- DMU has made yearly requirements available to CMS.
- By September each year a list of requirements to be sent to MOHSW /MOF for budget endorsement.
- By October each year, a definite distribution schedule prepared by CMS based on orders placed should be ready.
- By the beginning of each month, CMS to report on the payment made to MSD and actual position of balance of the CMS Zanzibar account at MSD.

**6. STORAGE**

**Situation Analysis**

CMS Zanzibar operate with two stores. The main store on Unguja is part of the MoHSW building and is approx. 400 m². In Pemba there is a second stores of
approximately 14am$^2$ At present however, the Chief Pharmacist is the person with overall responsibility, while at times other senior staff in the MoHSW interfere with CMS management activities. The main responsibility for the stores lies with the Pharmacist Incharge.

On Unguja, storage space is sufficient to serve the present need with good racking, shelves and storage facilities.

Security is a problem and, with several entrances and exits in the store, there is insufficient control of who walks in or out with possible result of stock leakage.

The present staffing level at CMS is as follows:-

1 - Pharmacist  
2 - Pharm.Technicians  
7 - Pharm.dispensers  
1 - Clerk  
6 - Store Attendants

There is a large amount expired stock in those stores at the present time. The last expired stock clearance was done over 9 years ago. Some of the expired drugs are chloroquine as a result of change in Malaria Treatment Policy.

The manual stock control system is efficiently managed and it is possible to follow a requisition from arrival at CMS to the supplies being delivered to the customers

The Zonal Store in Pemba is an old building. With the construction of a harbour at Mkoani it is now 50 kms from the arrival point of supplies. However, DANIDA kits are shipped direct to Wete harbour where the distance to Zonal store is just few metres.

The Storage Condition of Zonal Store Pemba is very bad. There is no Air Conditioners, fans, are not operating, no adequate light. The temperature inside the store exceed to 35$^\circ$C. Due to the many cracks covering the whole building provide accessibility to vermans and other pests is easy.  
The store needs emergency actions to be taken to equip of with all necessary storage conditions.

Storage of drugs and supplies at PHCU level, with kit items being placed in a cupboard, seems inadequate. Most of the PHCU buildings are old with many cracks, which risks the safety of drugs and supplies stored in them. In many cases, no stock control system is in place.
Goal:
- The goal is to make the CMS an efficient unit to cater for all drugs and medical supplies to the public sector.

Objective:
- To have a transparent storage system that enables each user of CMS to be fully aware of the movement of drugs and supplies.
- To have all planning done by the CMS on Unguja and to integrate all supplies for the public health sector in one organization.
- To upgrade the existing storage facilities where necessary.

Activities
- Access to the stores will be limited. This should be strictly limited. Authorized personnel only, and if necessary identity badges with photographs should be issued. This should minimize occurrence of “leakage”.

- All expired drugs should be disposed of by CMS in management and with Zanzibar Food and drugs Board management and this activity should be carried out at regular intervals, at least every two years. First activity to be carried out before 2005.

- Integrate the EPI vaccines and storage facilities

- CMS management will show the various donors, NGO, and Vertical Programmes that they can offer a safe reliable storage system that will encourage them to integrate their activities into CMS.

Indicators
- All goods in CMS are stored in a proper and efficient way and actual stock tally with the stock administration figures.
- Security system is placed for all Medical Stores.
- Vertical Programmes integrated into CMS
- Cooperation with MSD Dar es salaam mainland.
- Expired stock should be removed from CMS.
7. DISTRIBUTION

**Situation Analysis**
The distribution of the kits/supplies is done by ZMO through DHMTs who request monthly from CMS and distribute according to their own schedule.

Supplementary request from PHCCs and PHCUs are placed through the DHMTs, whereby the surplus from the DANIDA kits which is stored in CMS is used. The plan is to distribute these supplementary items at the same time as the kits, but due to a lack of suitable packing material this has not been happening.

The distribution schedule is planned to be completed in four working days in Unguja and 8 days in Pemba.

Zonal Medical Store in Pemba functions as a supplier of DANIDA kits to the DHMTs and services requisitions from three Hospitals, and 2 cottages Hospitals. A 3.5 tonnes vehicle donated by EDP is still available and function the task of drug distribution in Pemba.

As the present kit system ends by 2009, the MOHSW need to decide if they are going to buy kits or bulk drugs for supplies to PHCUs and PHCCs. If the latter is chosen, serious thought and planning will need to be done quickly, repacking and distribution. This will cause a major problem. Stock management and storage will also be a problem in the PHCUs.

Medical supplies for the MOHSW from abroad are received at CMS. Theoretically Pemba should received 40% of the quantity received at CMS and this distribution is done in less then one month.

