

**Review of National
Medicines Policy,
Review of the Namibia
National Pocket
Manual for Health
Workers, and
Determination of
Desirability for
National Standard
Treatment Guidelines
for Namibia**

Management Sciences for Health
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Strategic Objective 4

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ARIPO	African Regional Industrial Property Organization
ART	antiretroviral therapy
ARV	antiretroviral
CMS	Central Medical Stores
CPD	continuous professional development
EML	essential medicines list
FGD	focus group discussion
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HRD	human resources development
IMAI	Integrated Management of Adult Illnesses
IMCI	Integrated Management of Childhood Illness
MCC	Medicines Control Council
MoF	Ministry of Finance
MoHSS	Ministry of Health and Social Services [Namibia]
MSH	Management Sciences for Health
NAD	Namibian dollar
NAMAF	Namibian Association of Medical Aid Funds
NEMLIST	Namibia Essential Medicines List
NMP	National Medicines Policy
NMPC	National Medicines Policy Coordination
NMPL	Namibian Maximum Price List
NPMP	National Pharmaceutical Master Plan
PC&I	Pharmaceutical Control and Inspection
PHC	primary health care
PMIS	Pharmacy Management Information System
PMTCT	prevention of mother-to-child transmission
PSEMAS	Public Service Employees Medical Aid Scheme
PSN	Pharmaceutical Society of Namibia
RPM Plus	Rational Pharmaceutical Management Plus
RUM	rational use of medicines
SADC	Southern African Development Community
SEP	Single Exit Price
STGs	standard treatment guidelines
TB	tuberculosis
TC	Therapeutic Committee
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USAID	U.S. Agency for International Development
USD	U.S. dollar
VCT	voluntary counseling and testing
WHO	World Health Organization
WIPO	World Intellectual Property Organization

EXECUTIVE SUMMARY

Introduction

This assignment was undertaken at the request of the Management Sciences for Health (MSH)/Rational Pharmaceutical Management (RPM) Plus Program to review the National Medicines Policy (NMP) of Namibia and related laws and regulations with the view of proposing changes (if any) that would be entered into the revision of Namibia's National Pharmaceutical Master Plan (NPMP). The NMP and the accompanying NPMP were introduced in 1998 and 2000, respectively.

In addition, MSH/RPM Plus was to provide guidance on the review of the Namibia Pocket Treatment Manual for Health Workers and examine the possibility of developing comprehensive standard treatment guidelines (STGs) for Namibia's health sector.

Methodology

Three main methods were used to collect information for this report—

1. Interviews with stakeholders in the Ministry of Health and Social Services (MoHSS), Ministry of Finance (MoF), Ministry of Trade and Industry, Interim Health Professions Councils, Medicines Control Council (MCC), professional associations and councils, private pharmaceutical outlets, regional and district medical officers, pharmacists, and nurses
2. Focus group discussions with health providers at all levels of the health care delivery structure on desirability for comprehensive STGs
3. Desk review of legislations and relevant reports: included legislations related to the health sector and reports available in hard copy and on the internet

The activities and performance indicators set out in the NPMP were used to determine the extent of the implementation of the NMP.

Constraints

As is usual with such assignments, most of the working hours were spent moving from one appointment to the other as the desire is to talk to all stakeholders. To a very large extent most key stakeholders were consulted; however, in some instances there was not enough time to hold exhaustive discussions.

Key Findings

Review of Pocket Treatment Manual for Health Workers (Pocket Manual)

The Namibia Pocket Treatment Manual for Health Workers was first published in 1996 and was derived from the more extensive Treatment Manual for Clinics, which was developed and distributed in 1992. Its objective was to standardize treatment practices in the country, particularly at the primary health care level. The manual has not been revised since its introduction in 1996.

The Pocket Manual has been found to be an especially useful tool in clinical practice for nurses. However, there are various sections that require review as well as incorporation of recent treatment guidelines for malaria, antiretroviral (ARV) treatment, prevention of mother-to-child transmission, tuberculosis, Integrated Management of Childhood Illness, and new relevant topics.

In principle, review of the Pocket Manual should follow that of the Treatment Manual for Clinics, as was done originally. This approach is confounded by the proposal to develop comprehensive STGs, which may delay the revision of the Pocket Manual.

Desirability for Comprehensive Standard Treatment Guidelines

There is general recognition of the need to develop comprehensive STGs for use in both public and private health sectors of Namibia. Advantages that support the observation of the desirability for comprehensive STGs include promotion of rational use of medicines, cost containment, improved quality of care, and a training and orientation tool for foreign medical practitioners. Suggestions were made as to the format, content, and the process of development. An important observation was that the STGs should target both public and private sectors and therefore collaboration between these two sectors is important.

