

External Evaluation
of the Pharmaceutical Sector
in Mozambique

Consolidated Report
July 2007



REPÚBLICA DE MOÇAMBIQUE

**MINISTÉRIO DA SAÚDE
GABINETE DO MINISTRO**

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Technical Cooperation for
Essential Drugs and Traditional Medicine

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LIST OF ACRONYMS USED IN THE REPORT

ARV	Antriretroviral
CH	Central Hospital
CIMED	Information Centre for Medicines
CMAM	Central Drugs and Medical Supplies Procurement Service
CTTF	Technical Committee for Therapeutics and Pharmacy
DNS	Directorate for Health
FARMAC	Empressa Estatal de Farmacias
FCMSM	Common Fund for Medicines and Medical Supplies
GoM	Government of Mozambique
ICB	International Competitive Bidding
LCB	Limited Competitive Bidding
LNCQM	Mozambique Quality Control Laboratory
MISAU	Mozambique Ministry of Health
MNF	Mozambique National Formulary
MOH	Ministry of Health
NRA	National Regulatory Authority
ORS	Oral Rehydration Salts
PESS	Strategic Plan for the Health Sector
SDC	Swiss Agency for Development and Cooperation
SIGM	Drug Management Information System
TOR	Terms of Reference
WHO	World Health Organization

CONSULTANCY PROCESS AND REPORT PREPARATION

This report summarizes the results of a series of six World Health Organization (WHO) consultancies fulfilling the terms of reference (TOR) for the "External Evaluation of the Pharmaceutical Sector in Mozambique, 2005" as authorized by the Ministry of Health of Mozambique. The evaluation took place over a period of 11 months from April 2006. The TOR are contained in Annex 1.

The initial consultancy of this mission involved a survey of the pharmaceutical sector using the WHO Level 2 package of indicators, which had been adapted to the country situation. The report of the findings of the survey carried out in April 2006 is included as Annex 2. In addition to supporting the survey process, the WHO expert together with national counterparts reviewed and prioritized the TOR for subsequent consultancies. This is described in Annex 3.

The second phase of consultancies (June and July 2006) involved 4 experts. One of them, travelled to 2 provinces outside Maputo to gather information and to interview relevant persons about the procurement, distribution and use of medicines in the health services (full report in Annex 4). Two other experts, concentrated their time in Maputo with officials of the Ministry of Health and officers involved in the policy, financing, regulation and supply of medicines (Annex 5). A last one, focused on the quality control laboratory (full report in Annex 6). Other follow-up consultancies provided further in-depth analysis of procurement and storage (November 2006, Annex 7), and product registration and regulation (February 2007, Annex 8).

Mozambique's Health Partners contributed to the report, providing detailed comment and updated information on three occasions (in August and October 2006, and in March 2007) in response to developing draft versions of the report.

The final consolidated report and the proposed road map were prepared during a consultancy in June 2007 that included further consultations with the Minister of Health, the head of the Central Drugs and Medical Supplies Procurement Service (CMAM), the staff of the Pharmaceuticals Department and the Health Partners group.

PERFORMANCE AGAINST TERMS OF REFERENCE

The majority of the requirements of the TOR were met and the expected results were achieved, as noted above and as described in this report and the plan of action.

Two of the TOR were not addressed because the timing was inappropriate for carrying out the assessments requested, namely;

- analysis of the specific constraints of ARV supply: this was not done because a new system, based on strict accountability, had been started recently and was in the early stages of operation;
- assessment of the new drug management information system (SIGM): this was not possible because it was still in the very early stages of installation and implementation. (The installation consultants described the aims and objectives of the system, and it should be of great benefit to all aspects of medicine management when operating fully.)

Two TOR covering financial matters were not adequately met and can be addressed by WHO as part of the plan of work, namely;

- the effects of and lessons learned from the recent transfer of management of the Common Fund for Medicines and Medical Supplies (FCMSM) from the Swiss Agency for Development and

Cooperation (SDC) to Mozambique Ministry of Health (MISAU), and estimating the effects and risks of the planned integration of FCMSM (the procurement component) within the Common Fund of Support for the Health Sector (PROSAÚDE);

- the financing of the system:
 - the levels of budget execution
 - the cost recovery system
 - the level of integration of external support
 - how are the various partner initiatives in the pharmaceutical sector contributing to the sector-wide approach in health (SWAp) ?
 - proposals for a more coordinated, integrated financing system.

BACKGROUND

Immediately after independence, in 1975, the pharmaceutical sector became a priority for the Government, and for many years Mozambique pioneered numerous areas of pharmaceutical policy, receiving international recognition for this work.

Public sector drug expenditure is approximately 60-70% of the total national expenditure on pharmaceuticals, with the private sector confined to the major cities. Drug purchases are financed by the Government, with the support of international cooperation, through a common fund which accounts for between 60 and 70% of State expenditure on drugs. The purchase/import and supply of drugs for the National Health Service are planned and managed by the Ministry of Health, through CMAM.

Procurement and distribution of supplies is “contracted”, on a monopoly basis, to MEDIMOC, formerly the Government Central Medical Stores, which became a public company in 1977 and was privatised in 1999. MEDIMOC's monopoly on procurement and supply continued without a formal contract until a 2-year contract was signed in December 2004.

The Pharmaceutical Sector Strategic Plan of 1995 anticipated liberalisation of the sector within the context of the change to a market economy. The Plan identified strategic objectives and priority areas of activity. Primary among these was the need to functionally separate the regulatory powers (over both the public and private sectors) from the requirements to ensure efficient provision of the National Health Service; these two responsibilities were both vested in the single Pharmaceutical Department. Within the public sector, strategic objectives were identified for importation and sourcing (adequate financing, transparency of the process and MOH oversight of decisions); internal distribution (rationalisation of storage, improved administrative systems and improved prescribing); product quality assurance (through legislation, registration, inspection and improved storage) with LNCQM providing quality control support; rational drug use (via institutional interventions such as standard treatment protocols and information, and education and training for professionals and the public).

The legal framework for pharmaceuticals is set out in Act 4/98, which is currently being revised. A new bill is due to be discussed by key actors in the Government, the pharmaceutical sector and civil society, for submission to the Council of Ministers later in 2007. In addition, a chapter of the document *Government Directives for the Health Sector (DGSS)*¹ sets out the national drugs policy in detail. The legislative and regulatory framework follows the guidelines and policies recommended by WHO, in accordance with the various World Health Assembly resolutions.

During the last five years, the Ministry of Health has instigated several evaluations to assess the pharmaceutical sector, to determine progress made so far and to provide recommendations on improvements.

¹ República de Moçambique. Ministério da Saúde. Government Directives for the Health Sector. Versão Intermédia Final. Cidade de Maputo, Moçambique: Ministério da Saúde. 04 de maio de 2006.

In 2001, an internal evaluation was conducted to assess the main achievements and constraints faced by the pharmaceutical sector. In April-May 2003, an evaluation of the sector was conducted by an external team. The results of the external evaluation showed that significant progress had been made in the pharmaceutical sector. The report stated clearly that all health facilities were regularly restocked with *basic* medicines and that patients had access to these basic medicines without any financial barrier.

In June-July 2005, a joint mid-term evaluation of the “Plano Estratégico do Sector de Saúde (PESS) 2001-2005-2010” confirmed that the availability of high-quality medicines in all provinces is one of the main achievements, and the most important progress made in the pharmaceutical sector.

However, alongside these positive findings, the three evaluation reports pointed out several issues and challenges that remained to be tackled to improve pharmaceutical sector performance in Mozambique. The 2003 external evaluation identified major problems in the area of human resources; the lack of adequate laboratory quality control support for procurement; the absence of a contract with MEDIMOC together with the absence of competition; poor packaging of medicines at the time of dispensing; the uncertain basis for drug needs estimation; the fact that pricing practices favoured the trade sector; and the lack of clarity and effectiveness of the cost recovery scheme. In addition, the tertiary and quaternary hospitals frequently experience a low level of satisfaction in terms of the requisitions they made for specialized medicines. Furthermore, an audit conducted in April 2003 by the Ministry of Planning and Finance showed shortcomings in drug distribution.

In 2005, the Ministry of Health and its Health Partners drew up terms of reference for another external evaluation of the pharmaceutical sector, focusing on the issues and challenges that the sector continues to face. Subsequently, discussions were initiated at the WHO Regional Committee for Africa in August 2005 that led to WHO involvement.

The focus of this external evaluation, conducted by WHO, was to identify activities that would not only begin to address the issues and challenges but that would at the same time, make the most cost-effective use of the financial and human resources available in the public pharmaceutical sector in contributing to the country's overall health plan.

FINDINGS

These findings are based on a study of available documents and interviews with MOH officials. They are also based on interviews and discussions (some held during field trips) with staff and stakeholders concerned and involved with the supply and use of medicines within Mozambique's health services.

POLICY AND FINANCING

Current Structures and Functions in the Pharmaceutical Sector

The Pharmaceutical Department in the MOH is responsible for inspection, registration of medicines, licensing of pharmaceutical personnel and premises, and the issue of import licences for pharmaceuticals. The Laboratório Nacional de Controlo da Qualidade de Medicamentos (LNCQM) is responsible for quality testing of medicines. They both reported to the National Directorate for Health (DNS) but this no longer exists.

The Central Drugs and Medical Supplies Procurement Service (CMAM) is responsible for the purchase and supply of medicines and medical supplies for use in the national health service. CMAM initially received support, both personnel and financing, from external partners but at the time of writing almost all staff have transferred to the MOH payroll.

Empresa Estatal de Farmácias (FARMAC) is a “company” which consists of a chain of self-financing pharmacies. These were set up as state pharmacies in the form of a “state company”.

Planned Structures and Functions in the Pharmaceutical Sector

In the new “restructuring plan” for the MOH there will be a “National Regulatory Authority” (NRA) subordinate to the Ministry of Health but with a “reasonable level of independence”; this will replace the Pharmaceutical Department. The LNCQM will report to the NRA Director. CMAM will become a separate department and report to the National Directorate for Medical Assistance (responsible for curative services).

Policy Statements

There is a draft National Drugs Policy which was evaluated by some of the team, and all of their recommendations for review, amendment and the development of a linked plan of action are included in Annex 5.

Financing of Drug Supply

In 2005, the total funds available amounted to US\$74.0 million of which 44.9 million was from the common fund (PROSAÚDE). The Government finances US\$13.7 million of drug purchases. Partners contribute their money by placing it in a Swiss bank account and in this way the money is ring-fenced for pharmaceutical expenditure. Initially 10% was used for capacity building and audit, but now practice has been discontinued and all funds are used for procurement - meeting about 60-70% of requirements. Presently, institutional capacity building is financed by PROSAÚDE, within the overall MISAU budget. During the present discussions on the revision of the Memorandum of Understanding with the Health Partners, the Government decided that the integration of the medicine pool into the general common fund will be re-evaluated in the medium-term.

There is a cost-sharing system in place for dispensed medicines, and health facilities are allowed to retain 40% of the income to make supplementary purchases; the other 60% is returned to CMAM accounts. In Chimoio Provincial Hospital (the only hospital at which figures were collected) cost recovery income was about 3 billion Meticals in 2005, 7.4% of the total expenditure on medicines (40.5 billion Meticals).

HUMAN RESOURCES

There are 46 pharmacists working in Mozambique, 20 of them with the MOH, (18 Mozambican and 2 expatriate) and 26 in the private sector (3 Mozambican and 23 expatriate). The human resources situation in the pharmaceutical sector can be described as critical.

The distribution of the public sector pharmacists is as follows; CMAM – 10; MOH Pharmaceutical Department – 2; FARMAC – 1; 2 central hospitals – 2 each; and 3 provinces – 1 each. Public sector salaries are low, and the work is characterized by a lack of incentives and of decent working conditions and inadequate staff training.

Pharmacy technicians are responsible for managing and operating the drug supply system at provincial and district levels and they are, and should continue to be, the “backbone” of the pharmaceutical services. They do a lot of the work but because of insufficient numbers they also have to delegate many tasks to “agentes”/assistants who often work without adequate supervision.

PROCUREMENT AND SUPPLY MANAGEMENT (see also Annexes 4 and 7)

The purchase and supply of medicines and medical supplies for use in the National Health Service of Mozambique is planned and managed by the Ministry of Health through CMAM. Procurement is financed by the Government of Mozambique with the support of the partner community through pooled funding (the common fund).

Many supply activities are performed under contract by MEDIMOC, a company that was formerly state-owned but which is now a fully private enterprise.

CMAM has several sections each with their own distinct role and responsibilities, together with finance, administrative and information technology sections to support the activities;

- CMAM Planning is responsible for preparing needs estimates based on supply and consumption methods.
- CMAM Procurement uses the estimates to manage procurement, using the contracted services of MEDIMOC to perform many of the administrative activities of tendering, purchase contract monitoring, receipt, clearing and product quality control. Decisions concerning the award of contracts are made by CMAM.
- CMAM Distribution takes responsibility for managing and authorizing the movement of supplies to the provincial depots and the hospitals that receive direct supply. MEDIMOC is contracted to operate the central stores and implement the delivery of requisitions to provinces, central hospitals and some district hospitals in Maputo, according to specific time limits.
- CMAM Audit personnel visit provinces to monitor supply activities against the standard procedures.

Estimation of Needs

The CMAM Planning section estimates the annual needs of the Government health services (except for special programmes, malaria and TB) using the information obtained in the requisition and supply processes during the previous year. The process of requisition at district, provincial and central hospital levels involves the calculation of the adjusted monthly rate of consumption, and this forms the basis of all calculations for replenishment. The number of drug kits (there are 3 types in use) is also estimated, based on the previous year's outpatient statistics and staff competency levels.

Physicians had no involvement in the final estimates until this year when, at the insistence of the Minister of Health, they could input for the 2007 estimates.

Procurement

The national procurement law favours the use of competitive bidding for procurement of supplies. The majority of pharmaceutical and medical supply procurement uses competitive bidding of two types; Limited Competitive Bidding (LCB) and International Competitive Bidding (ICB).

When implementing LCB, CMAM uses prequalified suppliers (all international wholesalers) who were selected for a period of two years by a working-group composed of CMAM, MEDIMOC and a Dutch independent consultant (NIC). LCB is used for the bulk of procurement (including drug kits), and especially for that financed by the FCMSM. According to CMAM the process takes about 4 months from planning to the signing of contracts and a further 4 months to the receipt of goods - 8 to 9 months in total.

ICB is an open process used at the request of specific partners (notably the World Bank) for expenditure of their funds and can take between 12 and 24 months from planning to receipt of goods. Only emergency orders use a more flexible and quicker procurement method of national/international purchasing.

As noted above, the administrative tasks and paperwork associated with tenders, managing supplier contracts and clearing and receiving goods are all done by MEDIMOC on behalf of CMAM, following CMAM instruction as per the contract. There are several distinct steps in the procurement process, with 4 of them restricted to CMAM's remit as they are viewed as critical points: deciding priorities; matching needs with available funds; choosing the procurement method; and adjudicating contract awards.

Distribution

Distribution is carried out following written national operating procedures. There are two main methods (described below) for the distribution of supplies, the drug kit system and the "Via Classica" or requisition system. Special arrangements are made for the distribution of ARVs and materials for vertical programmes.

The drug kit system ensures the supply of essential medicines to primary care facilities by purchasing pre-packaged and sealed kits containing a fixed range and quantity (based on annual revisions) of essential

medicines and supplying them, unopened, directly to the health units. Drug kits are procured from overseas after competitive tendering and the sealed kits are imported via MEDIMOC, to be distributed through Provincial Stores to clinics.

The requisition system requires staff at each level in the system to count and record their stock at the end of each quarter and, using a standard form, to calculate the average monthly consumption rate. This rate is then used to estimate the needs for the next quarter. Therefore every three months each level in the supply system requisitions their supplies from the next level in the system – clinic from district, district/provincial hospital from province warehouse, province warehouse and central hospital from central stores. Each supplying depot or level confirms or amends the requisition according to their stock and ability to supply before sending the supplies.

For supply from central stores, requisitions are sent by provinces and central hospitals to CMAM for assessment and authorization of supply from central stores. Information is then communicated to the province/central hospital and MEDIMOC. MEDIMOC is responsible for delivery of the items within the time frames specified in the contract. MEDIMOC ensures delivery to central hospitals, general hospitals in Maputo and to provincial warehouses.

Treatment of HIV-positive patients with ARV medicines began in 2004. Because accountability is very important the supply of ARV products is carefully managed, based on the number of patients and the receipt of full information from the clinics. This “vertical” approach is proving labour intensive and may not be possible with the planned expansion of the programme.

Audit

The audit section of CMAM visits all provinces annually, with a team of two people working for 15 days in the company of the pharmacy technician in-charge of the provincial pharmacy department. Standard checklists are used to perform an audit at the provincial warehouse, in the provincial hospital (pharmacy store, outpatient dispensary and sample wards) and in one district store.

Follow-up briefings are given to the Provincial Director of Health and a full detailed report is completed on return to CMAM offices. A summary of findings, recommendations and actions is circulated widely to all those concerned for action. The timeliness of audit reporting was reported to be critical to ensure that appropriate decisions were made on the basis of the audit findings and recommendations.

PRODUCT QUALITY AND MEDICINES REGULATION (see also Annex 8)

Regulatory structures

Drug regulation and registration are the responsibility of the MOH Pharmaceutical Department. Technical staff numbers are limited to 2 pharmacists (1 being the department head) and 3 pharmacy technicians. The work of the Department is supported by three committees: the Committee for the Evaluation of Medicines at the time of registration; the Technical Committee for Therapeutics and Pharmacy (CTTF - drawn from the Faculty of Medicine) which provides advice for the national formulary; and the Committee dealing with drug information and pharmacovigilance issues, also based in the Medical Faculty in the Clinical Pharmacology Department.

When the registration system was created in 2003 there was a 3-year period for "extraordinary" registration allowed for drugs already in the market in Mozambique. These products are soon due for formal registration which will then last for 5 years. Over 3,700 products have received market authorization so far.

Inspection of both the public and private sectors is also a responsibility of the Pharmaceutical Department. However there are no full-time dedicated inspectors. Most inspection work is focused on the public sector and medicines quality.

Licensing of pharmacy premises (manufacturers, wholesalers and pharmacies) and personnel (pharmacists, technicians and agents) is the responsibility of the Pharmaceutical Department, which also issues import licences.

Legislation

The legislation and regulations governing the pharmaceutical sector date back to 1998 (Law 4/98) and 1999. A new law on medicines has been prepared in draft form and it is hoped that it will be discussed by the Assembly later in 2007. The law is technical in character with provision for the Minister of Health to make detailed regulations on specific subjects.

Quality Control Laboratory (see also Annex 6)

The National Laboratory of Quality Control of Medicines (LNCQM) was created in 1991 (Diploma Ministerial n°19/91, BR n° 9/1st series, 27 February 1991), with the principal objective of controlling the quality of medicines by checking their conformity with established international specifications. The LNCQM is funded by the State and has 28 staff (5 of whom have a University degree in chemistry or biology).

Test requests come mainly from MEDIMOC as part of the importation process; others come from hospitals and provincial health authorities when quality is in doubt. LNCQM does not determine the samples and as a consequence they may not always be truly representative. Currently the LNCQM has a capacity to analyse a maximum of 600 samples per year. The Laboratory would like to increase its workload and expand its field of activities to be able to cover as many analytical tests as possible and to ensure a complete control of medicines quality.

DRUG SELECTION AND USE

The Pharmaceutical Department, with the support of the advisory committees, was responsible for producing and revising the Mozambique National Formulary (MNF). The most recent revision of the Formulary is almost complete and updates the previous (1999) edition.

CMAM procures and supplies medicines that are included in the Formulary to the national health services. The primary aim of the Formulary is to help satisfy most of the essential medicines needs at primary and secondary levels of service. As a consequence tertiary level prescribers generally rely on patients to purchase their own “extra-formulary” items when these are prescribed. There is no method for accounting for such prescribing in order to get a full picture of prescribing and use of medicines.

The system used in hospitals for the replenishment of supplies to wards and departments requires detailed reporting of use. As a result there should be a lot of information available about the prescribing and supply of medicines; however it does not appear to be used to inform management decisions about prescribing habits.

One strong positive factor in the system is the sole use of generic names in prescribing, liberating the supply system from the restrictions of brand-names.

The tertiary institutions have not developed their own formularies to guide pharmacists and physicians on procurement, supply and use of medicines. None of the institutions appear to have effective drug and therapeutics committees.

The quality of prescribing is not routinely evaluated. The level 2 survey results indicate that for the common health problems of pneumonia and childhood diarrhoea antibiotics are being prescribed unnecessarily (see the following section “quality of prescribing”).

AN ASSESSMENT OF DRUG SUPPLY AND DISTRIBUTION IN THE HEALTH SYSTEM

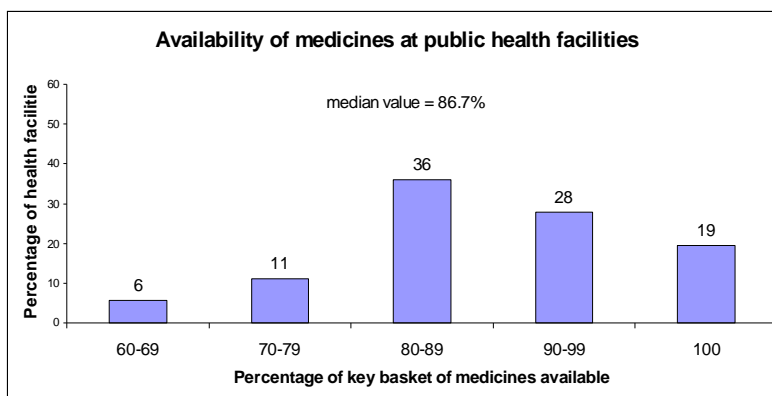
Over the last 5 years there have been several internal and external assessments of the pharmaceutical system in Mozambique that have included an assessment of the public sector medicines supply system. These assessments have frequently concluded that, despite the weaknesses in the system, there is an appropriate supply of essential medicines to all levels of the health care system.

This external evaluation, performed by WHO at the request of the Minister of Health, building on the improved supply situation compared to that of the previous 5 or 10 years and acknowledging that basic and essential drugs are largely available, is targeted at problems with the efficiency and performance of the system, and at improving the relevant skills and contribution of the staff.

The focus of the assessment is whether the pharmaceutical supply system is contributing to the goal of meeting the health needs of individuals and communities at all levels of the system, resulting in the legal and timely provision to any patient/customer of an appropriate cost-effective medicine and also the correct advice to maximize its effect.

Availability of Medicines - *Is there access to medicines at the time of need?*

The WHO indicator survey conducted in April 2006 (Phase 1 of the assessment) showed that a selected basket of 15 essential medicines (13 of which are in drug kit A) were available at the time of the survey in 87% of facilities (n=100) sampled. This is consistent with other similar studies in Mozambique and supports the finding that a basic range of essential medicines is available at all levels. In 83% of facilities, more than 80% of the basket of key medicines was found on stock shelves. In 47% of facilities, more than 90% of the basket of key medicines was found on stock shelves.



The 2004 annual report of CMAM, using their own audit information, records that of the 217 products classified as “vital”, 73% are available at least 75% of the time; and of national formulary items (constituting approximately 80% of total range supplied) 45% are available at least 75% of the time. These findings confirm that the problem area for availability is with the broader range of products deemed necessary for treatment at secondary and tertiary levels.

The current overall supply service level is about 50% for the whole range of medicines included in the estimates and ordered by the provinces and health facilities, with a lower percentage of success for the central hospitals which order the widest range. With such a limited level of availability it is inevitable that a lot of patients are not provided with the treatment they need, and the performance of the system is not acceptable in terms of access to the appropriate range of medicines, especially for secondary and tertiary care.

Primary health care is well served with a basic range of essential medicines and this should be maintained while efforts are made to improve access to a wider range of medicines at secondary, tertiary and quaternary levels. It is therefore important to ask the next question to ensure that all relevant and approved medicines are available at the time of need.

Range of Available Medicines - *Is the most appropriate treatment available for prescribers to use?*

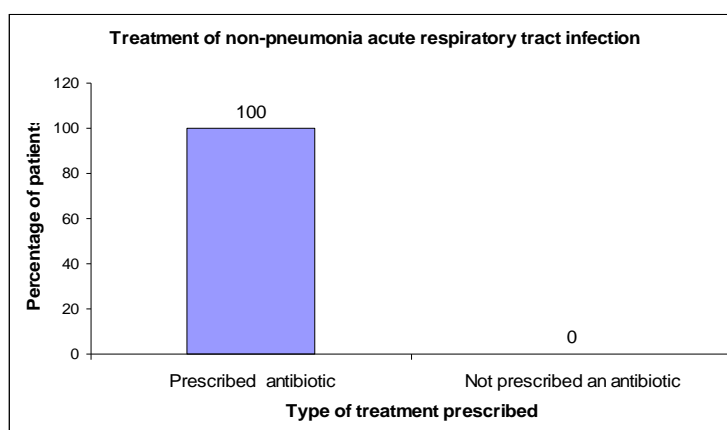
It is difficult to answer this question and there is no study that gives the evidence needed to provide a clear answer. The responses given during interviews with prescribers and pharmacists in provincial and central hospitals indicate that the limited range of regularly available medicines is restrictive to their practice and that they “have to use what is available” or rely on the patient to purchase in the private sector.

While clinicians will naturally hope for an ideal situation with access to a full range of items in all situations (regardless of resources) there should be adequate consultation with them to identify and agree on appropriate needs. CMAM has undertaken some consultations at the MOH during 2006 as an initial step to involve clinicians in developing estimates of need.

Quality of Prescribing - *Are medicines being prescribed and supplied according to therapeutic guidelines?*

The WHO indicator survey found that 95% of prescribed medicines are being supplied at the facilities sampled. A spot check done at an urban clinic in Beira provided a figure close to 90% and at CH Maputo the hospital pharmacist estimated he was able to supply 60% of prescribed items. In the latter case the hospital pharmacist suggested that the figure of 60% could be inflated because prescribers were informed of the stock situation and refrained from prescribing items that were out of stock. This raises the issue of whether prescribers are responding to patient need and requirement or to the list of available medicines, and so possibly compromising treatment.

Survey evidence of guideline compliance was very mixed, indicating positive compliance when dealing with diagnosed conditions (oral rehydration salts in (ORS) in diarrhoea, antibiotics in pneumonia). However in cases of diarrhoea, at the same time as complying with ORS guidance, there was a lack of compliance with advice about the use of antibiotics and antibiotics were still prescribed in 40% of cases. In the case of non-pneumonia upper respiratory tract infection the survey recorded 100% of patients were prescribed an antibiotic, which is in total contradiction to the guidelines.



Effectiveness of Treatment - *Are the prescribed and provided medicines likely to have the intended effect?*

This raises issues of product quality and also of patients’ use of medicines. The WHO indicator survey found that 60% of medicines were not labelled adequately but 75% of patients understood how to use their medicines correctly at the time of exit.

Because of the scheduling of the supply system and delivery programmes, medicines are stored for long periods of time at each level. The effects of inappropriate storage conditions can cause deterioration of the product and reduce its effectiveness.

Previous assessments have also mentioned the problem of the packaging used to deliver oral solid dose medicines to patients – i.e. in a paper or plastic bag – and its effect on product quality. Certainly this practice of dispensing into bags is not ideal and is totally inappropriate during hot, humid and rainy weather. In the latter situation there would be a significant impact on effectiveness probably making the medicine unusable. The problem could be corrected by ordering more products in packaging formats that preserve and protect the item and can be easily used for issue directly to patients, a practice which is now accepted for anti-TB and antiretroviral products using course of treatment packaging. In addition the use of blister/strip packs would reduce some of the workload in the pharmacy department where a lot of time is spent repackaging bulk into patient-ready packs.

Efficiency of the Supply System - *Is there waste in the system that could be reduced to increase the range of medicines available?*

The WHO level 2 indicator study did not indicate expiry problems for the tracer products of the study. However the Minister of Health is conscious of the level of waste and central warehouses (visited in June 2006) had some large quantities of common products that would expire before September 2006. It was reported that large quantities of drugs are wasted because they have passed their expiry date and one consultant observed that large quantities of some products (aspirin tablets, benzylpenicillin injection) have expired or are close to expiry in one of the central stores. It was not possible to check the possible reasons for this, whether the expiry date was already too close when they were received, whether they were incorrectly stored or whether orders overestimate demand.

The “high” rate of wastage due to expiry is blamed on delays in the procurement process at dispatch (due to late financing) and at receipt (delays in clearing). It may also be due in part to inaccurate estimation of needs (at both provincial and central levels) and to changes in treatment practice. The problem may also be exacerbated by the practice of holding large (maximum equivalent to 5 months) stocks at each facility.

There is evidence at clinics and provincial depots that the drug kit system, with its positive effect on availability, also contributes to waste because of the accumulation of large quantities of a few items at both clinics and provincial stores. This suggests that for those few items the rate of use is not consistent across the country or else the demand pattern has changed. Any drug kit system is particularly vulnerable to a sudden change in treatment practice. This has been illustrated by recent changes away from using chloroquine in the recommended national treatment for malaria, yet chloroquine tablets remain as one of the contents of the drug kit.

The use of large “hospital” packs (1000 tablets) may result in the supply of excess quantities to the peripheral levels of the health services when using the requisition system. Additionally their use risks some waste because tablets are much more likely to be physically damaged in transit when packed in 1000 tablet packs.

There is waste in the supply system in its present form, as noted above. There is also some waste caused by the practice of health workers accumulating extra stocks “just in case” (especially in hospital departments) because they have experienced supply system failure. There is also evidence of waste or loss (according to the CMAM audit department) in hospital wards, outpatient pharmacies and clinics, where detailed recording of supplies is inadequate and there are unaccountable discrepancies.

The large stocks held throughout the system result in increased risks of waste due to poor storage conditions and deteriorating quality, careless stock handling resulting in breakages, poor record-keeping resulting in confusion (CMAM found 24-40% non-compliance and WHO found 30% non-compliance in matching written records with actual stock levels) and opportunities for crime and misuse of government property.

Capacity of the Storage System - *Are storage facilities adequate?*

Staff at all levels complained of the lack of storage space for their stock of medicines and this may be correct because the delivery interval of 3-months requires a potential capacity for the storage of up to 5 months of stock at each point in the system. This is more than may be absolutely necessary.

Some facilities are difficult to supply at frequent intervals, especially during the rains, due to their location. Such facilities may require infrequent deliveries at intervals of more than one month, but many delivery points can be serviced within a day or half a day of Maputo. In such cases weekly or monthly supply intervals would be an option, thus reducing the levels of stocks throughout the system and the associated risks to quality and security, as well as reducing the pressure on storage space.

Storage facilities below provincial depot level are probably inadequate (certainly not suitable according to WHO indicators) for storing large volumes of stocks but may be adequate if the supply interval is reduced to one week or one month. The question of adequacy could then be reassessed.

The issue of adequacy of storage at central levels also depends on the delivery of bulk supplies - whether full annual stocks are delivered or whether they are supplied in smaller quantities at regular intervals.

Storage conditions and levels of efficiency at central level should improve significantly with the completion and use of the new central medical store in Maputo.

Capacity and Efficient Use of Human Resources - *Are staff numbers adequate and are they efficiently deployed?*

Pharmacists are a scarce resource in Mozambique. Government salaries for pharmacists are low and provide no incentive to remain in the service. Nevertheless there are 20 pharmacists employed in Government service, 10 of whom work at CMAM. The total number of pharmacists in the country, and particularly in the health services, is insufficient.

Pharmacists' skills should be deployed at the critical points in the system either as "doers" or as managers who are training, supervising and advising others. The three critical points are:

- In assessing and monitoring product quality/safety/efficacy at registration and in the supply system;
- As a member of the health team (at the Ministry of Health and in hospitals) collaborating with others to agree/provide for the therapeutic needs of an individual or a group of patients; and
- In ensuring and monitoring the safe and optimal use of medicines by patients (in the clinical environment).

In the hospital services the pharmacists who work in the central hospital pharmacy departments are under a lot of pressure, as they try to satisfy many requests for supplies working with the available limited human and physical resources. In CH Maputo there are just 2 pharmacists for 1400 hospital beds. In CH Beira the 2 pharmacists provide services to about 800 beds although the hospital often has more inpatients than beds. In the provincial hospitals the pharmacy service is managed by pharmacy technicians. The hospital services do not have enough staff to provide a good pharmacy service.

Pharmacy technicians are responsible for managing and operating the drug supply system at provincial and district levels and they are, and should continue to be, the "backbone" of the pharmaceutical services. They do a lot of the work but also because of insufficient numbers they have to delegate many tasks to "agentes"/assistants who often work without adequate supervision.

There will continue to be shortages of human resources for the foreseeable future.

PRIORITY PHARMACEUTICAL SECTOR ISSUES

DRUG FINANCING

The provision of extra designated financing (i.e. the common fund) by the donor partners has contributed significantly to the levels of availability of basic essential items in the health services. As noted above, resources could probably be used more efficiently if the areas in which there is wastage were addressed by improved management and systems that reduced the risks of waste.

Experience shows that removing the “ring-fence” from designated funds for pharmaceuticals creates risks and often has a negative effect on procurement and supply because, surprisingly, other needs are often placed ahead of medicines. One reason for this is that funds for pharmaceuticals are often large enough to tempt managers and administrators to “borrow” money for other activities with the initial, but usually failed, intention of replacement. Another reason is that it is tempting to think that patients can always pay for their medicines; this obviously penalises the low income and chronic illness groups among others. In a situation where there is no effective price control the private sector can take unfair advantage of the critical need for medicines.

If major changes are to be made in operating procedures, with CMAM taking a larger role in procurement, maintaining stable funding is important. Making changes in all areas at one time carries too many risks.

One important point in drug policy as a whole is the cost of financing, and potential systems of complete or partial cost recovery. A political decision to make drugs completely or partially free of charge, or to provide drugs free of charge under certain programmes or for particular diseases or groups of people, necessarily comes ahead of technical considerations.

HUMAN RESOURCES

At present, the human resources situation in the pharmaceutical sector may be described as critical, and calls for urgent action. This is particularly true in the regulatory department, in hospitals and in the provinces. Planning, harmonizing and identifying incentives for the necessary human resources are a matter of urgency. Health professionals working in the normative sphere, including registration, policy, quality control, inspection and logistics need to have coherent and equitable salary scales.

There appears to have been an imbalance in the assignment of resources between the Pharmaceutical Department at the Ministry of Health (MISAU) and CMAM, as well as an inequitable salary scale, a lack of incentives and of decent working conditions, and inadequate training of existing staff. Some pharmacists are relatively new to their tasks and have not had the opportunity to accumulate experience in the system. Some job descriptions may not be clear (especially in the provincial environment) and yet there is a need for pharmacists to contribute positively in the clinical areas in the provinces.

MOH, with appropriate external technical assistance to supplement and support experienced in-country personnel, should provide the opportunity for further management training and an opportunity for MOH pharmacists and “leading” pharmacy technician personnel to plan an effective, efficient and coordinated role for pharmacy personnel within the national health care system.

REGULATORY FUNCTION and QUALITY CONTROL

The provisional (extraordinary) register expires in 3 years, with the consequent risk of a shortage of many drugs as there is insufficient time to revise it and insufficient staff to carry out the necessary tasks. The assessment showed that Mozambique has in place a basic medicine regulatory system, backed by a drug law that is capable of performing very limited regulatory activities. In general, the existing regulatory system is inadequate to ensure the safety, quality and efficacy of medicines circulating in Mozambique.

The plan to establish a “relatively independent” national regulatory authority under the Minister of Health is to be encouraged, resulting in a clear distinction between regulation and service delivery. Such a plan will only be effective when staff numbers and skills match the job to be done.

The staff working in the national regulatory authority should be paid at a level that will allow them to be objective and uncompromised, and without conflicting interests in their work.

There is one possible anomaly in the plans and that is the inclusion of drug selection and rational use under the regulatory authority. Selection and rational use are much more closely related to service delivery than to regulation.

PROCUREMENT

The procurement system, while aiming for transparency, is inflexible (see below) and slow (see description of procurement - an 8 month cycle at its quickest), and is possibly complicated by operating via the MEDIMOC contract. The SIGM information system includes a module for procurement that has the potential to enable CMAM to perform most of the functions of procurement.

Unfortunately private wholesaler companies in Maputo were unavailable for discussions with the consultants in order to assess their capability to supply an alternative to MEDIMOC.

One of the reasons for the “heaviness” of the system is the use of the full process for all items regardless of the value as a percentage of the total cost. Therefore as much time and cost goes into purchasing an item that represents 0.001% of the total expenditure as goes into an item that represents 10% of the total expenditure. While it is important and necessary to obtain the very best value international prices for those relatively few items (about 20-25% of the total number) that are responsible for 80% of the total expenditure, the remaining 75 to 80% of items could be procured more flexibly, tendering for supply through national and local suppliers, and without significant impact on the budget. This would give opportunities for increasing competition locally, stimulating the local economy, and developing national suppliers to become more involved in supplying the Government.

The MOH, with short-term technical assistance if necessary, should plan to increase the role of CMAM in procurement based on the SIGM system and also to explore the options for national competitive bidding for those items (usually small quantities of expensive items) that fall within the 5-15% of expenditure at the lowest end of the expenditure analysis per item.

Estimation of needs is an integral element of procurement and in Mozambique those who implement the process acknowledge that it has significant weaknesses. Estimation of annual need is carried out each year and is based on data gathered from requests and issues. However the data is not validated as reflecting the true requirements to meet the treatment needs of the population. It is known that there are losses, irrational use and waste in the system (as noted above) as well as weaknesses in the preparation of requisitions throughout the system. The current basis for estimation is perpetuating both the good and the bad in the system.

The Health Minister has insisted on the involvement of physicians in giving input to current estimates. This is a good idea for items that relate to their own speciality. In reality the estimates for the use of basic essential medicines, such as paracetamol, ibuprofen, etc.) will not vary significantly from year to year therefore the quantification for them could be assessed every three or five years. The whole process

could be streamlined by focusing much more time on those items that are variable and vital or very specialized and high cost.

The MOH should perform a needs assessment for medicines based on epidemiological information and using recognized methodologies, together with appropriate consultation with prescribers at tertiary and quaternary levels.

DISTRIBUTION AND SUPPLY MANAGEMENT

For products other than ARVs or specific programme medicines, the distribution system uses two methods; the drug kit system and the “via classica” or requisition system.

The drug kit system is a relatively expensive way of buying stock, although it serves an important purpose in improving the supply of essential drugs to primary level facilities. However, the accumulating stocks of some kit items indicates that either the composition of the kits does not match real needs or that the system is no longer flexible enough for the supply situation. Certainly the composition of the kit needs revision and possibly reduction in size and content in an effort to reduce the dependence on kits and to increase the use of the requisition system. Additionally the kit may only be perpetuating bad practices in supply to patients unless a true needs assessment is performed. The MOH needs to review the purpose and /or composition of kits in the present situation and in the light of a needs assessment.

The requisition system follows a routine of quarterly orders and this results in large stocks accumulating at all points in the system, thus increasing the risks of loss, wastage and expiry and increasing the problem of limited space. As a logistics system it is not efficient, the question is whether the situation can support a change in the system.

Where distances are small, supply intervals should be increased to improve the flow of products through the system and to reduce stock levels in peripheral stores and units. Delivery from central to provincial and from provincial to district level could be contracted out. Delivery from the provincial to the district levels could be contracted out using smaller local transport companies in order to encourage the local economy and enterprise.

Provincial Level Management Practice

The present system of 3-monthly orders creates a very heavy workload for staff during the first two weeks of any quarter, both in creating their own requisitions from central level and responding to district and provincial hospital requisitions. There does not appear to be any attempt to schedule the workload into a consistent pattern, all the work is concentrated into the early days/weeks of any quarter. This concentration of work appears to be unnecessary but reflects adherence to the procedures. Training and reconsideration of the implementation of procedures could result in a more equitable distribution of work.

The MOH should prepare and run workshops for the heads of provincial pharmacy departments to improve their management of the processes and introduce a more logical schedule of supply appropriate for the available human resources, and the needs and location of the districts. Training could also be given on simple quality management systems that would improve accountability and performance.

Medicine Management in Tertiary and Quaternary Hospitals

Visits were made to Chimoio Provincial Hospital, Beira Central Hospital and Maputo Central Hospital. Discussions were held with the pharmacy department and brief courtesy calls were made to the office of the Medical Director in each hospital.

The human and financial resources in the pharmacy departments are inadequate for the workload, and yet in all situations staff members were working hard to provide and improve their service in a professional and commendable manner.

The physicians expressed satisfaction with the availability of essential medicines to deal with basic problems but dissatisfaction with the arrangements for the supply and availability of non-formulary items that form part of the treatment resources of a specialist doctor. This puts a lot of pressure on the

pharmacy department trying to meet these needs but with limited resources and restricted options for purchase. They spend a lot of time “fire-fighting” on supplies rather than being able to plan and implement their work in a rational way.

As a result of the debriefing session at the office of the DNS it was clear that the procurement options available to the central hospital pharmacists are neither clearly documented nor understood by the pharmacists concerned.

The two central hospitals estimated that they had stocks to supply prescription items to a level between 50% and 100% of what was prescribed. In Maputo the overall estimate was 60% with a similar figure for inpatient supplies in Beira.

Because the central hospitals are “flagships” of the service, and because patients with “specialist” health problems are part of the total health care need of the country, the MOH should conduct a much more in-depth study into the existing levels of pharmaceutical service and supply in the tertiary institutions and, given available resources, how they can be maximized to improve the service.

PATIENT ACCESS TO MEDICINES

The availability of medicines is discussed above under the assessment of the drug supply system. The conclusion is that while the limited list of targeted essential medicines is available throughout the system, the rest of the items in the Mozambique National Formulary List are only available 50% of the time. This must cause dissatisfaction for both prescribers and patients. From the results of the level 2 survey, prescribed medicines are affordable when supplied through the public system, therefore the limitation to access is availability rather than affordability.

RATIONAL USE OF MEDICINES

Rational use of medicines is influenced by many factors. The three main “players” in achieving rational use are the prescriber, the pharmacy/supplier and the patient or user.

One hospital pharmacist implied that availability was a factor that influenced prescribing. Prescribers may feel inhibited and be forced into using alternatives which are second best. Very little work has been done in analysing prescribing but the results of the level 2 survey discussed previously indicate that existing national treatment guidelines are not always being followed. An in-depth study of prescribing practice at both primary and secondary levels is an essential activity to inform any training.

The existence of updated, rational, evidence-based guidelines is a precursor to effective prescribing but compliance needs to be monitored constantly. Current national treatment guidelines should be thoroughly evaluated and updated, and their use monitored by institutional and national drug and therapeutic committees.

Even when prescribing is rational and medicines are available and supplied, the actual use of the medicines by patients may still compromise the benefits of the health services' actions. If the medicines are not correctly packaged they may deteriorate before the patient can use them; if the labelling is inadequate and the patient becomes confused the dosage used may not be accurate or effective; if the patient does not get the expected result they may stop using the medicines; if adverse effects occur they might also result in the cessation of treatment. There are many factors that cannot be controlled by the professional, but for some of the above particularly packaging and labelling, the risks can be reduced. The extra expenditure involved in ensuring the ongoing quality of the product (using protective packaging) would be justified if more patients could then use the products correctly rather than wasting them.

A study of the costs and benefits of changing the packaging of medicines (to blister packaging for outpatient use and using smaller packs for supplies to peripheral clinics) is necessary to inform decision-making.

RECOMMENDATIONS FOR ACTION

Objective:

Strengthen CMAM structure, human resources and management to enable the MOH to assume increased responsibility for the procurement of medicines

Problem:

The procurement system, while aiming for transparency, is inflexible and slow, using the same methodology for the majority of items regardless of their value, and with many activities contracted out and not fully under the control of the MOH.

Action:

A stepwise approach to build a procurement system that is robust by strengthening the capacity of CMAM. Development of a procurement structure with standard operating procedures, TOR for the governance structure and adaptation of tools to strengthen CMAM to perform more of the procurement functions, including the launching and adjudication of tenders.

Expected result:

A procurement schedule, defined functions, an outline of a procurement schedule, standard operating procedures, a shortened procurement schedule, improved turnaround times, and a more efficient and responsive system.

Activities:

Establish an appropriate administrative structure with adequate staffing levels and oversight bodies to support CMAM in implementing procurement.

Provide capacity building in planning and management (including financial and human resources management) for senior CMAM staff.

Redefine the functions of CMAM and MEDIMOC in procurement, and establish interim arrangements to ensure smooth transition as responsibilities change.