**Goal**
The goal is to ensure that public sector drugs and supplies are distributed through one Central Channel at regular planned intervals, so that they are available when and where needed.

**Objectives**
- To centralize distribution of all supplies for the public sector at regular planned intervals.
- To distribute all public sector drugs in an efficient and pre-planned manner.
- To maintain a planning system with standardized requisition forms and stock control system which will include pricing information for budgeting purposes.
Activities
- To continue with the present DANIDA kit system for at least the next five years, to guarantee timely, adequate supplies to the peripheral health facilities.
- To set up purchase and supply route in conjunction with MSD Dar es salaam to ensure continued supply of drug kit.
- CMS together with the DHMTs, will plan a delivery schedule for the drug kit. This schedule will be circulated to all the other programmes to enable them to integrate their deliveries with CMS.
- A budget will be prepared by CMS for the distribution of drugs and supplies which would include vehicle maintenance and running, costs.
- To maintain a set of forms during 2005 for requisitioning drugs and supplies, that will include financial data which can then be used for budgeting purpose by the requisitioning institutions.
- The vertical programmes will integrate their drug supply and distribution into the CMS system.
- All resources/budget available for each individual Programme will be pooled and money will be transferred to CMS to pay for distribution services rendered.
- The Vertical Programmes will also give CMS a prioritized monthly distribution list and share the cost.
- The delivery schedule may not be exactly as requested but will attempt to accommodate everyone’s requirements.

Indicators
- All drugs and suppliers are distributed according to the published plan.
- Supplies to all Vertical Programmes are managed by CMS.

8. PHARMACY BOARD

Situation Analysis
The present pharmacy Board still operates under the old Pharmaceutical and dangerous drug Act 1986. As such it is called the Pharmaceutical and Dangerous Drug Board or in short Pharmacy Board.

- The Pharmacy Board consists of 11 members, with the Director of Medical services being the Chairman. The Pharmacy Board answers directly to the Minister responsible for Health.
- The daily functions of the Board are performed by the Pharmacy Board Secretariat which is supposed to deal with Pharmaceutical inspection, drug
- registration, drug information quality control and control of drug importation.
- The Pharmacy Board meets at least 6 times per year.

**Goal**
To have fully functioning drug regulatory authority that ensure all pharmaceutical products reaching the patient in Zanzibar conform with acceptable standard of quality, safety and efficacy.
That all premises for manufacturing, storing and distributing products comply with specified requirements and to ensure that only sufficiently qualified staff are responsible for handling these products.

**Objectives:**
- To have Pharmacy Board and Pharmacy Board Secretariat which is capable of performing all the required task and the responsibility laid down by the Act.
- To improve quality control laboratory within the Pharmacy Board Secretariat to screen quality of drug circulating in the market.
- Pharmacy Board to have its own premises to undertake its function by 2006.

**Activities**
- The Minister responsible for health will be responsible for supervising functions of the Board and its secretariat.
- By November 2005 the Minister will appoint a full – time Registrar.

**Indicators**
- Appointment of full time registrar by the Minister.

**Outcomes**
- Delaying in the appointment of the registrar.

9. DRUG REGISTRATION

**Situation Analysis.**
Zanzibar is allowing only products registered by Tanzania Food and Drug Authority and those notified by Zanzibar Food and Drug Board (ZFDB) to circulate in the market.

**Goal**
Zanzibar to have its own drug registration system.
Objectives
To ensure that all drugs circulating in Zanzibar are Registered

Activities
- The Registrar shall keep Register of all Pharmaceutical products that have been registered for use in Zanzibar.
- Only Pharmaceutical product appearing in Register will be permitted to be imported in Zanzibar.

Indicators
- Administrative methods and procedures selected for the purpose of drug registration are in place.
- Importers and local manufactures are aware of these methods and procedures.
- Importers applying the methods and procedures setup.

expected outcome [Risk]
- Unofficial importation and drug donation.

10. LEGISLATION AND REGULATIONS

Situations analysis
The current Pharmaceutical and Dangerous Drug act dates back to 1986. The previous Master Plan provide for amendment of the Act, in order to bring it into conformity with the intentions of the National Drug Policy of Zanzibar. Various drafts have so far been worked out by the Board for a full new Act, the last one is on this year 2004 which is now in on second stage for discussion with other stakeholders before its presentation to the house of representative for rectification. The new Zanzibar Food and Drug Board will replace pharmaceutical and dangerous drug Act 1986 and will include food, cosmetic and traditional medicine & Alternative Medicine.

Goal
Effective implementation and legal enforcement of the National Drug Policy of Zanzibar.

Objectives
To have a new Zanzibar Food and Drug Board enacted that confirms with the requirement of the National Drug Policy and gives the National Drug Policy a legal foundation.
**Activities**
- The Board will discuss the draft with stakeholders in the light of the requirements of the National Drug Policy before December 2004.
- At the latest in February 2005 the Principal Secretary will bring the proposed new Act to the interministerial committee of PSs for approval.
- By May 2005 the Attorney General will have concluded the task of converting the draft of new Act into proper legal phrases.
- By September 2005 the new proposed act will be brought before the Zanzibar House of Representatives for approval.
- By November 2005 the new Act will be printed in sufficient copies to provide health care providers in both private and public sector copies will also be presented to all other relevant authorities and teaching institutions.
- Immediately after approval of new act Zanzibar Food and Drug Board will start enforcing the new act in support of the requirements of National Drug Policy.

**Indicators**
The new Pharmacy act approved by the House of Representatives.
Copies of the new act available and distributed.

**Outcomes**
Procedural delays in the process of enacting the new act.

**11. PROMOTION**

**Situation analysis**
The Pharmaceutical and Dangerous Drugs Board is in the way to amend the new Act so as to satisfy the requirement of the National Drugs Policy. Monitoring of adherence to ethical criteria and legal obligations on advertising and promotion are among the duties of the Board.

**Goal**
To protect consumers and health professional against false claims and/or biased information contained in either promotion or advertisements.

**Objectives:**
- To establish ethical criteria for the protection of consumers and health Professional

**Activities:**
- By July 2005 the Pharmacy Board will have developed ethical criteria for drug promotion and advertisement.
- Incorporation of the adopted ethical criteria into regulations to the act by the Board before end of 2005.
- The Pharmacy Board will develop a monitoring system for promotional activities which will include in reporting system to be used by drug inspectors to report on any advertisement which does not comply with the law.
- All advertisement and promotion activities should get approval by the Board.

**Indicators**
- Monitoring system for promotion activities in place.
- The approved system for drug advertisement and promotion by Pharmacy Board in place.

**Outcomes**
Close collaboration with other Ministries needed, in controlling Advertisement and Promotion.

**12. DRUG INFORMATION**

**Situation analysis**
The Drug Management Unit is the responsible body for the supervision of the publication of Zanzibar Essential Medicine List (ZEMLIST) formulary, Standard Treatment Guidelines and drug information Bulletin.
The Pharmacy Board to be Zanzibar Food and Drug Board provides necessary drug information for private sectors and also for medical professionals.

**Goal**
To ensure that correct and useful information about correct handling and use of drugs is available to health workers at all levels and to the end users.

**Objective**
To provide constant good quality and up to date drug Information to all drug users in the public and private sector.

**Activities**
- The Drug Management Unit (DMU) will be responsible for provision of the necessary Drug Information as a drug Information Center. The chief pharmacist as head of DMU will appoint one of the staff members of DMU as responsible person for the drug Information Bulletin and other drug Information services by 2005.
The pharmacist responsible for drug information will prepare annual working schedules and plans for drug information activities, which should include drug information programme for the public, for mass media in Kiswahili by July every year DMU will continue to organize drug use surveys and the drug committee will use workshops and other suitable cost effective intervention to improve the drug use in the public and private sectors and cooperates with the training unit of the Ministry responsible for health.

**Indicators**
- Only drug Information services issued by the Pharmacy Board is working.
- The Drug Committee reviewed and activated.

**Outcomes**
Pharmacists engaged in the Ministry are few. DMU not sufficiently staffed to cope with drug information services.

**13. QUALITY ASSURANCE.**

**Situation Analysis**
Quality Assurance of drugs exist in Zanzibar but need to be updated, the essential medicine imported by government and Private sector screened its quality by using Mini Lab. Kit. There is still need for a fully equipped Laboratory to handle all kinds of products.

**Goal**
To ensure that all drugs in Zanzibar are safe, effective and of good quality

**Objectives**
- To develop administrative methods and procedures that should be applied and followed by all importers of drugs into Zanzibar.
- To monitor adherence to these methods and procedures.
- To ensure that local manufacture of drugs comply with all requirement (such as GMP) for quality assurance of their products.

**Activities**
- In 2005 The Pharmacy Board Secretariat will make sure the new ZFDB is function to ensure the quality of drug.
- To establish a Modern Quality Control Laboratory.
14. VETERINARY DRUG SUPPLY

Goal
To ensure the safe and Rational Distribution storage, Prescribing Dispensing and use of Veterinary Products.

Objectives

i. All veterinary drugs circulating in the market of Zanzibar should be registered by the Zanzibar Food and Drug Board.

ii. Premises used to dispense Veterinary Drugs should be under the supervision of Veterinary surgeon or a duly qualified and Registered Pharmacist.

iii. The essential medicine concept shall equally apply in the control and utilization a veterinary drugs.