Establish a medicine procurement committee/tender board at the MOH and an expert committee on developing specifications for medicines, with CMAM providing the secretariat.

Separate the different procurement functions, to ensure compliance with good procurement practices and define specific roles and responsibilities to promote confidence and transparency in the system e.g. selection –“essential drug list” committee; quantification-CMAM/provinces; specification development-an expert committee; prequalification of suppliers - medicines procurement committee/tender board; adjudication of tenders - medicines procurement committee/tender board; processing of requests – CMAM; payments-finance department.

Determine national supply requirements in collaboration with the provinces, disease programmes and other contributing partners.

Review and refresh the list of prequalified suppliers for LCB procurement.

Objective:

Remove bottlenecks and achieving a functional and efficient medicines supply system

Problem:

The pharmaceutical sector evaluation confirmed other study findings, with a spotcheck of a selected range of essential medicines (which were largely medicines contained in kits) showing 87% availability in health facilities at all levels; however the current overall supply service level for the Via Classica system is approximately 50%. The centralised estimation of needs is based on consumption information but this does not appear to be adequately validated and may be perpetuating irrational use of medicines. The available medicines are only meeting a lower percentage (estimated at 60% or less) of needs at secondary and tertiary levels.

MEDIMOC is contracted to operate the central stores and implement the delivery of requisitions to the provinces and some hospitals. The distribution system uses quarterly order/delivery intervals regardless of the level or the distance of the facility from the store depot. This results in high volumes of stocks at all points in the system increasing the risks of product deterioration, loss, wastage and expiry, and exacerbating of storage space limitations. The drug kit system for primary health care level assures the supply of basic items to the peripheral levels but it is a relatively expensive method and results in the accumulation of excess stocks of some products. The new integrated computer system for the supply system should improve efficiency and information generation but the information still requires validation. Delivery of medicines to patients (both outpatients and inpatients) is not adequately supervised or managed in most situations, resulting in poor accountability; packaging for issue to patients poses a risk for maintaining product quality and ensuring safe and effective use.

Action:

Implement storage and delivery systems that are efficient in resource use and effective in ensuring that necessary medicines are available and fit for use. Build capacity in order to enhance performance.

Expected result:

Improved availability and reduced wastage of medicines. Improved job satisfaction and performance.

Activities: (many activities will run in parallel)

Implement a transitional approach for storage. This includes contracting out management (with clearly defined and contracted roles and responsibilities) of provincial/regional stores for an interim period with a CMAM pharmacist stationed to monitor contract implementation. CMAM will prepare its staff and assume management responsibility in the longer-term.

Plan and manage the transfer of stocks from the 8 current central stores to a single store, including the removal and destruction of items unfit for use.

Plan deployment of pharmacists at strategic points in the management and provision of pharmaceutical services, for example at CMAM and at provincial/regional stores in order to maximize the use of the limited pool of human resources.

Build capacity in provincial-based pharmacy personnel (along with mentoring of CMAM staff on procurement).

Review the levels of stocks of medicines and delivery intervals in order to minimize wastage; carry out a pilot study to evaluate the benefits and problems of more frequent deliveries and options for transport.

Conduct a review of drug kits, considering the range of drugs in the light of health priorities and quantities in terms of reducing shortages and wastage.

Provide technical assistance to evaluate pharmacy services, and the availability and use of medicines in the hospital sector.

Consider progressively contracting out medicines delivery.

Study the economic, quality assurance, storage, safety and workload implications of purchasing medicines in patient-ready packs versus bulk packs.

Objective:

Minimization of risk through effective drug regulation

Problem:

Ensure medicines that are sold and available in the market meet standards of quality efficacy and safety

Action:

Implement market control and a basic registration system. Strengthen regulatory oversight through effective law enforcement

Expected result:

Register of medicines that have been called up

Inventory of medicines that are in the public and private sector

Standard operating procedure, technical regulatory package and proforma letters

Activities: (many activities will run in parallel)

Minister to issue call-up notice for products on the market (review law and establish feasibility).

Database of all products on the market, suppliers, and importers to be developed in compiled within 3 months.

Implement administrative system and develop standard operating procedures for exchange of regulatory information within SADC and with other agencies through the support of WHO.

Define roles and functions of the staff of the drug regulatory authority, and draft MOU with other national drug regulatory authorities for exchange of regulatory information.

Define the QC laboratory role, functions and requirements to support regulatory functions including post-marketing surveillance and support to procurement functions of the MOH.

Train reviewers and inspectors to perform basic regulatory and enforcement functions.

Develop necessary software on palm tops for inspection divisions.

Objective:

Rational drug use

Problem:

Standard treatment guidelines are not always applied in daily practice. Currently the resource base of pharmacists is very limited, with most of them relatively new to their tasks and they have not had the opportunity to accumulate work experience in the system.

Patient safety is not guaranteed by drug dispensing in health facilities; nor is there adequate information and practice of repackaging represents a risk for the quality of the drugs dispensed.

MOH should provide the opportunity for prescribers and dispensers for further training in rational use and evidence-based treatment skills. Staff with managerial responsibilities should also be trained to promote and encourage rational drug use.

Action:

Improve the management and use of medicines by updating formularies and guidelines, providing professional development and implementing systems for monitoring and evaluation.

Expected result:

Skilled staff committed to rational drug use; provision to any patient/customer of cost-effective medicine improved;

Activities: (many activities will run in parallel)

Review current therapeutic guidelines to ensure that they are evidence-based and in line with international and regional guidelines

Develop a national network of pharmacy and therapeutic committees to operate at national (CTTF), provincial and central hospital levels to develop and manage policies on medicines prescription, dispensing and use in facilities.

Develop opportunities for health professionals to be updated and benefit from continuing professional development (preferably in a multidisciplinary environment).

Introduce aspects of rational treatment into training courses in faculties of medicine and pharmacy.

Objective:

Develop a human resources strategy for the pharmaceutical sector

Problem:

There are insufficient skills in the pharmaceutical sector, both in terms of numbers, and experience and capacity. At present, the human resources situation in the pharmaceutical sector may be described as critical, and calls for urgent action. It is estimated that there are 46 pharmacists working in Mozambique and 20 of them are with the Ministry of Health (18 Mozambican and 2 expatriate) and 26 with the private sector (3 Mozambican and 23 expatriate). This makes it urgent to develop a human resources policy for the pharmaceutical sector.

Action:

Improve the skills of existing personnel delivering pharmaceutical services and develop a mid- to long-term human resources strategy for the pharmaceutical sector.

Expected result:

Sufficient skilled personnel to improve the safe, effective and efficient supply of medicines.

Activities: (many activities will run in parallel)

1. Determine immediate priority capacity building needs for CMAM and COMED for the transition phase in order to operationalise CMAM and COMED roles (see procurement, distribution and regulatory sections).
2. Empower capacity at provincial and district levels.
3. Determine the competencies and skills required by health workers in facilities delivering pharmaceutical services to ensure safe and efficient drug supply.
4. Assess the competences of the people in health facilities who perform the tasks involved in delivering pharmaceutical services and who are not formally qualified – recognise prior learning.
5. Provide training to achieve the competencies and skills required for the people in health facilities who perform the tasks involved in delivering pharmaceutical services (fill the gaps).
6. Develop a mid-to long-term human resources strategy for the pharmaceutical sector.

Objective:

Develop monitoring and evaluation mechanisms for the pharmaceutical sector

Problem:

The importance of monitoring and evaluation is well recognized, however national capacity is limited and reporting systems are weak.

Action:

Strengthen national capacity to monitor and evaluate the different aspects of the pharmaceutical sector.

Expected result:

Periodic reports on the progress on implementing the strategy for the pharmaceutical sector.

Activities: (many activities will run in parallel)

1. Review and develop effective systems for monitoring, targeted at and providing essential information for management.
2. Strengthen capacities to undertake regular supervision and reporting.
3. Conduct periodic studies to monitor progress.

PLAN OF ACTION / ROADMAP

	Area of work	Recommendations/expected results	Activities	Duration	Starting date
I	CMAM structure, human resources and management				
1.1		CMAM structure and number of technical and administrative staff defined - job descriptions, working mechanisms and TORs for oversight bodies to support procurement and supply management, developed	Technical consultancies on human resources & management	three man-month	Jul-07
1.2		CMAM human resources strategy and plan for retaining staff, career development and skills building formulated, implemented and monitored			
1.3		Medicines procurement committee/tender board at the MOH and an expert committee on developing specifications for medicines (CMAM to be the secretariat to the procurement committee/tender board), established and monitored			
1.4		Mechanisms for coordination of procurement and supply management of medicines between CMAM, diseases programmes and partners established and monitored			

1.5		Pharmacists deployed at strategic points in the management and provision of pharmaceutical services e.g. at CMAM and at provincial/regional stores in order to maximize use of limited pool of human resources			
1.6		Capacity building of senior staff of CMAM and of provinces for planning and management	Training for senior staff of CMAM (10) and of provinces (10)	two one-week workshop	Sep-07
1.7		Procurement and supply management functions of CMAM and MEDIMOC, re-defined and captured in an MOU - a road map for scale up of CMAM activities, developed			Done
2	Procurement				
2.1		Procurement cycles & schedule (from estimation of needs through to awarding of tenders) defined for HIV & AIDS, malaria and TB and for other essential medicines	Technical consultancy on good practice for procurement	two man-month	07-Sep
2.2		Guidelines for good procurement practice (from estimation of needs through to awarding of tenders) reviewed, disseminated and their use monitored			
2.3		Tools for training on good procurement practice adapted			
2.4		Personnel from CMAM trained on good procurement practices e.g. selection, quantification, pre qualification of suppliers, tendering, contracting etc.	Training of 10 CMAM staff on good procurement practice	two one-week workshop	07-Oct
2.5		Participation of CMAM staff to regional and international workshops and seminars	Training of 10 CMAM staff on good practice for procurement	two international seminars	07-Nov
3	Storage and supply chain management				
3.1		Guidelines for CMAM to out-source (e.g. specifications, tendering and contracting) storage and distribution of medicines including at	Technical consultancy on good storage & distribution	two man-month	07-Sep

		provincial/regional stores level, developed and implemented	practice		
3.2		Guidelines for CMAM to plan and monitor efficiency of storage and distribution and effective delivery of medicines, developed and implemented			
3.3		Tools for good storage practice and for training of personnel developed and tested			
3.4		Tools for monitoring of medicines distribution and use developed and tested			
3.5		Training of CMAM and provincial/regional staff in good storage practice	Training of CMAM staff (10) and of provinces(30)	four one-week workshop	07-Oct
3.6		Training of CMAM and provincial/regional staff in medicines selection, quantification and good distribution practice and monitoring	Training of CMAM staff (10) and of provinces(50)	four one-week workshop	07-Oct
3.7		Planning and removal of medicines from current stores to new warehouse, coordinated and monitored			
3.8		Scale up of SIGM, its use monitored and personnel trained			
3.9		Levels of stocks of medicines and delivery intervals to be reviewed to minimize wastage; benefits and constraints of more frequent deliveries and options for transport explored and tested	Technical consultancy on supply management & pilot studies	two man - month	07-Nov
3.10		Conduct a review of drug kits system, the range of drugs in light of health priorities and quantities in terms of reducing shortages and wastage		two pilot studies	07-Nov
3.11		Assess volumes of expired medicines and propose options for safe disposal			
3.13		Study the economic, quality assurance, storage, safety and workload implications of purchasing medicines in patient-ready packs vs. bulk packs			

4	National Drug Regulatory Authority structure and management				
4.1		New medicines legislation and related regulations revised and adopted to bring all regulatory functions under one regulatory authority with adequate powers and responsibilities on all regulatory functions.	Technical consultancy	two man-month	07-Sep
4.2		NDRA human resources strategy and plan for retaining staff, career development and skills building formulated, implemented and monitored			
4.3		Roles and functions of the various units of the National Drug Regulatory Authority (NDRA) and job descriptions for staff clearly defined			
4.4		Appropriate financing mechanisms to sustain the NDRA operational activities established and monitored			
4.5		Standard, guidelines, procedures, guidance etc. should be established in written form for all drug regulatory functions and should be available for internal staff, external experts, customers and the general public.			
4.6		Record keeping and information management system of the authority will be strengthened.			
4.7		Appropriate software for facilitating information management and communication, purchased	procurement of software		Oct. 07
4.8		Software installed and staff trained for data entry and use of software monitored	Consultancy for installation of software and training of NDRA staff	three one-week training	Dec. 07
4.9		Integration to SADC regulatory information network facilitated			

4.10		Training of NDRA senior staff on planning and management	attendance to planning and management courses for 5 NDRA staff		Jan. 08
5	Medicines regulations and quality assurance				
5.1		National GMP, GDP and GPP guidelines developed	Technical consultancy	one man-month	Oct.07
5.2		A plan for routine inspection developed and database established			
5.3		Training of NDRA staff and of counterparts on use of GMP and GDP guidelines	Workshops for NDRA (5), CMAM (5) and health professionals (20)	three workshops	Jan. 08
5.4		Necessary guidelines and guidance on medicines registration developed and disseminated to staff and external experts	Technical consultancy	one man-month	Oct.07
5.5		Training of NDRA and counterparts should be carried out in medicines registration (dossiers evaluation)			
5.6		Define the QC laboratory role, functions and requirements to support regulatory and procurement functions			
5.7		The web site of the MoH should integrate information of the new NDRA and should be one of the major sources of information to stakeholders.			
5.8		Contribution to harmonization of regulatory procedures within SADC collaboration	Participation of NDRA senior staff to SADC meetings	2 staff to two SADC meetings	Nov.07
5.9		Strengthening of capacity of NDRA staff	Participation of NDRA senior staff to international meetings on regulations	2 staff participate to two meetings	Apr.08

6	Rational Use by Health Professionals				
6.1		Standard Treatment Guidelines and essential medicines list reviewed and updated	Technical consultancy on EM concept	two man-month	Fev.08
6.2		Staff at hospital, regional and provincial level trained on rational use of medicines	Regional training workshops organized for 100 health personnel	2 series of 3 regional workshops	March.08
6.3		Tools for monitoring availability and use of medicines at health institution levels developed	Technical consultancy	one man month	Fev.08
6.4		Training of personnel for surveys on availability and use of medicines			
6.5		Introduce aspects of rational treatment into training courses in faculties of medicine & pharmacy.			
7	Financing of medicines				
		Analysis of financial mechanisms for purchase of medicines - proposals for improving availability of medicines	Technical consultancy and survey		Sept.07
8	Monitoring of pharmaceutical sector				
		Monitoring of pharmaceutical sector carried out	Training, data collection and analysis		08-Sep

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REPÚBLICA DE MOÇAMBIQUE

**MINISTÉRIO DA SAÚDE
GABINETE DO MINISTRO**

Terms of Reference
External Evaluation of the Pharmaceutical Sector in Mozambique, 2005

1. Context

The Addendum to the Memorandum of Understanding, determines that before the end of 2005, or at any other time established in advance by the Signatories, there will be an independent evaluation of the Pharmaceutical Sector, paying particular attention to the systems for importing and distributing drugs and medical supplies destined for the SNS; the respective terms of reference shall be agreed upon by the Signatories.

The Mozambican pharmaceutical sector is going through very important changes due to significant progress made in the economic and health sectors following the post-war period. These positive changes in the pharmaceutical sector are the results of three main factors:

1. The amount of funds contributed by the government through the state budget to finance the pharmaceutical sector has gradually increased to reach 8.7 million USD in 2001, 9.5 million USD in 2002, 12.1 million USD in 2003, 12.9 million USD in 2004 and 12.9 million USD in 2005.
2. The financial contribution of Mozambique development partners to the pharmaceutical sector has also gradually increased to reach 28 million US dollars in 2005, while in 2002 the total amount was 26.5 million US dollars. In addition, several development partners are willing to increase their contribution to the development of the pharmaceutical sector especially in light of the growing burden of HIV/AIDS, tuberculosis and malaria
3. The structural reform of the pharmaceutical sector with a strategic operational plan formulated in 1995 and under implementation since 1997. The key strategy of the strategic operational plan is to separate regulatory functions from operational and commercial functions of the pharmaceutical sector in such a way as to prevent any conflict of interest between the two.

During the last five years, the Ministry of Health has launched several evaluations to assess the pharmaceutical sector, determine the progress made so far and provide recommendations on how to improve the pharmaceutical sector.

In 2001, an internal evaluation was conducted to assess main achievements and constraints faced by the pharmaceutical sector. The internal evaluation took approximately one year to complete and the results were discussed by both the Ministry of Health and development partners.

In April-May 2003, an external evaluation of the pharmaceutical sector was conducted by an external team. The results of the external evaluation show that significant progress has been made in the pharmaceutical sector. The report stated clearly that all health facilities were replenished regularly with *basic* medicines and that patients have access to these basic medicines without any financial barrier

In June-July 2005, a joint mid-term evaluation of the “Plano Estratégico do Sector de Saúde (PESS) 2001-2005-2010” confirms that the availability of high quality medicines in all provinces is one of the main achievements and the most important progress made in the pharmaceutical sector.

However, despite these positive results, the three evaluation reports pointed out several issues and challenges that remained to be tackled to improve the performance of the pharmaceutical sector in Mozambique. For example, tertiary and quaternary hospitals frequently experience a low level of satisfaction for the requisitions they made for specialized medicines. Furthermore, an audit conducted in April 2003 by the Ministry of Planning and Finance showed shortcomings in drug distribution.

2. Issues and Challenges of the pharmaceutical sector in Mozambique

The Mozambican pharmaceutical sector is facing several issues and challenges which can be grouped in four main categories: those related to policy and regulation, those related to the functioning of the CMAM, those related to human resources and other general issues and challenges.

2.1 Medicine regulatory authority

The main issues and challenges include:

- Lack of national pharmaceutical policy;
- Lack of implementation of the medicine regulatory law (4/98), (i.e.: Registration of medicines, and quality control) particularly important as the country is reliant on imported drugs;
- Lack transparency in pricing of drugs in the private sector,

2.2 Central Medical Store (CMAM)

The main issues and challenges faced by the CMAM include:

- Inadequate quantification of estimates at national, provincial and district levels;
- Long procurement cycle;
- Lack of clarity in the institutional and functional situation of CMAM within the Ministry of Health,
- The monopoly assigned to MEDIMOC in procurement, storage and distribution;
- Two different sectors of the MOH are responsible for the management of Medical supplies (DAG-Centro de Abastecimento) and Drugs (DNS-CMAM). This result, for example, in 2 separate logistics supply systems for injectable drugs and the syringes needed to inject these drugs.
- CMAM has been working over the last two years on the development of a drug management information system (SIGM) that will change radically the way it is working and integrate all its planning, procurement, warehousing and distribution functions.

2.3 Human Resources

- There is a crucial lack of staff (quantity and quality) for the whole pharmaceutical sector.
- Total reliance on external technical assistance for both CMAM and COMED;
- Reduced capacity of the pharmaceutical sector to take into account the increased needs of medicines and medical supplies due to HIV/AIDS, Tuberculosis and Malaria.

2.4 Other issues and challenges

Other important issues and challenges include

- Cost-recovery of medicines: the performance and effectiveness of the cost recovery of medicines in raising revenues and maintaining equity in access to health services;
- Low level of budget execution;
- Inefficient drug management and use of medicines in the public health sector;
- Low clients satisfaction with long queues and long waiting time in hospital and other health facilities pharmacies
- High level of “inventory discrepancies” and not documented issues in health facilities outpatient and ward pharmacies

3. Objectives of the external evaluation

3.1 General objective of the evaluation:

To assess the overall performance of the pharmaceutical sector and make recommendations on how to improve it.

3.2 Specific objectives:

The specific objectives of the external evaluation are:

3.2.1 To analyze the main achievements and weaknesses of the current strategic plan being implemented since 1997, regarding:

- a. the qualitative and quantitative availability of drugs, generics and specialties in the public sector,
- b. the level and structure of drug prices,
- c. the accessibility of drugs for patients,

3.2.2 To critically evaluate the development of A) reforms in policy and organization of the sector B) management of drug supply system at national level and C) functioning of drug supply in the health system and make clear recommendations on further improvements:

Ø A. The policy and organization of the sector

A.1 To evaluate *the current draft of the National Pharmaceutical Policy* on its adequacy and make clear recommendations on its improvement.

A.2 To perform *a critical assessment of regulatory functions*

- The policy regarding essential medicines,
- The pricing policy for medicines and medical supplies,
- The quality control,

- The registration of medicines,
 - The mapping of staffing levels and skills available for the pharmaceutical sector (including medicine regulatory agency);
- A.3 To analyze *the institutional position and Mandate of CMAM in the Ministry of Health structure*. The present organization should be compared with other similar agencies in African pharmaceutical systems, particularly within SADC member states, regarding their functions, status, organization, human resources, management, financing and accountability, including the functional/technical link with the ministry of Health. The ongoing functional study of the ministry of Health should be taken into account (and vice-versa).
- A.4 The efficiency and sustainability of the having two different sectors of the MOH responsible for the management of Medical supplies (DAG-Centro de Abastecimento) and Drugs (DNS-CMAM) and other possible options
- Ø B. The management of drug supply at the national level
- B.1 *Current procurement system and its alternatives*
The strengths and weaknesses of the current contracting out *should* be assessed, and especially:
- a. The procurement cycle and the procurement methods used up to date,
 - b. The possibility to engage other private companies in procurement, storage and distribution,
 - c. The expected impacts of such a choice,
 - d. Draft the criteria and ToRs for contracting a private agency(ies) on procurement, storage and distribution of medicines;
- B.2 The effects of and *lessons learned from the recent transfer of management of FCMSM (Common Fund for Medicines and Medical Supplies) from SDC to MISAU*, and estimate the effects and risks of the *planned integration of FCMSM* (procurement component) within PROSAUDE;
- B.3 *The financing of the system:*
The levels of budget execution,
The cost recovery system,
Level of integration of external support
- How are the various partner initiatives in the pharmaceutical sector contributing to the SWAP approach in health?
- Proposals for a more coordinated integrated financing system.
- B.4 ARVs
Analyse the specific constraints of ARVs supply.
- C. *The functioning of supply and distribution of drugs in the health system*
- The process of quantification of estimated country needs at district, provincial and national levels,
 - The assessment of the extra needs in medicines and medical supplies due to the burden of HIV/AIDS, Tuberculosis and Malaria and make sound recommendations on how to effectively take into account those needs at district, provincial and national level,

- The criteria of the distribution of drugs from the central to the peripheral levels,
- The effectiveness of the entire delivery chain up to the patients, at each level of the health system,
- The patients' level of satisfaction (staff behavior, waiting time at pharmacies, prices, non availability of drugs, etc.),
- The supply of tertiary and quaternary hospital in specialized medicines. Should this still be done by CMAM or should alternative mechanisms be investigated?
- Assess the new drug management information system (SIGM) being implemented, and evaluate its impact on planning, procurement, warehousing and distribution functions,
- The rational use of medicines in the public sector by professionals, including standards treatment guidelines.

4. Methodology of the external evaluation

The external evaluation is expected to be conducted using the following four methods:

4.1 A critical review of the existing documentation produced in the pharmaceutical sector

The evaluation team is expected to critically analyze all relevant documents relevant to the pharmaceutical sector in Mozambique.

A critical analysis should be made of the implementation of the recommendations put forward by the 2001 internal evaluation, the 2003 external evaluation, the 2003 MPF Audit.

4.2 An in-depth key informant interviews

The evaluation team is expected to conduct in-depth key informant interviews within and outside the health sector. The list of key informants should be established by main stakeholders including the Ministry of Health and Development Partners and agreed upon with the Ministry of Health.

4.3 A quantitative and qualitative survey

The evaluation team is expected to conduct a quantitative and qualitative assessment of the pharmaceutical sector using "WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situation", "the National Medicine Regulatory System-Country Profile" to assess the Medicine Regulatory Authority of Mozambique and "Household survey on Access and Use of Medicines" to determine patients/clients access to medicines.

A list of indicators to be monitored should be elaborated by the consultants during the first two weeks of the consultancy to be discussed with the main stakeholders including the MOH and development partners and agreed upon with the Ministry of Health.

Historical and Geographical analysis should be done in order to assess the progression made over the past years.

4.4 Field visit and direct observation

The evaluation team is expected to conduct field visit to health facilities, warehouses, and offices, inside and outside of Maputo City. The number of sites to be visited should be established so that

statistically representative conclusions can be drawn from the sample of health facilities visited and agreed upon with the Ministry of Health.

5. Duration of the external evaluation

The external evaluation is expected to start on 9 January 2006 and be completed by, 9 March 2006.

6. Expected results of the external evaluation

The following results are expected from the external evaluation team:

- The evaluation team is expected to produce an external evaluation report containing detailed discussions of the issues and challenges faced by the pharmaceutical sector on each of the objectives of the evaluation and clear recommendations on how to improve each of them and the pharmaceutical sector;
- A plan of action with specific and clear indication of relevant actions to be implemented to improve the performance and effectiveness of the pharmaceutical sector in Mozambique;
- Discussions of the findings and recommendations with the main stakeholders including the MOH and development partners;
- Present the results of the external evaluation at a one-day meeting with all stakeholders and development partners;

7. Profiles of consultants for the external evaluation

The evaluation team will be comprised of five members:

- A Team Leader, who must be a pharmaceutical expert with extensive knowledge in pharmaceutical policy, political economy and health economics in developed and developing countries;
- An expert on logistics management, financing and pricing in the pharmaceutical sector, with extensive knowledge of the private market, and alternative procurement and distribution systems;
- A pharmaceutical expert with extensive knowledge in Pharmaceutical quality assurance, conversant with relevant quality assurance/control standards and systems in developed and developing countries and has prior experience in evaluating assurance/control systems and medicine regulation area;
- A pharmaceutical expert with extensive knowledge of and experience in drug logistics and the formulation and implementation of national or provincial level programs for the rational use of drugs. Prior experience with large programs for rational utilization of drugs will be highly desirable;
- A public health specialist with extensive experience in managing and evaluating health service delivery at national and provincial level;

All members of the evaluation team are expected to have at least a good working knowledge of Portuguese.

If one or more of the consultants have several of the required expertise, the team size can be reduced accordingly.

The team leader is expected to be physically present in the country during the whole process of the evaluation and is responsible for the final evaluation report both in English and Portuguese versions.

Working conditions and relationship

All consultants will be contracted by the Ministry of Health and will work under the supervision of the special adviser to the Minister of Health.

Practical Arrangements

Workload: the proposed working program is expected to require from the consultants up to a total of 60 working days.

Proposed Period: January to March 2006

Cost of the evaluation

The total cost of the evaluation should not exceed 150,000 USD

Documents to be consulted

- CMAM Annual Report, 2004
- Report of the External evaluation 2003
- Proposta de estatutos da Central de Medicamentos (CMAM)
- República de Moçambique, Ministério da Saúde, Direcção Nacional de Planificação e Cooperação. 2001. Cenário de Despesa e Financiamento de Médio Prazo 2001 – 2005 para o Sector de Saúde.
- República de Moçambique. Ministério da Saúde. 2001. Plano Estratégico Sector Saúde 2000 – 2005 – (2010).
- Política e Legislação Farmacêutica
- Ministério da Saúde. Plano de Desenvolvimento de Recursos Humanos
- Declaração de Política Nacional de Saúde
- Relatório da análise funcional do MISAU - KPMG

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ACCESS AND USE OF MEDICINES IN MOZAMBIQUE

ASSESSING ACCESS AND USE OF MEDICINES

Essential medicines save lives, reduce suffering and improve health, but only if they are available, affordable, properly used and of good quality. Today, almost 2 billion people, one-third of the global population, lack reliable access to needed medicines. Evidence on access, use and quality of medicines is imperative to enable governments and other stakeholders to identify strengths and weaknesses, establish priorities, set targets and ultimately determine how to most effectively allocate scarce resources to improve the health of their populations.

In May 2006, the Mozambican Ministry of Health was supported by the World Health Organization (WHO) to carry out a national assessment of its pharmaceutical sector. The survey was conducted in public sector warehouses, public health facilities, private pharmacies and households. Using the *WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations* and the *WHO Household Survey to Measure Access and Use of Medicines*, the Ministry assessed the availability, affordability, conservation conditions and use of key medicines. The evidence obtained was used to determine the level of access and appropriate use of medicines, identify factors contributing to weaknesses, and identify strategies and policies to improve availability, affordability and use of medicines. This is one of a series of papers summarizing the results of similar surveys carried out by countries across Africa and elsewhere in the world.

BACKGROUND - MOZAMBIQUE

Mozambique is classified as a low income country by the World Bank with a per capita GDP of US\$ 314 (2004).

Basic health indicators	
Total population	19,424,000 (2004) ¹
Life expectancy at birth	45 years (2004) ¹
Per capita total expenditure on health	US\$12 (2003) ¹
Per capita government expenditure on health	US\$7 (2003) ¹
Per capita out-of-pocket expenditure on health	US\$2 (2003) ¹
Per capita total expenditure on medicines	US\$2 (2000) ²
Per capita government expenditure on medicines	US\$1 (2000) ²
Number of pharmacists	14 (2004) ³
Number of pharmaceutical technicians/assistants	604 (2004) ³
Population per pharmacist	1,387,000 (2004) ¹

1-World Health Report 2006, 2-World Medicines Situation 2004, 3-Global Health Atlas

Medicine policy indicators	
National medicine policy last updated	Draft 2006
Medicines law last updated	1998
National essential medicines list last updated	1999
National standard treatment guidelines last updated	1987
National formulary last updated	1999
Number of medicinal products approved to be marketed	3678
Prescribing by generic name in both public and private sectors	Obligatory

WHO questionnaire on structures and processes of country pharmaceutical situations 2006

METHODOLOGY

Five regions were selected for inclusion in the survey, the capital city, one of the least income generating regions, and three other randomly selected regions. The five regions were Cabo Delgado, Maputo, Niassa, Tete and Zambezia. Within these 5 regions, a total of 21 provincial/district warehouses and 37 public health facilities were randomly selected. In addition, 27 private pharmacies and 752 households were selected based on their proximity to the surveyed public health facilities. Data were also collected from the Beira regional warehouse.

A basket of 15 key medicines were chosen based on burden of disease, their use in all levels of health facilities, and their presence on the essential medicines list. Four additional medicines of interest to the Ministry of Health were also studied. At warehouses, public facilities and private pharmacies, these medicines were used to measure availability, presence of expired medicines on stock shelves, correspondence between stock cards and physical stock and price of medicines. Affordability, quality, and appropriate use of medicines were also measured by the survey.

The survey of households collected data on actions taken in response to a recent illness of one household member. Average weekly household expenditures on medicines and food were also recorded.

THIS SUMMARY REPORT

This draft summary report presents the key findings from the public warehouses, public health facilities, private pharmacies and households. The final draft summary paper will additionally present analysis of the results and conclusions.

ACCESS TO MEDICINES

In this survey, access to medicines is assessed through measuring affordability and availability of medicines.

Affordability is calculated in terms of the number of days the lowest paid unskilled government worker would have to work to pay for one treatment course for a tracer condition. At the time of the survey, the lowest paid unskilled government worker earned 40,000 Metical (US\$1.50) per day; it is estimated that more than half of the population live under this amount per day.

The table below illustrates the affordability of generic medicines for three common acute illnesses used in the survey as tracer conditions.

Tracer condition	Medicine	Number of hours' wages needed to pay for treatment course	
		Public facility	Private pharmacy
Pneumonia in children under 5	Amoxicilina	1/3 hour	8 hours
Malaria in adults	Amodiaquine + Sulfadoxina/pirimetamina	1/3 hour	7 hours
Malaria in children under 5	Amodiaquine + Sulfadoxina/pirimetamina	5 minutes	1½ hours

è The lowest paid government worker would have to work about 20 minutes to purchase the generic medicines in the public sector and a full day to purchase the same medicines in the private sector. In other words, generic medicines used to treat acute conditions are 18-24 times more expensive in the private sector than in the public sector.

The findings on affordability of medicines for acute conditions of this survey and a medicine prices survey carried out in 2004² were similar. The medicine prices survey additionally examined the affordability of medicines for chronic conditions.

The table below illustrates the affordability of generic medicines for three common chronic tracer conditions.

Tracer condition	Medicine	Number of hours'/days' wages needed to pay for 1 month's treatment	
		Public facility	Private pharmacy
Asthma	Salbutamol inhaler	2½ hours	3.9 days
Diabetes	Glibenclamide	¾ hour	1.7 days
Depression	Amitryptilline	2 hours	2.5 days

è For chronic conditions the lowest paid government worker would have to work around 2 hours to purchase a month's treatment course using generic medicines in the public sector and around 2-3 days to purchase the same treatment from a private pharmacy. In other words, generic medicines used to treat chronic conditions are 10-18 times more expensive in the private sector than in the public sector.

è An illustrative family buying medicine for a child with pneumonia, a month's treatment for a child with asthma, and a month's treatment for an adult with

² The survey was carried out by the Ministry of Health of Mozambique using WHO/HAI Medicine Prices Methodology (for methodology see: <http://www.haiweb.org/medicineprices/>)

diabetes would have to spend 3½ hours' wages to purchase generic medicines from the public sector and 6.6 days' wages to purchase the same generic medicines from a private pharmacy.

The large differences between the prices of medicines at public health facilities and private pharmacies can be partly explained by the fact that medicine prices in the public sector were set in 1999. As such, while prices at private pharmacies have risen since 1999, prices in the public sector have remained the same and thus, in real terms, have become increasingly cheaper than when they were set.

è Generic medicines, generally more affordable than branded medicines, represented 98.0% of medicines prescribed to outpatients at public health facilities.

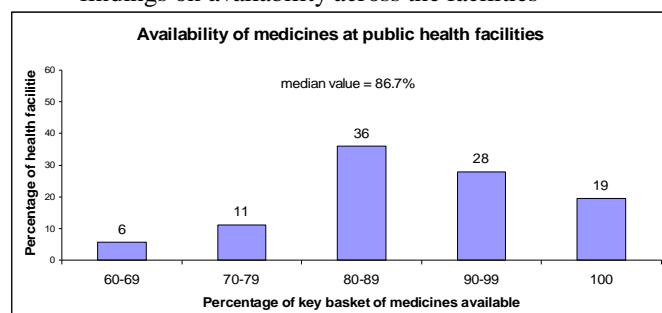
è Patients interviewed leaving the dispensing area of public health facilities reported paying a median of 2,800 Metical for their medicines plus fees (equivalent to ½ hour's wages for the lowest paid unskilled government worker).

Availability of medicines at public health facilities is measured by the percentage of prescribed medicines actually dispensed or administered to patients and the presence on stock shelves of a basket of 15 key medicines. The medicines included in the key basket were chosen based on burden of disease, their use in all levels of health facilities, and their presence on the essential medicines list.

è In the public health facilities, 94.7% of prescribed medicines were dispensed or administered to patients.

Overall availability of key basket of medicines (%)	Median	25th percentile	75th percentile
Warehouse	86.7	80.0	93.3
Public health facility	86.7	80.0	93.3
Private pharmacy	73.3	60.0	86.7

The chart below demonstrates the distribution of the findings on availability across the facilities



è In 83% of facilities, more than 80% of the basket of key medicines was found on stock shelves. In 47% of facilities, more than 90% of the basket of key medicines was found on stock shelves.

è In 17% of facilities, less than 80% of key medicines were found on stock shelves.

The table below shows the median availability of the 15 key medicines for public health facilities, public sector warehouses and private sector pharmacies.

Availability of medicines within the basket (%)	Public health facility	Public Warehouse		Private pharmacy
		Provincial/district	Regional (Beira)	
Acido benzoico acid + salicilico pomade	62.2	52.4	0.0	59.3
Amodiaquine cp 200mg	83.8	71.4	100.0	14.8
Amoxicilina suspensao 250mg/5ml	73.0	71.4	100.0	66.7
Clorfeniramina cp 4 mg	89.2	90.5	100.0	88.9
Cotrimoxazol cp 480 mg	97.3	95.2	100.0	85.2
Mebendazol cp 100 mg	97.3	81.0	100.0	88.9
Paracetamol cp 500 mg	94.6	85.7	100.0	81.5
Penicilina benzatinica injeccao 2.4MIU	83.8	81.0	100.0	70.4
Sais de reidratacao oral pacote para 1l	89.2	81.0	100.0	92.6
Sal ferroso + acido folico cp	94.6	71.4	100.0	55.6
Salbutamol cp 4mg	78.4	71.4	0.0	85.2
Sulfadoxina pirimetamina cp 500/25	94.6	90.5	100.0	85.2
Tetraciclina ofalmica pomada	100.0	95.2	100.0	59.3
Violeta de genciana	83.8	76.2	0.0	70.4
Vitamin A capsulas 200,000 IU	81.1	90.5	100.0	11.1

The table below shows the median availability of the four additional medicines which were not part of the basket, but for which information was collected as they were of special interest to the Ministry of Health.

Availability of medicines (%)	Public health facility	Public Warehouse		Private pharmacy
		Provincial/district	Regional (Beira)	
Artesunato cp 100 mg	24.3	38.1	0.0	59.3
Fluconazol cp 200 mg	2.7	4.8	0.0	33.3
Rifampicina + isoniazida cp 150/75	45.9	76.2	100.0	0.0
Vacina antitetanica 0.5ml	13.5	4.8	100.0	0.0

As a measure of functionality of the medicines supply system at the health facility level, the stock-on-hand figure on stock cards was compared to actual stock levels for each medicine in the basket.

è A median of 73.3% of stock-on-hand figures matched the actual stock on the shelves.

QUALITY AND SAFETY OF MEDICINES

As a measure of the quality of medicines, this survey combines the results of testing done for regulatory purposes with an assessment of whether basic conditions necessary to retain the quality of medicines are maintained in warehouses and public health facilities and an inspection of the expiry date of all stocked products of the key basket of medicines.

è In Mozambique in 2005, 465 medicine samples were collected for regulatory purposes, 457 of these samples were tested and 34 (7.4%) failed identity or assay. This testing was carried out by government quality control laboratories.

è Of 8 basic conservation conditions assessed in this survey, a median of 12.5% were not maintained in warehouses, 25.0% were not maintained in public health facility storerooms and 25.0% were not maintained in the dispensing areas of public health facilities. 50% of conservation conditions were not maintained in the Beira regional warehouse.

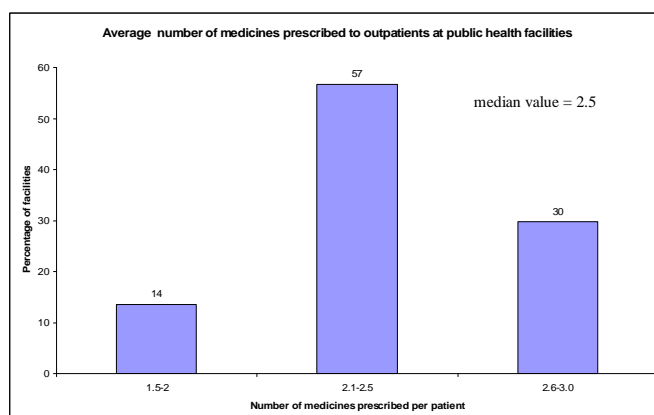
è Of the basket of medicines found on stock shelves, none were expired in public health facilities, warehouses or private pharmacies.

RATIONAL USE OF MEDICINES

Appropriate use of medicines in public health facilities is measured in this survey by the number of medicines per prescription, the number of prescribed medicines on the essential medicines list, the percentage of patients prescribed antibiotics or injections, patient knowledge about how to take the medicines dispensed to them and prescribing practices for a set of tracer conditions.

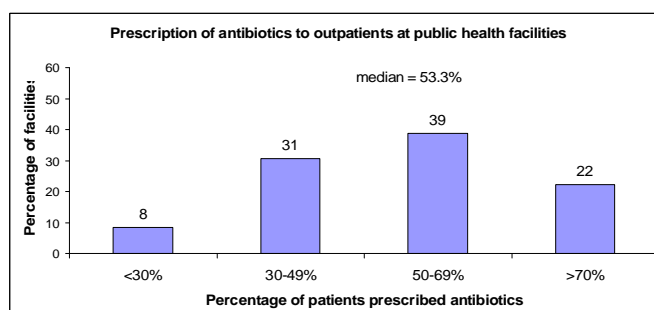
The survey also measured the percentage of public health facilities with copies of standard treatment guidelines and integrated management of childhood illnesses guidelines. In addition, the survey collected data on the occupation of the person responsible for dispensing medicines at each facility.

è The median number of medicines per prescription was 2.5. The chart below illustrates the variation of this prescribing around the median.



è 99.4% of prescribed medicines were on the essential medicines list.

è 53.3% of outpatients were prescribed antibiotics and 10% injections. The chart below illustrates the variation of prescribing of antibiotics around the median.



In this survey, patient knowledge about how to take medicines dispensed to them is assessed by the adequacy of the labelling of the medicines, i.e. the

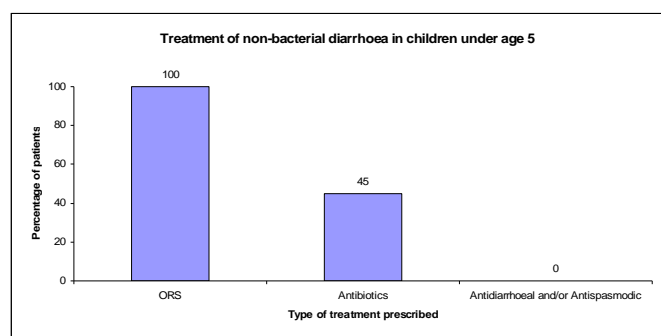
label includes the name of the medicine and how to take it, and whether patients leaving the dispensing area can describe how to take each dispensed medicine.

è 40.5% of medicines were adequately labelled. 76.7% of patients knew how to take all of their medicines.

At each health facility³, patient records were reviewed retrospectively over the previous 12 months. Ten cases each of four tracer conditions – non-bacterial diarrhoea in children under 5 years of age, mild/moderate pneumonia in children under 5 years of age, non-pneumonia acute respiratory tract infection in patients of any age and malaria in patients of any age – were assessed to evaluate the appropriateness of prescribing practices.

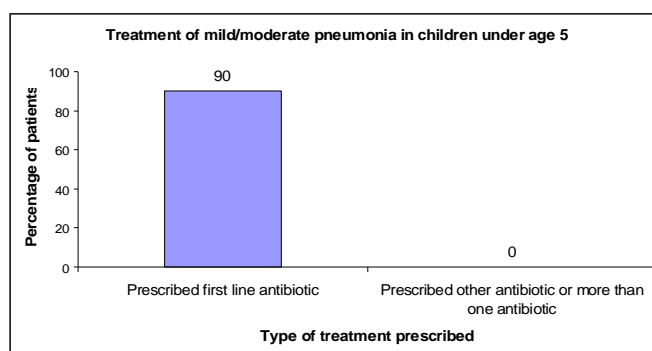
Children under 5 years of age suffering from non-bacterial diarrhoea should be prescribed ORS, but should not be prescribed antibiotics, anti-diarrhoeals or anti-spasmodics.

è A median of 100% of patients under 5 years of age suffering from non-bacterial diarrhoea whose records were reviewed were prescribed ORS, 45% were prescribed an antibiotic and 0% were prescribed an anti-diarrhoeal or anti-spasmodic.



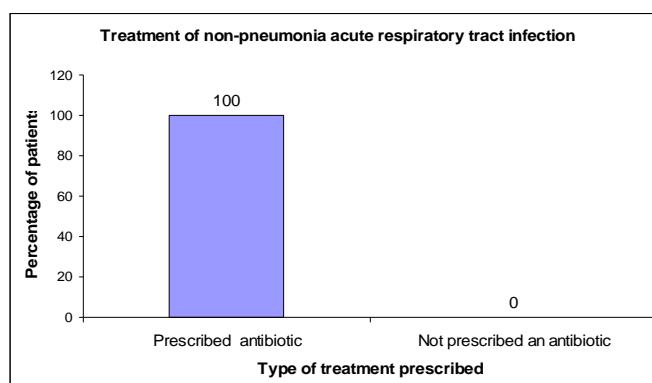
Patients with pneumonia should be prescribed the first line antibiotic only.

è 90% of patients with pneumonia whose records were reviewed were prescribed the first line antibiotic and a median of 0% were prescribed either another antibiotic or more than one antibiotic.



Patients with non-pneumonia acute upper respiratory tract infection should not be prescribed antibiotics.

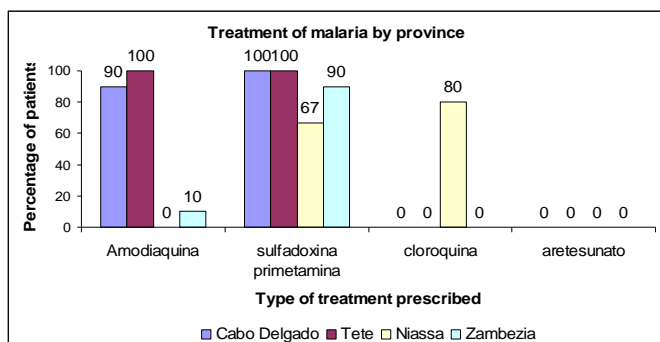
è Contrary to appropriate practice, a median of 100% of patients with non-pneumonia acute upper respiratory tract infection whose records were reviewed were prescribed an antibiotic.



First line treatment for malaria varies by province as the change to artemisinin combination therapy is at different stages of implementation. The following table and graph illustrate the percentage of patients prescribed each treatment by province for those patients whose records were reviewed.

Prescribed malarial treatment by province (%)	Cabo Delgado	Tete	Niassa	Zambezia
Amodiaquina	90.0	100	0.0	10.0
Sulfadoxina-primetamina	100	100	66.7	90.0
Cloroquina	0.0	0.0	80.0	0.0
Aretesunato	0.0	0.0	0.0	0.0

³ Data on treatment of tracer conditions was not collected in Maputo.



è Standard treatment guidelines were available in 94.6% of facilities. Integrated management of childhood illnesses guidelines were available in 82.8% of facilities.

è The occupations of a total of 31 persons responsible for dispensing medicines in public health facilities were recorded in the survey. Of these 9.7% were nurses, 87.1% were pharmacy technicians/auxiliaries of diverse categories and 3.2% were other. None were pharmacists and none were medical technicians.

HOUSEHOLD SURVEY

In this survey, 752 households were asked about the actions taken in response to an acute illness in a household member during the previous two weeks. 94.4% of the households surveyed lived within 5 km of a public health facility. The heads of 50.6% of the households had no formal education and a further 30.2% had some primary education. The median number of members in a household was 8.

Data on only one illness episode per household were included in the survey. Of the episodes included, 83.7% occurred in children 15 years of age or younger and 54.3% in males. 84.2% suffered from fever/headaches.

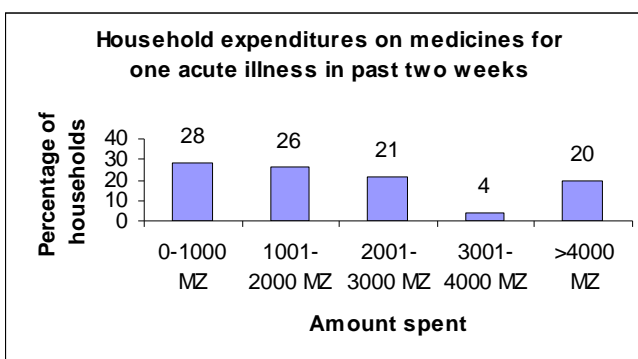
è 98.7% went to a public health facility. Seven respondents reported going to a traditional medical practitioner and three reported deciding which medicines to take on their own.

è 750 respondents reported having medicines prescribed or having taken medicines for the illness.

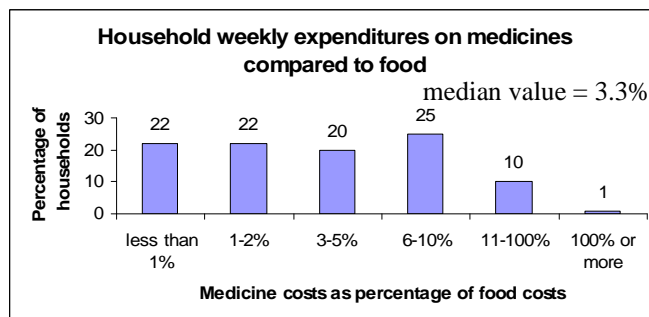
è 747 respondents obtained their medicines from public health facilities.

è 734 respondents were able to obtain all the medicines that were prescribed to them and 736 took all the medicines recommended to them.

è A median of 2000 Metical was spent on medicines for the illness (equivalent to 24 minutes' wages for the lowest paid unskilled government worker).



è The median amount spent on medicines for all members of the household during a week was 3500 Metical (equivalent to 42 minutes' wages for the lowest paid unskilled government worker). This is in comparison to the median weekly household expenditure of 140,000 Metical on food (equivalent to 3½ days' wages for the lowest paid unskilled government worker).



Scoping for Phase 2 of the External Evaluation

The Mozambique Ministry of Health's terms of reference of the "External evaluation of the Pharmaceutical sector of Mozambique, 2005" (in Annex 1 of this Consolidated Report). The key issues and objectives of the evaluation are summarized below and under the following five headings:

1. Policy and financing;
2. Procurement and supply management
3. Quality and MRA issues (including supplementary QC request)
4. Human resources
5. Drug selection and use

In summary the key points that were emphasized to me were:

- The policy issues on the table for the MOH Mozambique are not new and many of the issues were decided upon up to 10 years ago. These are primarily related to the splitting of policy and regulatory functions as well as designing an appropriate model for public sector procurement and supply management.
- The MOH is looking for is primarily confirmation that those policy directions are still sound for Mozambique (and hence preference working with WHO), as well as advice on how to manage the consequent transitions with minimal disruption.
- Consideration of the very limited human resource capacity is essential in planning for the mid-medium term in all aspects.
- There have been quite a number of both internal and external reviews carried over the years of the pharmaceutical sector in Mozambique – the latest in 2003. Many of these reviews were not specific or holistic enough to be useful to the MOH – or were overly optimistic on the situation
- With respect to new issues, the procurement and supply management/logistics are most complex and involve all levels of the system including a major change at the national level that needs careful management and advice to minimize disruption
- Working within the context of South African Development Community (SADC) on Quality Assurance (QA) issues is of prime importance – as well as looking at norms of managing central medical stores in SADC member states is specifically mentioned
- It is important to note that towards the end of the evaluation there will must be a presentation of key findings to the Ministry and collaborative partners
- The final report should also include a roadmap – including a costed plan of action for 2007 (with a vision for 2008/9 and beyond) [including consideration of budgeting for a WHO Medicines National Professional Officer (NPO)]

The table in Annex A below highlights those issues from within the very wide-ranging terms of reference emphasized as of primary importance since drafting of terms of reference in March 2005.

Documentation

In Annex B below, a list of documentation collected as preparatory material for phase 2 is presented.

Expert team for phase 2 and timing

A team of probably 5 experts is needed, as described on the next page is needed. The expectation is that the first draft report and costed work plan should be presented by 19 June.

Whilst concurrent presence of consultants is desirable, some of the inputs are more time consuming than others; mechanisms of ensuring consistency as well as coordination of the drafting of the final report need careful planning.

The team leader needs to be present for a presentation of key findings and recommendations at towards the end of the mission +/- 15 June

In order to meet the deadlines, the logistics expertise needed +/- w/c 22 May – rest of team +/- 5 June.

On Annex C below a table captures the profiles of consultants as taken from the original TOR for the Evaluation of the Pharmaceutical Sector in Mozambique, 2005.

		Estimated number of days +/-	Portuguese language skills	Issues emphasized as of primary importance since drafting of terms of reference in March 2005
1. Policy and financing		10 working days	Essential	<ul style="list-style-type: none"> • Policy issues relating to splitting of regulatory and policy/supply management • Expanding on drug policy issues within the context of the health policy • Financing of public sector drug supplies; cost recovery • Chaotic medicines pricing in the private sector
2. Procurement and supply management/ logistics		20 working days	Desirable	<ul style="list-style-type: none"> • Role and functions of CMAM (Central Medical Stores) (considering current framework of contracted out to privatized Medimoc and decision to change this • Developing an exit strategy for MOH from Medinoc to public management with selective sub-contracting • Functioning of the drug supply management system from national level -> patient through layers of warehousing – including measures to reduce theft & wastage • Appropriateness of stock management systems at district level for national quantification
3. Quality & MRA issues	MRA	10 working days	Essential	<ul style="list-style-type: none"> • Prioritization of activities and plan for building capacity to implement new medicines law and more autonomous MRA • The new medicines law will be largely drafted by May 2006, the evaluation should focus on how to implement
	QC lab	5 working days	Desirable	<ul style="list-style-type: none"> • “supplementary request” from MOH to main evaluation that on exploration is preferable to be incorporated within the recommendations with respect to the policy on and functions of the MRA
4. Human resources		5 working days	Desirable	<ul style="list-style-type: none"> • Framing a national 15-20 year human resource plan for the pharmaceutical sector to fit into the national HR Health plan (technical and managerial) • Removal of reliance on long-term foreign TA
5. Drug selection and use		10 working days	Desirable	<ul style="list-style-type: none"> • Drug selection and prioritization for procurement at the national level: process and buy-in by MOH and clinicians • Quantification of needs at the national level • Drug therapeutic committees in the large institutions – concerns over budget expenditure and low levels of satisfaction
TOTAL		60 working days		<p>Additional time may need to be budgeted for report writing</p> <p>This total does <u>not</u> yet include phase 1 or the time for support to the pharmaceutical situation survey</p>

Annex A:

Summarised issues and objectives from the Mozambique Ministry of Health's terms of reference

POLICY AND FINANCING ISSUES - as stated in the MOH terms of reference The key policy decisions that were in principle agreed in the late 1990's are now up for implementation: 1. Splitting of regulatory and policy/supply function 2. Taking back into public control procurement and storage and perhaps contracting out distribution		
ISSUES & CHALLENGES	SPECIFIC OBJECTIVES IN RELATION TO THIS ASPECT	
<p>Medicine regulatory authority</p> <ul style="list-style-type: none"> - Lack of national pharmaceutical policy; - Lack of implementation of the medicine regulatory law (4/98), (i.e. registration of medicines, and quality control) particularly important as the country is reliant on imported drugs; - Lack transparency in pricing of drugs in the private sector, <p>Central Medical Store (CMAM)</p> <ul style="list-style-type: none"> - Lack of clarity in the institutional and functional situation of CMAM within the Ministry of Health, - The monopoly assigned to MEDIMOC in procurement, storage and distribution; 	To analyze the main achievements and weaknesses of the current strategic plan being implemented since 1997	a. the qualitative and quantitative availability of drugs, generics and specialties in the public sector; b. the level and structure of drug prices; c. the accessibility of drugs for patients
	To critically evaluate the development of	A) reforms in policy and organization of the sector B) management of drug supply system at national level C) functioning of drug supply in the health system and make clear recommendations on further improvements
	To evaluate the current draft of the National Pharmaceutical Policy on its adequacy and make clear recommendations on its improvement.	
	To perform a critical assessment of regulatory functions	- The policy regarding essential medicines, pricing policy for medicines and medical supplies; quality control; registration of medicines; mapping of staffing levels and skills available for the pharmaceutical sector (including medicine regulatory agency)
	To analyze the institutional position and Mandate of CMAM in the Ministry of Health structure	The present organization should be compared with other similar agencies in African pharmaceutical systems, particularly within SADC member states, regarding their functions, status, organization, human resources, management, financing and accountability, including the functional/technical link with the ministry of Health. The ongoing functional study of the ministry of Health should be taken into account (and vice-versa).
	The efficiency and sustainability of the having two different sectors of the MOH responsible for the management of Medical supplies (DAG-Centro de Abastecimento) and Drugs (DNS-CMAM) and other possible options	

<p>Other important issues and challenges include</p> <ul style="list-style-type: none"> - Cost-recovery of medicines: the performance and effectiveness of the cost recovery of medicines in raising revenues and maintaining equity in access to health services; - Low level of budget execution 	<p>The management of drug supply at the national level: Current procurement system and its alternatives</p>	<ul style="list-style-type: none"> a. The procurement cycle and the procurement methods used up to date, b. The possibility to engage other private companies in procurement, storage and distribution, c. The expected impacts of such a choice, d. Draft the criteria and ToRs for contracting a private agency(ies) on procurement, storage and distribution of medicines;
	<p>The effects of and lessons learned from the recent transfer of management of FCMSM (Common Fund for Medicines and Medical Supplies) from SDC to MISAU, and estimate the effects and risks of the planned integration of FCMSM (procurement component) within PROSAUDE</p>	
	<p>The financing of the system and levels of budget execution,</p>	<ul style="list-style-type: none"> - The cost recovery system, - Level of integration of external support - How are the various partner initiatives in the pharmaceutical sector contributing to the SWAP approach in health? - Proposals for a more coordinated integrated financing system

PROCUREMENT AND SUPPLY MANAGEMENT/LOGISTICS- as stated in the MOH terms of reference

In the TORs there are mention of 2 experts:

1. An expert on logistics management, financing and pricing in the pharmaceutical sector, with extensive knowledge of the private market, and alterative procurement and distribution systems;
2. A pharmaceutical expert with extensive knowledge of and experience in drug logistics and the formulation and implementation of national or provincial level programs for the rational use of drugs. Prior experience with large programs for rational utilization of drugs will be highly desirable.

ISSUES & CHALLENGES	SPECIFIC OBJECTIVES IN RELATION TO THIS ASPECT	
<p>Central Medical Store (CMAM)</p> <p>The main issues and challenges faced by the CMAM include:</p> <ul style="list-style-type: none"> - Inadequate quantification of estimates at national, provincial and district levels - Long procurement cycle - Lack of clarity in the institutional and functional situation of CMAM within the Ministry of Health - The monopoly assigned to MEDIMOC in procurement, storage and distribution 	<p>To critically evaluate the development of</p>	<ul style="list-style-type: none"> A) reforms in policy and organization of the sector B) management of drug supply system at national level C) functioning of drug supply in the health system and make clear recommendations on further improvements
	<p>To analyze the institutional position and Mandate of CMAM in the Ministry of Health structure.</p>	<p>The present organization should be compared with other similar agencies in African pharmaceutical systems, particularly within SADC member states, regarding their functions, status, organization, human resources, management, financing and accountability, including the functional/technical link with the ministry of Health. The ongoing functional study of the ministry of Health should be taken into account (and vice-versa).</p>

<p>- Two different sectors of the MOH are responsible for the management of Medical supplies (DAG-Centro de Abastecimento) and Drugs (DNS-CMAM). { This result, for example, in 2 separate logistics supply systems for injectable drugs and the syringes needed to inject these drugs }</p> <p>- CMAM has been working over the last two years on the development of a drug management information system (SIGM) that will change radically the way it is working and integrate all its planning, procurement, warehousing and distribution functions.</p> <p>- Cost-recovery of medicines: the performance and effectiveness of the cost recovery of medicines in raising revenues and maintaining equity in access to health services;</p> <p>- Low level of budget execution;</p> <p>- Inefficient drug management and use of medicines in the public health sector;</p> <p>- Low clients satisfaction with long queues and long waiting time in hospital and other health facilities pharmacies</p> <p>- High level of “inventory discrepancies” and not documented issues in health facilities outpatient and ward pharmacies</p>	<p>The efficiency and sustainability of the having two different sectors of the MOH responsible for the management of Medical supplies (DAG-Centro de Abastecimento) and Drugs (DNS-CMAM) and other possible options</p>	
	<p>The management of drug supply at the national level: Current procurement system and its alternatives</p> <p>The strengths and weaknesses of the current contracting out should be assessed, and especially:</p>	<ul style="list-style-type: none"> - The procurement cycle and the procurement methods used up to date, - The possibility to engage other private companies in procurement, storage and distribution, - The expected impacts of such a choice, - Draft the criteria and ToRs for contracting a private agency(ies) on procurement, storage and distribution of medicines;
	<p>The effects of and lessons learned from the recent transfer of management of FCMSM (Common Fund for Medicines and Medical Supplies) from SDC to MISAU, and estimate the effects and risks of the planned integration of FCMSM (procurement component) within PROSAUDE;</p>	
	<p>Analyse the specific constraints of ARVs supply.</p>	
	<p>The functioning of supply and distribution of drugs in the health system</p>	<ul style="list-style-type: none"> - The process of quantification of estimated country needs at district, provincial and national levels - The assessment of the extra needs in medicines and medical supplies due to the burden of HIV/AIDS, Tuberculosis and Malaria and make sound recommendations on how to effectively take into account those needs at district, provincial and national level, - The criteria of the distribution of drugs from the central to the peripheral levels, - The effectiveness of the entire delivery chain up to the patients, at each level of the health system, - The patients’ level of satisfaction (staff behavior, waiting time at pharmacies, prices, non availability of drugs, etc.). - The supply of tertiary and quaternary hospital in specialized medicines. Should this still be done by CMAM or should alternative mechanisms be investigated? - Assess the new drug management information system (SIGM) being implemented, and evaluate its impact on planning, procurement, warehousing and distribution functions

QUALITY & Medicines Regulatory Authority (MRA) ISSUES - as stated in the MOH terms of reference		
The terms of reference request a “pharmaceutical expert with extensive knowledge in Pharmaceutical quality assurance, conversant with relevant quality assurance/control standards and systems in developed and developing countries and has prior experience in evaluating assurance/control systems and medicine regulation area”. There has also been a secondary request for a QC expert – MOH would see this expert’s work being part of, or feeding into the bigger evaluation, as recommendations on the QC lab cannot be made outside recommendations concerning the functions and capacity of the MRA.		
ISSUES & CHALLENGES	SPECIFIC OBJECTIVES IN RELATION TO THIS ASPECT	
Lack of national pharmaceutical policy Lack of implementation of the medicine regulatory law (4/98), (i.e.: Registration of medicines, and quality control) particularly important as the country is reliant on imported drugs;	To perform a critical assessment of regulatory functions	- Quality control, - The registration of medicines, - The mapping of staffing levels and skills available for the pharmaceutical sector (including medicine regulatory agency);

HUMAN RESOURCES - as stated in the MOH terms of reference		
Human resources are listed as one of the four main challenges:		
ISSUES & CHALLENGES	SPECIFIC OBJECTIVES IN RELATION TO THIS ASPECT	
There is a crucial lack of staff (quantity and quality) for the whole pharmaceutical sector. Total reliance on external technical assistance for both CMAM and COMED; Reduced capacity of the pharmaceutical sector to take into account the increased needs of medicines and medical supplies due to HIV/AIDS, Tuberculosis and Malaria.	To evaluate the current draft of the National Pharmaceutical Policy on its adequacy and make clear recommendations on its improvement.	
	To perform a critical assessment of regulatory functions - The mapping of staffing levels and skills available for the pharmaceutical sector (including medicine regulatory agency)	

DRUG SELECTION AND USE- as stated in the MOH terms of reference
 Whilst not explicitly identified as needed skill, when teasing out the other 4 issues reflected in the email, I realized there is some expectations on this issue, especially with respect to the drug budget at central and regional hospitals, which are apparently swallowing up the budget for medicines, yet the perception is that they do not have the right drugs. The profile of the consultants needed does however list: “A pharmaceutical expert with extensive knowledge of and experience in drug logistics and the formulation and implementation of national or provincial level programs for the rational use of drugs. Prior experience with large programs for rational utilization of drugs will be highly desirable” This together with the issues raised below, indicate to me that the issues are related to drug selection/STGs/PTCs – as well as perhaps some aspects of hospital drug management

ISSUES & CHALLENGES	SPECIFIC OBJECTIVES IN RELATION TO THIS ASPECT	
Inefficient drug management and use of medicines in the public health sector High level of “inventory discrepancies” and not documented issues in health facilities outpatient and ward pharmacies	To analyze the main achievements and weaknesses of the current strategic plan being implemented since 1997, regarding:	The functioning of supply and distribution of drugs in the health system
	The qualitative and quantitative availability of drugs, generics and specialties in the public sector, the accessibility of drugs for patients,	The process of quantification of estimated country needs at district, provincial and national levels The patients’ level of satisfaction (staff behavior, waiting time at pharmacies, prices, non availability of drugs, etc.). The supply of tertiary and quaternary hospital in specialized medicines. Should this still be done by CMAM or should alternative mechanisms be investigated? The rational use of medicines in the public sector by professionals, including standards treatment guidelines

Annex B:

List of documentation collected in preparation of Phase 2 of the Evaluation

Below is a summary of the documentation stated in the TORs as “essential reading” (marked **) – and other documents that may be useful for phase 2.

Documents provided in electronic versions

- Ministério da Saúde. Plano de Desenvolvimento de Recursos Humanos
- República de Moçambique. Ministério da Saúde. 2001. Plano Estratégico Sector Saúde 2000 – 2005 – (2010)
- Drug Management in IMCI study 2005
- Global Fund Proposal, 2002
- Primary Health Care in Mozambique, World Bank 2004
- Proposta de estatutos da Central de Medicamentos (CMAM) **
- MOH Operational plan 2005 PROPOSTA DO PLANO ECONÓMICO E SOCIAL 2006 SECTOR SAÚDE
- Central de Medicamentos e Artigos Médicos, Relatório de trabalho do ano 2005, JANEIRO 2005 ++ {Items marked “++” distributed by WR on 14 April (will be re-sent)}
- Central de Medicamentos e Artigos Médicos, Acta da Reunião ++
- Central de Medicamentos e Artigos Médicos, Siintese Sobre Apoio Institucional ++
- Central de Medicamentos e Artigos Médicos, Proposta Ref.: Data: 14 de Fevereiro de 2006, Assunto: Necessidades e Financiamento em 2006 ++
- Reunião do Grupo de Trabalho De Medicamentos, Síntese da Sessão de Trabalho, Data: 11 de Novembro de 2005, Presentes: Ver lista em anexo ++
- FCMSM (Common Fund for Medicines and Medical Supplies) provisional (2006) and confirmed (2005) contributions ++
- Aprovada por SExa. Ministro em Setembro de 2005 e com as alterações recomendadas, Versão Curta Préfinal – 4/11/05, Declaração de Política Nacional de Saúde
- WHO regulatory tool – self assessment – Mozambique, 2006

Documents that will be sent by DHL by WHO Representative in Mozambique (WR) to the Department of Technical Cooperation for Essential Drugs and Traditional Medicine (TCM) in Geneva

- CMAM Annual Report, 2004**
- Report of the External evaluation 2003 **
- Declaração de Política Nacional de Saúde**
- 2001 internal evaluation of the pharmaceutical sector
- April 2003 Audit by the Ministry of Planning and Finance
- Medicine regulatory law (4/98)
- Decreto 22/99-1999 (Provisions regarding medicines registration)
- Current draft of the National Pharmaceutical Policy
- Treatment guidelines for HIV&AIDS, TB and malaria
- Índice dos medicamentos registrados em Moçambique
- Price list for medicine in provincial hospitals (1999 – current version)
- Price list for medicine in central hospitals (1999 – current version)
- List of contents of drug kits, 2006

- Pharmaceutical sector strategic plan 1995 (Portuguese)
- Diagnostic study of the national system for importation of medicines, Coopers and Lybrand, 1999
- CMAM- sistema de gestão por objectivos (Management systems by objectives.), 1999 May, PriceWaterhouseCoopers.
- Diagnostic study of the national system for importation of medicines, Coopers and Lybrand, 1999

Documents that are in the Medicines Documentation Centre/TCM

- Pharmaceutical sector strategic plan 1995 (English) – *still applicable* (Portuguese version will be sent in hard copy by WR Mozambique)
- Report of mission/Precious Matsoso, August 2005
- National Medicines Regulatory System Profile, self assessment, 2006
- Review of DAP support to the National Essential Drugs Programme in Mozambique, German Velasquez 1993 & 1995
- MOH/MSH Pharmaceutical Sector Assessment 1993
- Strategy for the Pharmaceutical Area, MOH Mozambique 1995
- Fact finding mission for Belgian Bilateral Support, Mozambique, 1999
- Health Sector Profile, Mozambique 1998

Documents outstanding

Listed as essential in TORs

- República de Moçambique, Ministério da Saúde, Direcção Nacional de Planificação e Cooperação. 2001. Cenário de Despesa e Financiamento de Médio Prazo 2001 – 2005 para o Sector de Saúde. **
- Relatório da análise funcional do MISAU – KPMG **

Desirable

- June-July 2005, a joint mid-term evaluation of the “Plano Estratégico do Sector de Saúde (PESS) 2001-2005-2010”
- Decreto 21/99-1999 (Administrative and general provisions)
- Lei nº3/97-1997 (Provisions regarding narcotics and psychotropics)
- “harmonised manuals of procedures for provincial warehouses, hospitals, health centres and health posts”
- Essential drugs list (V, E and N lists)
- Draft of the revised standard treatment guidelines

Annex C: Detailed profiles of consultants for Phase 2 of the external evaluation

The evaluation team will be comprised of five members:

- A Team Leader, who must be a pharmaceutical expert with extensive knowledge in pharmaceutical policy, political economy and health economics in developed and developing countries;
- An expert on logistics management, financing and pricing in the pharmaceutical sector, with extensive knowledge of the private market, and alternative procurement and distribution systems;
- A pharmaceutical expert with extensive knowledge in Pharmaceutical quality assurance, conversant with relevant quality assurance/control standards and systems in developed and developing countries and has prior experience in evaluating assurance/control systems and medicine regulation area;
- A pharmaceutical expert with extensive knowledge of and experience in drug logistics and the formulation and implementation of national or provincial level programs for the rational use of drugs. Prior experience with large programs for rational utilization of drugs will be highly desirable;
- A public health specialist with extensive experience in managing and evaluating health service delivery at national and provincial level;

All members of the evaluation team are expected to have at least a good working knowledge of Portuguese.

If one or more of the consultants have several of the required expertise, the team size can be reduced accordingly.

The team leader is expected to be physically present in the country during the whole process of the evaluation and is responsible for the final evaluation report both in English and Portuguese versions

Report on Supply, Distribution and Use of Medicines

Detailed Report

June 2006

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BACKGROUND

During the last five years, the Ministry of Health has launched several evaluations to assess the pharmaceutical sector, determine the progress made so far and provide recommendations on how to improve the pharmaceutical sector.

In 2001, an internal evaluation was conducted to assess main achievements and constraints faced by the pharmaceutical sector. The internal evaluation took approximately one year to complete and the results were discussed by both the Ministry of Health and development partners.

In April-May 2003, an external evaluation of the pharmaceutical sector was conducted by an external team. The results of the external evaluation show that significant progress has been made in the pharmaceutical sector. The report stated clearly that all health facilities were replenished regularly with *basic* medicines and that patients have access to these basic medicines without any financial barrier

In June-July 2005, a joint mid-term evaluation of the “Plano Estratégico do Sector de Saúde (PESS) 2001-2005-2010” confirms that the availability of high quality medicines in all provinces is one of the main achievements and the most important progress made in the pharmaceutical sector.

However, despite these positive results, the three evaluation reports pointed out several issues and challenges that remained to be tackled to improve the performance of the pharmaceutical sector in Mozambique. For example, tertiary and quaternary hospitals frequently experience a low level of satisfaction for the requisitions they made for specialized medicines. Furthermore, an audit conducted in April 2003 by the Ministry of Planning and Finance showed shortcomings in drug distribution.

The focus of this external evaluation, conducted by World Health Organisation, is to identify activities that will begin to address the issues and challenges and at the same time to make the most cost-effective use of financial and human resources available to the public pharmaceutical sector in contributing to the health plan of the country.

TERMS OF REFERENCE AND ACTIVITIES

The given Terms of Reference are attached in full to this report. This report refers particularly to those terms of reference that relate to the systems for the procurement, distribution and use of pharmaceuticals in the national health system

The consultant met with WHO staff and with officials and health staff working in the Ministry of Health in Maputo, Beira, Sofala and Manica Provinces and two central hospitals. In addition visits were made to MEDIMOC offices and warehouses. Briefings were given to the Honourable Minister of Health and also at the conclusion of the visit to the National Director for Health (DNS) and concerned MOH staff. A brief time was also spent in consultation with the chief of FARMAC.

DESCRIPTION OF MANAGEMENT AND IMPLEMENTATION OF DRUG SUPPLY

The purchase and supply of medicines and medical supplies for use in the national health service of Mozambique is planned and managed by the Ministry of Health through their Central Medicines and Medical Supplies (CMAM) department. Procurement is financed by the Government of Mozambique with the support of the partner community through pooled funding (the common fund) which represents 60-70% of total expenditure on pharmaceuticals.

Many of the supply activities are performed under contract by MEDIMOC, a company that was formerly state-owned but is now a fully private enterprise.

CMAM has several sections each with their distinct role and responsibilities, as well as finance, administrative and IT sections to support the activities;

- CMAM Planning is responsible for preparing the estimates of need based on the patterns of supply and consumption.
- CMAM Procurement uses the estimates to manage procurement, using the contracted services of MEDIMOC to perform many of the administrative activities of tendering, purchase contract monitoring, receipt, clearing and product quality control. Decisions concerning the award of contracts are made by CMAM.
- CMAM Distribution takes responsibility for managing and authorizing the movement of supplies to the provincial depots and the hospitals that receive direct supply. MEDIMOC is contracted to operate the central stores and implement the delivery of requisitions to provinces, central hospitals and some district hospitals in Maputo according to specific time limits.
- CMAM Audit personnel visit provinces to monitor supply activities against the standard procedures.

Estimation of Needs

The Planning section estimates the annual needs of the government health services using the information obtained in the process of requisition during the previous year. The process of requisition at the district, provincial and central hospital levels involves the calculation of the adjusted monthly rate of consumption and this forms the basis of all calculations.

Procurement

The national procurement law prefers the use of competitive bidding for procurement of supplies and the majority of pharmaceutical and medical supply procurement uses competitive bidding of two types; Limited Competitive Bidding (LCB) and International Competitive Bidding (ICB).

When implementing LCB, CMAM uses pre-qualified suppliers (all wholesalers) who were selected for a period of two years by a combined working-group of CMAM, MEDMOC and an independent consultant (NIC) from the Netherlands. LCB is used for the bulk of the procurement, especially for that financed by the Common Fund for Medicines. The process reportedly takes about 4 months from planning to the signing of contracts and a further 4 months to the receipt of goods, 8-9 months in total.

ICB is an open process used at the request of specific partners (notably World Bank) for expenditure of their funds and reportedly can take between 12 and 24 months from planning to receipt of goods.

Only emergency orders use a more flexible and quicker procurement method of national/international shopping.

As noted above the administrative actions and paperwork associated with tenders, managing supplier contracts and clearing and receiving goods are all done by MEDIMOC on behalf of CMAM and following CMAM instruction as per the contract. There are several distinct steps in the procurement process of which 4 are exclusive to CMAM as the critical points; deciding priorities, matching needs with available funds, choosing the procurement method, adjudicating contract awards.

Distribution

Distribution is carried out following written national procedures. This requires staff at each level in the system to count and record their stock at the end of each quarter and, using a standard form, to calculate the average monthly consumption rate and use that to estimate the needs for the next quarter. Therefore every three months each level in the supply system requisitions supplies from the next level in the system – clinic from district, district/provincial hospital from province, province/central hospital from central. Each supplying depot or level then confirms or amends the requisition according to their stock and ability to supply and supply is made.

For supply from central level, requisitions are sent by provinces and central hospitals to CMAM for assessment and authorization of supply from central stores. Information is then communicated to the province/central hospital and MEDIMOC. MEDIMOC delivers the items within the time frames specified in the contract. MEDIMOC is responsible for ensuring delivery to central hospitals, general hospitals in Maputo and provincial warehouses.

Audit

The audit section of CMAM visits all provinces annually, a team of two persons working for 15 days in the company of the pharmacy technician in-charge of the provincial pharmacy department. Standard checklists are used to perform an audit at the provincial warehouse, in the provincial hospital (pharmacy store, outpatient dispensary and sample wards) and in one district store.

Follow-up briefings are given to the provincial director of health and a full detailed report is completed on return to CMAM offices. A summary of findings, recommendations and actions is circulated widely to all concerned persons for action.

AN ASSESSMENT OF THE FUNCTIONING OF SUPPLY AND DISTRIBUTION OF DRUGS IN THE HEALTH SYSTEM

Assessment always depends on the criteria used in the assessment process. Over the last 5 years there have been several internal and external assessments of the pharmaceutical system in Mozambique that have included an assessment of the supply system for medicines within the public sector. These assessments have frequently concluded that, despite the weaknesses of the system, there is an appropriate supply of essential medicines to all levels of the health care system.

This aspect of the external evaluation, performed by WHO at the request of the Minister of Health, whilst not denying the improved supply situation compared to that of 5 or 10 years previously and acknowledging that basic and essential drugs are largely available, is targeted at problems with the efficiency and performance of the system and at improving the relevant skills and contribution of the staff.

The focus of the evaluation is whether the pharmaceutical supply system is contributing to the goal of meeting the health needs of individuals and communities at all levels of the system, resulting in the legal and timely provision to any patient/customer of cost-effective medicine that is fit for purpose and provided with the correct advice to maximize its effect.

Availability of Medicines - *Is there access to medicines at the time of need?*

The WHO indicator survey conducted in May 2006 (phase 1 of the assessment) showed that for a selected basket of 15 essential medicines (13 being in drug kit A) they were available at the time of survey in 87% of facilities sampled. This is consistent with other similar studies.

The 2004 annual report of CMAM, using their own audit information, records that of the 217 “vital” items (estimated as 28% of the total range) 73% are available at least 75% of the time. Of national formulary items (approximately 80% of total range) 45% are available at least 75% of the time.

The current overall supply service level is at about 50% for the whole range of medicines included in the estimates, with a lower percentage of success for the central hospitals who probably order the widest range. With such a level of supply service it is inevitable that a lot of patients are not being provided with the treatment they need by the supply system and the performance of the system is not acceptable in terms of access to the appropriate range of medicines especially for secondary and tertiary care.

Primary Health Care is well served with essential medicines and this should be maintained whilst efforts are made to improve access to a wider range of medicines at secondary, tertiary and quaternary levels. It is therefore important to ask the next question to ensure that all relevant and approved medicines are available at the time of need.

Range of Available Medicines - *Is the most appropriate treatment available for prescribers to use?*

It is difficult to answer this question and there is no study that gives evidence to provide a clear answer. The responses given during interviews with prescribers and pharmacists in provincial and central hospitals indicate that the limited range of regularly available medicines is restrictive to their practice and that they “have to use what is available” or rely on the patient to purchase in the private sector.

Whilst clinicians will naturally hope for an ideal situation with access to a full range of items in all situations (regardless of resources) there should be adequate consultation with them to identify and agree on rational needs. CMAM has undertaken some consultation at the MOH during 2006 as an initial step to involve clinicians in developing estimates of need.

Quality of Prescribing - *Are medicines being prescribed and supplied according to therapeutic guidelines?*

Certainly medicines are being prescribed! and the WHO indicator survey found that 95% of prescribed medicines are being supplied at the facilities sampled. A spot check done at an urban clinic provided a figure close to 90% and at CH Maputo the hospital pharmacist suggested he was able to supply 60% of prescribed items. In the latter case the hospital pharmacist suggested that the figure of 60% was inflated because prescribers were made aware of the stock situation and refrained from prescribing items that are out of stock. This raises the issue of whether prescribers are responding to patient need and requirement or to the list of available medicines and possibly compromising treatment.

Survey evidence of guideline compliance was very mixed indicating positive compliance when dealing with diagnosed conditions (ORS in diarrhoea, antibiotic in pneumonia). However in cases of diarrhoea, at the same time as complying with ORS guidance, there was a lack of compliance with advice about the use of antibiotics and antibiotics were prescribed in 40% of cases. In the case of non-pneumonia upper respiratory tract infection the survey recorded 100% patients were prescribed an antibiotic in total contradiction to the guideline.

Effectiveness of Treatment - *Are the prescribed and provided medicines likely to have the intended effect?*

This raises issues of product quality and also of patients' use of medicines.

The WHO indicator survey found that 60% of medicines were not labelled adequately but 75% of patients understood correctly how to use their medicines at the time of exit. This suggests that the people of Mozambique will not exceed the general figure of 50% who take their medicines according to advice given. This may or may not influence the intended effect depending on the particular medicines.

Because of the scheduling of the supply system and delivery programmes, medicines are stored for long periods of time at each level and the effect of inappropriate storage conditions may cause deterioration of the product and reduce its effectiveness.

Previous assessments have also mentioned the problem of the packaging used to deliver oral solid dose medicines to patients – i.e. in a paper or plastic bag – and its effect on product quality. Certainly this practice of dispensing into plastic or paper bags is not ideal and is totally inappropriate during hot, humid and rainy weather. In the latter situation there would be a significant impact on effectiveness probably making the medicine unusable. The problem could be corrected by ordering more products in the strip or blister-pack format, a practice which is now accepted for anti-TB and antiretroviral products. In addition the use of blister/strip packs would reduce some of the workload in the pharmacy department where a lot of time is spent repackaging bulk into patient ready packs.

Efficiency of the Supply System - *Is there waste in the system that could be reduced to increase the range of medicines available?*

The WHO level 2 indicator study did not indicate expiry problems for the trace products of the study. However the Minister of Health is conscious of the level of waste and central warehouses still have some large quantities of common products that are due to expire before September 2006.

The high rate of wastage due to expiry is blamed on delays in the procurement process at dispatch (due to late financing) and at receipt (delays in clearing). It may also be due in part to inaccurate estimation of needs (at both provincial and central levels) and to changes in treatment practice. It is also partly caused by the procedure of holding large (maximum equivalent to 5 months) stocks at each facility.

There is evidence at clinics and provincial depots that the drug kit system results in accumulation of large quantities of a few items at both clinics and provincial stores. This suggests that for those items the rate of use is not consistent across the country or else the demand pattern has changed. The inflexibility of the drug kit system is particularly exposed by a change in treatment practice as illustrated by recent changes

in the recommended national treatment for malaria, whilst chloroquine tablets remain as a content of the drug kit.

The use of large “hospital” packs (1000 tablets) may result in the supply of excess quantities to the peripheral levels of the health services when using the requisition system. Additionally they risk some waste because tablets are much more likely to be damaged in transit when packed in 1000 tablet packs.

There is waste in the supply system in its present form as noted above. There is also some waste caused by the practice of health workers accumulating extra stocks “just in case” (especially in hospital departments) because they have experienced system failure. There is also evidence of waste or loss (according to the CMAM audit department) in hospital wards, outpatient pharmacies and clinics where detailed recording of supplies in and out is weak and there are unaccountable discrepancies.

The large stocks held in stores throughout the system result in many risks of waste due to poor storage conditions and deteriorating quality, careless stock handling resulting in breakages, poor record-keeping resulting in confusion (CMAM found 24-40% non-compliance, WHO found 30% non-compliance) and opportunities for crime and misuse of government property.

Capacity of the Storage System - *Are storage facilities adequate?*

Staff at all levels complained of the lack of storage space for their medicines and this may be correct because the delivery interval of 3-months requires the storage of up to 5 months of stock at each point in the system, more than may be absolutely necessary.

Some facilities may be difficult to supply at frequent intervals, especially during the rains, due to their location. Such facilities may require infrequent deliveries at intervals of more than one month but many of the delivery points can be serviced within a day or half a day. In such cases weekly or monthly supply intervals would be an option, thus reducing the levels of stocks throughout the system and the associated risks mentioned above as well as reducing the pressure on storage space.

Storage facilities are probably not adequate (certainly not suitable according to WHO indicators) for storing large volumes of stocks at points below provincial depot level but may be adequate if the supply interval is reduced to one week or one month. The question of adequacy could then be re-assessed.

The issue of adequacy of storage at central levels depends also on the delivery of bulk supplies, whether full annual stocks are delivered or whether they are supplied in smaller quantities at regular intervals.

Capacity and Efficient Use of Human Resources - *Are staff numbers adequate and are they efficiently deployed?*

Pharmacists are a scarce resource in the country of Mozambique. Government salaries for pharmacists are low and provide no incentive for them to remain in the service, nevertheless there 20 pharmacists employed in the government service of whom 10 work at CMAM. The total number of pharmacists in the country, particularly in the health services, is insufficient.

Pharmacists’ skills should be deployed at the critical points in the system either as “doers” or as managers who are training, supervising and advising others. The three critical points for medicines are:

- In assessing and monitoring product quality/safety/efficacy at registration and in the supply system;
- as a member of the health team (at the Ministry of Health and in hospitals) collaborating with others to agree/provide the therapeutic needs of an individual or a group of patients; and
- in ensuring and monitoring the safe and optimal use of medicines by patients (in the clinical environment).

In the hospital services the 5 pharmacists who work in the central hospital pharmacy departments are under a lot of pressure as they try to satisfy many requests for supplies working with the available limited human and physical resources. In CH Maputo there are just 2 pharmacists for 1400 hospital beds. In CH Beira the 2 pharmacists provide services to about 800 beds though the hospital often has more in-patients

than beds. In the provincial hospitals the pharmacy service is managed by pharmacy technicians. The hospital services do not have adequate staff numbers.

Pharmacy technicians are responsible for managing and operating the drug supply system at provincial and district levels and they are, and should continue to be, the “backbone” of the pharmaceutical services. They do a lot of the work but also because of insufficient numbers they have to delegate many tasks to “agentes”/assistants without adequate supervision.

There will continue to be shortages of human resources for some time into the future.

FINDINGS AND CONCLUSIONS

Quantification or Estimation of Need

Estimation of annual need is based on data gathered from requests and issues. However the data is not validated as being equal to the true requirements to meet the treatment needs of the people of Mozambique. It is known that there are losses, irrational use and waste in the system (as noted in previous pages) as well as weaknesses in the preparation of requisitions throughout the system. The current basis for estimation is perpetuating both the good and the bad in the system.

The MOH should perform a needs assessment for medicines based on epidemiological information and using recognized methodologies along with appropriate consultation with prescribers in the tertiary and quaternary levels.

Procurement

The procurement system, whilst aiming for transparency, is inflexible and slow, possibly complicated by operating via the MEDIMOC contract. It is important and worth the effort to obtain best value international prices for those items that are responsible for the top 80% of expenditure, but the remaining items could be procured more flexibly tendering for supply through national suppliers.

The SIGM information system includes a module for procurement that will enable CMAM to perform most of the functions of procurement thus reducing or eliminating MEDIMOC participation.

The MOH, with short term technical assistance if necessary, should plan to increase the role of CMAM in procurement based on the SIGM system and also explore the options for national competitive bidding for those items that fall within the last 5-15% of expenditure.

Distribution

The distribution system of quarterly orders and delivery is very cumbersome and inflexible resulting in large stocks accumulating at all points in the system increasing the risks of loss, wastage and expiry and increasing the problem of limited space.

Where distances are small, supply intervals should be increased to improve the flow of products through the system and to reduce stock levels in peripheral stores and units. Delivery from central to provincial and from provincial to district level could be contracted out. Delivery from the provincial to the district levels could be contracted out using smaller local transport companies so as to encourage the local economy and enterprise.

The drug kit system is a relatively expensive of buying stock although it has served an important purpose in improving the supply of essential drugs to primary level facilities. However either the composition of the kits is inappropriate or the system is no longer suitable for the supply situation. Certainly the composition of the kit needs revision and possibly reduction in size and content in an effort to reduce the dependence on kits and to increase the use of the requisition system. Additionally the kit may only be perpetuating bad practices in supply to patients unless a true needs assessment is performed. MOH needs to review the purpose and /or composition of kits in the present situation.

Provincial Level Management Practice

The present system of 3-monthly orders creates a very heavy workload for staff during the first two weeks of any quarter, both in creating their own requisitions from central level and responding to district and provincial hospital requisitions. There does not appear to be any attempt to schedule the workload into a consistent pattern, all the work is concentrated into the early days/weeks of any quarter. This appears to be unnecessary but reflects adherence to the procedures. Training and reconsideration of the implementation of procedures could result in a more equitable distribution of work.

MOH should prepare and run workshops for the heads of provincial pharmacy departments to improve their management of the processes and introduce a more logical schedule of supply appropriate for the available human resources and the needs and location of the districts. Training could also be given on simple quality management systems that would improve accountability, performance and the quality of service.

Development and Deployment of Human Resources

At the present time the resource base of pharmacists is very limited and many of them are relatively new to their tasks and have not had the opportunity of accumulated experience in the system. Some job descriptions may not be clear (especially in the provincial environment) and yet there is a need for pharmacists to contribute positively in the clinical areas in the provinces.

MOH, with appropriate external technical assistance to supplement and support in-country experienced personnel, should provide the opportunity for further management training and an opportunity for MOH pharmacists and “leading” pharmacy technician personnel to plan an effective, efficient and coordinated role for pharmacy personnel within the national health care system.