Activities

i. By January 2006 A veterinary essential drug list will be established and updated by a committee constituted by the Zanzibar Food and Drug Board.

ii. The Register shall keep Register of all Veterinary Drugs product that have been registered for use in Zanzibar by January 2006.

iii. Only Pharmaceutical products appearing in the Register will be permitted to be imported.

Indicators

i. A veterinary essential drug list to established.

ii. All veterinary drugs product circulating in the market are registered.

15. RATIONAL USE OF DRUGS

Situation Analysis
Rational drug use requires that patient receive medication appropriate to their clinical needs in doses that meet their individual requirements for an adequate period, and at the lowest possible cost to them and their community.

Rational drug use promotes quality of care and cost–effective therapy. It helps to ensure that drugs are used only when they are needed, and that people understand what the medicines are for and how to use them.

Problem of irrational drugs still exist because most of the PHC facilities do not have staffs who were sufficient trained in comprehensive patients management. This leads to irrational diagnosis, prescribing and dispensing.
The MOHSW has started program of in-service training on rational drug use in collaboration with WHO. Training of TOT on rational drug use was conducted in 2003.

The MOHSW has Training Unit (TU) under the Department of Planning which is responsible for local basic training programme for nursing, Clinical Officers and Laboratory assistants (Health Science) and post-basic training programmes[Community Health Nurse and continuing education (CE)] The Essential Drugs Concept has been incorporated in the Training curriculum of the above mentioned staffs.

Currently the pharmacy board is publishing a Pharmaceutical newsletter, which comes out quarterly in a year. This and other information materials, posters and leaflets will continue to be produced and disseminated to all health workers to impart to them on current drug information.

The ZEML and Standard treatment guidelines reviewed every regularly will continue to be used in the training of health workers to improve prescribing and dispensing habits.

Supervision of health facilities is currently the responsibility of the ZMOS and DHMTS. Supervision however is infrequently and not properly done with no follow up or supervision tools eg guideline. Reasons for this include inadequate means of transport and poor motivation for the supervision. DMU is recently introduced forms for monitoring drug use from the health facility level to central medical stores. These will be compiled every 3 months by the ZMO for further compilation of the Zanzibar drug utilization reviews and quantification. The forms will also lead to review of abnormal prescribing practices.

**Goal:**

To promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personal and to support the informed and appropriate use of drugs by the Community.

**Activities:**

- DMU will continue to train health workers on Rational Drug Use. All health care providers in Zanzibar in the public and private sector will have received such a training by 2008.
- A study to investigate RUD in Zanzibar using RUD indicators will be conducted in 2006.
- The Training Unit will collaborate with DMU, CEU to develop curricula for on the job implementation of STGs, ZEDL and over EDC elements, including proper dispensing and prescribing by 2007.

17.
DMU together with CEU/CECs will coordinate annual zonal and/or national meeting dealing with pharmaceutical issues coordinate annual zonal and/or issues considered relevant for CE activities.

The PB and DMU will review and further develop guidelines on the minimum standards, required for various pharmaceutical activities (compounding, dispensing, wholesaling etc) by 2009.

DMU will provide updated information to the TU regarding pharmaceutical issues, to be dispersed through basic and post – basic programs.

In July 2005, DMU will prepare for the TU an over view of the EDC, for inclusion in training curricula.

The TU will communicate to DMU changes in the use of training materials and seek its support in ensuring adherence to the EDC and NDP in selecting those materials.

By June 2006, DMU will develop and disseminate the guidelines on good dispensing practice to health workers in the public and private health facilities.

DMU will distribute ZEDL, STGs and Hospitals formulary widely health care providers in the public and the private sector whenever new editions have been prepared.

DMU will develop and disseminate supervision guidelines and other tools to all health providers by 2006.

Consumer education programmes on RUD will be developed and widely disseminated by 2007.

The DMU will prepare a meeting with ZMOs and DHMTs to adjust the guidelines where necessary to the conditions on Zanzibar.

Prescribers who are not qualified should not allowed to prescribing and dispenser.

DMU will collaborate with TU for the revision and annual updating of the CHS curricula for COHAS, Nurses which will always include the EDC and use the most recent ZEML and STGs by 2007.

**Indicators**

- Guidelines on the minimum standards for pharmacy practice developed and widely disseminated.
- Training curricula, updated on EDC, ZEDL and STGs available and regularly revised.
- Training materials used at CHS conform with EDC/NDP.
- Annual meetings by DMU and CEU/CECs on pharmaceutical CE activities.
- Information materials on good dispensing practice widely available in public and private sector.
- Supervision guidelines for Zanzibar develop and widely.
- Study an Rational Drug Use conducted in Zanzibar distributed to 2 MOs and DHMTS.

18.
**Outcome**
Training institutions in Zanzibar should use EDC, ZEML and STGs in training curriculam.
Prescribers and dispensers in Zanzibar prescribe and dispense rationally.
Consumers in Zanzibar to be well informed on rational drug use.

16. DRUG AVAILABILITY

**Selection**

**Situation analysis**
The existing Pharmaceutical and Dangerous Drug Act 1986 specifies requirement, rules and regulations for dealing with pharmaceuticals in Zanzibar. It is now not comprehensive. It regulates particularly the private sector, which was permitted to operate again in 1986. It is limited in scope by focusing particularly on storage, distribution and use. A proposed new Act restricts the import of drugs to only those, registered by the Pharmacy Board.

With the introduction of the National Drug Policy, new principles and approaches were introduced into the pharmaceutical products, selected by applying specific criteria. Zanzibar Essential Medicine List [ZEML] has been prepared by the Drug committee and classifies all drugs by their degree of importance to the health care system as either vital (V) essential (E) or non-essential (N) (VEN-system).

The Zanzibar Essential Medicine List (ZEML) is part of a dynamic system of rational treatment options and is closely related to the Standard Treatment Guidelines. It needs to be updated at regular intervals in order to continuously meet local needs.

**Goal**
The MOH SW will ensure that the ZEML is revised once every two years by a Drug and Therapeutic Committee. This is composed of the various type of Health Care Workers as proposed in the NDP.

STG and relevant curricula should be revised in accordance with the ZEML.

No drugs other than those registered by the Pharmacy Board will be allowed in the market.
Objectives

- To ensure that the Drug and Therapeutic committee represents the various types of prescribing and dispensing health care workers.
- To ensure that drugs are selected and classified every two years by the National Drug and Therapeutic Committee according to the criteria mentioned in the National Drugs Policy.
- To ensure that Standard Treatment Guidelines and relevant curricula reflect the latest Zanzibar Essential Medicine List.

- To ensure that the Pharmacy Board allows only registered drugs into Zanzibar.

Activities

- The head of drug Management Unit (DMU) will be responsible for the functioning of the Drug and Therapeutic committee. Head of DMU will be the secretary of the committee.
- DMU will disseminate form for health care workers to be used to request and motivate changes in ZEML and STGs and include the form in the Drug Information Bulletin and Pharmaceutical Newsletter.
- At least once every two years the Drug and Therapeutic Committee will meet on invitation from DMU to decide on the additions and deletions and revision of the ZEML and the STGs. Selection and use of drugs will be presented using generic names.
- The Principal Secretary will appoint the drug and therapeutic committee, seeking advice from DMU and other departments before June 2005.
- DMU will publish the ZEML once every two years, in June, DMU will publish the STGs once every two years in July. The mentioned drugs will be presented using generic names.
- The Drug Therapeutic Committee will annually review the curricula, used to train prescribing and dispensing health care workers trained in Zanzibar (e.g Clinical Officer, CHN and Nurses) to ensure incorporation of the essential medicines concept and latest versions of ZEML and STGs. The review will be initiated by DMU after, seeking cooperation with the relevant authorities of the training institutions and the Training Unit of the MoHSW.
- The food and Drugs Board will adopt the ZEML as one of the main criteria for allowing the importation of drugs into Zanzibar.

Indicators

- Existence of functioning Drugs and Therapeutic Committee appointed by PS and meeting held every three months and minutes taken
- Chief Pharmacist in DMU made responsible for functioning of the Drug & Therapeutic Committee.
ZEML printed and distributed by DMU every two years, in June.
- Only drugs on the ZEML available in the public health sector of Zanzibar.
- STGs Printed and distributed once every two years starting from 2005.

**Expected Outcomes:**
- ZEML to be revised periodically
- STGs to be revised periodically
- Drug and Therapeutic Committee to be revived

**17. HUMAN RESOURCES DEVELOPMENT**

**Situation Analysis**
Over past 8 years, the Pharmaceutical manpower situation has not changed very much. According to the present health manpower plan, 27 pharmacists are needed in the public sector (DMU, CMS, PB and Hospitals). In other words there is a current shortage of 15 Pharmacists. Only one pharmacist is available in whole Pemba Island. All public sector pharmacists work part—time in the private sector after normal working hours.

Other pharmaceutical cadres in the public sector of Zanzibar are also insufficient. The number of pharmaceutical personnel employed by government each year is smaller than those taking retirements. This means manpower for pharmaceutical staff is continuously going down. Most of pharmaceutical staff have accumulated in Unguja due to due to unattractive conditions in Pemba. Exact requirements for the mentioned carders in the private sector are unknown.