RECOMMENDATIONS FOR ACTION BY MINISTRY OF HEALTH

These recommendations are intended for action by the Ministry of Health - with technical assistance where appropriate and necessary

1. Plan and conduct a workshop for MOH pharmacists and some “senior” pharmacy technicians to receive training in the management of pharmacy services from external and national trainers. One outcome of a workshop could be a draft plan for the effective deployment and ongoing professional development of available human resources in the pharmaceutical services over the next 5 years.
2. Conduct a needs assessment for medicines required to meet the health needs of Mozambique public health services in order to validate or correct the projections of need for 2007.
3. Conduct a study of the economic, quality assurance, storage and workload implications of purchasing more medicines packaged in strips/blisters rather than bulk packs of 1000.
4. Following on from recommendation 1 conduct workshops for provincial pharmacy/hospital department staff concerning the management of pharmacy services.
5. Investigate and evaluate the options for CMAM conducting the procurement activities in full and using acceptable methods that would introduce more flexibility into the procurement of small quantity or lower cost items.
6. Select a pilot province and design and carry out a study involving more frequent deliveries to districts (including the options for transport) in order to evaluate the benefits and problems of changing the distribution system to more frequent deliveries.
7. Conduct a review of the drug kits in the light of accumulating unused items and the alternative options to maintain an effective supply of essential medicines and items to primary level services.

PLAN OF ACTION

	Recommendation	Activity	Time-frame	Outcome
1.	Plan and conduct a workshop for MOH pharmacists and some “senior” pharmacy technicians. Follow-up workshops for provincial/hospital pharmacists.	Training in the management of pharmacy services from external and national trainers with relevant experience.	As soon as possible and before December 2006. Training to be cascaded in 2007 to provide training for provincial and hospital pharmacists.	A draft plan for the effective deployment and ongoing professional development of available human resources in the pharmaceutical services over the next 5 years.
2.	Conduct a needs assessment for medicines required to meet the health needs of Mozambique public health services in order to validate or correct the projections of need for 2007.	CMAM to lead the activity using existing epidemiological and attendance statistics and some field studies. Will probably need some external assistance to plan the assessment.	As soon as possible and before February 2007 to be applied for the 2008 estimates.	An assessment of the true need of the country to evaluate the “reasonableness” of the current estimates.
3.	Study of the economic, quality assurance, storage and workload implications of purchasing medicines packaged in strips/blisters rather than bulk packs of 1000.	CMAM to lead the activity. Needs economist expertise to measure and cost various activities that would be affected. Accurate prices need to be carefully collected. Needs some baseline information so that a follow-up study can be done.	Should be done as a follow-up to, or parallel with, the needs assessment.	The conclusions could be tested or piloted during the procurement. Could lead to conclusions in time for 2008 procurement cycle. A follow-up study will be necessary to fully evaluate the implications.
4.	Investigate and evaluate the options for CMAM to conduct the full range of procurement activities.	a) Evaluate the full cost of MEDIMOC services in total and as a percentage. b) Assess, tabulate and cost the personnel and equipment requirements for CMAM to conduct full procurement. c) Provide training and support for change to CMAM if decided.	a) Cost of MEDIMOC can be done immediately from existing records. b) External expert mission to focus solely on this activity during 2006.	Evidence to inform decision on change or no change to procurement responsibility and practice. Plan leading to CMAM conduct of procurement.

5.	Select a pilot province to study the options and impact of more frequent deliveries to districts (including the options for transport)	Select an appropriate province. (CMAM distribution) Conduct a retrospective base study of stock situation in past 12 months (CMAM distribution) Draw up a detailed plan of action (CMAM/province/logistics advisor)	Activity for 2007	Evidence for the cost benefits of changing the frequency of the order distribution cycle.
6.	Conduct a review of the drug kits in the light of accumulating unused items	a) CMAM distribution to identify “dead stocks” in the system and identify those from the drug kit list. b) CMAM planning/MOH pharmacy department to review current plans for drug kit lists adjustment. c) Evaluate the need for drug kits in their present format.	Activity to be carried out during 2006/7 in preparation for 2008 procurement.	Either the end of the drug kit supply or a much smaller and more targeted drug kit related to the needs assessment findings.

Schedule of Meetings and Activities during the course of the Mission

DATE	PERSON	TITLE/POST
8 th June	Precious Matsoso Martin Auton Abeyneh Desta	Director TCM WHO Consultant AFRO Pharmaceuticals
9 th June	Dr El Hadi Benzerroug Dr Moha Dr Daisy Trovoada Chonguica Moreira Julio Mendes	WR Mozambique WHO Programme Officer HIVAIDS/EDM WHO Programme Officer IMCI Pharmacist -MOH/FARMAC CMAM administrator
12 th June	Dr Mouzinho A.O. Saide Tanya Sitoie Julio Mendes, Dr Moha	National Director for Health, MOH Acting Director CMAM/Head procurement dept.
	Brana Branquinho Joao Teixeira	Planning department, CMAM Manager ARVs, CMAM
	Marilene Madiva'dira K Bachubhai Angelo Nequice –	Distribution dept; pharmacist i/c Distribution dept., pharmacist Distribution dept. - logistician
13 th June	Rui Sousa C S Puspussow	CMAM Finance department
	Benedito Chauque Daitino Sarmili Ana Maria Jumbe	Audit dept. – pharmacist Audit dept. – pharm.technician Audit dept. – pharm.technician
	Ignacia Carnot Mario	Procurement department, CMAM
	Renato Ronda	CEO Medimoc
14 th June	Maria Helena Siteo	Director, Medimoc Beira Central Store
	Thoma Mwangura Paulino Viola Graziela Maria Joaquim	Chief, Sokala Provincial Pharmacy section Warehouse i/c, Sofala Provincial Store Pharmacist, Sofala province
	Lunds Eduard	Beira Centr.Hosp. warehouse i/c,(pharm.tech)
15 th June	Agostinio Filippe Estebuo Tiago Adraste Raul Sabonett	Chief Manica Provincial Pharmacy Department Manica Provincial warehouse i/c Head, provincial hospital pharmacy dept.
16 th June	Fonseca Julio Domingos Joaquim Chaamuenhe	Head, pharmacy dept. Beira Central Hospital Pharmacist Beira C.H.
19 th June	Steering group (see 9 th June)	Interim debriefing and discussion
	Chonguica Moreira	Manager, FARMAC
20 th June	Dr Helder Martins	Special Advisor to Minister of Health
	Dr Suraia Mussa Nanza	Head, Pharmaceutical Dept. MOH
	Arnold Handal	Coordinator of information systems, JSI/Deliver
21 st June	Minister of Health	
	Dr Francisco Candido Feliciano Mauricio	Director General, Maputo C.H. Head Pharmacy Dept. Maputo C.H.
22 nd June	Dimitri Pfeiffer Douglas Hamilton	Health sector specialist USAID Health Office, European Community
26 th June	Angelica Salomad	WHO NPO Tuberculosis,
28 th June	Final Debriefing MOH	

INTERIM BRIEFING FOR THE HONOURABLE MINISTER OF HEALTH

Objective of the pharmaceutical sector starts from the patient/customer with a health problem

The legal and timely provision to any patient/customer of cost-effective medicine that is fit for purpose and provided with the correct advice to maximize its effect.

The process

Import/manufacture of registered medicinal products of assured quality that are distributed to the point of need/use and provided on the basis of a rational sale/prescription following ethical and legal procedures.

The Structures

There are three separate issues

- assurance of product quality in the market (both public and private) – achieved through legislation, product registration, regulation and control of products, premises and professional practice
- guarantee of access through efficient systems of procurement, distribution and supply as well as control of prices on all sectors
- efficient use of medicines in the treatment of health problems at the health facilities.

Human Resources

Pharmacists are a limited resource therefore their intervention (or that of specially trained technicians) should be targeted at critical points in the process

In assessing and monitoring product quality/safety/efficacy at registration and in the market.

As a member of the health team collaborating with others to agree/provide the best course of therapy for an individual or a group of patients.

Seeking to ensure the safe and optimal use of pharmacotherapy by patients

i.e. in 3 specific areas – registration; rational use and monitoring/determining need;

managing/supervising at the point of delivery to the patient (in both public and private sectors)

(Pharmacists, as a scarce resource should not be used for desk/IT jobs that can be delegated to other staff following clear procedures)

The Supply System

Findings

Estimations are based on consumption but it is not validated

The procurement system, whilst aiming for transparency, is inflexible and slow.

The distribution system of quarterly orders and delivery is very cumbersome and inflexible resulting in a lot of stock at all points in the system (roughly estimated at about 24 months for the northern half) increasing the risks of loss, wastage and expiry

The drug kit system is relatively expensive and appears to be confusing the stock situation with accumulating excess stocks of some products.

Process and system management is poor at provincial levels.

The new integrated computer system should improve efficiency and information generation.

Individuals appear to be doing their work sincerely and well but quality of service, accountability and performance could be improved with training and staff development.

Possible Solutions

Estimation and Quantification – the new information system should improve the quality of estimation and the accuracy will come from the accuracy of orders throughout the previous period of time – basic work should be done by clerks/technicians with limited pharmacist involvement.

Procurement – reduce/eliminate the involvement of Medimoc in the procurement process using the new information system to manage the process.

Contract directly for the process of receiving and clearing of goods at the ports.

Reduce the volume of procurement activity by using 2 year contracts on a draw-down basis for common items where use is guaranteed and prices are stabilized.

Target procurement effort at ensuring supply for priority therapies and value for money procurement for high cost items/high volume items. Possibly tender for small volume items through local suppliers/agents?

Storage and Distribution – increase the frequency of deliveries (especially from provincial depots) based on distances involved (within 2 hours deliver weekly, otherwise monthly) thus increasing the “freshness” of supplies and reducing peripheral stock levels and the risks of loss, wastage and expiry. Plan schedules for depots to distribute to districts in order to spread the workload over a week/month. Involve logisticians and managers rather than pharmacy staff in the details of supply and distribution (there is no dispensing involved!).

Contract out delivery process (using local small enterprise at the periphery?)

Abolish the drug kit system and use a “top-up” system of supply for clinics based on maximum stock levels.

Rational Use – improve the monitoring of prescribing and use and the involvement of pharmacists in therapy and in confirming the rational and actual need for supply.

PRESENTATION FOR FINAL BRIEFING IN THE MINISTRY OF HEALTH

Objective of the Pharmaceutical Sector

End-point and starting point is the patient/customer need;

The legal and timely provision to any patient/customer of cost-effective medicine that is fit for purpose and provided with the correct advice to maximise its effect.

Process to Achieve Objective

Import/manufacture of selected registered medicinal products of assured quality that are distributed to the point of need/use and provided on the basis of a rational sale/prescription following ethical and legal procedures.

Three Issues in the Process

- assurance of product quality in the market (both public and private) – achieved through legislation, product registration, regulation and control of products, premises and professional practice
- guarantee of access through efficient systems of procurement, distribution and supply as well as control of prices on all sectors
- efficient use of medicines in the treatment of health problems at the health facilities or pharmacies

Human Resources for Pharmacy

Pharmacists are a limited resource in Mozambique, therefore their intervention (or that of specially trained technicians) should be targeted at critical and priority points in the process

In assessing and monitoring product quality/safety/efficacy at registration and in the market i.e. REGISTRATION

- As a member of the health team collaborating with others to agree/provide the best course of therapy for an individual or a group of patients i.e. RATIONAL USE AND MONITORING NEED
- Seeking to ensure the safe and optimal use of pharmacotherapy by patients i.e. MANAGING/SUPERVISING AT THE POINT OF DELIVERY TO PATIENTS/CLIENTS
- *(Pharmacists, as a scarce resource should not be used for desk/IT jobs that can be delegated to other staff following clear procedures)*

Findings on Supply System

- | Estimations are based on consumption but it is not validated
- | The procurement system, whilst aiming for transparency, is inflexible and slow.
- | The distribution system of quarterly orders and delivery is very cumbersome and inflexible resulting in a lot of stock at all points in the system (roughly estimated at about 24 months for the northern half) increasing the risks of loss, wastage and expiry
- | The drug kit system is relatively expensive and appears to be confusing the stock situation with accumulating excess stocks of some products.
- | Process and system management is poor at provincial levels.
- | The new integrated computer system should improve efficiency and information generation.
- | Individuals appear to be doing their work sincerely and well but quality of service, accountability and performance could be improved with training and staff development.

Possible Solutions for the Supply System

- **Estimation and Quantification**
 - the new information system should improve the quality of estimation but the accuracy will come from the accuracy of orders reflecting real need throughout the previous period of time
 - conduct a needs assessment
 - basic work should be done by clerks/technicians with targeted pharmacist involvement.

- **Procurement**
 - Reduce/eliminate the involvement of Medimoc in the procurement process using the new information system to manage the process.
 - Contract directly for the process of receiving and clearing of goods at the ports.
 - Reduce the volume of procurement activity by using 2 year contracts on a draw-down basis for common items where use is guaranteed and prices are stabilised.
 - Target procurement effort at ensuring supply for priority therapies and value for money procurement for high cost items/high volume items. Possibly tender for small volume items through local suppliers/agents?

- **Storage and Distribution**
 - increase the frequency of deliveries (especially from provincial depots) based on distances involved (within 2 hours deliver weekly, otherwise monthly) thus increasing the “freshness” of supplies and reducing peripheral stock levels and the risks of loss, wastage and expiry
 - plan schedules for depots to distribute to districts in order to spread the workload over a week/month
 - involve logisticians and managers rather than pharmacy staff in the details of supply and distribution (there is no dispensing involved!)
 - contract out delivery process (using local small enterprise at the periphery?)
 - abolish the drug kit system and use a “top-up” system of supply for clinics based on maximum stock levels

- **Rational Use**
 - improve the monitoring of prescribing and use and the involvement of pharmacists in therapy
 - use information to confirm the rational and actual need for supply
 - improve the delivery/quality to patients by introducing blister/strip packs for outpatient use

Draft Recommendations

- Plan and conduct a workshop for MOH pharmacists and some “senior” pharmacy technicians to receive training in the management of pharmacy services from external and national trainers and also to propose a plan for the effective deployment and ongoing professional development of available human resources in the pharmaceutical services over the next 5 years.
- Conduct a needs assessment for medicines required to meet the health needs of Mozambique public health services in order to validate or correct the projections of need for 2007.
- Conduct a study of the economic, quality assurance, storage and workload implications of purchasing more medicines packaged in strips/blisters rather than bulk packs of 1000.
- Following on from recommendation 1 conduct workshops for provincial pharmacy/hospital department staff concerning the management of pharmacy services.
- Investigate and evaluate the options for CMAM conducting the procurement activities in full and using acceptable methods that would introduce more flexibility into the procurement of small quantity or lower cost items.
- Select a pilot province and design and carry out a study involving more frequent deliveries to districts (including the options for transport) in order to evaluate the benefits and problems of changing the distribution system to more frequent deliveries.
- Conduct a review of the drug kits in the light of accumulating unused items and the alternative options to maintain an effective supply of essential medicines and items to primary level services.

Translated from Portuguese



**MISSION TO EVALUATE THE PHARMACEUTICAL SECTOR
IN THE REPUBLIC OF MOZAMBIQUE**

REPORT

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Maputo, Republic of Mozambique

June/July, 2006

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EXECUTIVE SUMMARY

A Mission to assess the Pharmaceutical Sector of the Republic of Mozambique was jointly planned by the Ministry of Health (MISAU) and the World Health Organization (WHO).

The terms of reference were developed to include two distinct phases for the assessment. The first phase focused on the drafting of the terms of reference, on planning the WHO Level II Study (Assessment of Countries' Pharmaceutical Situations) and on updating the 2005 Level I Study (another component of the same Assessment), while the second phase included a series of consultancy activities on medicines policy, supply and rational use of medicines and a national quality control laboratory.

In agreement with officials at the Ministry of Health, the following report presents the main findings, as well as an outline for a future plan of action, in the form of the WHO medicines policies framework. This outline includes topics on policy and regulation, human resources, supply and management, rational use, research and development and monitoring and evaluation.

Development of the outline was achieved by means of review and analysis of policy documents, of Levels I and II results (in the Annex) and of outcomes produced by the consultancy on supply and rational use in Maputo, Sofala and Manica Provinces. This visit was carried out during a three-week period, and included administrative and health facilities in districts and capital cities and a series of interviews with key informants.

The final part of this report includes recommendations and next steps, in order to help further directives and goals established by the current medicines policy of Mozambique, stated in the document named "Government Directives for the Health Sector".

The specific evaluation component dealing with the national quality control laboratory, finalized in July, will be soon forwarded, separately, by WHO.

INTRODUCTION

Immediately after independence, in 1975, the pharmaceutical sector became a priority for the Government, and for many years, Mozambique pioneered pharmaceuticals policy.

The public sector meets approximately 80% of the country's needs, the private sector being confined to the major cities. At present, purchase/import and supply of drugs for the National Health Service are planned and managed by the Ministry of Health, through the Central Drugs and Medical Supplies Procurement Service (CMAM). Drug purchases are financed by the Government, with the support of international cooperation, through a common fund which accounts for between 60 and 70% of State expenditure on drugs.

A considerable proportion of drug supplies are obtained through a private company - Medimoc. This firm, which was set up one year after independence, operated as a State enterprise before being privatized. (There are discrepancies between documentary sources and statements made to the mission concerning the exact date on which it was privatized; 1998 or between 2000 and 2001). The exclusive supply contract awarded to Medimoc apparently presents a number of operational problems and problems of principle. Already in 2003, an internal evaluation of the pharmaceutical sector suggested breaking up Medimoc's monopoly of drug supplies.

As regards regulation of the pharmaceutical sector, the legal framework is set out in Act 4/98, which is currently being revised. According to information received, a new bill is due to be discussed by key actors in the Government, the pharmaceutical sector and civil society, for submission to the Council of Ministers before the end of this year. It is hoped that it will be adopted by mid-2007.

In addition, a chapter of the document *Government directives for the Health Sector* (DGSS) sets out in detail the national drugs policy. Besides this specific section, it also refers repeatedly to pharmaceutical care when referring to the population's state of health, the main diseases, the population's health needs and the priorities the Government needs to address. We shall draw attention to the importance the document assigns to recruiting and training human resources and to rationalizing the use of the existing human and material resources.

Also with regard to pharmaceutical care, it is worth noting that the *Directives* constantly refer to objectives and targets which are directly consonant with the guidelines for rational use, quality and access proposed by the World Health Organization (WHO).

This allows us to affirm that there is a suitable legislative and regulatory framework which and follows the guidelines and policies recommended by WHO, in accordance with the various resolutions of the World Health Assembly.

In line with the terms of reference laid down for this mission by the Government, and in consultation with Ministry of Health officials, it was decided to organize this report around the WHO guidelines for development and implementation of a national pharmaceutical policy, which constitute phase 2 of the evaluation. Attention was directed to political and regulatory aspects, questions of supply, management and rational use, research and development, monitoring and evaluation, and an analysis was made of policy documents and of the recent Level I study undertaken on Mozambique (2005).

The report also contains, in annex, the Level I (carried out in 2005) and Level II (recently completed) reports on Mozambique. The next evaluation component, in accordance with the terms of reference, will be the ad-hoc surveys of quality control laboratories, carried out in July 2006, the report on which is to be sent separately by WHO.

Lastly, a set of recommendations is made as a contribution to putting into practice the principles and goals defined in the Medicines Law and policy set forth in the *Government Directives for the Health Sector*.

INITIAL FINDINGS

Policy

- In the document *Government Directives for the Health Sector*, which is currently being approved, the chapter on “Drugs policy” sets objectives and targets for many of the components of a drugs policy. After the proposal has received final approval, a plan of action will need to be drawn up.

Human resources

- At present, the human resources situation in the pharmaceutical sector may be described as critical, and calls for urgent action. It is characterized by imbalance in the assignment of existing resources between the Pharmaceuticals Department at the Ministry of Health (MISAU) and CMAM, as well as an inequitable salary scale, a lack of incentives and decent working conditions and inadequate training of the existing resources;
- As was pointed out by different key respondents who were interviewed by the members of the mission, there are currently 46 pharmacists working in Mozambique. Twenty of them are with the Ministry of Health, (18 Mozambican and 2 expatriate) and 26 with the private sector (3 Mozambican and 23 expatriate). This makes it urgent to regulate human resources policy, so as to narrow this gap as much as possible.

Logistics

- Exclusive rights over purchase/import, clearance through customs, storage, inspection and distribution have been awarded to a private firm (Medimoc), with no clear and effective control by MISAU;
- There is no validation of the quantities needed for supplies; estimates of demand are made on the basis of historical data, simply repeating previous orders. There is no advance programming system with direct estimates of demand in districts and provinces. Reports shed little light on the situation;
- Although the Level I study came to the same conclusion as other audits, estimating drug availability at 87% (mainly in the form of kits) at all levels, the visit to health facilities showed that at the secondary and tertiary levels, only 60% of actual needs are met;
- The purchasing process is rigid and slow;
- The somewhat rigid system of quarterly orders leads to a workload backlog for the local teams and to storage problems, with an overestimation of the space needed to store orders. The system is particularly problematic and causes unnecessary disturbance at distribution points close to central stores, where distribution could be more frequent;
- It was reported that large quantities of drugs are lost because they have passed their expiry date. It was not possible to check the possible reasons for this, whether the expiry date was already too close when they were received, whether they were incorrectly stored or whether orders overestimate demand;
- The system of kits seems to be a source of shortages on one hand and of wastage on the other, as well as of high handling costs, which is unjustified;
- Considerable losses through misappropriation were also reported; there do not seem to be even the minimum number of trained staff to take responsibility for storage and management of drugs in health facilities and hospitals in the districts and provinces. Of the 20 pharmacists in the public sector, only 7 work in the provinces.

Selection

- The Technical Committee for Pharmaceutical care (CTTF) should be operational and independent.

Registration

- The provisional (extraordinary) register expires in 3 years, with the consequent risk of a shortage of many drugs as there is insufficient time to revise it.

Rational use

- In the majority of districts and provinces there is no pharmacist able rationally to manage and dispense drugs, even less to carry out clinical activities, pharmacovigilance etc;
- In many health facilities, districts and provinces, registers of use are inadequate;
- Patients' safety is not guaranteed by drug dispensing in health facilities; nor is there adequate information and the practice of repackaging represents a risk for the quality of the drugs dispensed.

Monitoring and evaluation

- There are no human resources nor is training provided to perform monitoring and evaluation;
- The CMAM audit system, the only one qualified in the country, lacks sufficient staff to carry out audits in the districts or even of CMAM itself.

ANALYTICAL MATRIX FOR PHARMACEUTICAL POLICY

WHO indicators			MOZAMBIQUE		
n	INDICATOR	DESCRIPTIVE QUESTIONS	DGSS ¹ document	Level I evaluation ²	RECOMMENDATIONS AND OBSERVATIONS
1	Existence of an official NMP document.	<p>Generally speaking, a national drugs policy should foster equity and sustainability of the pharmaceutical sector.</p> <p>The main objectives of a NMP are to ensure:</p> <ul style="list-style-type: none"> • Access: equity of availability and payment capacity for essential drugs, including drugs from traditional medicine (plants and others) • Quality: quality, safety and efficacy of all drugs. • Rational use: promotion of safe and cost-effective use of drugs for treatment by health professionals and users <p>The document should receive final official approval and be available. It should also set out the main strategies proposed by the Government, and should be revised/updated every 5 years</p>	P	A	<ul style="list-style-type: none"> • Regulation of the National Medicines Policy (NMP) and of its constituent parts by the country's ordinary law without which it is impossible to ensure it is operational, in accordance with the DGSS document and Law 4/98 • Careful detailing of the plan of action set out in the document which identifies the goals of NMP • The document on national health policy should be analysed in full to highlight items directly connected with drugs (e.g., those specific objectives that require coverage of the population to treat various diseases), and these should be tied to and coordinated with the specific goals set forth in articles 45, 46, 47 and 48, to avoid clashes or discrepancies • The details should include, goal by goal or by group of goals, the criteria employed by MISAU: ranking of goals, sequence of goals (if appropriate), updated deadlines for completion of implementation, those responsible for implementation, expected outcomes • Those responsible for implementation would then be invited to prepare the actions required to attain the goals for which they are responsible, together with deadlines, structure and required resources, processes involved, partnerships within and outside MISAU and expected outcomes.

¹ If referred to in the NMP document S (Yes), N (No), P (Partially/not explicitly)

² If WHO has carried out a relevant Level I evaluation: A (Evaluated); NA (Not evaluated)

WHO indicators			MOZAMBIQUE		
n	INDICATOR	DESCRIPTIVE QUESTIONS	DGSS ¹ document	Level I evaluation ²	RECOMMENDATIONS AND OBSERVATIONS
1a	Existence of guidelines for formulating and revising NMP	Processes, objectives and goals, preliminary and revised versions, how restricted dissemination will be ensured, formal endorsement by actors participating in formulation, nationwide dissemination and strategies for implementation	N	A	<ul style="list-style-type: none"> • Norms and criteria should be developed, through a summary plan of action, by a joint committee with representatives of MISAU, health services, public sector, private sector, communities and civil society, convened by MISAU, for revising and updating NMP and Law 4/98, which is currently being revised. The norms should be given official status and published, so as to ensure participation and transparency • Validation of the current NMP and of Law 4/98, at a seminar in October 2006 • Revision of NMP should be undertaken every 5 years
Access			DGSS document	Level I evaluation	RECOMMENDATIONS AND OBSERVATIONS
2	Payment capacity should be a component of the NMP document	• Commitment by the Government to guaranteeing access by improving payment capacity (final cost of product x average income of population);	S	A	• Clarification by the Government, of which drugs are free of charge, and which charges apply to others in public services
		• Elimination or reduction of taxes and duties on all essential drugs, introduction of price-control mechanisms and of price brackets (maximum and minimum prices)	S	A	• Adoption of norms for price-control mechanisms so as to ensure strict compliance with margins by wholesalers and retailers. These margins should be made public
		• For generic drugs: encouraging competition by policies on generics, generic substitution and Good Supply Practices	S	A	• Ensure, where public procurement is concerned, that preference is given to procurement of generics since these are cheaper than identical proprietary drugs.

WHO indicators			MOZAMBIQUE		
n	INDICATOR	DESCRIPTIVE QUESTIONS	DGSS ¹ document	Level I evaluation ²	RECOMMENDATIONS AND OBSERVATIONS
		<ul style="list-style-type: none"> For proprietary drugs: negotiation of prices, competition via price information and substitution, application of the TRIPS safeguards, such as: compulsory licensing, parallel imports, use of the possibility of producing generics as soon as patents expire (Bolar exception), use of the transition period authorized by Doha, for application of TRIPS (until 2016), etc 	N	A	<ul style="list-style-type: none"> Develop in Mozambique, within the ambit of MISAU and of CMAM, technical capacity to address the challenges posed by the TRIPS and TRIPS-plus agreements to public health, in particular as regards drugs, and specifically exercise of the right to postpone implementation of the agreements until 2016 Develop technical capacity within CMAM to negotiate prices Add this topic to NMP

3	The NMP document addresses questions of drug financing	<ul style="list-style-type: none"> • Commitment to measures to improve efficiency and reduce wastage and misappropriation 	P	A	<ul style="list-style-type: none"> • Prioritized estimate of needs. This calls for a pharmacist and a technical team to determine demand in collaboration with the area's health professionals (district and province) • Demand is calculated by CMAM • Procurement must be scheduled so as to supply items to provinces and districts in accordance with their needs and not on the basis of a predetermined delivery schedule • Drug kits must be evaluated to ensure that they do not encourage inequitable use, constitution of secondary stocks or wastage. • Items that must be procured through competitive bidding (public tender) must be separated from those that may be procured by direct negotiation, provided this is in compliance with the relevant legislation. The aim is to speed up procurement of items whose consumption varies considerably or which are for use in emergencies. In addition, very expensive items or items in category A on the Pareto curve (ABC) should not be procured through direct negotiation. • Procurement time should be reduced and administrative processes streamlined for heavily consumed items. • The procurement order should be drawn up by CMAM • The order should clearly state the acceptable expiry date for the medicines purchased. • Supplies, customs clearance, distribution and storage in district, provincial and central stores should be under the control of CMAM • Audits should be extended to districts and provinces • Local responsibility for misappropriations and wastage • Local recruitment of pharmacists and skilled technical staff to ensure stock quality
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		<ul style="list-style-type: none"> • Priority for government funding for diseases with high incidence or prevalence and to the poor and those without access to care 	S	A	<ul style="list-style-type: none"> • Extension of free treatment for this category of diseases and for the poorest, referred to in the NMP, will need to be implemented via a feasibility study undertaken by MISAU, to avoid the risk of breaks in supply once it has started.
		<ul style="list-style-type: none"> • Development of reimbursement of medicines under public and private health insurance schemes 	N	A	<ul style="list-style-type: none"> • Voluntary use of the National Drug Formulary by the private sector
		<ul style="list-style-type: none"> • Cost recovery from users only as a temporary measure to fund drugs 	N	A	
		<ul style="list-style-type: none"> • Limited use of development loans, in compliance with national priorities 	N	A	
		<ul style="list-style-type: none"> • Adoption of national or WHO rules on drug donations 	N	A	<ul style="list-style-type: none"> • Drawing up requirements for donors who wish to send medicines to Mozambique • Drafting of minimum requirements for identification and quality (monographs) of drugs for donation • These drugs should be valid for a long period and be on the country's essential drugs list or on a specialized list of level 3 or level 4 facilities
4	The NMP document provides for national drug manufacture.	Government manufacture	S	A	<ul style="list-style-type: none"> • Encouragement for local drug manufacture
		Private manufacture	S	A	<ul style="list-style-type: none"> • Encouragement for local drug manufacture within the framework of DGSS and of the Medicines Law
Access/Rational Use			NMP document	Level I evaluation	RECOMMENDATIONS AND OBSERVATIONS
5	The NMP document should address issues connected with the supply system.	<ul style="list-style-type: none"> • Promotion of public-private partnerships for drug supply and in distribution systems 	S	NA	<ul style="list-style-type: none"> • Clear recognition that public-private partnerships are possible and desirable in the area of drugs

	<ul style="list-style-type: none"> • Commitment by the public sector to good supply practices 	S	A	<ul style="list-style-type: none"> • CMAM should remain within MISAU, provided it is directly answerable to the Minister, with the same status on the organization chart as the regulatory authority • Immediate training for CMAM staff, to enable them to take responsibility for: <ul style="list-style-type: none"> ○ Understanding different methods of drug programming applicable to Mozambique ○ Planning drug-supply activities ○ Programming (planning) on the basis of expected demand, with local supervision (districts and provinces) by CMAM staff ○ Preparation of a delivery schedule in accordance with clients' needs (districts and provinces) ○ Drafting of an edict on public bidding for drugs ○ Approval of firms and technical prequalification of them ○ Full technical specifications of the drugs to be procured ○ Evaluation and award of bids ○ Drafting and approval of contractual norms for successful bidders ○ Management of storage and distribution or management of contract by these services ○ Providing support for supply, monitoring and evaluation processes ○ Internal audit of processes
	<ul style="list-style-type: none"> • Publication/availability of prices of drugs and inputs 	N	NA	<ul style="list-style-type: none"> • Publication/availability of prices practiced by CMAM in competitive bidding
	<ul style="list-style-type: none"> • Feasibility of supply systems during health emergencies 	N	NA	<ul style="list-style-type: none"> • After broad discussion, inclusion of the topic into the health agenda

		<ul style="list-style-type: none"> • Stock control, adoption of measures to prevent losses and misappropriation 	S	A	<ul style="list-style-type: none"> • See indicator n°3 • CMAM should develop manuals and training on stock control, monitoring and evaluation for local stock managers • The managers should report to CMAM
		<ul style="list-style-type: none"> • Guarantee that unnecessary, surplus or expired drugs will be discarded 	N	NA	<ul style="list-style-type: none"> • CMAM should develop manuals and training on stock control, monitoring and evaluation for local stock managers • The standards developed should be incorporated into health and environmental legislation
Quality/Rational Use			NMP document	Level I evaluation	RECOMMENDATIONS AND OBSERVATIONS
6	The NMP document includes guidelines on regulation and quality assurance.	<ul style="list-style-type: none"> • Government commitment to regulation of drugs, including the commitment to providing a sound legal foundation and human and financial resources 	S	A	<ul style="list-style-type: none"> • Urgent training to enable staff to assume drug regulatory functions • Proposal of a career plan and proper remuneration as this is a sensitive area that needs well-paid professionals • Require officials in the sector to sign a declaration that they have no conflict of interest
		<ul style="list-style-type: none"> • The regulatory authority must be autonomous to ensure there are no conflicts of interest 	N	A	Obs: The proposed organization chart of MISAU provides for the separation of the regulatory body and CMAM
		<ul style="list-style-type: none"> • Commitment to Good Manufacturing Practices (GMP), inspection and compliance with health legislation 	S	A	<ul style="list-style-type: none"> • Regulation of drug handling procedures as a matter of urgency • No authorization for the manufacture and sale of extemporaneous drugs until a sound regulatory process is in place and operational

	<ul style="list-style-type: none"> • Quality control and quality assurance for drugs 	S	A	<ul style="list-style-type: none"> • Integration of the following processes (but not their administration): health registration, supply, production (if applicable), use (in health facilities, hospitals and community pharmacies), inspection and control, monitoring and evaluation, preserving the independence of the monitoring body and CMAM • Extension of the provisional (extraordinary) registration period for five years, to allow time for completion of the revision of the register without any shortages occurring. From then on, keep definitive registration for five years and as far as possible limit the extraordinary registration period. • Increase the fees charged to register drugs in Mozambique as a contribution to meeting MISAU's costs and to avoid making it worthwhile to market drugs of no interest for health • Publication or broad dissemination of data on all drugs registered in Mozambique
	<ul style="list-style-type: none"> • Regulation of drugs used in traditional medicine, including plants 	N	A	<ul style="list-style-type: none"> • Preparation of a list of drugs in the traditional pharmacopoeia considered to be essential, in accordance with clinical and treatment protocols • Development of a formulary for traditional drugs which may or may not be included in the current national formulary • The list and formulary to be revised every two years

	<ul style="list-style-type: none"> • Introduction and implementation of pharmacovigilance systems 	S	A	<ul style="list-style-type: none"> • Introduction of a pharmacovigilance system, building on the existing core • Agreement on the concepts to be used and application of the programme • Contact with the WHO programme, based in Uppsala, Sweden, for guidance • Development of a notification form, data base, information flow chart and constitution of the system • Constitution of a specialist committee (physician, pharmacist, clinical epidemiologist and others as appropriate) • The system should be based within the regulatory authority • Provide material (furniture, computer, fax, telephone, literature, Internet access and data bases etc) and human resources (pharmacist or physician -20 hours per week and an administrative officer – staffing will depend on the rate of development of the programme) for the system's HQ • Set up reporting units in provincial and district hospitals • Encourage reporting by health professionals • Set up a continuing education programme on pharmacovigilance for health professionals in Mozambique • Once the initial objectives have been attained, apply for Mozambique to join the WHO PV programme
	<ul style="list-style-type: none"> • Commitment to regulating information on drugs and advertising 	S	A	<ul style="list-style-type: none"> • Submission of the draft law
	<ul style="list-style-type: none"> • Exchange of information with partners and international organizations 	N	NA	<ul style="list-style-type: none"> • Determine needs in terms of technical and academic cooperation • Within the ambit of the technical cooperation agreement with the Oswaldo Cruz Foundation and neighbouring countries

Rational Use		NMP document	Level I evaluation	RECOMMENDATIONS AND OBSERVATIONS	
7	The NMP document includes guidelines on rational use of drugs	• National multi-disciplinary committee with a mandate to coordinate policies on drug use	N	A	<ul style="list-style-type: none"> • Clarify relations between this Committee and CTTF. Contrary to CTTF, this Committee is responsible for advising the health registration system. • The Committee's rules of procedure need to be drawn up (if there are none), setting out, at least: <ul style="list-style-type: none"> ○ Its composition (based on technical and not political considerations) ○ Absence of conflict of interest a sine qua non for membership ○ Operational rules ○ Working procedure • The Committee must possess a mandate and be completely independent • It must be a standing committee, with rotating membership
		• Development of evidence-based clinical protocols on which to base selection of essential medicines, training for health professionals, drug prescriptions, RUM ³ , drug supplies and reimbursement	S	A	<ul style="list-style-type: none"> • Courses on evidence-based rational pharmaceutical treatment
		• Promotion of the essential medicines and rational use of medicines concepts via classroom and practical training courses for health professionals	S	A	<ul style="list-style-type: none"> • Courses on evidence-based rational pharmaceutical treatment • These professionals will serve as future multipliers for regular academic courses
		• Promotion of generic prescription via classroom and practical training courses for health professionals	S	A	Obs: already widely adopted in Mozambique

³ Review of Use of Medicines (studies)

	<ul style="list-style-type: none"> • Establishment and implementation of and support for Committees on Pharmaceuticals and treatment 	N	A	<ul style="list-style-type: none"> • Implantation of CTTF (akin to the National Committee) in district and provincial hospitals to serve as repositories for policies on medicines prescription, dispensing and use in facilities.
	<ul style="list-style-type: none"> • Academic training in pharmaceutical treatment using problem-solving methods 	S	A	<ul style="list-style-type: none"> • Teaching professionals to teach rational treatment in training courses via the possibility of technical cooperation with the Oswaldo Cruz Foundation, via courses on evidence-based pharmaceutical treatment will provide regular courses in faculties of medicine and pharmacy
	<ul style="list-style-type: none"> • Continuing and in-service education for physicians as a requirement for a permit to practice 	S	A	<ul style="list-style-type: none"> • Determination of the requirements • Deciding where and how these professionals are to receive their qualifications • Seeking subregional technical cooperation or exchange for training and providing the necessary resources
	<ul style="list-style-type: none"> • Availability and provision of independent and appropriate information on medicines 	S	A	<ul style="list-style-type: none"> • Setting up the CIM network in at least 3 or 4 provinces in Mozambique so as to provide health professionals with an opportunity to consult about medicines • Providing the network with the minimum material (books, data base, computer, telephone, fax) and human resources (at least one pharmacist working 20 hours a week) to cater for the system's user's

		<ul style="list-style-type: none"> • Educating users about medicines and development of educational strategies 	N	A	<ul style="list-style-type: none"> • Action by provincial and district managers and hospital pharmacists • Involvement of the CIM network • development of simple teaching aids for the population • Presence in community pharmacies, hospitals and outpatient services of trained pharmacists and pharmaceutical technicians to provide patients with guidance when medicines are dispensed • Training for groups of users and chronic-disease patients through meetings, chats and exchanges of experience, with the participation of pharmacists and other health professionals, with the aim of teaching them how to deal with their condition and correctly to use medicines • Services providing users and patients with guidance on medicines, and related group activities may and should take place in community pharmacies and especially within the scope of the Farmac network.
		<ul style="list-style-type: none"> • Mechanisms to prevent financial inducements being offered to prescribers and dispensers 	P	A	<ul style="list-style-type: none"> • Regulation of professional categories working in health, with the constitution of Councils that include professional ethics committees • Provide a system to explain conflicts of interest to MISAU officials and any other specialists invited by MISAU to sit on committees
Access/ Quality/Rational use			NMP document	Level I evaluation	RECOMMENDATIONS AND OBSERVATIONS
8	The NMP document suggests strategies for selecting essential medicines	<ul style="list-style-type: none"> • Adoption of the essential medicines concept, so as to determine priorities for government involvement in the pharmaceutical sector 	S	A	<ul style="list-style-type: none"> • See indicators 6 and 7

According to WHO, the list must be revised every two years, The essential medicines concept is central to the NMP.	• There are two stages in the selection of essential medicines: (1) Registration	S	A	<ul style="list-style-type: none"> • See indicator 6 • This requires sufficient human and material resources • Ideally registration should be separate from those responsible for inspection and health regulation
	• (2) Selection of suitable essential medicines for Mozambique's epidemiological profile	S	A	<ul style="list-style-type: none"> • See indicator 7
	• Definition of selection criteria (use of suitable evidence, cost-effectiveness studies etc)	N	NA	<ul style="list-style-type: none"> • Adoption of selection criteria must be carried out by CTF at MISAU • Examples of possible selection criteria: <ul style="list-style-type: none"> I – medicines registered in conformity with health legislation; II – epidemiological consideration; III – proven therapeutic value, based on sound evidence of use on humans emphasizing safety, efficacy and effectiveness; IV – preferably medicines with a single active ingredient; V – active ingredient identified using the International Non-proprietary Nomenclature (INN); VI – sufficient information on the pharmacotechnical, pharmacokinetic and pharmacodynamic properties; VII – lower purchase price and storage, distribution and control costs; VIII – lower daily and total treatment cost, while preserving safety, efficacy and quality; IX – concentrations and pharmaceutical forms, dosage regimen and presentations, taking into account: <ul style="list-style-type: none"> a) ease of administration to patients; b) age group; c) ease of calculating required dose; d) ease with which doses may be broken down or multiplied; e) stability profile suited to conditions of storage and use

		<ul style="list-style-type: none"> • Definition of the selection process (standing national committee, members without conflicts of interest, comparative evaluation of efficacy, safety, effectiveness etc) 	N	NA	<ul style="list-style-type: none"> • Ensuring the sustainability of CTTF • See indicator 7 <p>Obs: The National Drug Formulary is being redrafted</p>
		<ul style="list-style-type: none"> • Medicines selection system provides a guarantee for traditional and plant medicines 	N	A	<ul style="list-style-type: none"> • As above, with consideration for the adoption of specific criteria to judge how essential traditional medicines are. • A separate list is suggested
9	The NMP document addresses questions of research and development (R&D)	<ul style="list-style-type: none"> • Operational research into access to medicines, quality and rational use aims to provide a better understanding of those factors that affect use of medicines and to identify the best methods of selection, supply, distribution and proper use of medicines. It is an essential tool for diagnosing the policy's impact and determining which results influence managerial decisions. 	N	NA	<ul style="list-style-type: none"> • Conduct studies into the use of medicines • Conduct pharmacovigilance studies • Carry out monitoring and evaluation of pharmaceutical care • Carry out evaluation for managerial and decision-making purposes
		<ul style="list-style-type: none"> • Pharmaceutical and clinical research include the development of new drugs for orphan diseases, new pharmaceutical forms and methods of delivery, new manufacturing processes and clinical evaluations of efficacy, safety and effectiveness. 	N	NA	<ul style="list-style-type: none"> • Thorough evaluation, by MISAU, of clinical research protocols operating in Mozambique – constitution of a national research ethics council, within the ambit of MISAU, of national jurisprudence, independent from COMED and clear statement that members have no conflict of interest • Careful evaluation of pharmaceuticals research development priorities, especially in the light of the TRIPS and TRIPS-plus agreements
10	NMP sets out goals for human resources development and training	<ul style="list-style-type: none"> • The Government is responsible for planning and supervising the development, training and further training of work teams and career plans for the human resources needed by the pharmaceutical sector 	P	A	<ul style="list-style-type: none"> • Training for technical staff already assigned • Recruitment of new pharmaceutical professionals for training • Career plan • Equitable remuneration for staff performing regulatory, registration and supply functions • Suitable level of remuneration for pharmacists and technicians to serve as a recruitment mechanism and incentive

		<ul style="list-style-type: none"> • Definition of the minimum educational and training requirements for each category of staff; 	N	A	<ul style="list-style-type: none"> • Cooperation with university (ies) to establish requirements • Provide additional training if necessary
		<ul style="list-style-type: none"> • Determination of requirements in terms of external technical cooperation (national and international) 	N	NA	<ul style="list-style-type: none"> • This needs to be ad-hoc, in accordance with MISAU's priorities • Technical cooperation must be capable of training local technicians to work independently • Technical cooperation must involve recognized local expertise, so as to anchor and consolidate the work performed and encourage internal exchange and local strengths • Within the sphere of the subregional technical cooperation agreement and with the Oswaldo Cruz Foundation
11	The NMP document refers to monitoring and evaluation of drugs policies	<ul style="list-style-type: none"> • Explicit commitment by the Government to the principles of monitoring and evaluation 	N	A	<ul style="list-style-type: none"> • Incorporation into the text of NMP
		<ul style="list-style-type: none"> • Baseline evaluation of the country situation carried out at the time the policy is implemented 	N	A	<ul style="list-style-type: none"> • Level I and II studies already completed in Mozambique • Broad dissemination and discussion of the results, involving MISAU, economic agents, universities, communities and civil society and managers • proposed time table for improvements • Integration of the time table into the policy document
		<ul style="list-style-type: none"> • Monitoring of the pharmaceutical sector by means of systematic indicator-based surveys 	N	A	<ul style="list-style-type: none"> • Local training in monitoring and evaluation
		<ul style="list-style-type: none"> • Independent external evaluation of the policy's impact on all sectors of the community and of the economy every 2 or 3 years 	N	NA	<ul style="list-style-type: none"> • Sub-regional technical cooperation with WHO

RECOMMENDATIONS HAVING PRIORITY

The analytical matrix provided in annex (Annex 1), sets out more detailed suggestions and recommendations for virtually all the components of national drugs policy defined by the Government of Mozambique. It is impossible to do everything simultaneously, and priorities need to be set in order to deal with the most urgent matters. This chapter attempts to set forth a timetable, based on the priorities identified by the mission.

Policy

The chapter of the “Government Directives for the Health Sector” dedicated to drug policy needs closely to be analysed in order to identify points requiring special regulation in order for them to be implemented.

One important point in drug policy as a whole is the cost of financing and potential systems of complete or partial cost recovery. A political decision to make drugs completely or partially free of charge, to provide drugs free of charge under certain programmes or for particular diseases or groups of people necessarily comes ahead of technical considerations and according to the studies under way is referred to in the Directives.

Human resources

Planning, harmonizing and identifying incentives for the necessary human resources is a matter of urgency. Health professionals working in the normative sphere, including registration, policy, quality control, inspection and logistics need to have coherent and equitable salary scales. We recommend the following immediate measures:

- Preparation of a plan setting out the resources required for the next three years;
- Introducing more flexibility into human resources plans and ongoing studies;
- Training serving pharmacists in areas with priority, such as in competitive procurement, computerized management of supply processes, inspection and registration;
- Training technical staff in local stock management and monitoring via the use of simplified indicators;
- Decide on the need for technical exchanges with other countries to train national staff. Technical assistance should not itself manage supply, but train national human resources for management tasks;
- Begin training serving staff in areas with priority and with the support of WHO through the Collaborating Centre on drugs policy at the Oswaldo Cruz Foundation's Sérgio Arouca National Public Health School, which has a signed a technical cooperation agreement with the Mozambican Ministry of Health.

Logistics

Responsibility for supplies, which is currently delegated by contract to the firm Medimoc, should gradually be transferred to CMAM. At the same time, we suggest that MISAU begin training technical staff to assume their new responsibilities as soon as possible:

- Examine the possibility of appointing a technical assistant for one or two years, from WHO or via international cooperation;
- Organize a national meeting, in the form of a seminar, at which the organization of human resources for the next five years would be determined. The target audience would consist of pharmacists and pharmaceutical technicians from the public sector and the topic addressed would be drug management in the public sector. It would be a good idea also to involve final

year students in the seminar. This training would provide an excellent opportunity to draw up a plan for the assignment of the human resources available in Mozambique;

- In line with this recommendation, we suggest that regional seminars be organized in 2007;
- Evaluation of drug requirements, on the basis of the country's list of essential drugs, in order to estimate demand for the next three years;
- A pilot study should be made to estimate the different supply schedules in regions, provinces and health facilities;
- Review ownership of and the need for the drug kits that have been distributed;
- A plan of action (for immediate application) needs to be drawn up for the handover of Medimoc's responsibilities to CMAM;
- CMAM should acquaint itself with Medimoc's existing procurement processes and conditions from the present until termination of its contract, in order to plan supply measures on termination of the contract and to make provision for possible shortages;
- On termination of the contract with Medimoc, CMAM should start limited competitive bidding before beginning international competitive bidding. For 80% of the drugs most needed, procurement should cover two years. CMAM should be allowed flexibility to procure the remaining 20 to 15% of drugs, which are available domestically, in small quantities.

Selection

- Constant revision of the list of essential drugs in order to improve supplies.

Registration

- Introduction of fast-track registration so as not to miss the opportunity to purchase drugs not yet registered in Mozambique but which are available at attractive prices on the international market, while maintaining CTTF's requirements as regards efficacy, safety, effectiveness etc.

Rational use

- Training courses on rational use and evidence-based treatment for prescribers and dispensers;
- Involvement of human resources with managerial responsibilities in activities to promote rational use, as irrational prescription and dispensing are decisive for logistics and use.

Monitoring and evaluation

- Training in monitoring and evaluation applied to pharmaceutical care;
- Broad dissemination and discussion of the results of the WHO Level II study recently carried out in Mozambique;
- Development and adoption of monitoring and evaluation tools for use by the public sector, including the methodology for the Level II study.

THE NEXT STEPS

- Organization of the Seminar to validate DGSS and the Drugs Act;
- MISAU seminar for the pharmaceutical sector;
- Plan of Action for CMAM.

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ANNEX 1:

**OUTCOME OF WHO THE LEVEL I (2005) AND LEVEL II (2006) -
STUDIES TO EVALUATE THE PHARMACEUTICAL SITUATION IN
MOZAMBIQUE**



REPÚBLICA DE MOÇAMBIQUE

MINISTÉRIO DA SAÚDE
GABINETE DO MINISTRO

“REVISED FILLED LEVEL I TOOL FOR MOZAMBIQUE”

Questionnaire on structures and processes of country pharmaceutical situation

Country	Moçambique (Afro)	Date (dd/mm/yyyy)	
Name of respondent(s)		Position(s)	

1. NATIONAL MEDICINES (DRUG) POLICY (NMP)		
1.1 Is there a National Medicines Policy (NMP) document? (See glossary for a definition of NMP.) If no, skip to 1.4. Is it an official or draft document? What year was it last updated?	Yes/No/Don't Know No Official/Draft/Don't Know Draft Year _____	
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budgets, and timeline? If yes, when was it last updated?	Yes/No/Don't Know No Year _____	
1.3 Is the NMP integrated into a published/official national health policy/plan? If yes, when was it last updated?	Yes/No/Don't Know No Year _____	
1.4 Is there a national policy on traditional and complementary/ alternative medicine (TM/CAM) either as part of the medicines policy or health policy or as a separate document? (TM/CAM is defined in the glossary.) If yes, when was it last updated?	Yes/No/Don't Know No Year _____	
1.5 Has a national assessment/indicator study been conducted? If yes, what areas have been studied and when was the most recent study covering each area conducted?	Yes/No/Don't Know Yes	
  <p>Overall pharmaceutical situation: Yes/No/Don't Know Yes Year <u>2003</u> Rational use/prescription audit: Yes/No/Don't Know Yes Year <u>1999</u> Access: Yes/No/Don't Know Yes Year <u>2003</u></p>		

2. LEGISLATION/REGULATION		
<p>2.1 Is there a medicines law? If yes, when was it last updated? Which of the following areas are covered by medicines legislation and when was each last updated?</p> <p>Establishment of regulatory authority: Yes/No/Don't Know Yes Year <u>1998</u></p> <p>Marketing authorization of pharmaceuticals: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Manufacturing of medicines: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Distribution of medicines: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Promotion & advertising of medicines: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Importation of medicines: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Exportation of medicines: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Licensing & practice of prescribers: Yes/No/Don't Know Yes Year <u>1977</u></p> <p>Licensing & practice of pharmacy: Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Herbal medicines (<i>See glossary for definition</i>): Yes/No/Don't Know No Year <u>_____</u></p> <p>Empowers inspectors to enter premises and collect samples and documentation: Yes/No/Don't Know Yes Year <u>1977</u></p> <p>Requires transparency, accountability and code of conduct in regulatory work: Yes/No/Don't Know Yes Year <u>1977</u></p>	<p>Yes/No/Don't Know Yes Year <u>1998</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know Yes Year <u>1977</u></p> <p>Yes/No/Don't Know Yes Year <u>1999</u></p> <p>Yes/No/Don't Know No Year <u>_____</u></p> <p>Yes/No/Don't Know Yes Year <u>1977</u></p> <p>Yes/No/Don't Know Yes Year <u>1977</u></p>	
2.2 System and operation of medicines registration:		
a) Is marketing authorisation required for medicines to be sold? If yes, how many medicinal products have been approved to be marketed? (<i>express as number of dosage forms & strengths</i>)	<p>Yes/No/Don't Know Yes</p> <p>Total <u>3678</u></p>	
Is marketing authorization required for herbal medicines to be sold? If yes, how many herbal medicinal products have been approved to be marketed? (<i>express as number of dosage forms & strengths</i>) (<i>See glossary for a definition of herbal medicines</i>)	<p>Yes/No/Don't Know No</p> <p>Total <u>_____</u></p>	
b) Are there detailed written guidelines, including reference guidelines and criteria, for submitting applications for the registration of medicinal products? Are there guidelines covering the registration of herbal medicines?	<p>Yes/No/Don't Know No</p> <p>Yes/No/Don't Know No</p>	
c) Is the WHO Certification Scheme certificate required as part of the marketing authorization process?	<p>Yes/No/Don't Know Yes</p>	
d) Is INN used in the registration of medicines?	<p>Yes/No/Don't Know Yes</p>	
e) Is a list of all registered products publicly accessible? (<i>Registered product is defined in the glossary.</i>)	<p>Yes/No/Don't Know No</p>	
2.3 Is there a computerized registration system that facilitates retrieval of information on registered products? (<i>Registration system is defined in the glossary.</i>)	<p>Yes/No/Don't Know Yes</p>	
Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, contraindications, side effects, etc.), authorized companies, and/or approved medicines?	<p>Yes/No/Don't Know No</p>	
2.4 Is licensing a requirement? (<i>Licensing is defined in the glossary.</i>) If yes, is it based on site inspection of:	<p>Yes/No/Don't Know Yes</p> <p>Manufacturers: Yes/No/Don't Know Yes</p> <p>Importers/wholesalers: Yes/No/Don't Know Yes</p> <p>Retail distributors/pharmacies: Yes/No/Don't Know Yes</p>	
2.5 Are there written national guidelines/codes/checklists for the inspection of:	<p>Manufacturers: Yes/No/Don't Know No</p> <p>Importers/wholesalers: Yes/No/Don't Know No</p> <p>Retail distributors/pharmacies: Yes/No/Don't Know No</p>	

2.6 Is prescribing by generic name obligatory in the: Public sector: Private sector:	Yes/No/Don't Know Yes Yes/No/Don't Know Yes	
Is generic substitution permitted at: (Generic substitution is defined in the glossary.) Public pharmacies: Private pharmacies:	Yes/No/Don't Know Yes Yes/No/Don't Know Yes	
2.7 Is promotion/advertisement of medicines regulated by: Company self-regulation: Government agency or medicines regulatory authority:	Yes/No/Don't Know No Yes/No/Don't Know Yes	
Are civil society/non-governmental organizations involved in review, assessment, or surveillance of promotion/advertisement of medicines?	Yes/No/Don't Know No	
Do regulations on promotion/advertisement of medicines include: (See glossary for the distinction between promotion and advertisement.) Published ethical criteria for medicines promotion: Pre-approval for promotional materials: Pre-approval for advertisement materials: Explicit prohibition on advertising prescription medicines: Detailed restrictions on advertising non-prescription medicines:	Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know Yes Yes/No/Don't Know No	
2.8 Are adverse drug reactions (ADR) monitored? If yes, what is the total number of each of the following for the most recent year for which data is available? Total number of validated ADR reports received: Total number of reporting physicians: Total number of physicians in country:	Yes/No/Don't Know _____(Year ____) DK <input type="checkbox"/> _____(Year ____) DK <input type="checkbox"/> _____(Year ____) DK <input type="checkbox"/>	
Are ADR of herbal medicines monitored?	Yes/No/Don't Know	
3. QUALITY CONTROL OF PHARMACEUTICALS		
3.1 Testing of medicines samples collected last year for regulatory purposes (i.e. including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities): Total number of samples collected: Total number of samples tested: Total number of samples that failed identity or assay:	Total number of samples _____ 465 _____ 457 _____ 34	Don't Know <input type="checkbox"/> Don't Know <input type="checkbox"/> Don't Know <input type="checkbox"/>
3.2 Where have the above samples (see 3.1) been tested: Government quality control laboratory: Local academic institutions: Quality control laboratory in another country: Private quality control laboratory:	Percentage of total samples tested 100% _____% _____% _____%	Don't Know <input type="checkbox"/> Don't Know <input type="checkbox"/> Don't Know <input type="checkbox"/> Don't Know <input type="checkbox"/>

4. ESSENTIAL MEDICINES LIST (EML)					
4.1 Are there Essential Medicines Lists (EML)? (<i>An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list</i>)		Total number of medicines	Year of last update		
National EML:	Yes/No/DK	Yes	1999		
State or provincial list:	Yes/No/DK	No			
List for primary health care:	Yes/No/DK	No			
4.2 Are EMLs being used in:	Public sector procurement:	Yes/No/Don't Know	Yes		
	Public insurance reimbursement:	Yes/No/Don't Know	No		
	Private insurance reimbursement:	Yes/No/Don't Know	No		
4.3 Are local herbal medicines included on the national EML?	Yes/No/Don't Know	No			
5. MEDICINES SUPPLY SYSTEM					
5.1 Who is responsible for public sector drug procurement and distribution? What percentage of the total cost is each responsible for?		Procurement	Distribution		
Ministry/Department of Health:	Yes/No/DK	Yes	100%	Yes/No/DK	No
Non-governmental organization (NGO):	Yes/No/DK	No	0%	Yes/No/DK	No
Private institution contracted by the government:	Yes/No/DK	Yes	100%	Yes/No/DK	Yes
Individual health institutions:	Yes/No/DK	No	0%	Yes/No/DK	No
5.2 Is government procurement limited to medicines on the EML?	Yes/No/Don't Know	Yes			
If no, is a percentage of the budget set aside for non-EML items?	Yes/No/Don't Know	No			
What is the percentage?					
5.3 Type of tender and percentage of the total cost for each: (<i>Tender is the process by which competing bids are entered for a particular contract.</i>)			Percentage of total cost		
National competitive tender:	Yes/No/DK		0%		
International competitive tender:	Yes/No/DK	Yes	84%		
Negotiation/direct purchasing:	Yes/No/DK	Yes	16%		
5.4 Is drug registration a prerequisite for government purchases?	Yes/No/Don't Know	Yes			
6. MEDICINES FINANCING					
6.1 What is the total public or government budget for medicines in US\$ for the most recent year for which data is available?	\$ _____ 44, Year 2003				
6.2 Are there guidelines on medicines donations that cover the public sector, the private sector, or non-governmental organizations (NGO)?	Public Sector	Private Sector	NGO		
	Yes/No/DK	Yes/No/DK	Yes/No/DK		
6.3 Which medicines are free at primary public health facilities:	Yes/No/Don't Know			No	
All medicines are free of charge:	Yes/No/Don't Know			No	
Malaria medicines are free:	Yes/No/Don't Know			Yes	
Tuberculosis medicines are free:	Yes/No/Don't Know			No	
Sexually transmitted diseases medicines are free:	Yes/No/Don't Know			Yes	
HIV/AIDS-related medicines are free:	Yes/No/Don't Know			Yes	
Medicines are free to those who cannot afford them:	Yes/No/Don't Know			No	
Medicines are free for children under 5 years of age:	Yes/No/Don't Know			No	
Medicines are free for pregnant women:	Yes/No/Don't Know			Yes	
Medicines are free for elderly persons:	Yes/No/Don't Know			Yes	
No medicines are free of charge:	<input type="checkbox"/> (Don't Know <input type="checkbox"/>)				
6.4 Which fees are charged in public health facilities:	Yes/No/Don't Know				
Registration/Consultation fees:	Yes/No/Don't Know				
Dispensing fees:	Yes/No/Don't Know				

<p>Flat fees for medicines: Yes/No/Don't Know Flat rate copayments: Yes/No/Don't Know Percentage copayments: Yes/No/Don't Know Yes <i>(Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.)</i></p>				
<p>6.5 Is revenue from fees or drug sales used to pay the salaries of public health personnel in the same facility?</p>	Always/Frequently/Occasionally/Never/DK Never			
<p>6.6 Health insurance: <i>(Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget.)</i> What percentage of the population has health insurance? Are medicines covered by health insurance? Of the covered medicines, what percentage of the cost is covered:</p>	<p>Public</p> <p>All/Some/None/DK Don't know All/Some/None/DK Don't know %</p>	<p>Private</p> <p>All/Some/None/DK All/Some/None/DK %</p>		
<p>6.7 Is there a pricing policy on medicines that covers the public sector, the private sector, or non-governmental organizations? If yes, does it apply to: All medicines, some or none: Is maximum wholesale mark up established in laws/regulations: If yes, amount: _____% Maximum retail mark up established in laws/regulations: If yes, amount: _____% Duty on imported raw pharmaceutical materials: Duty on imported finished pharmaceutical products:</p>	<p>Public sector</p> <p>Yes/No/DKYes All/Some/None/DK All Yes/No/DKNo _____% Yes/No/DKNo _____% Yes/No/DKNo Yes/No/DKNo Yes/No/DK</p>	<p>Private sector</p> <p>Yes/No/DKYes All/Some/None/DK Some Yes/No/DKYes _____% Yes/No/DKYes _____% Yes/No/DKNo Yes/No/DK</p>	<p>NGO</p> <p>Yes/No/DK Don't know All/Some/None/DK Don't know Yes/No/DKNo _____% Yes/No/DKNo _____% Yes/No/DK Yes/No/DK</p>	
<p>7. ACCESS TO ESSENTIAL MEDICINES</p>				
<p>7.1 In your opinion, what percentage of the population has regular access to essential medicines (i.e. minimum of 20 most essential medicines available and affordable at public and private facilities within a one-hour walking distance)?</p>	_____%			
<p>7.2 What percentage of: The population is within one-hour walking distance to: Facilities have essential medicines available: The population can afford essential medicines at:</p>	<p>Public health facility</p> <p>_____%</p> <p>_____%</p> <p>_____%</p>	<p>Private health facility</p> <p>_____%</p> <p>_____%</p> <p>_____%</p>	<p>Public or private retail drug outlet</p> <p>_____%</p> <p>_____%</p> <p>_____%</p>	
<p>8. PRODUCTION</p>				
<p>8.1 What is the medicines production capability in the country? Research and development of new active substances: Production of pharmaceutical active starting materials: Formulation from pharmaceutical starting materials: Repackaging of finished dosage forms:</p>	<p>Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know No</p>			

8.2 For each of the following types of local production, indicate number of factories and total annual sales in US\$ for the most recent year for which data is available: Starting materials: Finished products: Products containing active substances developed/marketed for the first time during the last 5 years:	Number of factories _____ _____ _____	Sales in US\$ \$ _____ \$ _____ \$ _____	Year _____ _____ _____	Don't know DK <input type="checkbox"/> DK <input type="checkbox"/> DK <input type="checkbox"/>		
8.3 What is the total volume and US\$ value of the medicines market? Generic medicines compose what percentage of market volume and value?	Volume _____, Value \$ _____ Volume _____%, Value _____%					
9. RATIONAL USE OF MEDICINES						
9.1 Are there standard treatment guidelines (STGs) produced by the health ministry/department for major conditions? (STGs are recommendations about how to treat a clinical condition.) National STG: STG for hospital level: STG for primary health care level:	Yes/No/DK Yes Yes/No/DK Yes/No/DK	Number of conditions/diseases _____ _____ _____	Year of publication or review 1987 _____ _____			
9.2 Is there a National Medicines Formulary manual? (A formulary manual contains summary drug information.) If yes, does it cover only medicines on the Essential Medicines List? What year was it last published/reviewed:	Yes/No/Don't Know Yes Yes/No/Don't Know Year 1999					
9.3 Are any of the following aspects of the essential medicines concept generally part of the basic curricula in most health training institutions/universities for: (Essential medicines are those that satisfy the priority health care needs of the population. See glossary for a definition of problem-based pharmacotherapy.) Doctors: Nurses: Pharmacists: Pharmacy assistants: Paramedical staff:	Essential Medicines List Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes	Standard Treatment Guidelines Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK	Problem-based pharmacotherapy Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK	Rational prescribing Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes Yes/No/DK Yes		
9.4 Are there independent publicly or non-commercially funded obligatory continuing education programs which include use of medicines for: Doctors: Nurses/midwives/paramedical staff: Pharmacists: Pharmacy aides/assistants:	Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know No Yes/No/Don't Know No					
9.5 Is there a public or independently funded nationally accessible (e.g. by phone) medicines information centre or service co-ordinated by the Ministry of Health, academia, and/or a non-commercial non-governmental organization that provides information on demand to: Prescribers: Dispensers: Consumers:	Yes/No/Don't Know Yes Yes/No/Don't Know Yes Yes/No/Don't Know Yes					
9.6 Has there been any public education campaign concerning rational medicines use in the previous two years conducted by Ministry of Health/non-governmental						

organization/academia on the following topics: Use of antibiotics: Use of injections: Other topics/issues:	Yes/No/Don't Know No		
9.7 How often do the following personnel prescribe at the primary health care level in the public sector? Doctors: Nurses/midwives/paramedical staff: Pharmacists: Pharmacy aides/assistants: Personnel with less than one month formal health training:	Always/Frequently/Occasionally/Never/DK Always Always/Frequently/Occasionally/Never/DK Occasionally Always/Frequently/Occasionally/Never/DK Never Always/Frequently/Occasionally/Never/DK Never Always/Frequently/Occasionally/Never/DK Never		
9.8 Is there a government department with a specific mandate to promote the rational use of medicines and co-ordinate medicines use policies?	Yes/No/Don't Know Yes		
9.9 What proportion of facilities have a drugs and therapeutics committee? (A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction) Referral hospitals: General hospitals: Regions/provinces:	All/Most/Half/Few/None/Don't Know All/Most/Half/Few/None/Don't Know All/Most/Half/Few/None/Don't Know		
Is there a mandate for drugs and therapeutics committees in the national medicines policy?	Yes/No/Don't Know Yes		
9.10 Is there a national strategy to contain antimicrobial resistance?	Yes/No/Don't Know Yes		
Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance?	Yes/No/Don't Know Yes		
Is there a funded national intersectoral task force to coordinate the implementation of interventions to promote appropriate use of antimicrobials and prevent the spread of infection?	Yes/No/Don't Know		
9.11 Are the following medicines sold over the counter without any prescription? Antibiotics: Injections:	Always/Frequently/Occasionally/Never/DK Occasionally Always/Frequently/Occasionally/Never/DK Occasionally		
10. INTELLECTUAL PROPERTY RIGHTS PROTECTION AND MARKETING AUTHORIZATION (See glossary for definitions of terms used in this section.)			
10.1 Is patent protection legally provided for pharmaceutical products? If yes, indicate: Year introduced: Type: Duration of patent validity:	Yes/No/Don't Know Process/Product/Both/Don't Know		
10.2 Which intellectual property right protection regime/activities are provided for traditional medical knowledge? TRIPS: Sui generis regimes: Digital library: National inventory of medicinal plants: Others: None:	Yes/No/DK Yes/No/DK Yes/No/DK Yes/No/DK Yes/No/DK <input type="checkbox"/> (DK <input type="checkbox"/>)	Year introduced	Duration of data protection

ACCESS AND USE OF MEDICINES IN MOZAMBIQUE

ASSESSING ACCESS AND USE OF MEDICINES

Essential medicines save lives, reduce suffering and improve health, but only if they are available, affordable, properly used and of good quality. Today, almost 2 billion people, one-third of the global population, lack reliable access to needed medicines. Evidence on access, use and quality of medicines is imperative to enable governments and other stakeholders to identify strengths and weaknesses, establish priorities, set targets and ultimately determine how to most effectively allocate scarce resources to improve the health of their populations.

In May 2006, the Mozambican Ministry of Health was supported by the World Health Organisation (WHO) to carry out a national assessment of its pharmaceutical sector. The survey was conducted in public sector warehouses, public health facilities, private pharmacies and households. Using the *WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations* and the *WHO Household Survey to Measure Access and Use of Medicines*, the Ministry assessed the availability, affordability, conservation conditions and use of key medicines. The evidence obtained was used to determine the level of access and appropriate use of medicines, identify factors contributing to weaknesses, and identify strategies and policies to improve availability, affordability and use of medicines. This is one of a series of papers summarizing the results of similar surveys carried out by countries across Africa and elsewhere in the world.

BACKGROUND - MOZAMBIQUE

Mozambique is classified as a low income country by the World Bank with a per capita GDP of US\$ 314 (2004).

Basic health indicators	
Total population	19,424,000 (2004) ¹
Life expectancy at birth	45 years (2004) ¹
Per capita total expenditure on health	US\$12 (2003) ¹
Per capita government expenditure on health	US\$7 (2003) ¹
Per capita out-of-pocket expenditure on health	US\$2 (2003) ¹
Per capita total expenditure on medicines	US\$2 (2000) ²
Per capita government expenditure on medicines	US\$1 (2000) ²
Number of pharmacists	14 (2004) ³
Number of pharmaceutical technicians/assistants	604 (2004) ³
Population per pharmacist	1,387,000 (2004) ¹

1-World Health Report 2006, 2-World Medicines Situation 2004, 3-Global Health Atlas

Medicine policy indicators	
National medicine policy last updated	Draft 2006
Medicines law last updated	1998
National essential medicines list last updated	1999
National standard treatment guidelines last updated	1987
National formulary last updated	1999
Number of medicinal products approved to be marketed	3678
Prescribing by generic name in both public and private sectors	Obligatory

WHO questionnaire on structures and processes of country pharmaceutical situations 2006

METHODOLOGY

Five regions were selected for inclusion in the survey, the capital city, one of the least income generating regions, and three other randomly selected regions. The five regions were Cabo Delgado, Maputo, Niassa, Tete and Zambezia. Within these 5 regions, a total of 21 provincial/district warehouses and 37 public health facilities were randomly selected. In addition, 27 private pharmacies and 600 households¹ were selected based on their proximity to the surveyed public health facilities. Data were also collected from the Beira regional warehouse.

A basket of 15 key medicines were chosen based on burden of disease, their use in all levels of health facilities, and their presence on the essential medicines list. Four additional medicines of interest to the Ministry of Health were also studied. At warehouses, public facilities and private pharmacies, these medicines were used to measure availability, presence of expired medicines on stock shelves, correspondence between stock cards and physical stock and price of medicines. Affordability, quality, and appropriate use of medicines were also measured by the survey.

The survey of households collected data on actions taken in response to a recent illness of one household member. Average weekly household expenditures on medicines and food were also recorded.

THIS SUMMARY REPORT

This draft summary report presents the key findings from the public warehouses, public health facilities, private pharmacies and households. The final draft summary paper will additionally present analysis of the results and conclusions.

ACCESS TO MEDICINES

In this survey, access to medicines is assessed through measuring affordability and availability of medicines.

Affordability is calculated in terms of the number of days the lowest paid unskilled government worker would have to work to pay for one treatment course for a tracer condition. At the time of the survey, the lowest paid unskilled government worker earned 40,000 Metical (US\$1.50) per day; it is estimated that more than half of the population live under this amount per day.

The table below illustrates the affordability of generic medicines for three common acute illnesses used in the survey as tracer conditions.

Tracer condition	Medicine	Number of hours' wages needed to pay for treatment course	
		Public facility	Private pharmacy
Pneumonia in children under 5	Amoxicilina	½ hour	3 hours
Malaria in adults	Amodiaquine + Sulfadoxina/pirimetamina	½ hour	3 hours
Malaria in children under 5	Amodiaquine + Sulfadoxina/pirimetamina	¼ hour	1 hour

è The lowest paid government worker would have to work around half an hour to purchase the generic medicines in the public sector and around 3 hours to purchase the same medicines in the private sector.

¹ In Niassa, data were not collected from a sufficient number of households and so this region is not represented in the presentation of results below.

A medicine prices survey carried out in 2004¹ found that the affordability of medicines for acute conditions was very similar to that found in this survey. The medicine prices survey additionally examined the affordability of medicines for chronic conditions.

The table below illustrates the affordability of generic medicines for three common chronic tracer conditions.

Tracer condition	Medicine	Number of hours/days' wages needed to pay for 1 month's treatment	
		Public facility	Private pharmacy
Asthma	Salbutamol inhaler	2½ hours	3.9 days
Diabetes	Glibenclamide	¾ hour	1.7 days
Depression	Amitriptyline	2 hours	2.5 days

∞ For chronic conditions the lowest paid government worker would have to work around 2 hours to purchase a month's treatment course using generic medicines in the public sector and around 2-3 days to purchase the same treatment from a private pharmacy.

∞ An illustrative family buying medicine for a child with pneumonia, a month's treatment for a child with asthma, and a month's treatment for an adult with diabetes would have to spend 4 hours' wages to purchase generic medicines from the public sector and 8.6 days' wages to purchase the same generic medicines from a private pharmacy.

The large differences between the prices of medicines at public health facilities and private pharmacies can be partly explained by the fact that medicine prices in the public sector were set in 1999. As such, while prices at private pharmacies have risen since 1999, prices in the public sector have remained the same and thus, in real terms, are much cheaper than when they were set.

∞ Generic medicines, generally more affordable than branded medicines, represented 98.0% of medicines prescribed to outpatients at public health facilities.

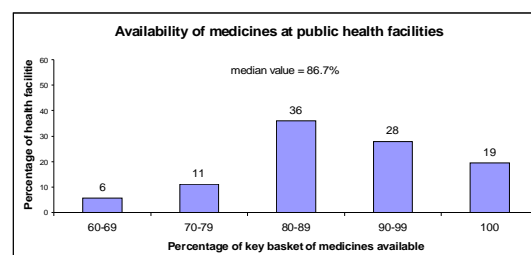
∞ Patients interviewed leaving the dispensing area of public health facilities reported paying a median of 2,800 Metical for their medicines plus fees (equivalent to ½ hour's wages for the lowest paid unskilled government worker).

Availability of medicines at public health facilities is measured by the percentage of prescribed medicines actually dispensed or administered to patients and the presence on stock shelves of a basket of 15 key medicines. The medicines included in the key basket were chosen based on burden of disease, their use in all levels of health facilities, and their presence on the essential medicines list.

∞ In the public health facilities, 94.7% of prescribed medicines were dispensed or administered to patients.

Overall availability of key basket of medicines (%)	Median	25th percentile	75th percentile
Warehouse	86.7	80.0	93.3
Public health facility	86.7	80.0	93.3
Private pharmacy	73.3	60.0	86.7

The chart below demonstrates the distribution of the findings on availability across the facilities



∞ In 83% of facilities, more than 80% of the basket of key medicines was available. In 47% of facilities, more than 90% of the basket of key medicines was found on stock shelves.

∞ In 17% of facilities, less than 80% of the key medicines were available.

The table below shows the median availability of the 15 key medicines for public health facilities, public sector warehouses and private sector pharmacies.

Availability of medicines within the basket (%)	Public health facility	Public Warehouse		Private pharmacy
		Provincial/district	Regional (Beira)	
Acido benzoico acid + salicilico pomade	62.2	52.4	0.0	59.3
Amodiaquine cp 200mg	83.8	71.4	100.0	14.8
Amoxicilina suspensao 250mg/5ml	73.0	71.4	100.0	66.7
Clorfeniramina cp 4 mg	89.2	90.5	100.0	88.9
Cotrimoxazol cp 480 mg	97.3	95.2	100.0	85.2
Mebendazol cp 100 mg	97.3	81.0	100.0	88.9
Paracetamol cp 500 mg	94.6	85.7	100.0	81.5
Penicilina benzatinica injeccao 2.4MIU	83.8	81.0	100.0	70.4
Sais de reidratacao oral pacote para 1l	89.2	81.0	100.0	92.6
Sal ferroso + acido folico cp	94.6	71.4	100.0	55.6
Salbutamol cp 4mg	78.4	71.4	0.0	85.2
Sulfadoxina pirimetamina cp 500/25	94.6	90.5	100.0	85.2
Tetraciclina ofalmica pomada	100.0	95.2	100.0	59.3
Violeta de genciana	83.8	76.2	0.0	70.4
Vitamin A capsulas 200,000 IU	81.1	90.5	100.0	11.1

¹ The survey was carried out by the Ministry of Health of Mozambique using WHO/HAI Medicine Prices Methodology (for methodology see: <http://www.haiweb.org/medicineprices/>)

The table below shows the median availability of the four additional medicines which were not part of the basket, but information was collected as they were of special interest.

Availability of medicines (%)	Public health facility	Public Warehouse		Private pharmacy
		Provincial/district	Regional (Beira)	
Artesunato cp 100 mg	24.3	38.1	0.0	59.3
Fluconazol cp 200 mg	2.7	4.8	0.0	33.3
Rifampicina + isoniazida cp 150/75	45.9	76.2	100.0	0.0
Vacina antitetanica 0,5ml	13.5	4.8	100.0	0.0

As a measure of functionality of the medicines supply system at the health facility level, the stock-on-hand figure on stock cards was compared to actual stock levels for each medicine in the basket.

è A median of 73.3% of stock-on-hand figures matched the actual stock on the shelves.

QUALITY AND SAFETY OF MEDICINES

This survey combines the results of testing done for regulatory purposes with an assessment of whether basic conditions necessary to retain the quality of medicines are maintained in warehouses and public health facilities and an inspection of the expiry date of all stocked products of the key basket of medicines.

è In Mozambique in 2005, 465 medicine samples were collected for regulatory purposes, 457 of these samples were tested and 34 (7.4%) failed identity or assay. This testing was carried out by government quality control laboratories.

è Of the 8 basic conservation conditions assessed in this survey, 12.5% were not maintained in warehouses, 25.0% were not maintained in public health facility storerooms and 25% were not maintained in the dispensing areas of public health facilities.

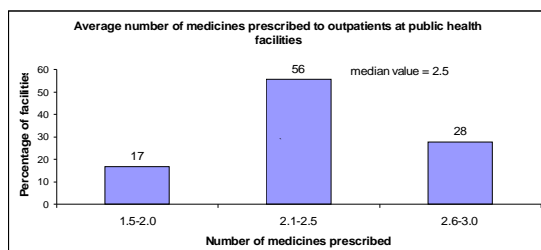
è Of the basket of medicines found on stock shelves, none were expired.

RATIONAL USE OF MEDICINES

Appropriate use of medicines in public health facilities is measured in this survey by the number of medicines per prescription, the number of prescribed medicines on the essential medicines list, the percentage of patients prescribed antibiotics or injections, patient knowledge about how to take the medicines dispensed to them and prescribing practices for a set of tracer conditions.

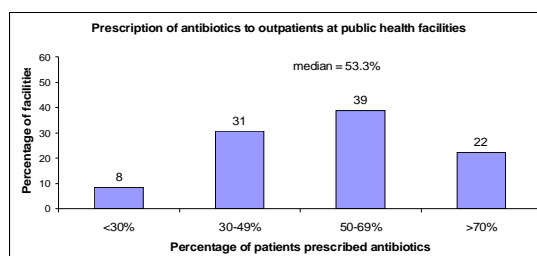
The survey also measured the percentage of public health facilities with copies of standard treatment guidelines and integrated management of childhood illnesses guidelines. In addition, the survey collected data on the occupation of the person responsible for dispensing medicines at each facility.

è The median number of medicines per prescription was 2.5. The chart below illustrates the variation of this prescribing around the median.



è 99.4% of prescribed medicines were on the essential medicines list.

è 53.3% of outpatients were prescribed antibiotics and 10% injections. The chart below illustrates the variation of prescribing of antibiotics around the median.



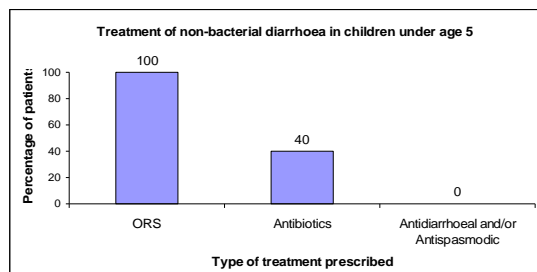
In this survey, patient knowledge about how to take medicines dispensed to them is assessed by the adequacy of the labeling of the medicines, i.e. the label includes the name of the medicine and how to take it, and whether patients leaving the dispensing area can describe how to take each dispensed medicine.

è 40.5% of medicines were adequately labeled. 76.7% of patients knew how to take all of their medicines.

At each health facility, patient records were reviewed retrospectively over the previous 12 months. Ten cases each of four tracer conditions – non-bacterial diarrhoea in children under 5 years of age, mild/moderate pneumonia in children under 5 years of age, non-pneumonia acute respiratory tract infection in patients of any age and malaria in patients of any age – were assessed to evaluate the appropriateness of prescribing practices.

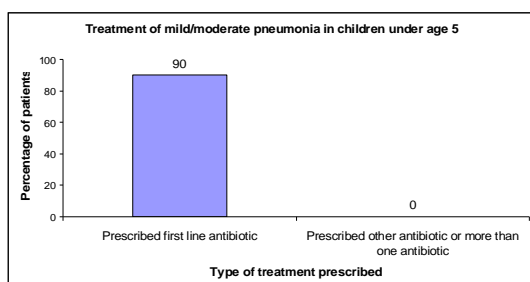
Children under 5 years of age suffering from non-bacterial diarrhoea should be prescribed ORS, but should not be prescribed antibiotics, anti-diarrhoeals or anti-spasmodics.

è All patients under 5 years of age suffering from non-bacterial diarrhoea whose records were reviewed were prescribed ORS, 40% were prescribed an antibiotic and a median of 0% were prescribed an anti-diarrhoeal or anti-spasmodic.



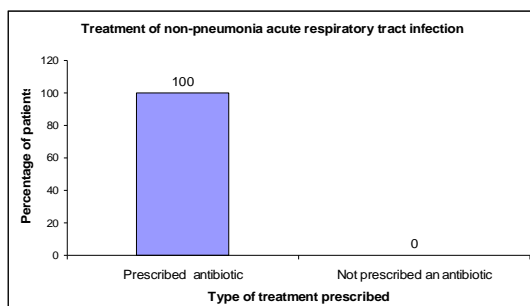
Patients with pneumonia should be prescribed the first line antibiotic only.

90% of patients with pneumonia whose records were reviewed were prescribed the first line antibiotic and a median of 0% were prescribed either another antibiotic or more than one antibiotic.



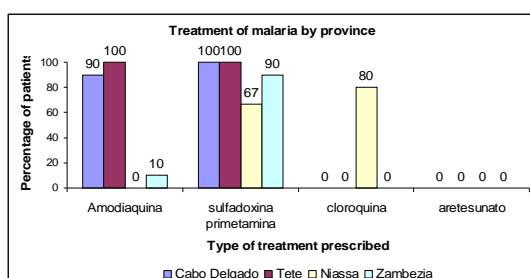
Patients with non-pneumonia acute upper respiratory tract infection should not be prescribed antibiotics.

Contrary to appropriate practice, 100% of patients with non-pneumonia acute upper respiratory tract infection whose records were reviewed were prescribed an antibiotic.



First line treatment for malaria varies by province as the change to artemisinin combination therapy is at different stages of implementation. The following table and graph illustrate the percentage of patients prescribed each treatment by province for those patients whose records were reviewed.

Prescribed malarial treatment by province (%)	Cabo Delgado	Tete	Niassa	Zambezia
Amodiaquina	90.0	100	0.0	10.0
Sulfadoxina-primetamina	100	100	66.7	90.0
Cloroquina	0.0	0.0	80.0	0.0
Aretesunato	0.0	0.0	0.0	0.0



Standard treatment guidelines were available in 93.1% of facilities. Integrated management of childhood illnesses guidelines were available in 82.8% of facilities.

The occupations of a total of 31 persons responsible for dispensing medicines in public health facilities were recorded in the survey. Of these 9.7% were nurses, 87.1% were pharmacy technicians, agents, or auxiliaries and 3.2% were other. None were pharmacists and none were medical technicians.

HOUSEHOLD SURVEY

In this survey, 600 households were asked about the actions taken in response to an acute illness in a household member during the previous two weeks. 95.2% of the households surveyed lived within 5 km of a public health facility. The heads of 49.0% the households had no formal education and a further 29.0% had some primary education. The median number of members in a household was 7.

Data on only one illness episode per household were included in the survey. Of the episodes included, 84.5% occurred in children under 15 years of age and 54.0% in males. 85.7% suffered from fever/headaches.

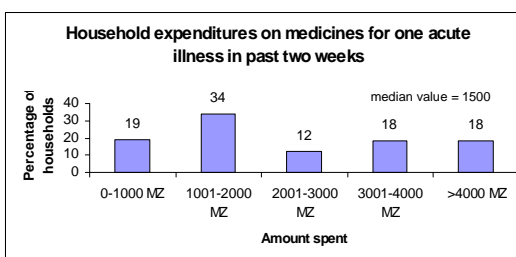
98.8% went to a public health facility. Six respondents reported going to a traditional medical practitioner and one decided which medicines to take on her own.

All reported having medicines prescribed or having taken medicines for the illness.

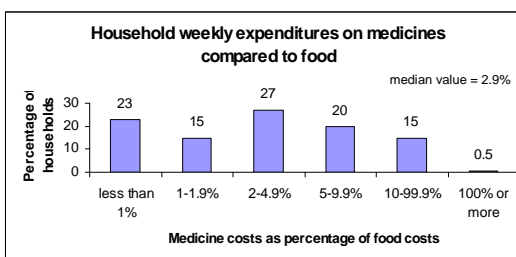
99.8% obtained their medicines from public health facilities.

97.8% were able to obtain all the medicines that were prescribed to them and 97.8% took all the medicines recommended to them.

A median of 1500 Metical was spent on medicines for the illness (equivalent to 18 minute's wages for the lowest paid unskilled government worker).



The median amount spent on medicines for all members of the household during a week was 3000 Metical (equivalent to 36 minute's wages for the lowest paid unskilled government worker). This is in comparison to the median weekly household expenditure of 140,000 Metical on food (equivalent to 3½ day's wages for the lowest paid unskilled government worker).



**REPORT OF THE VISIT TO THE LABORATORIO NACIONAL
DE CONTROLO DA QUALIDADE DE MEDICAMENTOS
(LNCQM)**

NAME AND ADDRESS OF THE LABORATORY

Laboratorio Nacional de Controlo da Qualidade de Medicamentos (LNCQM)

Ministerio da Saude

Avenida Eduardo Mondlane 1086, C. Postal 264

Maputo, Moçambique

DATES OF THE VISIT

From 31st July to 4th August 2006

VISITORS TEAM

Name of the visitor: Marta Miquel Figuerol

European Directorate for the Quality of Medicines (EDQM), Department of Biological Standardisation and OMCL Network (DBO), Council of Europe

Strasbourg, France

VISIT REPORT

Date of issue of the Draft Visit Report: **4th August 2006**

Date of issue of the Final Visit Report: **9th August 2006**

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1. INTRODUCTION

The National Laboratory of Quality Control of Medicines (LNCQM) was created in 1991 (Diploma Ministerial n°19/91, BR n° 9/1st series, 27 February 1991), as an institution subordinated to the National Directorate of Health (DNS) of the Ministry of Health, with the principal objective of controlling the quality of the medicines by checking their conformity with the established international specifications. The LNCQM is funded by the state.

Currently the Chemistry department of the LNCQM is located on the fourth floor of the Ministry of Health building, sharing the facilities with the National Laboratory of Food and Water Hygiene (LNHAA). The department of Microbiology, the administrative assistants and the finances service are located on the first floor of the building, and the Director's office is located on the third floor.

The tests performed in the LNCQM are: organoleptic (aspect, colour, smell), pharmacotechnical (uniformity of mass, mean mass, disintegration/dissolution, extractable volume, appearance of solution, description, reconstituted solution, re-suspension, uniformity of dosage), physical and physico-chemical (pH, TLC, related substances test), chemical (colour, spectrophotometry, volumetric titration), and microbiological (sterility and microbial content limit test).

The reduced size of the facilities dedicated to the LNCQM activities could be a limitation for the adequate functioning of the lab (acquisition of new equipment, limitation of the type and number of tests performed, etc) and the proper development of a Quality management system.

In addition to the LNCQM staff, the consultant met the Honourable Minister of Health, the Honourable Vice-Minister of Health, the Director of the Direcção Nacional de Saude (DNS), the staff of the National Laboratory of Food and Water Hygiene, the Director of the Laboratory of the Faculty of Pharmacy of ISCTEM (Superior Institute of Science and Technology of Moçambique), and the deputy Director of the Center of Medicines (Central de Medicamentos e Artigos Médicos, CMAM).

Persons interviewed at LNCQM:

Director: Ana Raquel Fernandes Siteo

Head of Standardisation and Quality Assurance: Ana Paula da Silva Mandlaze

Head of the Microbiology department: Benedita Isabel Jorge Ronda

Head of the Chemical department: Guilhermina Albertina Nhampulo

Biologist: Pedro Limited Pires

Technician in the Microbiology department: Cesarea Wassiquete

Pharmacy technician in the Chemical department: Arminda Banze

2. PURPOSES OF THE VISIT

In accordance to the request received from the Ministry of Health of Mozambique, the visit was mainly based on the following aspects:

- Definition of the adequate structure of the LNCQM and its responsibilities
- Interrelationship of LNCQM with other bodies in the pharmaceutical sector
- Requirements in relation to the number of staff and their qualifications
- Requirements concerning acquisition and maintenance/qualification of laboratory equipment

The visit was also aimed to establish a documentation system (including a Quality Manual, general and analytical working instructions, personnel records, etc), an equipment management system, develop training programmes, and establish an internal audit system.