Zanzibar used to train Pharmaceutical cardes in its Collage of Health Science – Mbweni until 1992. Lack of continuing plan ended the course. Zanzibar is thus totally dependant on education on the Mainland or else where abroad.

Training to upgrade the skills and improve performance of local pharmaceutical personnel is non-exiting, but it is recognized as an omission that needs to be addressed.

**Goal**
The goal is to ensure that Zanzibar becomes self sufficient in its requirement for properly trained and skilled pharmaceutical staff in both public and private sectors.
**Objectives**
- To increase number of pharmacists and other pharmaceutical staffs in the public and private sectors.
- To harmonize training of pharmaceutical staff with Tanzania Mainland.

**Activities**
- To investigate possibilities for continuing education of pharmaceutical personnel, in collaboration with the Training Unit in the MOH
- By June 2005, DMU will have carried out a rational analysis of staff requirements in the public sector, prioritize the requirement for the various institutions and consider reasonable options for posting available staff more evenly. An estimate will also be made for the private sectors
- DMU will initiate merging of the two cadres Pharmaceutical Technician and (locally trained) Pharmaceutical Assistants into only one cadre named ‘Pharmaceutical Technicians” in order to harmonize with the Mainland.
- DMU will initiate the above course to be trained in Zanzibar at College of Health Science to avoid totally dependent on Mainland.

**Indicators**
- At least 27 Pharmacists are available in public health sector to cover the needs.
- Training of Pharmaceutical Technician is taking place.
- Proper allocation for the present pharmaceutical staff to all areas where shortage has taken place.
- Course of Specializations for Pharmacist (e.g Traditional Medicine, Pharmacognosy)
- At least 33 Pharmacists are needed for private sector.

**18. DISPOSAL OF EXPIRING AND UNWANTED DRUGS**

**Situation Analysis**
There is accumulation of expired drugs and chemicals in various places of storage both in the public and private institutions. This is caused by shortage of funds for disposal and lack of proper reporting system. The great bulk however is the result of donations of medicines and chemical which are pushed by Donors without following Government regulation or Guidelines.
Disposal of expired and unwanted drugs is done under the supervision of the Pharmacy Board in collaboration with other partners e.g Department of Environment.
Objectives
- To ensure that appropriate methods for the disposal of expired drugs are applied so as to avoid contamination of environment and endangering community health.
- To ensure that regulations and guidelines for donations and regular importations are followed by donors and importers.

Goal
To ensure that all unwanted and expired drugs, medical supplies and unwanted waste in the public and private sector are disposed of promptly, efficiently and safely.

Activities
- Stock checking to be conducted annually.
- To set up proper reporting system of expired and unwanted pharmaceutical medical supply, and other chemicals from various institutions.
- Donated drugs are not entered into the Government inventory or considered state property unless specifically accepted by the regulation set up by Board.
- The task to be conducted in collaboration with other sectors eg Department of Environment and should be run periodically.
- Guidelines for disposal of expiring and unwanted drugs are prepared.

Indicators
- Distribution of forms for recording of expiration of drugs to the public and private Health facilities.
- Circulation of guidelines for accepting drug donation.

Expected Outcome (Risk)
- Interference by politicians in accepting drug donation.

19. LOCAL PRODUCTION

Situation Analysis:
There is no local production of Pharmaceuticals neither in public nor in private. The former Pharmaceutical Master Plan has highlighted the importance of such plant, but then nothing has been produced.

The old Government Pharmaceutical plant now is under the ownership of Ministry of Finance instead of MOHSW in order to minimize the importation of finished products and save foreign currency, the government invites interested donors for joint venture.
Goal:
To promote the National Pharmaceutical industry both public and private with the aim of increasing self sufficiency in production and packaging and reducing the dependence of foreign suppliers.

Objectives
- To acquire modern Pharmaceutical technology and become self reliant in the production of Pharmaceuticals.

Activities:
1. To negotiate with interested partners interested with local production of Pharmaceuticals.
2. To train adequate number of personnel to cover both public and private sector production operation.
3. To provide protection to the local pharmaceutical production.

Indicators:
1. Production of pharmaceuticals starts in public or private sectors.
2. Minimize the amount of imported finished pharmaceutical products.
3. Reduced or waved the import duty on basic materials and packages.

20. RESEARCH AND DEVELOPMENT

Situation Analysis
All on going research activities in MoHSW are under the Zanzibar Medical Research Council, There is no research going on the Pharmaceutical Sector. Ministry aims to support research and development activities which facilitate the achievement of the Pharmaceutical Sector.

Goal:
Establishment of organized and Coordinated Pharmaceutical Research Programme.