An evaluation of the quality documentation and procedures was made, and a list of recommendations is provided in order to improve the Quality Management System, which is currently in the first stage of implementation.

The reference document followed for this evaluation is the international standard **ISO/IEC 17025:2005**: "General requirements for the competence of testing and calibration laboratories".

3. TOPICS EVALUATED

1. Organisation and structure of the LNCQM

Discussions were held in relation to the best structure for the LNCQM. The LNCQM is currently subordinated to the National Health Directorate (DNS). There will be changes in the structure of some departments of the Ministry very soon, and the LNCQM will be under the authority of the Pharmaceutical Department, which is responsible for the registration of medicines in the country. The laboratory has a clear distinction between the two types of activities, chemical/ physicochemical/pharmacotechnical, and microbiological, and this should be reflected in the final structure. Currently staff holds posts for which they are not officially appointed (e.g. Quality Manager, Heads of the departments, etc).

2. Quality management system

The Quality management system is in a first stage of implementation. A good basis exists, and the importance of a quality system is well understood by the Director of the laboratory and the Quality Manager, who did a Master on “Development of a Quality Management System for the LNCQM” at the University of Navarra, Spain.

3. Quality Manual

The Quality Manual is currently in draft. It is well structured, in accordance with the chapters of the ISO 17025 standard, and it makes reference to the internal written procedures.

4. Document control and Standard Operating Procedures (SOP = PNT in Portuguese)

SOPs are currently under preparation, covering the management system and the technical activity. New SOPs will be created according to the identified needs.

5. Review of tests requests

6. Any test request received at LCNQM is evaluated and signed for approval. Tests requests come mainly from MEDIMOC (a private logistics company, contracted by CMAM, in charge of the procurement, storage and distribution of medicines in the country), the others come from hospitals and provincial health authorities.

7. Purchasing of medicines and supplies

The main part of the purchases is done through the Central de Medicamentos e Artigos Médicos (CMAM). The CMAM makes an annual purchase plan of medicines and reagents, based on the consumption of the previous year and on prescriptions made at medical visits. CMAM has a staff of 26 people (of which 7 are pharmacists and 7 pharmacy technicians).

All medicines circulating in Mozambique are imported. The CMAM has 3 systems of purchase: LCB (limited tendering), funded by CMAM, only for those companies included in a list of pre-qualified providers (made by CMAM, in relation to criteria as quality and costs); ICB (unlimited tendering), funded by the World Bank, in which any provider can participate; and the “Shopping” system, also open to all companies, used in case of urgency and for new therapies for which there is no identified provider.

MEDIMOC, on behalf of CMAM, stores the medicines and every trimester distributes the pre-defined quantities to the provincial stores. The provincial store sends then the medicines to the district stores. As explained by the deputy head of CMAM, Tania Siteo, the storage conditions are not always optimal in the provincial and district stores (no air conditioning, no ventilation, etc). Renovation is currently done in some of them. Every year the CMAM audits all provincial stores to check the management of stocks and storage conditions. If there are doubts about the quality of a product, it is sent to LNCQM for testing.

CMAM sends samples for quality control test to LNCQM, so the laboratory has no direct control on the quantities and lot numbers received. Sampling and distribution is done by MEDIMOC. In some cases the quantity of samples received at LNCQM is not big enough and they are not representative of the batches imported.

CMAM obtains the medicines mainly from distributors, not directly from the manufacturers (located in The Netherlands, India, China, etc), which means that manufacturers are not always well known. A direct purchase to the manufacturers would allow a better control in the selection of certified and well established companies and increase the assurance on the quality of the medicines obtained.

CMAM also distributes to LNCQM the necessary reagents for the testing of medicines. LNCQM defines its needs in reagents once per year. This list is sent to CMAM, who follows the purchase procedure of tendering. MEDIMOC stores the reagents and distributes them to LNCQM once they have been (visually) checked as compliant with the pre-defined specifications.

There exists a direct purchase procedure at LNCQM for the acquisition of small quantities of certain materials (e.g. glass material), independently from CMAM and MEDIMOC.

8. Internal quality audits, corrective actions

Internal audits are performed in the lab by the quality manager in both departments, chemical and microbiological. The procedure for internal audits is in draft.

9. Management review

The SOP for the periodical review of the quality system is in draft. A discussion was held about the minimum topics that should be discussed at the Management review, in accordance with the ISO 17025 standard.

10. Competence of personnel and related documentation

A discussion was held in relation to the necessary documentation to be included in the Personnel files to prove the competence, experience and skills of staff (see recommendations).

Currently the staff of LNCQM is 28 people (of which 5 have a University degree in Chemistry or Biology).

11. Premises

It was seen that the premises currently available at LNCQM are not big enough to allow a future development of the laboratory. The acquisition of new equipment and the performance of new analytical techniques are conditioned to the lack of space.

12. Test methods

For the evaluation of the quality of the products, the LNCQM applies the specifications contained in 3 pharmacopoeias: United States Pharmacopoeia (2003 USP 26/NF 21), British Pharmacopoeia (BP, 2001 Vol I and II) and International Pharmacopoeia (IP). If necessary, other scientific documentation is used. The lab also has the Indian (1996) and the Portuguese (1997) Pharmacopoeias.

No additional verification/validation of the transferred pharmacopoeial methods is done (see recommendations).

13. Equipment maintenance, calibration, qualification

Currently no equipment maintenance, calibration, qualification and monitoring of temperature procedures are in place (see recommendations).

14. Reagents and Reference standards

The stock of reagents in the laboratory is well kept in locked safety cupboards, and they are codified according to their characteristics (organic, solvents, acids, oxides, bases, etc). Only the necessary quantities for the routine daily work are kept in the work place.

The reagents and material warehouse (located inside the facilities of the “Centro de Manutenção”, 10 minutes far from the Ministry by car), was visited together with the 2 people responsible for the stocks. Once a week, they check the stocks in the lab and come to the warehouse to take the necessary material for reposition. The facilities were found very clean and well organised. There is air conditioning in the reagents room, but temperature is not monitored. There is an inventory list of reagents (classified in the same way as in the lab) and of laboratory material. It was seen that these facilities are quite big, but only a small part is occupied.

Expiry date is not assigned to reagents and reference substances in case this date is not provided by the manufacturer.

15. Reference standards are kept in the fridge in the Chemistry department. Some old reference substances are kept only for identification and training purposes. The newest ones are used for the testing.

16. Handling of test samples

All samples received at the LNCQM come directly to the Chemistry department. They are registered in a log book with an internal code and all information about the sample is recorded. Samples that should also be tested in the microbiology laboratory are sent there directly by the chemistry laboratory. Once at the microbiology lab, they are registered in a log book (keeping the same registration number) with all information.

Samples not yet analysed are separated from samples archived after testing. In the chemistry department, samples are archived in several locked cupboards. In the microbiology laboratory, samples are kept either in the fridge or outside, but they are not locked.

Samples found non-compliant are kept until their expiry date. Samples found compliant are sent to the hospital to be used before their expiry date.

17. Test reports

Technical staff uses laboratory books to record observations, calculations and results. The pages are numbered and both the technician and the supervisor of the laboratory sign on it. From these data, an analytical report is elaborated, which is checked by the Head of the department. Information concerning the sample and the results obtained are encoded in a very complete database (Access), and the final certificate is printed. The certificate includes all information related to the sample analysed, allowing a good traceability, including the test methods followed, the results, and a conclusion (pass / fails). The final certificate is signed by the technician who carried out the test and the Director of the LNCQM. Certificates are sent back to the requestor of the quality control tests.

18. Visit to the Faculty of Pharmacy of ISCTEM (Instituto Superior de Ciências e Tecnologia de Moçambique)

A visit was made on the 3rd of August at the ISCTEM facilities. The Director of LNCQM and the consultant met the coordinator of the Pharmacy courses, Dr Röseler Ventura. The aim of the visit was to discuss about the possibilities for a future cooperation between ISCTEM and LNCQM to share

experience and knowledge and avoid a duplication of efforts and a waste of resources. This collaboration would concern the subcontracting of tests currently not available at LNCQM, training of staff, calibration of equipment, and the possibility of using their central server to store electronic data, provided that confidentiality is fully ensured.

The laboratory of the Faculty of Pharmacy is currently implementing a quality management system based on ISO/IEC 17025. Some important steps are already in place, for example a calibration programme for lab equipment (for this purpose, instruments are sent to Portugal). By end of 2006 they will receive new equipment (HPLC, GC), financed by the Mozambican Government through the World Bank.

One of their current projects is the elaboration of the “Formulario Nacional”, a compilation of monographs for the preparation, quality control and calculation of price of the “magistral formulations” prepared in the pharmacies. The Faculty of Pharmacy also elaborates this type of formulations for the Hospital Central de Maputo.

4. RECOMMENDATIONS

As a general recommendation, a big investment should be done in relation to 3 main topics:

- **Improvement of the laboratory facilities** (provide more space, make a better use of the existent resources and, at a short-term, consider the possibility of establishing an independent facility for the LNCQM)
- **Training of personnel** in specific areas (chemical, physico-chemical and microbiological analytical techniques for the quality control of medicines; qualification of equipment; validation of analytical methods; quality assurance)
- **Acquisition of laboratory equipment** to increase the type and number of tests performed and ensure a more reliable and complete control of the quality of medicines in the country. This is conditioned to the enlargement of the lab facilities

Organisation and structure of the LNCQM

- 1- The structure of the LNCQM should be clearly defined and an organisational chart should be made official. A structure is proposed in Annex AA for the individual context of the LNCQM. The most appropriate denomination for the different “entities” in the different hierarchical levels should be decided, trying to avoid any conflict with the general rules of the Ministry of Health.
- 2- A Quality Manager should be officially nominated, who, irrespective of other duties and responsibilities, shall have the defined responsibility and authority for ensuring that the quality management system is implemented and followed. The Quality Manager (which can be a part-time function) shall report directly to the highest level of management in the laboratory.
- 3- The needs concerning staff (technical, supervisory and support staff) should be fixed in relation to the type and amount of work performed. A proposal is presented in Annex BB.
- 4- The fact that the LNCQM shares the facilities with the National Laboratory of Food and Water Hygiene, and that the LNCQM is distributed in 3 different floors at the Ministry of Health could represent an inconvenience for the good development of the laboratory and for the acquisition of new equipment and expansion of the testing activities in the future. Consider making a better use of the current LNHHA facilities, where the LNCQM is located (some rooms are not used, e.g. room where the old HPLC is stored), and of the “Centro de Manutenção” (where the reagents and material warehouse is located), currently used only at one third of their capacity.

Quality Management System

- 5- The Quality Manual should be finalised and issued as soon as possible, in accordance with the recommendations given during the visit. All laboratory staff should read and understand the Quality Manual, and it should be easily accessible to all of them for consultation at any time. A Quality Policy, issued under the authority of the director of the laboratory, should be included in the Manual. An internal meeting could be organised to present the Quality Manual to the personnel.
- 6- The draft SOPs should be finalised as soon as possible, and the structure, codification, approval, periodical review, change control, history of changes, distribution, and archiving systems should be described in a written procedure. Forms used to record data are in draft. They should also be codified and controlled as part of the quality system documentation.
- 7- Management of external documentation: the surveillance of the new versions of guidelines, pharmacopoeias and other reference documents should be more frequent (currently is done every 3 years), to make sure that the latest version is used.
- 8- Finalise the procedure for the periodical internal audits, prepare an audit schedule (approved by the Director), define the methodology, reporting of the non-conformities and follow-up of corrective actions.
- 9- Corrective actions implemented as a consequence of non-conformities detected during routine work (e.g. out of specification results, departure from the established procedures, equipment breakdown, etc), should also be recorded and followed-up.
- 10- Write a procedure to deal with retests done in case of out-of-specifications results (OOS), including the number of retests allowed, acceptance criteria, reporting of the results, responsibilities, etc.
- 11- Finalise the procedure for the periodic (e.g. annual) review of the quality management system (Management review), topics to be discussed, members who should attend the meeting, reporting of the conclusions, follow-up of corrective actions, and implement it as soon as possible.

Equipment

- 12- On the basis of the Good Practices for National Pharmaceutical Control Laboratories (GPCL), Appendix 2, issued by WHO in 18 Sept 2003, concerning the equipment required for a medium-sized pharmaceutical control laboratory, a comparison has been made between the ideal situation and the available equipment at the LNCQM, to determine the immediate and medium-term needs for the acquisition of equipment. The proposal is presented in Annex CC. **Equipment in bold is considered to be indispensable for the good functioning of the lab and should be acquired in the shortest delay** (when more than one unit is needed, at least one unit should be acquired immediately, the rest can be acquired later on). If necessary, and in order to accommodate the new equipment in the lab, a better use of the facilities should be made, or the facilities of the Laboratory of Food and Water Hygiene could be temporarily used. **The rest of the equipment can be acquired at a medium-term** (conditioned to the available space in the laboratory).
- 13- It is indispensable to establish a programme for the periodical maintenance, qualification and calibration of laboratory equipment (external services may be contracted, taking into account that the user is the final responsible for the instrument). All staff has to be trained for the periodic basic verification of equipment. Specific staff has to be trained for the periodic internal qualification and calibration of equipment (e.g. balances calibrated externally 1/year: calibrations should be done internally between two external calibrations, by using the calibrated weights). It will be necessary to allocate a part of the equipment budget to the acquisition of

reference standards for the internal calibration of equipment (e.g. thermometers, weights, UV filters to calibrate the spectrophotometer, tablet disintegration equipment, etc).

- 14- Establish a policy and a procedure for the periodic monitoring of the temperature in fridges, incubators, and rooms with pre-defined environmental conditions, by using calibrated thermometers.

Personnel

- 15- Some staff will leave the LNCQM soon, and new staff will have to be contracted. To avoid losing competent and experienced people, motivation of staff should be increased by, for example, providing them training to improve their technical skills and expand their field of activities, organising periodical internal meetings to make them participate in the development of the laboratory and discuss possibilities for improvement, involving them in the internal audits (e.g. the Head of Chemistry and the Microbiology divisions could be trained as internal auditors and perform audits together with the Quality Manager), etc. The motivation will also increase by officially nominating the persons holding the different positions in the laboratory.
- 16- Training courses for staff should be organised in the different areas of competence as soon as possible. A proposal is presented in Annex DD. In addition to the technical training, and as highlighted by the Honourable Vice-Minister of Health, training on English language is also very important to facilitate the participation of staff in international courses. Training in English will also give staff the possibility to communicate with an international network of medicines control laboratories and regulatory authorities. Alternatively, training courses could be searched in Portuguese or Spanish speaking countries to facilitate the communication. The WHO could help the LNCQM to find appropriate organisers of training courses and, whenever possible, sponsor the travel and accommodation to attend such courses
- 17- A personnel file should be prepared for each member of staff, containing the documentation proving their competence, experience and skills:
 - a. Curriculum vitae
 - b. Job descriptions, signed, defining responsibilities, authority, duties
 - c. Training records (from internal courses)
 - d. Training certificates (from external courses)
 - e. Confidentiality agreements, if this is not included in the job contract
- 18- A list of names, signatures and initials for all staff (to allow quick traceability of signatures or initials on raw data) should be prepared and regularly updated.
- 19- There should be a SOP for the introduction of new personnel, including tests to be performed and acceptance criteria for qualification.
- 20- Personnel performance is evaluated once a year by the Director. Take this opportunity to discuss about the training needs for staff, compile this information and use it to prepare the yearly training plans.

Testing of medicines

- 21- The LNCQM has prepared a list of 226 medicines (taken from the list of medicines authorized in the country), selected according to criteria such as stability, cost and therapeutic relevance. From this list, another list has been prepared containing the medicines for which LNCQM doesn't have the technical capacity and material resources for their quality control. In the future, when new facilities, equipment and trained staff will be available, these analyses will be performed at LNCQM. In the meantime, the possibility of analysing these medicines in a WHO-financed laboratory should be considered.

Test method validation

- 22- There should be a procedure for the validation of analytical methods. Staff involved in this activity should be appropriately trained. According to ICH (International Conference for Harmonization) requirements, a formal validation has to be performed for new developed methods. When transferring standard methods to the lab (e.g. pharmacopoeial methods), only a transfer check (verification of suitability) has to be done to show that under the conditions of use in the individual laboratory, the method is adequate.

Recording of data

- 23- Pencil and corrector fluid should be forbidden in the lab records (e.g. logbooks for the registration of samples, technician lab-books). When mistakes occur in records, each mistake should be crossed out, without obscuring original data, and the correct value entered alongside. Such alterations shall be signed (or initialled) and dated by the person making the correction (good documenting practices).
- 24- As a general rule, in the laboratory records of original observations and calculations, all information necessary to enable the repetition of the test should be recorded (identity of personnel responsible for the testing and the person supervising the results, identification of the equipment used, lots of reagents, date of testing, etc).

Sampling

- 25- Sampling for quality control test at LNCQM is done by MEDIMOC. In some cases the samples received are not representative of the batches imported. The minimum number of samples required for the performance of the quality control tests should be redefined, in accordance with the production volume. A written procedure should exist describing the sampling process (statistical basis for a representative sampling, methodology, responsibilities, recoding of ambient conditions at the moment of the sampling and transportation, etc).

Handling of samples

- 26- Label clearly the spaces dedicated to the storage of samples not yet analyzed and the archive of analyzed samples, to avoid any confusion (e.g. fridge in the Microbiology laboratory).

Monitoring the quality of tests

- 27- It is recommended to participate more frequently in Proficiency testing studies, both in the physico-chemical and microbiological field (check the feasibility of participating in the PTS organised by WHO and EDQM (European Directorate for the Quality of Medicines), or other national or international bodies, if appropriate in relation to the type of tests performed at LNCQM).

Reagents

- 28- It is recommended to record the lot number in the inventory sheet of reagents stored at the reagents and materials warehouse (located inside the facilities of the “Centro de Manutencion”), to ensure that old lots are used first, and to allow complete traceability in the records.
- 29- Establish a general policy for the attribution of expiry dates to commercial reagents (when not provided by the manufacturer), reference substances, and in-house prepared media and solutions (except when they are immediately used). This could be based on previous experience with the use of these substances. The expiry period can be extended if the suitability of the reagent is demonstrated by the appropriate checks.
- 30- The current system of annual supply of reagents to the LNCQM via the CMAM does not always fit the specific needs of the lab, for example in the case of the reference substances and critical reagents (e.g. thermally instable reagents, of very frequent use, needing specific storage conditions, etc). Evaluate the possibility for the lab to purchase this type of reagents and the reference substances independently from CMAM. An independent purchase system already exists in the LNCQM for other type of materials, with a pre-defined budget. This budget could be readapted accordingly to cover also these reagents and reference substances. This independency could also allow a better selection of providers according to pre-established quality criteria.

Microbiology Department

- 31- The containers of culture media should be labelled to indicate the identity, concentration, storage conditions, preparation date, expiry date or recommended storage periods and the person responsible for the preparation (see labels used in the chemical laboratory). The validity period of the in-house prepared culture media should be pre-defined.
- 32- Sterility test: growth promotion test should be performed to validate the suitability of the culture media (see Pharmacopoeia).
- 33- An environmental monitoring is currently done with settlement plates, but there are not acceptance criteria defined for the cfu counts (as an example, a limit of 5 cfu is applied at the laboratory of ISCTEM). There should be a procedure for dealing with situations in which these limits are exceeded.
- 34- It should be ensured that the air conditioner used in the room where sterility test is performed is not a source of contamination (e.g. appropriate maintenance of the filters, periodical environmental monitoring). Ensure that microbial counts in that room are in accordance with the pharmacopoeial requirements for the sterility test.
- 35- Currently the type of microbiological tests performed is very limited and the quantity of samples analysed very low. External training on specific microbiological techniques for the quality control of medicines should be organised as soon as possible in order to enlarge the field of activities and the workload of the Microbiology department and ensure a more complete testing of medicines and a better use of the facilities and staff.

Proposals for the future development of the LNCQM

- 36- A training to one of the regional laboratories financed by WHO in Africa (e.g. Centro de Garantia de Calidad de Medicamentos (CENQAM), in South Africa), where a quality management system is already well established, could be foreseen for some members of the LNCQM (especially focused on issues like calibration of equipment and validation of analytical methods). After that, a member of the visited regional lab could come to LNCQM to perform an on-site technical training (e.g. for specific analytical methods).

- 37- The field of activities of the laboratory could be enlarged in the future by taking the responsibility for the quality control of cosmetics, herbals, vaccines and other biological products, for which currently there is no clear control.
- 38- Regional laboratories (e.g. one in the centre of the country and one in the north) could be created in the future, under the supervision of the LNCQM, in order to ensure a better coverage of the country and reduce the delays of transportation from the entry point in Moçambique up to the LNCQM (avoiding thus degradation due to inadequate storage conditions of the medicines).
- 39- It could be foreseen to implement a market surveillance programme to ensure a proactive investigation of the quality of the products available on the market, and not only when there are complaints. For this purpose, sampling could be done at the different points of distribution in the country (hospitals, warehouses, pharmacies, etc), in accordance with a pre-defined sampling plan, based on appropriate statistical methods, and samples would be analysed at the LNCQM.
- 40- A collaboration with the Faculty of Pharmacy of ISCTEM could be sought concerning subcontracting of tests which are not available at LNCQM due to lack of equipment or technical knowledge, training of technical staff, calibration of equipment (the laboratory of the Faculty has already a calibration programme on place), and the possibility of using their central server to store electronic data in a secure way, provided that confidentiality is fully ensured.

5. IMPLEMENTATION PLAN FOR CRITICAL ACTIONS

IMMEDIATELY (Before end 2006)	Define the structure of LNCQM and elaborate an organisational chart
	Improve/enlarge the LNCQM facilities and make a better use of the existing space in the Laboratory of Hygiene of Water and Food
	Identify the possibilities for new facilities for the LNCQM in view of a short-term move
	Officially nominate a Quality Manager (independent from any other position and reporting directly to the Director)
	Officially nominate the persons holding the different positions in the laboratory
	Increase the motivation of staff
	Finalise the Quality Manual and make it available to all staff. Include a Quality Policy (signed by the Director of LNCQM) in the Quality Manual. Organise an internal meeting to present the Quality Manual to the personnel
	Finalise the draft SOPs as soon as possible, and describe in a written procedure the structure, codification, approval, periodical review, change control and history of changes, distribution and archiving systems. Forms used to record data should also be codified and controlled as part of the quality system documentation.
	Identify the appropriate institutions for the training of personnel and find the necessary budget. WHO could help the LNCQM to find appropriate organisers of training courses and, whenever possible, sponsor the travel and accommodation to attend such courses
	Identify the specifications required for new equipment, in view of their acquisition at short-term (Design Qualification, "DQ")
	Perform a more frequent surveillance of the new versions of external documentation, especially reference analytical methods such as pharmacopoeias
	Finalise and put into practice the procedure and the related documentation for periodical internal audits and follow-up of corrective actions. Establish an audit programme.
	Finalise and put into practice the procedure for the periodical management review of the quality system
	Record and follow-up the corrective actions implemented as a consequence of non-conformities detected during routine work (e.g. out of specification results, departure from established procedures, equipment breakdown, etc)
	Write a procedure to deal with retests done in case of out-of-specifications results (OOS), including the number of retests allowed, acceptance criteria, reporting of the results, responsibilities, etc
	Prepare the personnel files with the documentation related to the competence, experience and skills of staff
	Prepare a list of names, signatures and initials for all staff, to allow quick traceability of signatures or initials on raw data, and update it regularly
Write a SOP for the introduction of new personnel, including tests to be performed and acceptance criteria for qualification.	
Include in laboratory records all information necessary for the traceability of the test results (identity of personnel, equipment used, lots of reagents, date of testing, etc)	

IMMEDIATELY (Continuation)	Record the lot number in the inventory sheet of reagents stored at the reagents and materials warehouse (located inside the facilities of the “Centro de Manutenção”) to ensure that old lots are used first
	Assign expiry dates to reagents, reference substances, in-house prepared culture media and solutions (based on previous experience or literature)
	Evaluate the possibility of purchasing reference substances and critical reagents (e.g. thermally instable, of very frequent use, needing specific storage conditions, etc) independently from CMAM. If necessary, use the already existing system at LNCQM for independent purchases and adapt the current budget to cover also this type of substances
	Define the minimum number of samples (sampling is done by MEDIMOC), required for the correct performance of the quality control tests, in accordance with the imported volume. Write a procedure describing the sampling process (statistical basis for a representative sampling, methodology, responsibilities, recoding of ambient conditions at the moment of the sampling and transportation, etc)
	Microbiology lab: label the containers of culture media to indicate the identity, concentration, storage conditions, preparation date, expiry date or recommended storage periods and the person responsible for the preparation
	Sterility test: carry out the growth promotion test to validate the suitability of the culture media (see Pharmacopoeia)
	Define acceptance criteria for the cfu counts in the Microbiology laboratory (environmental monitoring) and establish a procedure for dealing with situations in which these limits are exceeded
	Check that the air conditioner used in the room where sterility test is performed is not a source of contamination and ensure that microbial counts in that room are in accordance with the pharmacopoeial requirements for the sterility test
	Establish a programme for the periodical maintenance, qualification and calibration for the currently available equipment in the laboratory
	Organise a training to one of the regional laboratories financed by WHO in Africa (e.g. Centro de Garantia de Calidad de Medicamentos (CENQAM), in South Africa), where a quality management system is already well established.
Consider the possibility of controlling the quality of medicines for which LNCQM does not have the technical capacity and material resources, in a WHO-financed laboratory, until LNCQM has the appropriate facilities, equipment and trained staff	

SHORT TERM (Before end 2007)	Implement the knowledge acquired during the visit to the WHO laboratory (see immediate actions), and organise a visit of one of its members (who collaborated in the training of LNCQM staff), to make a follow-up
	Consider the possibility of establishing an independent facility for the LNCQM
	Consider the possibility of establishing a collaboration with the Faculty of Pharmacy of ISCTEM concerning the subcontracting of tests, training of technical staff, calibration of equipment and the possibility of using their central server to store electronic data in a secure way (provided that confidentiality is fully ensured)
	Buy reference standards for the internal calibration of equipment (e.g. thermometers, weights, UV filters, etc)
	Establish a periodic monitoring of the temperature in fridges, incubators, and rooms with pre-defined environmental conditions, by using calibrated thermometers
	Establish a procedure for the validation of analytical methods
	Buy the following priority equipment: 1 Top-loading balance 1 Analytical balance micro (5 digits) 1 Microscope (binocular) 1 Potentiometric titrimeter 1 Heating mantle for flasks 1 Water-bath (20 litres) 1 Desiccator 1 Ultrasonic bath (10 litres) 1 Water distilling apparatus (10 L/h) 1 Water deionizing equipment (10 L/h) 1 Melting point apparatus 1 Polarimeter 1 HPLC with variable length UV-VIS detector 1 Safety cupboard for toxic/flammable/volatile products
	Attend the following training courses: - External training on Laboratory management for 1 - 2 people - External training on Quality Assurance for, at least, the Quality Manager - Internal training on quality assurance for all staff - External training on analytical techniques for the control of the quality of medicines in the chemical and physico-chemical field (in particular for HPLC, Dissolution test, UV-Vis spectrophotometry) for 2 – 3 people - External training on analytical techniques for the control of the quality of medicines in the microbiological field for 1 person - External training on validation of analytical methods, for 2 people from Chemistry lab and 1 person from Microbiology lab - External training on maintenance, calibration and qualification of equipment, for the Quality Manager and 1 – 2 technical people - External training on security procedures in the laboratory, for 2 people (one person from the Microbiology department and one from Chemistry) - External training on Good Laboratory Practices for, at least, the Quality Manager - External training on English language, at least for the staff for which a technical external training is planned, and other members if necessary

SHORT TERM (Continuation)	Participate more frequently in Proficiency Testing Studies (where appropriate), both in the physico-chemical and microbiological field
	<p>Contract new staff (for replacement staff, the urgency of contracting will be conditioned to the time when staff leaves):</p> <ul style="list-style-type: none"> - 2 people with university degree (e.g. one Pharmacist and one Chemist) for the Chemical department (one of them will be Head of department), both will be responsible, in addition to their responsibilities, for the maintenance and qualification of equipment in the Chemical department. - 1 Biologist for the Microbiology department, who will be also responsible for the maintenance and qualification of equipment in the Microbiology lab - 1 technician with medium level education for the Microbiology department

MEDIUM TERM (Before end 2008)	<p>Buy the following equipment:</p> <ul style="list-style-type: none"> 1 Top-loading balance 1 Heating mantles for flasks 2 Water-bath (20 litres) 1 Desiccator 1 Safety cupboards for toxic/flammable/volatile products 1 Centrifuge (floor model) 1 Vortex mixers 1 Hot plates with magnetic stirrers 1 Drying oven (60 litres) 1 Refrigerator 1 Ultrasonic pipette cleaner 1 UV-Vis spectrophotometer, double beam, with recorder 1 IR spectrophotometer with accessories and recorder 1 Disintegration test equipment 1 Crushing strength tester 1 Friability tester
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LONG TERM (Before end 2010)	Consider creating regional laboratories under the supervision of LNCQM, to ensure a better coverage of the country, reduce the delays of transportation to LNCQM and avoid the degradation due to inadequate storage conditions
	Consider implementing a market surveillance programme to ensure a proactive investigation of the quality of the products available in the market (hospitals, warehouses, pharmacies, etc)
	Consider enlarging the field of activities of the LNCQM by taking the responsibility for the quality control of cosmetics, herbals, vaccines and other biological products, for which currently there is no clear control

6. FINAL COMMENTS

It is important to highlight the strong motivation and commitment of all staff interviewed, and in particular the commitment of the Honourable Minister of Health, who has a clear vision of the crucial position of the laboratory in the national pharmaceutical sector, and its important role in the protection of the public health.

Currently the LNCQM has a capacity to analyse a maximum of 600 samples per year. The laboratory would like to increase the workload and expand its field of activities to be able to cover as many analytical tests as possible and ensure a complete control of the quality of medicines. For this purpose it would be indispensable to invest in the training of staff and in the acquisition of new equipment, as mentioned in the report.

The visitor would like to encourage the LNCQM staff to continue developing their quality system, the basis of which has already been established and well understood.

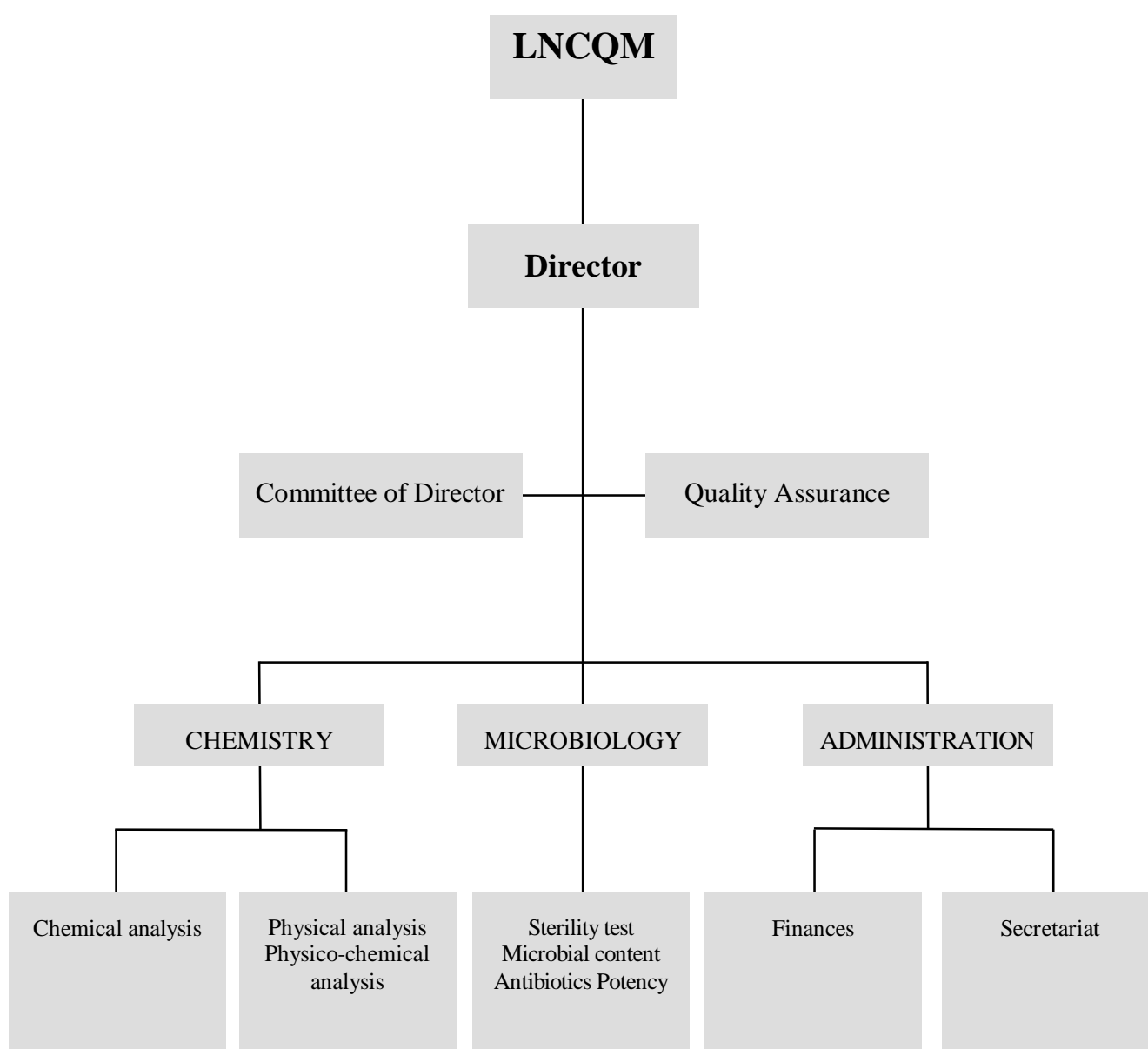
A follow-up visit could be foreseen in the coming 12 to 18 months, to evaluate the level of development of the quality management system, after the implementation of the recommendations listed in this report.

Conclusion

As a conclusion, by improving the LNCQM facilities, providing training to staff and acquiring the necessary equipment it will be possible to increase the type and number of tests performed at LNCQM, ensuring a more complete, reliable and efficient control of the medicines in the country.

Annex AA

Proposal of structure of the LNCQM



Annex BB

Proposal for distribution of staff in the LNCQM

“Organisational entity” in LNCQM	Position	N° of staff	Minimum qualifications
Direction	Director	1	University degree and experience in the field of quality control of medicines
Standardisation and Quality Assurance	Quality Manager	1	University degree and specific (external) training in Quality assurance
Chemistry	Head	1	University degree in Chemistry, and specific (external) training in chemical analysis for the quality control of medicines
Chemistry (chemical analysis)	Technical staff with responsibility for the management of equipment	2	University degree (e.g. Chemistry and Pharmacy) with (external) training on the use, maintenance and qualification of equipment for chemical analysis, and (internal) training in chemical analysis for the quality control of medicines
	Technical staff	8	Medium level education and (internal) training in chemical analysis for the quality control of medicines
	Support staff	1	Basic level education
Chemistry (physical and physico-chemical analysis)	Technical staff	3	Medium level education and (internal) training in chemical analysis for the quality control of medicines
	Support staff	1	Basic level education
Microbiology	Head	1	University degree in Biology, specific (external) training in microbiological analysis for the quality control of medicines, and (external) training on the use, maintenance and qualification of equipment for microbiological analysis
	Technical staff	2	Medium level education and (internal) training in microbiological analysis for the quality control of medicines
	Support staff	1	Basic level education
Administration	Technical staff	3	Medium level education (accountability, administrative assistants)
	Maintenance staff	2	Basic level education
	Driver	1	Basic level education
TOTAL:		28	

Note: the number of staff may increase in relation to the increase of workload and expansion of the field of activities

Annex CC

Proposal for acquisition of equipment for the LNCQM

Department of Chemistry

Name of instrument	Quantity			
	Requested by WHO *	Available in the lab	Ideal	Needed
Top-loading balance	1-2	-	2	2
Analytical balance semi-micro (4 digits)	2	2	2	-
Analytical balance micro (5 digits)	1	-	1	1
Microscope (binocular)	1-2	-	1	1
Equipment for TLC and accessories	1	1	1	-
Potentiometric titrimer	1	-	1	1
Micrometer calipers	1	1	1	-
Heating mantles for flasks	6	-	2	2
Centrifuge (floor model)	1	-	1	1
Shaker (wrist-action)	1	1	1	-
Vortex mixers	2	-	1	1
Hot plates with magnetic stirrers	3-4	3	4	1
Water-bath (20 litres)	2-3	-	3	3
Vacuum rotary evaporator	1-2	1	1	-
Drying oven (60 litres)	2-3	1	2	1
Vacuum oven	1	1	1	-
Desiccators	2	-	2	2
Refrigerator	1	2	3	1
Ultrasonic bath (5 litres)	2	1	1	-
Ultrasonic bath (10 litres)	-	-	1	1
Ultrasonic pipette cleaner	1	-	1	1
Water distilling apparatus (10 L/h)	1	-	1	1
Water deionizing equipment (10 L/h)	1	-	1	1
Melting point apparatus	1	-	1	1
Polarimeter	1	-	1	1
pH meters	2	3	3	-
HPLC with variable length UV-VIS detector	1	-	1	1
UV-Vis spectrophotometer, double beam, with recorder	1	1	2	1
IR spectrophotometer with accessories and recorder	1	-	1	1
Karl Fischer titrator	1	1	1	-
Disintegration test equipment	1	1	2	1
Dissolution test equipment	1	1	1	-
Crushing strength	1	-	1	1
Friability tester	1	-	1	1
Safety cupboards for toxic/flammable/volatile products	-	2	4	2

Department of Microbiology

Name of instrument	Quantity			
	Requested by WHO *	Available in the lab	Ideal	Needed
pH-meter	1	-	1	1
Microscopes	2	1	2	1
Membrane filter assembly for sterility test	1	1	1	-
Colony counter with magnifier	1	1	1	-
Laminar air flow unit	1	1	1	-
Hot-air sterilizer	1	2	1	-
Incubators, 60 litres	2-3	1	2	1
Anaerobic jar	1	-	1	1
Zone reader	1	-	1	1
Water bath (thermostatically controlled)	2	1	1	-
Refrigerators	2	1	1	-
Autoclaves	2	2	2	-
Cleaning device for glassware, especially for cleaning pipettes	2	-	2	2
Shower and eyes rinse device	-	-	1	1

* WHO Good Practices for National Pharmaceutical Control Laboratories (GPCL), Appendix 2 (18 Sept 2003)

Note: Equipment in bold is considered to be indispensable for the good functioning of the lab and should be acquired in the shortest delay (when more than one unit is needed, at least one unit should be acquired immediately, the rest can be acquired later on). The rest of the equipment can be acquired at a medium-term (conditioned to the available space in the laboratory).

Annex DD

Proposal for staff training

Type of training	Internal/External	Staff who should follow it	Priority
Laboratory management	External	1 - 2	High
Basic training on the quality management system	Internal (given by the Quality manager)	All staff	High
Quality Assurance	External	At least the Quality Manager	High
Analytical techniques for the control of the quality of medicines (chemical, physico-chemical, in particular for HPLC, Dissolution test, UV-Vis spectrophotometry)	External	2 - 3 people	High
Analytical techniques for the control of the quality of medicines (microbiological)	External	1 person	High
Validation of analytical methods	External	2 from Chemistry 1 from Microbiology	High
Maintenance, calibration and qualification of equipment	External	Quality Manager + 1 – 2 technical people	High
Security procedures in the laboratory	External	1 from Chemistry 1 from Microbiology	High
Good Laboratory Practices	External	At least the Quality Manager	Moderate
English language	External	At least the staff for which an external training is planned, and other members if necessary	Moderate

Notes:

- Training courses with high priority should be carried out **before end 2007**
- Training courses could be searched in Portuguese or Spanish speaking countries to facilitate the communication. The WHO could help the LNCQM to find appropriate organisers of training courses and, whenever possible, sponsor the travel and accommodation to attend such courses
- In the case of external courses, the knowledge acquired should be immediately transferred to all the LNCQM staff by organising an internal training. This training should be appropriately documented.

**PREPARATION OF AN IMPLEMENTATION PLAN
/ PLAN OF ACTION FOR PROCUREMENT
AND SUPPLY MANAGEMENT
IN MOZAMBIQUE**

**Department of
Technical Cooperation for Essential Drugs and Traditional Medicine,
World Health Organisation**

October-November 2006

Prepared by Bada Pharasi

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1. TERMS OF REFERENCE

Under the supervision of the WHO Representative in Mozambique, the technical guidance of the Director TCM and the Coordinator EDM in AFRO and on the basis of the findings of the WHO evaluation of the pharmaceutical sector in Mozambique, the consultant's brief was to carry out the following:

- 1- Assist the CMAM in the development of necessary tools for the assessment of medicines and medical supplies needs; estimate necessary human and financial resources required and plan for building capacity of personnel involved.
- 2- Assist with the establishment of a tender board; develop tools and mechanisms for the board to operate including for the establishment of internationally accepted tender methodology; assist for the establishment of a reliable source of supplies.
- 3- Assess needs for storage and distribution in central medical stores in the country in terms of the structure, tools, effective logistics mechanisms and capacity needed to ensure effective practices and provide advice and a plan for the training of personnel
- 4- Assess needs for human resources and develop a plan and approach to strengthen capacity in health facilities with regard to selection, quantification, storage and distribution and monitoring of medicines use - develop relevant tools and training material
- 5- Quantify any wastage of medicines arising from oversupply through the kit system; review the cost benefit of the current kit system; make recommendations for modification of the kit content or the distribution system to improve cost effectiveness.
- 6- Review the level of harmonization of the National Formulary, hospital lists and treatment guidelines and draw up a plan for any corrective revision that may be required.
- 7- Carry out other tasks as requested by WHO Representative that are in line with findings and recommendations of the evaluation of the pharmaceutical sector and that will help improve procurement and supply management in the country

[1st November 2006].

2. BACKGROUND

This assignment was necessitated, by and large, by the outcomes and recommendations emanating from the report "External Evaluation of the Pharmaceutical Sector in Mozambique". Clearly, however, there had already been a political decision for certain aspects of pharmaceutical services delivery to undergo drastic changes, and the Evaluation's findings and recommendations could be seen, in part, as justifying and endorsing that decision.

The Evaluation made its findings based on a study of available documents, interviews and discussions with officials in the Ministry of Health and with staff and stakeholders involved with the supply and use of medicines within the health services of Mozambique.

A description is given of the funding of pharmaceutical services, the human resources situation (which is described as quite grave), the procurement and medicines supply management system, the greater part of which is out-sourced to a private company that has been holding a monopoly for a considerable period.

The Evaluation gives recommendations, some very specific, some general, with a draft implementation roadmap to be followed. The roadmap had a time frame of 3 months, spanning from October to December 2006, which was, presumably, the intended duration of this consultancy.

3. METHODOLOGY

A month was allocated for the completion of this assignment. This was against the expectations of CMAM officials, who indicated that they had expected 3 months to be allocated to the task. The bulk of this time was necessarily going to involve the consultant acquainting himself with the structure, modus operandi and current state of Mozambique's health services, in general, and pharmaceutical services, specifically and to a more intimate extent. The feasibility of implementing the policy decisions and the Evaluation's recommendations would then be weighed against an assessment of the existing skills and capacity within CMAM. Based on the assessment, it would then be necessary to identify training needs in order to close the skills gaps, as well as identify and propose operational changes that would have to be made in line with the recommendations and policy decisions. Finally, an Implementation Plan/Plan of Action would need to be drafted which would be presented to WHO and the Minister of Health for consideration.

From the terms of reference, it is clear that the work for this assignment was to be confined almost entirely to the medicines procurement and distribution aspects of Mozambique's pharmaceutical services. This was confirmed in discussions with WHO Geneva and the WHO mission in Mozambique. Thus, the bulk of the interaction was with officials of CMAM, the procurement unit of the pharmaceutical service. However, for one to place in context the challenges facing CMAM, it was going to be necessary to gain a holistic understanding of the health service of the country as a whole, and of the pharmaceutical services in particular. Thus, a number of interviews took place outside CMAM, although, given more time, it would have been fulfilling to have spent more time with other role players in the pharmaceutical services and the national Department of Health.

The methodology consisted of the following:

- Interviews with key officials of the Central Agency for Medicines and Medical Supplies (CMAM), the general manager of MEDIMOC, the pharmacist in charge at Maputo Central Hospital, the director of pharmaceutical services, a member of the Technical Commission for Medicines and Medical Supplies (CTTF) who is also attached to the Pharmacovigilance Unit at the local university, some of the service providers involved in the development and implementation of the Integrated Management System for Medicines (SIGM), and officials of Management Sciences for Health (MSH), a Boston-based American non-governmental organization that had some involvement in the training of pharmacy personnel in Mozambique in the early nineties;
- Visits to the 10 satellite medicines depots around Maputo, the pharmacy department of the Maputo Central Hospital, a health centre in Maputo, and the new central medicines depot currently under construction in Maputo;
- Studying relevant documentation. In addition to the reports on the assessment of Mozambique's pharmaceutical services covering the periods from 2003 to the most recent Evaluation Report, documents which also provided valuable insight into the state of Mozambique's medicines supply and procurement system included a 1994 MSH report entitled "*Ministry of Health of Mozambique: Rational Pharmaceutical Management Project – Mozambique Pharmaceutical Sector Assessment Final Report*" and a 2004 World Bank report, "*Primary Health Care in Mozambique – Service Delivery in a Complex Hierarchy*". The most recent documents describing tender procedures and guidelines in Zambia and South Africa were also consulted. Finally, of particularly useful application in the practical medicines procurement setting was a 1992 WHO manual, "*Drug Procurement Procedures and Documents Manual*", which was specifically prepared to assist with international tendering in Nigeria and which was produced with the assistance of the World Bank.
- Much insight into the workings of and challenges facing Mozambique's pharmaceutical services was gained through attendance of the 3-day National Pharmacy Workshop held in Maputo, at the beginning of the mission. Although the proceedings were conducted in Portuguese, the consultant managed, through interpretation and translation, to benefit immensely from attending

the workshop by talking to some of the participants and gleaming through some of the reports presented.

- After 4 weeks of interviews, discussions and observations, a workshop was organized which was attended by the staff of CMAM and at which the preliminary recommendations around an implementation plan were presented and thoroughly brainstormed with the participants.
- The recommendations were presented to the Minister of Health the next day. His reaction to the recommendations is indicated against each of the key recommendations further in the report.

4. OBSERVATIONS AND DISCUSSION

As already indicated above, there had already been a policy decision that MEDIMOC's functions would be taken over by CMAM.

It needs to be pointed out from the outset that the structure and the nature of relationships within the various components of the Mozambican Pharmaceutical Services Directorate, and the lines of communication between the Directorate and the National Department of Health, do present somewhat of a challenge for any outsider seeking to interact with the services. There are clearly no set lines of communication between the Director Pharmaceutical Services and CMAM, with the procurement unit appearing to be a separate entity with direct lines of communication to the national department and even the Ministry. The hospital departments of the central hospitals also seem to be directly accountable to the overall head of the hospitals, and do not necessarily take the cue from the Pharmacy Directorate on any common policy issue.

Also, as pointed out by the External Evaluation, it is an unusual situation that the responsibility for medicines selection through overseeing the national formulary is vested in the Pharmacy Directorate, which is the same entity that is also responsible for medicines registration and regulation, a function that would more aptly be handled by an independent medicines regulatory authority with its own secretariat.

However, given that the Ministry has expressed a desire for assistance with the establishment of a formal medicines regulatory body, it is to be hoped that this awkward situation will be addressed at the same time.

With regard to CMAM seemingly functioning independently and having a hotline to the Ministry, so to say, this is clearly a manifestation of the Minister's desire, which he expressed several times during this consultancy, to give priority to making essential medicines available by devoting as much resources and attention to the procurement and distribution functions of the pharmaceutical services as possible. In fact, the Minister has expressly stated that he wishes to see the public sector gain full control of medicines procurement over the next 3 years. Given the levels of availability of essential medicines, especially at the primary health care level of the health service, that have been achieved, it is difficult to fault this strategy.

What one would still hope to see, however, is some strengthening of role of coordination that clearly remains the prerogative of the Head of Pharmaceutical Services. Overall leadership, coordination, liaison and guidance vested in one person will particularly be required if implementation and monitoring of the Plan of Action is to be a success, which is what this consultancy is charged with.

4.1 MEDIMOC

MEDIMOC was created as a State company in 1977 from some of the 31 companies that had been involved in medicines importation. Between 1977 and 1979 MEDIMOC competed with about 4 other companies, but in 1979 was granted exclusive rights for the importation of all medicines into the country. Due to management capacity problems at CMAM, MEDIMOC eventually took over the functions of warehousing and distribution. MEDIMOC became semi-private in 1999 (the Government of Mozambique retains a 30% shareholding) but continued to enjoy the monopoly of being the sole importer and distributor of medicines and medical supplies on behalf of the State.

In an interview with the managing director of MEDIMOC, it was indicated that the organization, 80% of whose activities are said to be devoted to executing its contractual obligations to the Government, has a staff complement of about 125, of which 10 are pharmacists and economists. Interestingly, visits to the medicines depots in Maputo revealed that no pharmacists were deployed at any of the depots. Also, the staff seen at the depots seem to constitute a very small fraction of the staff complement. It has to be assumed that the bulk of the pharmacists and economists are employed in the importation side of the business, possibly mostly servicing the 20% of the importation activities which are with the private sector. It was not possible to determine exactly what the job descriptions of the pharmacists and other staff members who may be involved in the medicines importation side of the business were. It would appear, however, that in as far as the State side of the business is concerned, many of their staff could be deemed to be redundant. Expressed differently, it would seem that far less human resources are devoted to MEDIMOC's business with the State than they are remunerated for.

The managing director expressed concern at the fate of the bulk of its 125 employees once all functions had been taken over by CMAM. What would seem to compound the problem is the fact that their salaries are significantly higher than those paid by the Government to CMAM employees.

After years of operating without a contract, MEDIMOC was awarded a two-year contract which expires at the end of December 2006. The contract has been extended for another 12 months, during which time MEDIMOC is expected to transfer all functions and skills to CMAM in the areas that they have been responsible for.

No written confirmation of the intention to terminate MEDIMOC's contract permanently had as yet been conveyed to them in November 2006. When this is done, it would also be advisable that this formal notification be accompanied by a memorandum outlining MEDIMOC's obligations with regard to handing over functions and transferring skills to CMAM, with a time table that includes time frames and that would commence in January 2007.

4.2 Central Medicines and Medical Supplies Procurement Service (CMAM)

The challenges facing CMAM in the next 12 months include taking over the functions of MEDIMOC with regard to importation and customs, preparation of tender documents and overseeing of tender functions, warehousing and distribution, taking over and managing the new medicines depots in Beira and Maputo, as well as implementing the SIGM and the recommendations of the External Evaluation. Of necessity, an assessment of CMAM's capacity to meet all of these functions needed to be performed.

CMAM is led by a director and is made up of the divisions of Projects and Planning, Procurement and Importation, Distribution, Finance and Internal Audit.

4.2.1 The Projects and Planning Unit is responsible for identification and quantification of needs in terms of essential medicines and anti-retrovirals (ARVs). However, the unit is currently not involved in the planning and quantification of supplies for the various parallel programmes, which include medical supplies, blood and consumables for other programmes (Blood bank, malaria, TB, immunization, etc). Requirements for these programmes are submitted directly to the Procurement and Importation Unit. It is the intention, though, for the unit to coordinate with the various programmes to ensure that planning for all medicines and medical supplies is done comprehensively within CMAM. With time, it is also the intention to come up with a database for the use of the kits, and to do forecasting studies of utilization, leading to rationalization of the composition of the kits. The unit was advised to draw up a schedule for the incorporation of the procurement of all medical supplies through CMAM.

The unit is staffed by 3 pharmacists, one of whom is on contract and will eventually be leaving. In a document outlining their needs for the new tasks, the officials of CMAM give an indication of additional staff requirements for each and every unit. *Additional* staff requirements for this unit are 1 pharmacist, 2 pharmacy technicians and 1 technical manager.

4.2.2 The Procurement and Importation Unit. Once the list of medicines from Planning has been approved by the Minister, the list is handed to Procurement. Procurement receives lists of requests from all the programmes via Planning. Procurement prepares tenders and sends the lists to MEDIMOC, asking

them to prepare the tender documents (instructions to bidders). The tender documents go back to Procurement and are reviewed by Procurement for fairness, ensuring, inter alia, that the call for products is by generic name and that there is no reference to company-specific names. At the same time, MEDIMOC also supplies a proposed list of bidders to Procurement, based on the prequalification process.

In a country that purchases the bulk of its medical supplies on international tender, there is necessarily a very complicated procurement chain that includes various procedures from prequalification, inviting of tenders, importation, customs clearance, application for the release of funds from the central bank, payment of suppliers and eventual delivery of supplies. A number of problems and potential problems were detected in the procedures. In order to gain a clear understanding of the problems here, it would be necessary to give a detailed description of the process.

The prequalification of suppliers used to be the sole prerogative of MEDIMOC until the donors, with the concurrence of the Minister of Health, decided that this was to be done by the Department of Health. The Department, with the assistance of WHO, then contracted NIC, a Dutch company, to do the prequalification. NIC's track record includes doing procurement for Tanzania and Uganda, doing procurement of EDP kits for Mozambique and other countries on behalf of the Dutch government up to 2002 and acting as consultants to WHO.

The prequalification of suppliers was last done in 2004 and needs to be reviewed. NIC prepared two documents - one outlining the requirements from the potential bidders, and the second one outlining the evaluation guidelines. The call for suppliers was then advertised in the local press and the UN Development magazine. Companies sent their profiles and all other documents – one set to NIC in the Netherlands and another to CMAM. Two months were allowed for evaluation from the closing date. There was one process for the prequalification of essential medicines, a separate one for the EDP kits and yet another for the programmes – TB, X-ray, disposables, etc.

In order to qualify, companies had to score at least 55 points. Once a certain number qualified, a short-list of the 10 best companies was compiled. Where some of the short-listed companies had not fulfilled all their obligations/requirements, they would be replaced by those in line from the rest of the qualified companies.

The short-list was sent to MEDIMOC, which then invited the companies to submit bids. This is known as Limited Competitive Bidding (LCB). This is the main tender type used in the country. Occasionally, the International Open Tender (IOT) system is also applied. IOT is said to be problematic as it leads to the receipt of many poorly prepared tender documents, but it is a requirement of bodies such as the World Bank. IOT is also said to be very tedious and time-consuming. Typically, companies are given 41 days to submit. It is the same period for LCB, but cut down to 30 days for emergencies.

The opening of bids is chaired by CMAM. Two types of system are used for the tender process: i) If they use funds from the pool of donors, the process goes to SGS, a French company which reviews the tender documents on behalf of the donors and does short-listing. If satisfied, they then declare the process free and fair and approve. Thus, SGS will be present when the bids are opened. Presently, CMAM, SGS, MEDIMOC and the bidders attend the opening of tenders, and every one of these parties signs the bids. Effectively, SGS represents the donors. ii) SGS is not present if it is the State budget which is used for the purchasing of supplies.

MEDIMOC then prepares a spreadsheet to compare the bids (evaluation of bids). For the adjudication of medical supplies, samples are sent to every programme (TB, Blood bank, etc), which then submit technical reports to CMAM. If the technical reports show discrepancies, MEDIMOC's decision must be changed, as the technical specifications prevail over price.

It would appear that quality assurance is an area that has been neglected. There have been very few cases of suppliers' bids being rejected as a result of their products failing to meet the required technical specifications. Yet examples abound of products that should have been rejected owing to poor quality. Maputo Central Hospital has compiled a list of products of inferior quality, an example being adhesive

zinc oxide plaster that is not adhesive. At one of the satellite depots in Maputo, products were deteriorating in storage due to the use of packaging that does not meet the tender specifications.

MEDIMOC then submits the final report to CMAM, which, in turn, sends it on to the Department of Health for the Minister's approval. The Minister reportedly personally goes through the reports. In the first 6 months of the present Minister's reign, almost every tender document has been sent back for explanations and review. He has now taken over from the deputy minister as the one who interrogates the awards. While this thorough interrogation of the tender awards is commendable, it is unfortunate that it has to be done at the highest level in the Ministry, given the Minister's busy schedule. *Unavoidably, this has resulted in crucial delays.* (CMAM initially submits the documents to the national director for scrutiny, and receives them back in 3 days. They are then re-submitted to the Minister, and are usually returned in about 15 days)

Once approval is received from the Minister, CMAM instructs MEDIMOC to sign the contracts on behalf of the Minister. If it is donor money that is used, the reconciled financial and technical reports have to be sent to SGS at the same time as they are initially sent to the national director of health. CMAM sends the awards to the Central Bank for the release of funds.

MEDIMOC informs the successful bidders of the details of the awards and asks them to submit pro-forma invoices. *Serious delays and other problems are encountered at this stage.* The successful supplier sends the pro-forma invoice to MEDIMOC, which passes them on to CMAM. Based on the pro-forma invoice and adjudication results, CMAM prepares a Request for Payment, which is submitted to the Department of Health's Directorate of Administration and Management (DAG), although before that it must first go to the Minister for approval – "Approval of Payment". If the funds are from the General Common Fund, DAG will pay directly to CMAM. If the money is from the Government budget, DAG will send the request to the Ministry of Finance, which will pay DAG, whence the money flows through CMAM to MEDIMOC.

MEDIMOC will then open the Letters of Credit (LOC) with the successful suppliers. This enables the bank to begin the process of payment of suppliers on presentation of certain documents, e.g. Bill of Lading, etc.

Delivery times are counted from the opening of the Letters of Credit. The pro-forma invoice is also used to start the importation process. First, MEDIMOC applies to the Directorate Pharmaceutical Services for BIEF (authorization for pharmaceuticals to enter the country). Then MEDIMOC applies to Customs for the clearance of the goods. The Intertecht Testing Service (ITS), on behalf of Customs, performs pre-shipment inspection at the source. The import licence number is sent to the supplier, who invites ITS over to inspect the goods. ITS in the country in question will send a report to ITS Maputo, who may issue a Clean Report of Findings (CRF) if all is well and no discrepancies are detected. MEDIMOC then takes the entire set of documents to Customs to clear the goods.

If ITS finds discrepancies during its inspection, they will issue a Non-negotiable Report of Findings (NNRF). On the basis of this, there will be no clearance, no payment and no shipment. But if the goods are sent anyway, they will be kept by Customs, and the importer (CMAM) fined 5% of the value of the goods. The issuing of NNRF signifies a lot of problems – the goods could be kept for at least 25 days while storage has to be paid for.

Notable areas of serious concern that need to be addressed as a matter of urgency in the above process are as follows:

- *It would appear to be a common occurrence for suppliers to be paid merely on the basis of the lodging of the LoCs and presentation of certain documentation, even before shipment begins, and without the necessary inspection being enforced.*
- *Once the supplier has been paid and the goods shipped, the supplier often abrogates all responsibility for the safety and security of the goods. No agent is present to receive the goods at the port on behalf of the supplier in order to guarantee that the goods have been received in*

good order and have not deteriorated during shipment. Corrective/punitive action is seldom taken, if any, against the contracted supplier.

- *The above process describes the process as it pertains to medicines, for which import duties are not payable. For medical supplies and equipment, payment of import duties has to be applied for. This involves using HS Coding to get the dutiable amount, then starting the whole process all the way up to DAG, then to the Minister of Finance. The latter will issue a document to be presented to Customs, back through the same route to CMAM and, eventually, MEDIMOC. THIS COULD TAKE UP TO 2 TO 3 MONTHS.*

Several remedies need to be considered in order to address the above problems, which cost the Mozambican Government lots of financial resources in unfruitful expenditure.

Firstly, it should be ensured that suppliers are paid only once it has been certified that the goods have been received in good order at one of the country's ports. The Government could even consider having as a tender condition the requirement that all suppliers have a presence in the country. An immediate advantage of this would be Government's ability to apply any sanctions against the supplier for failing to meet the tender specifications or any other requirements, including refusal to accept the goods. The case of the non-adhesive zinc oxide plaster comes to mind again. The successful bidder for the supply of the zinc oxide is a company based in Denmark, but which sources the products from a Chinese-based company. Clearly, the Government has very little recourse to remedial or punitive action in this case.

Secondly, there appears to be no reason why CMAM or MEDIMOC should bear the responsibility and cost of Customs clearance on behalf of the suppliers, other than that it has been historically the case. The Government could consider leaving this responsibility to the suppliers, but putting in place support mechanisms and concessions that would facilitate the clearance process for importers. This would also have the effect of removing a great burden from the under-staffed CMAM.

Admittedly, it could be argued that resorting to such measures may present new costs to suppliers, which would be passed on to the Government by the supplier, or simply discourage foreign-based companies from tendering. However, these are issues that will need to be explored in greater detail before any position is taken either way.

Thirdly, while it is commendable that no duty is payable on medicines, it appears illogical that certain medical supplies and equipment, many of which are used in conjunction with or as an aid to medicines, are not exempt from payment of duty. The reasons for this were, admittedly, not explored by the consultant. It is recommended that the revocation of duty on medical supplies and medical equipment be carefully considered by the Government.

All of the above tasks are daunting when one considers that the unit is staffed by 1 logistician (economist), 1 pharmacist and 2 customs technicians only. A second pharmacist was moved from Procurement and is now involved with the drugs management information system (SIGM) on a full-time basis. The logistician has been with the unit for about 9 years, most of which have been spent in procurement. He is training the rest of the staff, who are all relatively new, but will be leaving at the end of the year. He is the only employee of CMAM who has participated in the pre-qualification process, and has useful insight into its strengths and weaknesses. His presence during the review of the pre-qualification process would be vital. If CMAM is to take over successfully the functions of MEDIMOC, it will be crucial that the services of this experienced official be retained, even if for a short contract lasting 3 to 6 months, during which time he would foresee the transfer of skills from MEDIMOC to the CMAM Procurement staff. During the presentation of the recommendations to the Minister in November, he undertook to extend the contract of the official at once.

CMAM have indicated that, ideally, they will need the following *additional* staff in the Procurement and Importation Unit: 1 pharmacist, 1 legal practitioner, 2 pharmacy technicians, 1 general nurse, 1 technical manager (administration officer), 1 accountant and 2 administration assistants. Removal of the responsibility for Customs clearance would clearly have a bearing on staff requirements.

4.2.3 The Distribution Unit is responsible for overseeing and authorizing the movement of supplies to the regional depots and the hospitals. Requisitions are sent by the regional depots and hospitals to this unit of CMAM. They analyze and verify quantities and decide how much to supply. If there are not enough stocks to meet the demand, CMAM Distribution applies rationing, using a formula that takes into account the number of hospital beds, quantity at hand, etc. Once quantities have been finalized, MEDIMOC is instructed to supply from the depots. (Actual management of the medicines depots and deliveries to the provinces and hospitals is the responsibility of MEDIMOC)

The staff complement of this unit is currently 3 pharmacists and 2 pharmacy technicians. *Additional* staffing requirements for the Distribution Unit as indicated by CMAM include 5 pharmacy technicians, 1 laboratory technician, 4 administration officers, 3 logisticians, 6 general hands, 2 drivers and 3 administrators. It is foreseen that a pharmacy technician will be deployed to each of the 3 regions.

4.2.4 Internal Audit Unit. This unit is currently responsible for ensuring procedures are followed down the distribution chain. They also do on-the-job training and can recommend further training where they perceive gaps. It is intended that they also do auditing throughout the various units across the organization. They have only 2 staff members at the moment, viz a pharmacist and a pharmacy technician.

They have identified *additional* staffing requirements of 1 pharmacist, 3 pharmacy technicians, 1 accountant/auditor and a media and administration officer. It is pointed out, however, that auditing is normally done in pairs and that they should, ideally, look at employing 2 instead of 1 auditor.

4.2.5 Administration and Finance Unit. This unit, responsible for all the usual financial duties, will need additional accountants and administration assistants.

4.2.6 The Information Technology Unit, responsible for providing IT support, which will include maintenance of the SIGM, is currently being staffed by contract staff. They will require the full-time services of a database administrator and a network administrator.

4.3 Integrated Management System for Medicines (SIGM).

SIGM was created by integrating the databases of the different units in CMAM. Prior to this, the various units operated as stand-alone units and information exchange among the units was done through the printing of hard copies. Implementation of the system is still in progress. It is intended for the system to integrate all the processes within CMAM, capture all procurement transactions, information on contracts and contractors, and allow for electronic placing of orders.

The officials list the following as important achievements as a result of implementation of SIGM:

- The nature of the system is such that once contracts have been finalized, data cannot be tampered with. This is touted as a particularly major achievement, as it will ensure the integrity of the information in the system is protected. The system will also allow for a trailer report showing exactly who was working on what and at what time.
- The new system allows CMAM Procurement to know what has been received at the warehouses. This was previously not possible, with the warehouse receiving stocks that went unrecorded.
- The system will allow for automatic back-orders, making it unnecessary for clients to re-order items which had not been supplied against the last order.
- The system has the flexibility to play around with pack sizes in order to supply the exact quantities wanted by a province.
- The system now allows CMAM to create orders, which is said to be crucial. It allows for communication between CMAM Procurement and the warehouses. Procurement will now have at its disposal the necessary information to control receipts, orders, etc. Crucially, quantities of donations received were often not recorded. Most information about donations was not forthcoming. Now all of this will be captured centrally.

4.4 Warehousing and Distribution

Ten medicines depots scattered around Maputo were visited during November. So-called Depot No 8 and Depot No 9 are the largest, with MEDIMOC directing operations from No 8. The rest of the depots, the satellite depots, were clearly necessitated by the lack of adequate storage space at the main depots. Judging from the inventory in the smaller depots, there was no pattern as to the type of stocks to be kept in each one of them. Boxes of Kits A, B and C were to be found in almost every one of them, mixed with boxes upon boxes of infusions, injectable antibiotics, dressings and stationery. In one depot (Bagamoyo) large stocks of UNFPA condoms were observed which had reportedly deteriorated due to excessive heat.

The value of the stocks in the satellite depots, including the expired ones, could not be readily ascertained. Stock cards are not kept at the satellite depots, although all the stocks were said to be accounted for at Depot no 8. Although the depots are kept locked, there is no round-the-clock security provided, with personnel dispatched there as and when required. Notably, should anyone who has access to the keys drive to one of the depots and remove stocks, no-one would be the wiser for a considerable period of time. No records are kept of visits undertaken by personnel to the depots for whatever reason.

Cartons in the warehouses bore no special markings to differentiate them from stocks meant for the private sector, and interviews with some CMAM staff revealed that, indeed, there was no difference in appearance between stocks seen in private facilities and those belonging to the public sector.

It was agreed that CMAM would carry out an inventory of stocks in all the satellite depots in December and put in place stock cards. Security personnel would be stationed at the depots and CMAM officials would do weekly checks. These new security measures would remain in place until the stocks were transferred to the new central depot.

The new central medicines depot still under construction in Maputo was also visited in November. Although occupancy of the depot was planned for February 2007, the assistant site manager warned that, due to some (unspecified) constraints, the depot was unlikely to be ready for occupation until June 2007. The new depot in Beira is already functional and its management was to revert to CMAM before the end of 2006.

Owing to a number of factors, including the fact that stocks have to be transferred from the satellite depots around Maputo to the new depot, the imminent transfer of functions from MEDIMOC to CMAM, the need for CMAM staff to be given warehousing training, and the possible change of ordering schedules (see under "Recommendations"), it is recommended that CMAM plan around an occupancy date of September 2007.

According to the Report of the External Evaluation, storage facilities at all levels were inadequate as a result of the quarterly ordering intervals, which requires the storage of up to 5 months of stock (including 2 months' buffer stock) at each point in the system. This inadequacy of space was, indeed, in evidence at Maputo Central Hospital and at the satellite depots.

The possibility of introducing shorter supply intervals was discussed with CMAM Distribution staff and with the pharmacists at Maputo Central Hospital. In the view of the pharmacists at Maputo Central Hospital, more frequent supply intervals (e.g. monthly) would increase the burden on their already depleted staff, but there was general agreement that, with proper planning, monthly scheduling of orders would be quite feasible.

An objection raised to this proposal came from the IT experts responsible for implementation of the SIGM. They warned that the planning of SIGM was initiated years ago and that its development was closely linked to the quarterly supply intervals. Changing the frequency of supply would, in their view, require a re-designing of the information management system. The logistics consultants sub-contracted to implement the system in the depots believe, however, that SIGM is adaptable to such changes. Clearly, an information management system that displays such inflexibility would pose problems for any future attempts to bring about improvements to the system, and its long-term usefulness could be called into question.

Another idea that was raised with the CMAM staff was the possibility of introducing direct deliveries from the suppliers to the regional depots and the hospitals, particularly of bulky consignments such as vacolitrés. In line with the foregoing proposal, orders would be placed on a monthly basis with the suppliers. This would reduce congestion at the central medicines depot in Maputo. However, it was pointed out that multiple deliveries would result in excessive import duties and other costs having to be paid. This may be so, given that only medicines are exempt from the payment of import duties, while medical sundries, which form a considerable percentage of all supplies used in the health system, still attract import duty. The idea of revoking import duties for all medical supplies was raised earlier. This would remove what appears to be the major obstacle to direct supplies to the regions and the hospitals.

Finally, with regard to warehousing and distribution, it has to be pointed out that, in terms of the policy decision, CMAM might find itself having to take over from MEDIMOC even before completion of the central medicines depot. They may not be able to find and train the staff to take over all functions at all the satellite depots to enable the system to function optimally in the short term.

The likelihood of the new depot being ready for occupation any time from February 2007 is even more daunting, given the current lack of readiness of CMAM, which is characterized by lack of warehousing expertise as well as the requisite numbers of suitable staff.

Experience of warehousing and distribution trends in South Africa has shown that management of procurement and distribution has been more efficiently and cost-effectively managed when the functions have been out-sourced to private contractors. But this has been successful only where effective monitoring and evaluation mechanisms have been put in place. Furthermore, effective monitoring and evaluation mechanisms in this regard can only be implemented by authorities who have a sound understanding of medicines procurement, warehousing and distribution. This is a stage that still has to be attained by CMAM.

It is for this reason that it would not be wise for CMAM to resort to out-sourcing warehousing and distribution *immediately* upon taking over from MEDIMOC.

It is vital, therefore, that CMAM engage the services of a logistics/warehousing expert as soon as possible, and certainly far ahead of the opening of the central medicines depot. It would be necessary for such an expert to move into the depot even before the completion of its construction, in order to familiarize themselves with the lay-out and make timely interventions where they deem it necessary to deviate from the planned construction to ensure smooth logistical operations. The expert would have to develop standard operating procedures (SOPs) for depot operations, which would include determining, if necessary, new ordering and delivery time-tables in consultation with the hospitals and the regional depots, as well as transport arrangements. The feasibility of direct deliveries would also be given greater attention at this stage.

The expert would then have to determine optimal staffing levels, based on the envisaged workload of the depot, working closely with CMAM. It is not inconceivable that this may affect the current operational culture at CMAM, where interaction between the various units had seemed to be somehow disjointed until the advent of the medicines management information system. As the national Procurement Unit, CMAM's various units will have to be less discernible as separate entities. Another possibility is that officials of CMAM Distribution may have to be more intimately involved in overseeing the processes at the depot than is the case at present. Even where contracting out of the depot services is considered, a pharmacist at a senior level would have to represent CMAM at the central medicines depot on a full-time basis.

Once the systems are in place, the SOPs finalized and CMAM staff well-acquainted with the warehousing and distribution operations, the director of CMAM would be in a position to make a determination as to whether optimal staffing levels for running operations internally are attainable, or whether it might be more advisable to consider contracting out the services. Obviously, considerations other than merely having enough staff come into the equation when out-sourcing is considered. For one, the high turnover of staff in the public sector as a result of uncompetitive salaries is a trend that will invariably always result in staff shortages. Entrusting the task of providing the services to a private entity on a contractual basis enables the principal to insist on a certain set of standards being in place for the agreed period of

time, as the purchaser of the services. Penalties would also be applicable. Another important consideration is that risk (of losses due to theft or expiry) is transferred to the contractor.

The decision whether to out-source or not will have to be taken as soon as possible in the new year in order for the tender specifications to be prepared timeously.

4.5 The Kit System

The medicines kits are pre-packed overseas, with a fixed composition and quantity of essential medicines appropriate for the primary health care level, and shipped directly to the primary health care units, where there are no doctors, via the regional medical stores, which do not temper with them. The composition of the kits, A, B and C, is in line with prescriber levels, with Kit A being for the highest level, that is for health centres where patients are seen by a medical assistant (a qualified nurse who has been given specialized clinical training).

The kit system has ensured that most medicines are available at the PHC level. But it is also responsible for many items accumulating and eventually expiring, as the supply quantities are fixed and do not take into account the current requirements or disease profiles of a particular district or health centre. It is also noteworthy that, even though there was a policy change which led to chloroquine being replaced by amodiaquine and the sulfadoxine and pyrimethamine combination at the end of 2004, chloroquine continues to be supplied in the kits in 2006. So, effectively, while the kit system ensures the availability of essential medicines at the PHC level, this is achieved at a huge cost in terms of medicines being supplied needlessly and expiring on the shelves.

It was not possible, within the time allocated for this assignment, to quantify the wastage of medicines arising from oversupply through the kit system. Furthermore, it would be premature, at this stage, to make concrete recommendations for modification of the kit content. Only once the Maputo central medicines depot is up and running and an assessment completed of its ability to improve the medicines distribution system and, possibly, take on more of the distribution responsibility, will it be possible to give more attention to rationalizing the kit system.

The overwhelming view is that the kit system should not be shelved, but that efforts should be made to ensure that the composition of the kits reflects the health needs of a particular region. In the Minister's view, dealing with the kits is not an immediate priority. The possibility of the kits being prepared in Maputo was rejected by most as this would mean supplies being transported by road from Maputo, which could be even more expensive and would result in long delays, given the state of the national roads.

What is being recommended to the authorities is to ensure that all health facilities are fitted with facsimile machines, which would allow them to submit their own orders based on their needs, eventually. Management of the new central medicines depot in Maputo will be encouraged to dedicate some effort to establishing communication mechanisms with the facilities so as to allow for emergency interventions from time to time. A plan for revamping the kit system will have to be embarked on by the depot management, as pointed out above.

4.6 Central Hospitals

One of the terms of reference requires an assessment of the needs for human resources and development of a plan and approach to strengthen capacity in health facilities with regard to selection, quantification, storage and distribution and monitoring of medicines use. It calls specifically for the development of training materials and tools.

The External Evaluation highlighted the shortage of human resources in the entire pharmaceutical service in the public sector, singling out the low Government salaries for pharmacists and lack of incentives as a major reason for the inability to retain pharmacists in the system.

Maputo Central Hospital, with about 1600 beds, has only 2 pharmacists who, between the two of them, have to attend to administration and management issues, liaise with the hospital executive, supervise 13

medium and 33 basic pharmacist's assistants/technicians, supervise pharmacy interns and other trainees and deal with a workload of over 400 out-patients per day.

And yet Maputo Central is the best-staffed of all the hospitals!

The amazing level of work achieved by the pharmacy department at Maputo Central Hospital has to be seen to be believed. No doubt, the same level of commitment would be evident at the rest of the hospitals, an assessment that would be easy to make from attendance of the 3-day national pharmacy workshop. But, as the External Evaluation observed, there will continue to be shortages of human resources for some time into the future. It also remarks that 'pharmacy technicians are responsible for managing and operating the drug supply system at provincial and district levels and they are, and continue to be, the "backbone" of the pharmaceutical services.'

A national Human Resources Commission for pharmacy is in existence, but their task is clearly to come up with a long-term strategy for producing pharmacy personnel and for devising means of keeping them in the public sector. Clearly, this strategy will have to be characterized by a bias for churning out more pharmacy technicians, ensuring that pharmacists are utilized mostly in positions of supervision and in the more clinically demanding positions in the central hospitals and the medicines registration system.

In the short and medium term, it is recommended that training be provided in the areas of rational medicines use, quantification (at all levels), ordering and stock control in the hospitals and the primary care clinics. Of particular importance will be the setting up of pharmacy and therapeutics committees (PTCs), initially in the central hospitals, but, eventually, in some or the other form, in the district hospitals as well. A concrete proposal relating to on-the-job training is presented in the attached Plan of Action (POA).

4.7 Medicines Selection

The External Evaluation recommends the updating of formularies and treatment guidelines and the implementation of systems for professional development and for monitoring and evaluation. This consultancy was thus requested to "review the level of harmonization of the National Formulary, hospital lists and treatment guidelines and draw up a plan for any corrective revision that may be required".

The head of pharmaceutical services indicated that review of the national formulary, which had last been reviewed in 1999, was in the process of being finalized and that she did not envisage that they would need any assistance with that. Medicines selection was the responsibility of her directorate, which was assisted in the task by the Technical Committee for Therapeutics and Pharmacy (CTTF). The current membership of the CTTF included 2 pharmacists, one of whom was from the manufacturing industry and 8 medical practitioners in the specialities of anaesthetics, obstetrics, cardiology, pharmacology (3) and internal medicines (2).

There is, nevertheless, wide agreement that pharmacy and therapeutics committees need to be set up in the hospitals. As it is, specialists in the central hospitals are increasingly prescribing items which are not on the national formulary, forcing the pharmacy departments to stock more and more non-formulary items in the absence of any clear standard operating guidelines for such purchases.

A programme for training in the setting up and functioning of pharmacy and therapeutics committees is included in the recommended Programme of Action.

5. RECOMMENDATIONS

Transfer of functions from MEDIMOC to CMAM

(1) It will be necessary for the decision to end MEDIMOC's involvement in pharmaceutical services to be formalized through official written notification. This should be accompanied by, or followed up with, the signing of a memorandum of understanding that details the functions to be handed over by MEDIMOC together with a time-table outlining the transfer of skills with deadlines. In line with the

Minister's expressed wish that MEDIMOC's involvement be terminated completely by December 2007, it must be aimed for the transfer of functions to CMAM to be completed by the end of September 2007.

Pre-qualification and Tendering Procedures

(2) Seeing that the current pre-qualification list expires in 2007, it is recommended that the review of the evaluation guidelines and tender procedures be embarked on immediately, with the involvement of the World Health Organization (WHO) and the Ministry of Finance. This will ensure the involvement of parties not involved intimately in the awarding of tenders and bring about transparency. To this end, the South African Department of Health has been requested to share its database of pre-qualified suppliers with Mozambique's Department of Health in order that the list of potential suppliers to be targeted be expanded. This process should be finalized by the end of March 2007.

(3) Adequate measures should be taken to ensure that the invitation to companies for pre-qualification is published locally, regionally and internationally through the publication of the United Nations.

(4) Proposed terms of reference (TORs) for the establishment of a Medicines Tender Committee for the procurement of medicines, medical supplies and related services by the department of Health are herewith attached as Annex AAA. The TORs are a generic reproduction following a study of tender procedures by other authorities in the region. They are, necessarily, by no means comprehensive. Gaps will have to be filled in which take into account the financial management requirements of Mozambique. An example of such an area is the financial level at which procurement units are delegated powers to make purchases on their own without having to approach the tender committee. It would also not have been possible to complete the entire TORs for the Tender Committee in the time allocated. The procedures which have been in application to date for the adjudication of tenders will still be quite applicable. It is recommended that the establishment of the Tender Committee and the appointment of its members be completed by March 2007.

Warehousing and Distribution

(5) It is clear that it will be some time yet before the new central medicines depot in Maputo is functional and stocks transferred to it. Storage of stocks in the satellite depots in Maputo is nowhere near satisfactory. It is recommended that MEDIMOC be instructed to carry out an inventory of stocks in all the satellite depots and put in place stock cards. The value of the stocks that have expired must be recorded. Arrangements should be made to destroy expired stocks immediately.

(6) A plan should be made by MEDIMOC to re-distribute stocks with a short expiry date. This should also apply to similar stocks in the depots in the rest of the country.

(7) Security personnel should be deployed at all the satellite depots with immediate effect.

(8) CMAM must do weekly security checks at all the depots.

(9) For purposes of future interventions, September 2007 must be identified as the date at which Maputo Central Medicines Depot will be ready for operations.

(10) As CMAM does not have at its disposal the necessary expertise to manage warehousing activities of the scale that will be undertaken at the new depot, it is recommended that the services of a logistics/warehousing consultant be engaged for a period of 6 to 12 months. The consultant will be expected to develop standard operating procedures for depot operations and determine the levels and numbers of staff required.

(11) The consultant, in consultation with CMAM and regional depot officials, must conduct a review of the ordering schedule with a view to implementing more frequent ordering intervals.

(12) The consultant will also be expected to investigate the possibility of direct deliveries to the regional depots and hospitals by the suppliers.

(13) If staff levels are deemed to be sufficient and outsourcing of the depot services therefore unjustified, the consultant must assist CMAM with the recruitment of a warehouse manager (to be in place by May 2007), identify and appoint the rest of the staff required for warehousing and distribution and conduct training (by August 2007). Staffing will be deemed to be sufficient by mutual agreement between the consultant and the director of CMAM.

(14) A schedule must be prepared for the transfer of stocks from the satellite depots to the new central depot by September 2007.

(15) In the event of the determination being made that it will be more cost-effective to contract out warehousing and distribution services, the warehousing consultant will assist in the preparation of tender specifications for this purpose. These should be prepared and tenders invited such that the successful contractor should occupy the depot by July 2007. The specifications will have to include clear monitoring and performance evaluation tools as well as suitable penalties and incentives.

SIGM

(16) The medicines information management system (SIGM) is a vital cog to the medicines procurement and distribution system. CMAM should be required to have in place an implementation and training schedule by January 2007 that fits in with the rest of the POA.

The Kit System

(17) It is recommended that CMAM and CTTF jointly lead review of the composition of the kits in such a manner that regional health needs are taken into consideration. The kit system should, therefore, not be done away with at this stage. This should be done in time for the commencement of the new supply cycle of January 2008.

(18) CMAM, with the assistance of the warehousing consultant, must look into the feasibility of supplying the kits from the Maputo central medicines depot in the longer term. If possible, this should be done in time for the supply cycle of January 2008.

Equipment

(19) All hospitals and medicines ordering centres must be equipped with fax machines so as to enable them to place orders with the medicines depots. This facility will be particularly important for the rural facilities in the event that consideration is given to the scrapping of the kit system with its automatic deliveries.

(20) Central hospitals need to be equipped with computers for dispensing and stock control, as well as for the ARV supply programme.

Training

(21) Short term training aimed at improving service delivery must be arranged to happen on an on-going basis. Training in several areas of pharmaceutical service provision and for medical and nursing staff needs to be embarked on. It will be advisable that a national workshop on the training needs of the country be arranged for all the units of the pharmaceutical service so that a schedule for training can be worked out and agreed upon. It is recommended that renowned training organizations, funders and members of the country's pharmaceutical services come together in such a workshop, to be held not later than the end of March 2007. Training programmes for the longer term could be adopted at this workshop.

6. PLAN OF ACTION / ROADMAP

Area	Activity	Time Frames	Comments
Selection	<ol style="list-style-type: none"> 1. Setting up of Pharmacy & Therapeutics Committees (PTCs) in the hospitals, for the selection of medicines for use at the facility level, and related training. 2. A study visit by 2 or 3 members of CTF to South Africa's Medicines Control Council on registration and inspection functions 	<ol style="list-style-type: none"> 1. April-Dec 2007 2. Feb 2007 	<ol style="list-style-type: none"> 1. This to be preceded by National Pharmacy Training Workshop 2. Contact was made in Nov '06 with SA Health Minister & MCC Registrar
Quantification	<ol style="list-style-type: none"> 1. Training of hospital pharmacy and warehouse staff in the quantification of medicines needs; 2. Training in the use of a tool for the quantification of ARVs 	<ol style="list-style-type: none"> 1. June-Dec '07 2. June-Dec '07 	
Prequalification	<ol style="list-style-type: none"> 1. Finalize review of prequalification & evaluation guidelines & procedures 2. Review tender requirements & appointment of Medicines Tender Committee 	<ol style="list-style-type: none"> 1. Nov '06-Mar '07 2. Jan-Mar '07 	<ol style="list-style-type: none"> 1. CMAM to enlist involvement of WHO & Finance Ministry in prequalification process for transparency 2. Arrange to visit Zambian or SA Tender Board, if required
Transfer of functions from MEDIMOC to CMAM	<ol style="list-style-type: none"> 1. Official notification to MEDIMOC & memo on hand-over & skills transfer 2. Finalize schedule & time-table for transfer 	<ol style="list-style-type: none"> 1. Dec '06 2. Jan '07 	Process to be led by CMAM logistician following schedule
Procurement	<ol style="list-style-type: none"> 1. Short course in procurement methods, for CMAM Procurement staff; 2. Prepare CMAM for take-over (including Planning, Procurement, Distribution, Auditing, Finance & IT); 3. Prepare & implement skills transfer schedule between CMAM & MEDIMOC; 4. Purchasing of supplies for all programmes to be coordinated within CMAM – ensure smooth transfer with the programmes; 5. The members of the Auditing unit may have to undergo training in Monitoring and Evaluation (M&E) 	<ol style="list-style-type: none"> 1. Feb '07 2. Jan-June '07 3. Jan-June '07 4. Finalize by Oct '07 for implementation by Jan '08 	<ol style="list-style-type: none"> 1. WHO to assist 2&3. Head of Procurement to lead, with WHO Logistics expert 4. CMAM Planning to lead process 5. USAID could be approached for training

Warehousing & Distribution	<ol style="list-style-type: none"> 1. Have MEDIMOC do inventory in all Maputo depots & place stock cards & have security guards full-time 2. CMAM to do weekly checks at satellite depots 3. Locate logistics/warehousing advisor at Maputo central warehouse to identify staffing needs, determine standard operating procedures (SOPs), recruit & train staff; <p>alternatively:</p> <ol style="list-style-type: none"> 4. Contract logistics advisor to prepare specifications for warehousing & distribution, and outsource the function 5. MEDIMOC & CMAM to prepare schedule for transfer of stocks to new depot 	<ol style="list-style-type: none"> 1. Dec '06 2. From Dec '06 till move to new depot 3. Convey request at once to WHO, arrange for start date of Feb '07 4. Convey request at once to WHO, arrange for start date of Feb '07 5. Deadline for transfer Sept '07 	<p>WHO and/or Partners to assist with recruitment of logistics advisor.</p> <p>Crucial for advisor to be involved in all Warehousing & Distribution activities</p> <p>Facilities in South Africa can also be visit. Contact with SA's Minister of Health already initiated to this end</p>
Training	<p>Organise national pharmacy training workshop, to discuss training needs & coordinated training schedule, over 3 days</p> <p>Topics: Pharmacy & Therapeutics Committees; Rational Drug Use; Quantification; Drug Ordering & Stock Control</p> <p>Presenters: WHO; MSH/RPM Plus⁷; USAID; Pharmacovigilance Unit at E Mondlane University</p> <p>Participants: Pharmacists from Pharmacy Directorate, CMAM, regional depots and hospitals, plus senior pharm technicians</p>	<p>Finalize in Jan '07, to be held towards end of Mar '07</p>	<p>National Health Director to appoint coordinator/organizer.</p> <p>This is for short courses, mainly on-the-job training. Educational visits and longer term training outside the country also to be considered</p>
Rational Drug Use	<ol style="list-style-type: none"> 1. Use consultant to review standard treatment guidelines; 2. Organize for review of composition of kits, based on regional profiles; 3. Consultant to train medical, pharmacy, nursing & other prescribing staff in rational drug use, at hospital & primary health care level 4. Train pharmacy & community health centre staff in Dispensing, Ordering & Stock Control 	<p>April '07, on-going</p>	<p>This and most other training courses dependent on outcome of training workshop.</p> <p>Workshop to determine lengths of stay of trainers & expenses, as well as expenses for any foreign visits.</p>

⁷ Management Sciences for Health (MSH) is a USA-based not-for-profit organization which assists governments globally, especially in the developing world, in the implementation of programmes aimed at improving the delivery of health services. Rational Pharmaceutical Management Plus (RPM Plus) is an MSH programme which focuses on the improvement of pharmaceutical services. RPM Plus was involved in various training programmes in Mozambique in the 80's and 90's and produced training materials in Portuguese, which would only need to be up-dated. Some of the members of the Pharmacovigilance Unit at the Medical School were trained as trainers, using the RPM Plus training materials and tools. RPM Plus has a regional office in Pretoria, South Africa.