Objectives
- To rationalize drug use through provision of correct information, data on compliance, prescribing etc.
- To improve pharmaceutical technology through research in specific identified areas.
Activities:
1. To identify areas for research.
2. To seek necessary support from international organization interested in research e.g WHO (Contacts to be done by MoHSW by mid 2005)
3. To conduct Rational Drug use Training.
4. To cooperate with the research council so as to benefit from the facilities available with council e.g training and funds.
5. To comply with ethical and other standards set up by Research Council and those of Food Drug legislation.

Indicators:
1. Areas for research surveys identified and prioritized.
2. Organised research activities taking place by (2006)
3. Publication, documents (as a result of conducted research) available.
4. There should be motivation for the staff to conduct research.

21. AFFORDABILITY

Situation analysis:
Affordable prices are an important pre-requisite for ensuring access to essential drugs in the public and private sectors.

The long and critical shortage of drugs in the public sectors in Zanzibar together with the low economic power of the population has contributed to some extent to the comparable high prices of drugs in the market.

Promotion of generic as one of the measures to increase affordability has been part of the National Drug Policy since 1990. The use of generic names promotes competition among equal medicines from different sources or suppliers, identified by international non proprietary names (INN) Generic prescribing and dispensing is therefore promoted in the public and private sectors to reduce any costs, and increase drug availability and consumer access. It also promotes rational use of drugs at every level of the health care system.

The Ministry of Finance has also for sometime abolished some taxes on drugs on the essential drug list as well as for raw materials.

Goal
To make medicines affordable to the public.
Objectives

1. The Use of generic names promoted to all health providers in the public and private sector.
2. To promote the use of interval and external reference price, to guide procurement at the Central Medical Stores and Medical Stores Department to prevent unreasonable high prices.
3. The MoHSW to make available essential drugs at all times in the public sector.
4. To encourage consumer groups in Zanzibar to demand not only for good quality drugs but also for reasonable prices of medicines in Zanzibar.
5. The Government to be encouraged to part in place strategies aiming to increasing affordability of drug to the public, such as reduction of drug taxes, tariff etc. especially to essential drug.

Activities

1. The Central Medical Store to use good procurement practices including the use of interval and external reference prices by 2005.
2. DMU and the Pharmacy Board to conduct a study on drug pricing in the private and public sector in Zanzibar by 2006.
3. DMU to negotiate with MoF for increase in financial allocation for procurement of medicine (Ministry of Finance).
4. Consumer (Charges point)

Indicator

1. Generic prescribing and dispensing widely done by all health workers.
2. Study on drug pricing conducted.

Expected Results

- Results from the pricing study used to develop policies, which will lead to affordable prices of medicine in Zanzibar.

22. INTERSECTORAL COOPERATION

Situation analysis

Health management teams are still working. Contributions and participation of DHMTs which are under ZMO are clearly seen during epidemic such as cholera, National Vaccination days and others.

Vertical programmes activities are integrated through Central Medical Stores during implementation of the new health sector reform activities.
The Ministry of Health through DMU is coordinating with the following sectors:
- Ministry of Finance.
- Medical Council.
- Association of Private Health Service Providers.
- Research councils an others.

**Goal**
- To have increased coordination and integration in line with the decentralization processes of the Ministry.

**Objective.**
- To deconcentrate i.e to transfer resources and authority to the periphery of MoHSW, but still within full control of the MoHSW.
- To integrate all vertical programme in line with what is laid out in the Health Sector Reform Document.
- To sustain the inter ministerialand intraministerial committees.

**Activities**
- Activate Health Management team by July 2005
- Development uniform planning, budgeting, accounting, auditing and monitoring systems for HMTS.
- Implementations of measures by the Ministry to work into effective approaches to multisectoral collaboration in the line within the Health Sector Reforms.
- Implement activities to sustain the present work of the mentioned committees.
- Implement coordination and integration of physical distribution via CMS for all vertical programmes.

**Indicators.**
Integration of various activities via HMTs actively started to work.

**23. INTERNATIONAL COOPERATION**

**Situation Analysis.**
There is still technical assistance going on in order to maximize the efficient utilization of the limited resources available in implementation of ZNDP.
The following donors are actively cooperate with the Pharmaceutical sector through MoHSW:

- WHO
- DANIDA
- Unicef
- Some National Government like China, USA and others together with NGO’s
- Religious organization.

**Goal:**
Continuous cooperation with international donor, agencies in order to assist MoHSW in improving health activities.

**Objective**
To continue in operation and development of the Pharmaceutical sectors.

**Activities:**
- Ministry of Health constantly look for more cooperative donor.
- To prepare write up for our important needs.
- Maintenance of donors.

24. PATENT

**Situation analysis**
Zanzibar still uses the 1932 decree on patents and this implies to administer secondary registration of patents.

The World Intellectual Property Organisation (WIPO) has been approached to help in drafting a new patent law compliant with TRIPS and DOHA flexibilities.