Medicines regulation & registration	<ol style="list-style-type: none"> 1. Consultant to help set up medicines regulatory authority (MRA), with SOPs; 2. Arrange visit to South Africa's Medicines Control Council by MRA staff (1 week); 3. Set up and train medicines inspection unit 	WHO consultant expected to arrive Dec '06; will set up own schedule and fit into overall training schedule	
Equipment	<ol style="list-style-type: none"> 1. Community health centres & hospitals should all be equipped with basic equipment to enhance the ordering of medicines, e.g. fax machines, computers, internet 2. Install computers for drug management at Maputo Central Hospital (at least 4 required, including 1 for the ARV programme) 	On-going throughout 2007	Directorate Pharmaceutical Services to prepare budget for equipment and submit to Minister by Feb '07

Coordination of the Plan of Action

The above Plan of Action includes activities that will span right across the various units of the Pharmaceutical Services. A coordinator will be required who will be accorded the necessary authority to monitor implementation of the POA in all the units.

The POA Coordinator will

- ✓ Liaise between the Pharmacy Directorate, CMAM, the Ministry, WHO and the Partners;
- ✓ Familiarise him/herself with the training programmes and liaise with the trainers;
- ✓ Ensure deadlines are met by all role-players;
- ✓ Arrange for monitoring and evaluation of all programmes in the POA;
- ✓ Give periodic progress reports

✓ ANNEX AAA:

Medicines Tender Committee: Duties and Terms of Reference (Guideline)

1. Membership

Chairman: Director of Health Services

Voting members: Director Pharmaceutical Services (Vice-chairman)
Director Finance & Administration
A representative Hospital Pharmacist
A representative Provincial Medical Director
A representative of the provincial medicines depots
A representative of Treasury

Non-voting members: Director CMAM
CMAM section heads for Procurement, Planning, Distribution, and Audit (one of whom shall serve as secretary for the committee)

Observers: Country Representative: WHO
Two representatives of the Health Partners Group

- (1) All appointments to the Tender Committee will be done by the Minister of Health
- (2) Subject to the provisions of this section, a member shall hold office for a period of two years, provided that a retiring member may be reappointed.
- (3) Upon the expiry of the period for which a member is appointed, he/she shall continue to hold office until his successor has been appointed, but in no case shall such further period exceed three months.
- (4) A member shall cease to hold office-
 - (a) subject to subsection (3), upon the expiry of the period for which he/she is appointed or reappointed;
 - (b) if he/she is adjudged or otherwise declared to be of unsound mind;
 - (c) if he/she is adjudged or otherwise declared to be bankrupt;
 - (d) if he/she is lawfully detained or his/her freedom of movement is restricted under any law in force in Mozambique;
 - (e) if he/she is sentenced to a term of imprisonment exceeding six months;
 - (f) if he/she is absent from three consecutive meetings of the Board without reasonable cause;
 - (g) upon the expiry of not less than one month's notice in writing of his/her intention to resign given by him/her to the Chairman;
 - (h) if he/she is removed by the Minister of Health.

2. Remuneration.

A member other than a public officer or an employee of a parastatal body shall be paid such remuneration or allowance as the Minister may from time to time determine.

3. Functions of the Committee.

(1) The functions of the Committee shall be to regulate and control the procurement of medicines, medical supplies and services for the Department of Health of Mozambique and any other bodies as the Minister of Health may determine.

(2) Without prejudice to the generality of subsection (1), the Committee may-

(a) formulate rules and regulations governing the procurement of medicines, medical supplies and services for the Department of Health of Mozambique and any other bodies as the Minister of Health may determine;

(b) advertise locally and abroad tenders for the procurement of medicines, medical supplies and services for the Department of Health of Mozambique and any other bodies as the Minister of Health may determine;

(c) regulate the procedures relating to the award of contracts on behalf of the Department of Health of Mozambique;

(d) formulate the conditions under which any rules and regulations governing the procurement of goods and services for the Department of Health of Mozambique and any other bodies as the Minister of Health may determine may be varied or waived.

4. Establishment of sub-committees.

(1) The Committee may, for the purpose of carrying out its functions, establish sub-committees and delegate to any such sub-committee such of its functions as it may deem fit.

(2) The Committee may appoint as members of a sub-committee established under subsection (1), persons who are or are not members of the Committee and such persons shall hold office for such period as the Committee may determine.

(3) Subject to any specific or general direction of the Committee, any sub-committee established under subsection (1) may regulate its own procedure.

(4) If a person is present at a meeting of the Committee or any sub-committee of the Committee at which any matter is the subject of consideration and in which matter such person or his spouse is directly or indirectly interested in a private capacity, he/she shall, as soon as practicable after the commencement of the meeting, disclose such interest and shall not, unless the Committee otherwise directs, take part in any consideration or discussion of, or vote on any question touching upon, such matter.

(5) A disclosure of interest made under this section shall be recorded in the minutes of the meeting at which it is made.

5. Meeting procedures.

(1) The Committee shall regulate its own procedure and the validity of any proceedings, act or decision of the Committee shall not be affected by any vacancy in the membership of the Committee or by any defect in the appointment of any member or by reason that any person not entitled so to do took part in the proceedings.

(2) For the transaction of its business, the Committee shall meet at such places and at such times, being not less than once every three months, as the Chairman may determine.

(3) At any meeting of the Committee, one-half of the members holding office at that time shall form a quorum.

(4) There shall preside at every meeting of the Committee the Chairman or, in the absence of the Chairman, the deputy Chairman or, in his/her absence, such member as the members present may elect for the purpose of that meeting.

(5) A decision of the Committee on any question shall be by a majority of the members present and voting at a meeting of the Committee and, in the event of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to his deliberative vote.

(6) Notwithstanding the provisions of subsection (5), a decision may be made by the Committee on any urgent matter by the circulation of the relevant papers among the members, and by the expression in writing of the views of the majority thereof:

Provided that any member shall be entitled to require that any decision shall be deferred until the matter is considered at a meeting of the Committee.

(7) The Committee may invite any person, whose presence is, in its opinion, desirable, to attend and to participate in the deliberations of a meeting of the Committee but such person shall have no vote.

(8) The Committee shall cause minutes to be kept of the proceedings of every meeting of the Committee and of every meeting of any sub-committee established by the Committee.

6. The Seal of the Committee [Optional]

(1) The seal of the Committee shall be such device as may be determined by the Committee and shall be kept by the Secretary.

(2) The Committee may use a wafer or rubber stamp in lieu of the seal.

(3) The affixing of the seal of the Committee shall be authenticated by the Chairman and the Secretary, or by the Chairman and one other person authorised by a resolution of the Committee.

7. Confidentiality.

(1) No person shall, without the consent in writing given by or on behalf of the Committee, publish or disclose to any person, otherwise than in the course of his duties, the contents of any document, communication or information whatsoever, which relates to, and which has come to his knowledge in the course of, his duties on behalf of the Committee.

(2) Any person who knowingly contravenes the provisions of subsection (1) shall be guilty of an offence and shall be liable to a penalty as the Minister may deem appropriate.

(3) If any person having information which to his knowledge has been published or disclosed in contravention of the provisions of subsection (1) unlawfully publishes or communicates any such information to any other person, he shall be guilty of an offence and shall be liable to a penalty as the Minister may deem appropriate.

The Central Medicines and Medical Supplies Procurement Service (CMAM) is already poised to function as the **central medicines procurement unit**, and will have responsibilities for both procurement and warehousing.

In order to improve planning and to facilitate a more rational circulation of medicines and medical supplies within the health system, it is recommended that CMAM coordinate the procurement of all medicines and medical supplies on behalf of all the vertical programmes (e.g. tuberculosis, malaria, Blood Bank, etc) as well. To this end, CMAM should liaise closely with all the other programmes in the health system.

The main responsibilities will be to:

Planning and Procurement

- Operate the supplier prequalification system, receiving guidance from the Medicines Tender Committee. Preference may have to be given to companies based locally or elsewhere in the region, to ensure that recourse can be taken timeously in the event of supplier failure.
- Maintain records on pre-qualified suppliers.
- Communicate with external agencies regarding supplier prequalification and performance.
- Prepare a consolidated list for the procurement of essential medicines based on the national formulary.
- Collate the drug requirements of all the health institutions utilizing data available from the central warehouse, or carry out quantification procedures, or ensure they are properly accomplished for the health institutions (such procedures would include a morbidity-based analysis and a consumption-based analysis of drug requirements).
- Prepare bid documents following Government of Mozambique regulations and, where required, World Bank guidelines or the guidelines of donors/funders where relevant.
- Distribute procurement notices inviting pre-qualified companies to apply for bid documents.
- Publicly open submitted bids, prepare a bid evaluation report, and submit recommended contract awards for approval by the Medicines Tender Committee and/or donors' representatives, as the case may be.
- Prepare contracts for award.
- Dispatch approved contract awards to successful bidder companies.
- Determine appropriate clearance procedures with Customs, providing the necessary support to importing contractors while ensuring that they take full responsibility for Customs clearance and guaranteeing that goods are delivered in good conditions at the ports of entry.
- Control order status and monitor the delivery of goods to the central medicines warehouse, maintaining close coordination with the central warehouse.
- Arrange for the transport of goods to the central warehouse or regional warehouses, as the case may be, from port of entry for imported goods, or from supplier factory/warehouse for goods manufactured within Mozambique.
- Inspect goods received at the central medicines warehouse to ensure compliance with specifications.
- Arrange for quality control steps.
- Serve as advisory body to all the health system facilities in all procurement-related matters.
- Ensure that suppliers are paid promptly on confirmation of contracts satisfactorily completed, the end-point of which shall be goods received at the medicines warehouses or any other specified destination, in good order.
- Monitor supplier performance and order status, and have standard operating procedures (SOPs), with suitable penalties, to this end.

- Implement and operate the procurement information system, including dissemination of information to the health facilities on sources and prices of commonly procured items. This would be necessary only in the event that regional warehouses and central hospitals have the authority to make direct purchases from the contractors.
- Operate the supplier monitoring system, including review of quality control test results on all suppliers participating in project tenders.

Central Medicines Warehouse

- Receive and store medicines, dressing and medicinal supplies, serving as the major storage depot. The possibility of certain items, especially of a bulky nature, being sent by suppliers directly to the regional warehouses, should be investigated.
- Maintain adequate storage conditions for medicines and other medical supplies.
- Ensure efficient distribution of drugs and medical supplies to end users.
- Liaise closely with the Directorate Pharmaceutical Services for BIEF (authorization for all pharmaceuticals entering the country).
- Maintain adequate inventory control and management.
- Liaise closely with regional warehouses.
- Ensure adequate stock control by regular monitoring of product shelf lives and quality.
- Provide or coordinate training on quantification, procurement, the procurement information system (SIGM), etc to the procurement units of all the health facilities.
- Play an advisory role to all the health facilities in all procurement-related matters, which involves travel to the regions to visit procurement units.

Staffing

- The head of CMAM, who shall be a pharmacist.
- At least 3 pharmacists/logisticians, whose responsibilities shall include:
 - Supplier prequalification: external communications with suppliers and regulatory agencies;
 - Supplier monitoring: internal communications with user institutions, quality control laboratories, etc;
 - Analysis of bids;
 - Training of procurement staff at the health facilities.

Other desirable staff shall include one professional staff member with management/business administration background and experience in bulk procurement, and a contract management specialist.

The rest of the staffing requirements, including support staff for secretarial, clerical and administrative functions, shall be determined in consultation with CMAM officials.

Given the serious shortage of pharmacists and in line with a recommendation from the External Evaluation, emphasis should be on utilizing the services of logisticians and skilled supply chain managers, rather than pharmacists, in the details of supply and distribution.

It will be the prerogative of the director of CMAM, in consultation with the Minister of Health, to outsource any of the services described above, but in line with recommendations already discussed with the Minister.

**Report of a Rapid Review of the
Medicine Regulatory Authority of Mozambique**



Alain Prat, TCM/World Health Organization
Eshetu Wondemagegnehu, WHO consultant

World Health Organization, Geneva
February 2007

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Executive Summary

A review of the drug regulatory system of the Republic of Mozambique was conducted by the World Health Organization (WHO) in co-operation with the Government of the Republic of Mozambique from 21 to 23 February 2007. The review focused on the current drug regulatory and control activities which are carried out by the Ministry of Health of Mozambique.

The Pharmaceutical Department within the Ministry of Health is the main body responsible for regulating medicines in the country. Currently the Department carries out regulatory functions, namely medicine registration, registration of pharmacy professionals, inspection and licensing of pharmaceutical manufacturers, importers and distributors.

The assessment showed that Mozambique has in place **a basic** medicine regulatory system backed by drug law that is capable of performing **very limited regulatory activities**.

Weaknesses have been observed in certain areas including poor organization, inadequate legislation, absence of guidelines, procedures and standard operating procedures (SOPs) etc. It has inadequate number of qualified, trained and skilled staff, inadequate and unsustainable funding, inadequate infrastructure, etc. In general, the existing regulatory system is inadequate to ensure the safety, quality and efficacy of medicines circulating in the Mozambique. There is need for reorganizing the existing system and strengthen it. This may be through a systematic implementation of the specific and general recommendations made in this report.

Main recommendations

- In the transitional period to establish formal link between the different bodies performing drug regulatory functions based on written directive to ensure responsibility and accountability and promote better communication.
- Legislation and related regulations to be revised to bring all the regulatory functions under one authority. In particular, the revision needs to create a drug regulatory authority with adequate powers and responsibilities on all regulatory functions
- The new DRA to be provided appropriate financing mechanisms to sustain its operational activities. The fees structure to be revised to reflect the complexity of tasks and legal provision to use part of the fees collected to supplement government budget to be provided.
- The process of product registration is very limited because of limitation in the number, qualification and skills of human resources involved in the process. The development of internal staff capacity as well as external expertise should be of first priority. The Drug Committee should be reactivated with adequate compensation/incentive and training. Meetings should be organized on regular basis. The use of external expert should be expanded.
- The development of human capacity should be taken as priority by recruiting additional personnel and improving the skills and performance of technical staff and by arranging training programmes that can lead to demonstrated improvement in qualification of key staffs.
- Guidance on code of conduct, conflict of interest and confidentiality should be developed for both internal staff and external experts and implemented.
- A system for market control should be established. A coordinated anticounterfeiting program involving all enforcement authorities should be established and procedures for combating counterfeit medicines should be developed.
- National GMP, GDP, GPP guidelines should be established by adopting or adapting the WHO guidelines as minimum requirements for licensing manufacturers, distributors and retail outlets and widely distributed to all stakeholders. A deadline should be set for all local importers and distributors to comply with applicable requirements and agreed upon. Compliance to requirements should be check by means of regular inspection.

- The website of MoH needs to be transformed to integrate information of the new authority and should be one of the major sources of information for stakeholders.
- The record keeping and information management system of the authority should be improved through adequate use of Information Technology (IT) and the production of regular and up to date reports to guide operational and policy decisions.
- An active participation of all stakeholders in Pharmacovigilance activities should be strongly promoted in particular for the private sector.

Abbreviations

CIMED	Centro de Informacao sobre medicamentos
CMAM	Central de Medicamentos e Artigos Medicos
COMED	Conselho do medicamento
CPP	Certificate of Pharmaceutical Product
CTTF	Comissio Tecnica de Terapeutica e Farmacia (CTTF)
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
INS	Instituto national de Saude
IT	Infromation Technology
LNCQM	Nacional de Controlo da Qualidade de Medicamentos
MEDIMOC	Empresa Estatal de Importação e Exportação de Medicamentos
MOH	Ministry of Health
WHO	World Health Organization

1 Purpose of the mission

The purpose of the mission is to:

- review the existing legal framework and regulatory system with regard to pharmaceuticals in order to provide a view of the national regulatory capacity against a set of predefined parameters;
- identify gaps in medicine regulatory system and make recommendations to address these gaps;
- develop a work plan to improve drug regulation system together with the national authority.

2 Method of work

The review was carried out using a questionnaire developed by WHO. Information was collected through interviews with staff of Pharmaceutical Department of the MOH. The mission also reviewed documents made available by the Pharmaceutical Department.

3 Members of the mission

Members of the mission included:

Mr Alain Prat, MRS/TCM/WHO Geneva

Mr Eshetu Wondemagegnehu, WHO Consultant

4 Findings and recommendations

4.1 Organization of the national regulatory system

The establishment of medicine regulation started in 1975 following independence of the country however actual activities started in 2001. Currently, the Pharmaceutical Department "Departamento farmacéuticos" under the "Direcção Nacional de Saúde" within Ministry of Health is the main body responsible for regulating medicines in the Republic of Mozambique. Current functions of the Department include:

- Registration of human medicines,
- Registration of pharmacy professionals,
- Import control
- Inspection and licensing of manufacturers, importers, wholesalers and pharmacies.

In addition, other institutions under the MoH carry out regulatory functions. These include:

- pharmacovigilance by "Centro de Informação sobre medicamentos" (CIMED)
- control of clinical trials by Instituto Nacional de Saúde (INS)
- provision of scientific and technical drug information by CIMED
- testing the quality of medicines by Laboratório Nacional de Controlo da Qualidade de Medicamentos (LNCQM)
- Control of Medical devices by the Department of Medical Assistance

Control of cosmetics is the responsibility of the Ministry of Commerce whereas control of veterinary medicine is under the Ministry of Agriculture.

Gaps

- Medicine regulatory functions are distributed among different organizations without any formal linkage or communication system to coordinate the different activities or exchange information on the outcomes of regulatory functions, for example, between LNCQM and the Pharmaceutical Department, between CIMED and the Pharmaceutical Department, etc.
- There is no organization responsible for the control of herbal and traditional medicines.

Recommendations

- in the immediate short term establish formal linkage between the different organizations engaged in regulatory activities to coordinate activities and improve communication.
- in the medium term bring the various regulatory functions under one organizational structure that is semi-autonomous in decision-making, recruitment of staff and management of its resources.
- in the long term introduce the control of herbal and traditional medicines, cosmetics, medical devices and veterinary medicines under the same organization.

4.2 Legislation and regulations

Several legislation and regulations related to medicinal products and practices exist (see annex 1), in particular on the pharmaceutical practices and licensing of pharmacies, on the registration of medicines, on the licensing of manufacturers, importers, wholesalers, on the definition of price of medicines and on narcotic drugs and Psychotropic substance.

These regulations established different institutions such as Ministry of Health, Comissio Tecnica de Terapeutica e Farmacia (CTTF), Conselho do medicamento” (COMED), Centro de investigacao em saude within the Instituto nacional de Saude involved in the different regulatory functions.

Gaps:

- Several pieces of regulations on medicinal products and practices exist but there is no legal provision to control herbal and traditional medicines and cosmetics.
- There are no regulations to establish a pharmaceutical council.

Recommendations:

Legislation and regulations form the foundations of medicine regulation. Because medicine involves several stakeholders that have different motives and interests, legislation and regulations need to be comprehensive, clear and should define clearly the powers, functions and responsibilities of the authority as well as the regulated firms. It is therefore recommended to:

- Formulate a comprehensive medicine legislation (primary law) by revising and consolidating the existing laws and regulations dealing with medicinal products and practices
- Develop appropriate regulations for the administration of the medicine legislation.

Regulatory authority (The Pharmaceutical Department)

Law No 4/98 provided the establishment of Medicines Council, “Conselho do medicamento” (COMED) with very broad responsibilities however the council was never established as stated in the law. Instead, the responsibilities of the council were delegated transitionally (date not fixed) to the Pharmaceutical Department by Decree No 21/99. However, there was no consideration made in terms of availability of human and financial resources, organizational structure, logistics etc. when the responsibilities were delegated to the Pharmaceutical Department.

In accordance with the delegation provided, the Pharmaceutical Department has the following responsibilities:

- Develop national formulary of medicines
- Advise on the terms of the present law on pharmacy and medicines
- Develop therapeutics guidelines for main pathologies
- Advise on decision for registration and to issue certificate
- Organize the control of the quality of medicines
- Instruct the licensing of manufacturer, importer, distributors and issue respective certificate of registration
- Authorize shops to sale over the counter products
- Prepare and communicate technical and scientific information on medicines
- Assure the control of narcotic drugs and psychotropic substances in accordance with international conventions
- Register pharmacy professionals
- Approve the selling prices for medicines
- Promote the rational use of medicines
- Organize and perform pharmaceutical Inspection

Gaps

- it is not clear when the Medicines Council will be established and delegation given to the Pharmacy Department will end.
- the responsibilities delegated to the Department are extremely wide and some are not related to regulatory activities, for example, the preparation of therapeutic guidelines and national formulary, promoting rational use of medicines or control of the prices of medicines.
- the Department has not been provided the appropriate organizational structure that will enable it to perform the tasks delegated nor it has formally approved organigram, defined mission, vision and objectives,
- The provision of technico-scientific information is carried out by Centre for information on medicine (CIMED) although it is the Pharmaceutical Department the one to whom these activities have been delegated.
- The critical function of pharmaco vigilance is not performed by the Pharmaceutical Department but by CIMED.

Recommendations:

- It is strongly recommended to establish by law a national medicine regulatory authority that is administratively and financially semi-autonomous. The authority should be under the supervision of the Minister of Health.
- The authority should be provided the necessary powers and its functions and responsibilities should be clearly defined.

4.3.1 Funding of the Pharmaceutical Department

The Department has no specific annual government budget allocated to it. It depends on government funding which it gets in the form of staff salaries and office supplies from the MOH. Fees collected by the Department are transferred directly to government treasury.

Gaps

- Inadequate and unsustainable funding is one of the major problems for the Department to plan and carry out its functions adequately and effectively.

Recommendations

- The new authority should have adequate and sustainable funding mechanism. Government should allocate specific annual budget to operate regulatory functions and fees collected through the provision of services should be used to supplement government budget.

4.3.2 Human resources

Currently, the Department has 4 pharmacists, 3 pharmacy technicians, and 3 administrative staff to carry out the above mentioned functions. Three of the four pharmacists and two of the pharmacy technicians joined the department less than six months ago. The Department is also supported by a team of external experts in the assessment of applications of medicines for registration. Job descriptions have been presented for the different functions performed within the Pharmaceutical Department.

Gaps

- The staff has not received any special training to enable them to carry out their functions effectively and efficiently. In general, the staff number is inadequate, and lack the necessary qualification, experience and skills.
- There is no in-house training programme and formal induction programme for new staff. Training programmes planned can not be implemented due to lack of funding.
- There is no autonomy in the recruitment of staff.
- Substantial gaps in salaries have been reported among similar professionals working in different organizations for example between the Pharmaceutical Department and CMAM.
- No code of conduct or code of ethics for the personnel working in the Department neither for the external experts.
- Language remains a barrier for communication and development of competencies and understanding of the problems/challenges.

Recommendations

Having appropriate number of qualified human resources is critical for successful implementation of drug regulation. Medicine regulation is a legal as well as a scientific and technical matter requiring highly qualified, experienced and skilled professions to carry out the various regulatory activities. It is recommended that:

- government should employ people with the necessary qualification, knowledge and skills to ensure effective drug regulation.
- Employees must be individuals of integrity and should be well remunerated, particularly since drug regulation involves various stakeholders with commercial interests who may try to exert pressure on the authority in order to secure favourable decisions.
- Training programmes should be organized for internal staff and external experts from time to time to improve their knowledge and skills.

4.3.3 Regulatory tools

Regulatory tools, such as standards, guidelines and procedures equip the drug regulatory authority with the practical means of implementing the drug regulation. Lack of appropriate tools leads to erratic decisions making and lack of transparency.

Gaps

- The Pharmacy Department has not developed most of the tools necessary for its staff as well as for its customers. Tools that are currently available are not comprehensive and easily available to the public.

Recommendations

- Standards, guidelines, procedures, guidance etc should be established in written form for all drug regulatory functions and should be available for internal staff, external experts, customers and the general public. These tools should then be used to guide those involved in the implementation of regulatory processes and practices.

4.3.4 Infrastructure

The availability of appropriate facilities-offices/rooms, shelves, computers, vehicles, equipment, etc is necessary for the smooth functioning of a medicine regulatory authority.

Gaps

- The Pharmacy Department does not have enough offices and storage facilities. The working environment is extremely poor and confidential documents that should be kept under lock and key are kept unsecured.
- There is lack of transport facilities especially for inspectors and this has been the main reason for not undertaking routine inspection and market surveillance activities.

Recommendations

- Enough offices and rooms as well storage facilities for documents should be provided
- Adequate logistics should be available

4.3.5 Transparency and accountability

A medicine regulatory authority deals with issues that have direct effect on the health and well being of the general public. Powers and responsibilities are given to the authority with the belief that it will function transparently and will be accountable to the supervisory body, the public and its customers.

Gaps

- most of the guidelines, procedures, guidance, etc are not published. Those available are not comprehensive and easily available.

- There is no guidance to prevent any conflict of interest and no code of conduct for staff and external experts.

Recommendations

- Guidelines, procedures, guidance, etc for staff as well as for clients and external experts should be published and made easily accessible.
- Guidance to prevent conflict of interest should be developed and implemented and there should be code of conduct for staff and external experts.

4.3.6 Information Technology (IT)

Computerization of the regulatory system and processes will facilitate regulatory activities. Posting regulatory decisions, guidelines, procedures, etc will improve the transparency of the authority. At present the authority has three old computers. In house developed soft ware based on access is used to store information on registered products and licensed medicine outlets. The computers are not networked and there is no IT expertise in house.

Gaps

- There is no IT personnel to support or maintain the system and the computers available are not adequate and networked.

Recommendations

- Adequate number of computers should be provided and networked
- The software developed by WHO should be installed to facilitate information management and communication.
- Staff should be trained in the installation, management and data entry.

4.4 Regulatory functions

4.4.1 Product Registration

There are legal provisions requiring the registration of human medicines as well as for registration of variations. A system for registration of medicines was initiated in 1999 but actual operation began in 2001 with the introduction of a provisional registration system valid for 3 years. The system has now been extended to another 3 years. There is a list of provisionally registered products (published January 2005) and the number of provisionally registered is said to be 10,000. All provisionally registered products are required to pass through the formal registration process (reregistered) before the expiry of the validity date.

Two kinds of exemptions have been identified-orphan products and products imported by MEDIMOC for public sector are not required to be registered

Registration is valid for 5 years. After this period applicants are required to ask for renewal. There are three approaches for the registration of medicines:

- Complete registration for new chemical entities;
- Abbreviated registration for well established drugs based on submission of Certificate of Pharmaceutical Product (CPP) and summary of evaluation;
- Recognition of decisions made by other medicine regulatory authorities (based on communication of CPP, and summary of product characteristic (SPC) and summary of documentation on safety, efficacy and quality.

Guidelines on registration have been published by the department in the form of leaflets.

The process of registration involves review of quality data by staff of the Pharmacy Department. Dossiers are then passed together with the report on quality data to external experts (CTTF members) for assessment of safety and efficacy data. Once assessment has been completed reports are established by experts and applications are passed through the CTTF to the Minister of Health for decision. The CTTF is composed of 10 professionals of different competencies. Minutes of meetings are registered.

CTTF stopped reviewing applications in March 2006 because the MOH stopped to provide appropriate remuneration/incentives to CTTF members for the services they provide. This action has resulted in a backlog of around 385 applications.

Gaps

- The number of staff is not adequate
- Guidelines on submission of applications are not comprehensive and there is no guidance on bioavailability, stability, etc.
- There are no guidelines for internal staff as well as for external experts on how to assess applications.
- Incentives for services provided by experts is not adequate and as a result the experts have stopped operating.
- There is no written criteria for selection of members of the expert, CTTF.
- Training has not been provided for external experts and internal staff.
- There is no up-to-date list of registered products publicly available and registered products are not published in official gazette
- Exemption of registration have to be limited
- The Scope of the CTTF is very wide and vary from the registration of medicines to the establishment and maintenance of the national formulary and the elaboration of therapeutics guidelines.

Recommendations

- The number of assessors should be increased to deal with the administrative and quality part of the dossier
- In view of the limited availability of qualified, experienced and skilled staff to make full assessment of applications in-house, the regulatory authority should be allowed to use external experts.
- The necessary guidelines and guidance on medicine registration should be developed and disseminated to external experts, staff of the authority, its customers and all stakeholders.
- Staff and external experts should sign conflict of interest form.
- Criteria for the selection of external experts should be developed and implemented.
- In-house and external training programmes should be arranged for staff and external experts to improve their knowledge and skills in dossiers assessment.
- To establish a fast track mechanism for registration of imported products by public sector
- The advisory committee should be more focused on the registration process of medicines. Another committee should be involved in the other areas such as therapeutic guidelines, national formulary or economic and pricing issues.

4.4.2 Regulatory Inspections and enforcement

There is legal provision, law No 4/99 Articles (7h) and (42)8, for inspection of premises, collection of samples, issuance of notice of non compliance and confiscation of products and checking conformity to good manufacturing practices (GMP).

Inspection of pharmaceutical establishments is carried by the Pharmaceutical Department as well as by Provincial Health Departments although the latter has not been given official delegation to carry out inspections. There are three inspectors (one pharmacist and two pharmacy technicians) within the Department of pharmaceuticals. Inspectors are given special letter to inspect drug establishments. Sanctions are defined in article 44 for infraction of the law. Inspectors have power to close and to prosecute establishments who violate the laws.

There is one manufacturer (intravenous solutions), 45 importers and distributors (11 are active), 229 private pharmacies and public pharmacies in hospitals/clinics and 22 shops selling over the counter drugs.

There are check lists for inspection of importers, wholesalers, private pharmacies and public hospitals. Inspectors have received some training but not adequate.

Gaps

- The number of staff is not adequate
- Inspection is inadequate and there is no planned routine inspection as such due to lack of logistics.
- No guidelines on GMP have been published
- There are no legal provisions requiring compliance with good distribution practices (GDP) and no guidelines on GDP have been published.
- There is no special provision in the law to designate pharmaceutical inspectors.
- No regular reporting of inspections of pharmacies carried out by the provinces.
- No training program performed and there is need to develop competencies on inspection
- There is no enough logistics to perform inspection.
- Information on inspection is not readily available and there is no database on inspection

Recommendations

Inspection of pharmaceutical establishments is an important function of a medicines regulatory authority. Inspection helps to ensure that operations are carried out in accordance with the approved standards and guidelines. In doing so, inspectors uncover weaknesses and deficiencies as well as actual or potential errors in medicine production, quality control, storage and distribution of medicines. It is therefore recommended that:

- The number of inspectors should be increased and there should be a training programme to improve their knowledge and skills.
- The inspectorate should be provided adequate logistics and there should be planned routine inspection.
- There should be legal provision requiring compliance with good distribution practices and guidelines on good distribution practices should be developed and published.
- guidelines on good manufacturing practices should be developed and published
- Provincial health departments should be officially delegated to perform inspection and should be required to submit inspection reports.
- Information on inspection should be readily available and there should be database on inspection.

4.4.3 Licensing of manufacturers, importers, exporters, wholesalers and retailers

Licensing of manufacturers, importers, exporters, wholesalers and retailers is carried out by the Pharmaceutical Department. Pre-licensing inspections are required to issue licenses. For licensing of private pharmacy, pre-inspection are performed by the provincial authorities. Conditions for issuing licenses are written down in the form of leaflets. Licenses are issued after approval by the Minister of Health. Licenses have no validity date.

Gaps

- No licensing of public pharmacies in hospital

Recommendations

- Licensing should be required for public pharmacies

4.4.4 Registration of pharmacist

The pharmaceutical department is in charge of the registration of pharmacist and professionals of pharmacy.

Gaps

- No body, organization or institution is in charge of regulating and controlling the practices of the profession of pharmacist.

Recommendations

- Legal provisions should establish a body corporate in charge of the definition of standards and skills to be attained by person practicing pharmaceutical activities, of the establishment and maintenance of a register of pharmacist, of controlling the practices and of performing disciplinary functions.

4.4.5 Monitoring Clinical trials

The Pharmaceutical Department authorizes the importers of investigational products for clinical trials: It issues import permit for each consignment of investigational products. There is no inspection made by the department. There are no Good Clinical Practice Guidelines applicable. It was reported that Ethics oversight is performed by the INS.

Gaps

- No legal provision requiring authorization by the DRA of clinical trials
- No legal provision requiring compliance with Good Clinical Practices
- No guidelines on good clinical trials practices published
- No inspections of clinical trials
- Staff not trained in inspection of clinical trials.

Recommendations

- Legal provisions should be provided in order to require authorization of clinical trials by DRA and compliance to GCP and GLP.
- Guidelines on good clinical practice should be developed and published

- Inspectors should be trained in good clinical practice and good laboratory practice (GLP) and there should be inspection of clinical trials.

4.4.6 Import and export control

The Pharmacy Department issues import permit for each consignment of medicines that enters into the country. This is required by the drug law. The process involves the following: Application is sent by importers with the list of products intended to be imported filled in a form issued by the Pharmacy Department. Department checks if products mentioned in the application are the same as those registered and then issues authorization to import. There is no actual inspection of consignments carried out by the inspection unit. Cases of illegal importation of medicines have been reported.

Data of imported medicines is entered in a database. Import permit is also issued for investigational products.

Gaps

- Registration is not a prerequisite for issuing import permit for medicines imported by and for the public sector
- No inspection at port of entry to check if products coming into the country are those approved by the Pharmacy Department.
- There is no guidance on submission of applications for import permit.
- There is no formal collaboration with the customs authority to ensure that there is no illegal importation of medicines taking place.

Recommendations

- Registration should be a prerequisite for issuing Import permit
- Issuance of import permit should be supported, as far as possible, by actual inspection of products at customs warehouse.
- The drug regulatory authority should establish close cooperation with customs.

4.4.7 Market control

Once medicines are on the market it is necessary to carry out market surveillance activities to ensure that products are stored and distributed under appropriate conditions and in accordance with the regulations. Such activity should also ensure that no expired, poor quality and counterfeit medicines circulate on the market. Inspectors should collect samples of suspected products and carry out quality tests and investigations.

Gaps

- There is no market control activity carried out at the moment. Inspectors do not carry out market surveillance activities and there is no quality testing activity conducted.

Recommendations

- Inspectors should conduct market surveillance programmes as often as possible. They should collect samples from time to time to test the quality of medicines.

4.4.8 Control of promotion and advertisement

There is a legal provision prohibiting promotion of medicines to consumers. Scientific and medical information can be provided to practitioners and health care professionals in compliance with the summary of product characteristics. Communication of such information should be authorized by the director of hospital. The law requires distribution of free samples and gifts to professionals to be regulated. In practice, there is no control of drug promotion and advertisement by the Pharmaceutical Department.

Gaps

- No control or enforcement activities exerted by the Pharmaceutical Department on advertisement and promotion activities.

Recommendations

- Legal provision should require the authorization of promotion and advertisement materials by the DRA and a fee system should be introduced for control of advertisement and promotion materials
- Control on promotion and advertisement activities should be performed.

4.4.9 Pharmacovigilance

Pharmacovigilance activity began in 2004. Currently it is taking place only in 10 districts. CIMED is in charge of data collection, investigation and reporting. A team of three professionals, a pharmacist from Pharmaceutical Department and 2 doctors are responsible for this activity. A template is used to report adverse drug reaction. CIMED makes classification of incidents following the WHO guidelines and sends feedback to information providers. Reference materials, such as Martindale, National Formulary of Mozambique, the South African National Formulary are used for investigation. Information collected is entered into database and sent to the Uppsala Centre.

Health professionals working in the public sector in the 10 districts have been trained on how to fill the report format (yellow paper). The plan is to expand the training to the private sector and later to the whole country. A pharmacist from the Pharmaceutical Department has also been trained on the WHO guidelines.

An Information bulletin has been published in March 2006 and guidance on pharmacovigilance is available in the Portuguese language.

There is an agreement between CIMED and the Pharmaceutical Department defining roles and responsibilities but no link is formalized between the two institutions.

Gaps

- Pharmacovigilance does not cover the whole country nor the private sector
- There is no legal provision for manufacturers, importers or distributors to participate in pharmacovigilance.
- No formal linkage between CIMED and the Pharmaceutical Department
- No training provided

Recommendations

- Pharmacovigilance should cover the whole country and the private sector
- There should be obligation for manufacturers, importers/distributors to participate in pharmacovigilance.
- In the short term, a formal linkage between CIMED and Pharmaceutical Department should be established
- In the long term, the pharmacovigilance should be integrated as part of the national drug regulatory authority
- Training should be provided to all staff involved in pharmacovigilance

4.4.10 Quality Control

The National quality control laboratory (NCQL) has 26 staff of whom 20 are qualified professionals 6 administrative staff. At the moment there is no link between the Department of Pharmaceuticals and the NCQL. The aim is to integrate the NCQL as part of the national drug regulatory authority. The laboratory tests the quality products imported by the public sector. Staff of the laboratory are not involved in inspection or registration activities.

Gaps

- There is no formal linkage between the laboratory and the department of pharmaceuticals.

Recommendations

- In the short term create link between the laboratory and pharmaceutical Department
- In the long term the laboratory should be part of the national drug regulatory

5 Conclusion and recommendations

The assessment has shown that Mozambique has in place a basic medicine regulatory system backed by law. The Pharmaceutical Department which is the main regulatory body is found within the MOH and is supervised by the Director General of Health. The Department has no organigram. It has a limited number of staff who lack the necessary qualification, experience and skills to carry the different regulatory functions. The different regulatory functions are scattered horizontally among different government institutions without any formal linkage or communication system.

It is recommended that the various regulatory functions should come under one semi-autonomous national drug regulatory authority that has independence in decision-making, management of its human and financial resources and recruitment of staff. Government should allocate annual budget and the DRA should be able to use the income generated from fees to run its operations.

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Annex AAAA

List of people met

His Excellency the Minister of Health of the Republic of Mozambique

De El Hadi Benzeerroug, WHO Representative, Mozambique

Dr Abdou Moha, HIV/AIDS, WHO Office Mozambique

Mrs Suria Nania, Head of Pharmaceutical Department, Ministry of Health of Mozambique

Ms Sultana Razaco, Head of Registration of Medicines, Pharmaceutical Department

Ms Sureia Hassam, responsible for Pharmacovigilance, , Pharmaceutical Department

Ms Felicidade Sebastion, responsible for narcotics and psychotropics and inspector

Mr Mauricio Azenedo, Inspector, Pharmaceutical Department

Mr Joso M Nhaea, inspector, Pharmaceutical Department

Ms Diana, Longe, responsible for control of import

Ms Ana Raquel F. Siteo, Director of National Drug Quality Control Laboratory (NDQCL)

Ms Benedita Isabel Jorge Ronda, Head of Microbiology Department, NDQCL

Ana Paula da Silva Mandlaze, Head of Standardization and Quality Assurance, NDQCL

Ms Arminad Banze, Pharmacy technician in the Chemical Department, NDQCL

Annex BBBB

List of documents provided

Legislation and regulation

- Decreto n°13/75 establishing a "Central de Medicamentos e Artigos Medicos" (CMAM)
- Portaria n°46/75 de 6 de Setembro. Establishing a "Comissao Tecnica de Terapeutica e Farmacia (CTTF)
- Portaria n°105/77 de 17 de Marco on authorisation to sale medicines for non pharmacy (Over The Counter) and fixing the list of medicines
- Decreto n°16/88 establishing a "Fundo Social para medicamentos e suplementos Alimentares Infantis"
- Diploma Ministerial n°109/90 on the definition of price of medicines
- Lei n°3/97 establishing a legal framework for narcotics and psychotropic substances
- Decreto n°41/97 de 18 de Novembro establishing a "Gabinete Central de prevencao e Combate a droga (GCPCD)
- Diploma Ministerial n°94/97 establishing the organization of MoH
- Lei n° 4/98 de 14 de Janeiro establishing a legal framework for medicines
- Decreto n°21/99 regulating the pharmaceutical practices and in particular the licensing of pharmacies
- Decreto n°22/99 regulating the registration of medicines
- Diploma ministerial n°98/2000 de 9 de Agosto on fees for the registration of medicines
- Despacho on 22 de Dezembro de 2000 on extraordinary registration of medicines
- Despachp on 26 de Marco de 2001 establishing a "Comissao Tecnica de Registo de Medicamentos" (CTRM)
- Despacho on 4 de Julho de 2001 designating the CTTF members
- Diploma ministerial n°39/2003 regulating the opening of pharmacy
- Diploma ministerial n°222/2004 establishing the "Centro de investigacao em saude de Manhica" on investigation on Health

- proposition of a new law on the regulation on medicines with rational
- proposition of a new law establishing a national pharmaceutical board/Order

Guidance, procedure and check list

- Guidance on registration of medicines in Mozambique
- Guidance for the licensing of importers and storage of medicines
- Guidance for the licensing of a pharmacy
- Notification form for adverse drug reaction
- Information bulletin n°1 on adverse drug reaction
- Protocole to inspect a pharmacy
- Protocole to inspect a pharmacy of a clinic
- Protocole to inspect an importer
- Check list for the registration of medicines (Completed)
- Check list for the registration of medicines (Abbreviated)

Human resource and planning

Terms of reference for staff in charge of control of narcotics

Terms of reference for staff in charge of licensing

Terms of reference for staff in charge of inspection

List of staff employed by the pharmaceutical department

Operational planning for year 2007-03-07

Annex CCCC

Informative Road Map

Area to be addressed	Short term 6 month	Medium term 1-2 years	Long term 3-5 years
National regulatory system	To establish formal linkage between the different organizations engaged in regulatory activities in order to coordinate activities and improve communication.	To bring the various regulatory functions on medicines under one organization that is semi-autonomous in decision-making, recruitment of staff and management of its resources.	To introduce the control of herbal and traditional medicines, cosmetics, medical devices and veterinary medicines under the same organization.
Legislation and regulations		To formulate a comprehensive medicine legislation dealing with medicinal products and practices To develop appropriate regulations for the administration of the medicine legislation.	
Regulatory authority		To establish by law a national medicine regulatory authority with the necessary powers and its functions and responsibilities.	
		To provide the authority with adequate and sustainable funding.	
	To establish and perform training program for internal staff and external experts.	To select and employ people with the necessary qualification, knowledge and skills.	
	To establish Standards, guidelines, procedures, forms for all drug regulatory functions		
	To provide with adequate logistics in particular for inspection	To provide with enough offices and rooms as well storage facilities for documents	

	<p>To developed and implement guidance to prevent conflict of interest</p> <p>To develop a code of conduct for staff and external experts.</p>	<p>To published and make easily accessible guidelines, procedures, forms, etc for staff as well as for clients and external experts.</p>	
	<p>To provide with adequate number of computers</p>	<p>To install the software developed by WHO on registration.</p> <p>To train staff in the installation, management and data entry.</p>	
Product Registration	<p>To use external experts for registration</p> <p>To develop the necessary guidelines and guidance on medicine registration</p> <p>To establish and sign conflict of interest form for staff and external experts</p> <p>To develop and implement training programs for staff and external experts in dossiers assessment</p>	<p>To increase the number of assessors for administrative and quality part of the dossier</p> <p>To determine criteria for the selection of external experts and implement.</p> <p>To establish a fast track mechanism for registration of imported products by public sector</p> <p>To make the advisory committee (CTTF) focus on registration of medicines</p>	
Regulatory Inspections	<p>To develop and implement a training program for inspectors.</p> <p>To establish a planning of routine inspection.</p> <p>To delegate performance of inspection to Provincial health departments with requirements to submit inspection reports.</p>	<p>To increase the number of inspectors</p> <p>To establish legal provision requiring compliance with good distribution practices</p> <p>To develop guidelines on good distribution practices</p> <p>To develop guidelines on good manufacturing practices</p> <p>To establish a data base on inspection</p>	
Licensing of manufacturers, importers, wholesalers and retailers		<p>To license public pharmacies</p>	
		<p>To establish a body corporate in charge of pharmaceutical practices.</p>	

Monitoring Clinical trials		To develop legal provisions on authorization of clinical trials by DRA and compliance to GCP and GLP. To develop guidelines on good clinical practice and GLP and publish	To train Inspectors in good clinical practice and good laboratory practice (GLP) To make inspection of clinical trials.
Import and export control	To establish close cooperation with customs.	To inspect products at customs warehouse and port of entry. To issue import permit with background information from registration	
Market control	To develop and implement a market surveillance program	To collect samples to check the quality of medicines.	
Control of promotion and advertisement		To establish legal provision requiring the authorization of promotion and advertisement materials by the DRA To introduce a fee system for control of advertisement and promotional materials	To perform control over promotion and advertisement activities
Pharmacovigilance	To establish formal linkage between CIMED and Pharmaceutical Department To train staff involved in the pharmacovigilance	To establish legal provision for manufacturers, importers/distributors to participate in pharmacovigilance. To develop Pharmacovigilance in order to cover the whole country and the private sector	To integrate pharmaco vigilance as part of the national drug regulatory authority
Quality Control	To establish a formal link between the laboratory and pharmaceutical Department	To test samples to check the quality of medicines.	To integrate the laboratory as part of the national drug regulatory