The Ministry of Health and Social Welfare will collaborate with the responsible Ministries to ensure that public health is given first priority in international negotiations.

**Goal:**
To ensure that the protection of patents for pharmaceutical products or processes does not infringes upon the accessibility of safe effective and affordable essential drugs.
**Objectives:**

1. To ensure that protection mechanisms in building the TRIPS Agreement for developing countries to be included in the regulations.

2. The MOHSW are responsible for health will coordinate with other government ministries particularly justice and trade to ensure that public health, interest are taken into accounts in international negotiation..

**Activities**

1. DMU and the Pharmacy Board to meet regularly with the Ministry of Justice and constitutional affairs and the Ministry of Trade and industry and other stakeholders to discuss issues on patents.

2. The Pharmacy Board to ensure that TRIPS Agreement issues are incorporated in the current Act by 2006.

3. DMU and Pharmacy Board to prepare information on TRIPS Agreement and disseminate to policy makers and all health workers as well as the community by 2005.

**Indicators:**

1. Meetings with Ministries of Justice and Trade and other stakeholders held and minutes taken.

2. TRIPS Agreement to be incorporated in new Act.

3. TRIPS widely disseminated.

**Expected results (outcome)**

TRIPS issues dealing with patents widely disseminated and implemented.

**25. TRADITIONAL MEDICINE**

**Situation Analysis**

Zanzibar with its tropical maritime climate covered with a variety of plants and spice both natural and cultivated, has a great potential for the use of Traditional Medicine. The practice of Traditional Medicine using herbs is well –established in Zanzibar. The Traditional Herbalist have usually acquired their well-guarded knowledge from their grandfathers.

With the increase in shortages of drugs in the public sector and their high prices in the private sector, the demand for Traditional Medicine is slowly increasing, particularly because of the fact that its cost is in most instances lower and some people even practice self-medication with herbs.
The Ministry of Health is aiming at facilitating promotion of its developments and rationalization of its use.

**Goal**
To create a health sector in which the most effective elements of both modern and Tradition practices co-exist and complement each other in the provision of self and food quality practice.

**Guidelines Principal**
1. Regulation and policies governing Traditional Medicine should be formulated.
2. Traditional Medicine unit should be strengthen in order to regulate and promote Traditional Medicine practices.
3. Development of technology for industrial scale production of Traditional Medicine should from long term policy of Traditional Medicine.
4. Research in Traditional and alternative medicine will be encourage to revaluate on quality and safety of traditional and alternative medicine.
5. Alternative medicines practitioners will be encourage to co-operate with workers in the formal health sector, particularly in programmes where these can be involved to promote good health to the people.

**Objectives**
To conduct research the area of Traditional Medicine with the aim of establishing a knowledge base sufficient for collaboration between and Tradition practitioner of medicine.

To establish a common forum where this knowledge is shared between the two parties.

To establish relationship with Traditional Medicine practitioners.

**Activities**
- The MOHSW to develop the TM act by 2006.
- The MOHSW to develop a TM board which will over see the practice of TM in Zanzibar by 2007.
- The TM Unit to develop and disseminates widely in English and Swahili by 2008.
- The TM to stand registering TM practitioners in Zanzibar by 2007.
- Before July 2006 TM Unit to all a meeting of a group of Traditional herbalist to explain the Government policy and objectives on TM and facilitate formation of herbalist Associational as a initiative to organize them.
- By end of 2006, establish areas for research in TM, locating the resources and commission if the studies.
Indicators

- Forum for the exchange of ideas established.
- Traditional Medicine Act developed and disseminated.
- In place.
- A system for registration of TM practitioners in place.
- Research in Traditional Medicine conducted.
- Various Traditional Medical policy guidelines.
- Developed and widely circulated.

26. MONITORING & EVALUATION

Situation Analysis
A system for monitoring and evaluation is a constructive and evaluation is a constructive management tool that enables an ongoing assessment of progress, and contributes to the necessary management decision. It also provides transparency and accountability, and creates standard by which comparisons can be made between health facilities, districts or countries over time. All of this may produce the necessary evidence that progress is being made or not, and can be used to get support from interested parties and policy makers.

The Zanzibar National drug and its master plan first developed in 1990 and 1995 respectively. Although the master plan had indicators for measuring the implementation of the NDP, monitoring and evaluation of the NDP was not done.

With the revision of the NDP in 2004, aspects of Monitoring and Evaluation have been included to assist in the years of its implementation. The WHO has already developed a tool for a comprehensive evaluation of the NDP which can be adopted by any of its member’s states.

Goal
To support the successful implementation of the Zanzibar National drug policy by establishing mechanisms for monitoring and evaluating the impact of the Zanzibar National drug policy.