Review of the National Medicines Policy

The current laws in Namibia regarding control of pharmaceuticals, professional health practice, and the draft bill on traditional healers are comprehensive. Review of the major elements of the NMP and the laws related to the pharmaceutical sector raised some issues.

1. Legislation

Acts of Parliament Affecting the Pharmaceutical Sector

Several acts have been passed by the Parliament of Namibia that affect pharmaceutical practice. These include various acts establishing the Interim Professional Health Councils and the Medicines and Related Substances Control Act.¹ These acts are generally comprehensive. For

¹ Government of the Republic of Namibia. *Medicines and Related Substances Control Act of 2003* (No. 13 of 2003). Windhoek: Parliament. <<http://www.parliament.gov.na/parliament/billsandacts/Actdetail.asp?ActID=85>> (accessed Apr. 27, 2006).

example, the professional bodies acts have already resulted in the setting up of the Interim Health Professions Councils that have a common central administration and are cooperating in promoting various activities, particularly, continuous professional development, which is emphasized in all Parliament of Namibia acts.

All the new laws are in the early stages of implementation and regulations have not been finalized and passed. There was also the view that enforcement of the laws was weak.

Medicines and Related Substances Control Act (No. 13 of 2003): Challenges

The Medicines and Related Substances Control Act, passed in 2003, is not in effect because problems have been detected concerning the interpretation and implementation of aspects relating to the veterinary section of the act, which requires amendments before implementation. This delay means that the considerations in the NMP that drove the act cannot be put into force. Regulations in force now are therefore those made based on the earlier Medicines and Related Substances Control Act, 1965 (No.101 of 1965).

It was also observed that the present location and personnel structure of the MCC greatly compromised its autonomy and efficiency. The current situation then poses a broader question of whether the NMP should be reviewed now when the law emanating from the policy is yet to be effected.

Other Bills in Preparation

There are other bills in preparation related to matters raised in the NMP. These bills are mainly from the Ministry of Trade and Industry and address issues related to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and regional cooperation. These include the bill on Standards and Competition Law² (a Namibian Competition Commission has been set up).

Proposed Bill on Traditional Healers

There is a draft bill on traditional medicine circulating for comment. However, it is increasingly obvious that there is the need to effect the policy considerations in the NMP to streamline practice in this area of health care.

2. Rational Use of Medicines

Many of the activities listed in the NPMP under rational use of medicines (RUM) have been initiated mainly through the Coordination subdivision of NMP. Implementation, however, has not been comprehensive largely as a result of staffing problems at headquarters and in the regions. Unimplemented activities include appropriate use of medicines at the community level, establishment of a Drug Information Centre, and the instituting of a pharmacovigilance program. The subdivision has also undertaken serial RUM indicator studies across the country that provide information on progress or changes in the indicators.

² Government of the Republic of Namibia. *Competition Act of 2003* (Act No. 2 of 2003). Windhoek: Parliament. <http://www.tralac.org/pdf/Competition_Act_Namibia.pdf> (accessed Apr. 27, 2006).

3. Human Resources Development

The lack of qualified staff poses the leading threat to the development of the pharmaceutical sector in Namibia. The situation affects pharmacists and pharmacist's assistants. In addition, there are disparities in the distribution of the pharmacy professionals within the public sector and between the public and private sectors. About 80 percent of pharmacists are in the private sector. Those in the public sector are found in the larger health facilities. Other health professionals are also affected; there are about 700 vacant posts in the MoHSS. The difficulties faced in filling these vacancies are related to availability of qualified persons, freezing of some posts, and budget cuts. The staffing situation is worsened by the Ministry embarking on new programs without hiring additional staff, absenteeism, and death from HIV/AIDS (including the pool from which new staff will be derived).

The implications for quality health care and in particular, the ARV program, include increased work load and unplanned shifting of tasks within requisite training; for example, pharmacist's assistants doing the work of pharmacists, and nurses covering for doctors. Although some needs are being addressed by recruitment through support from The President's Emergency Plan for AIDS Relief team in Namibia and the Global Fund to Fight AIDS, Tuberculosis and Malaria, it is questionable if this assistance is sustainable.

4. Pricing of Pharmaceuticals

Two major institutions drive the financing of health in Namibia—the public sector overseen by the MoF and the medical aid fund (including the Public Service Employees Medical Aid Scheme [PSEMAS] and the private sector Namibian Association of Medical Aid Funds [NAMAF]). The implementation of the Namibia Maximum Price List and PSEMAS' policy of generic prescribing is helping to control prices. However, in the private sector dispensing doctors, polypharmacy, and perverse incentives keep the prices of medicines up.

In addition, PSEMAS' "no limit" policy poses a threat to the survival of the PSEMAS and it may be prudent for PSEMAS to consider a ceiling on reimbursement levels as is the case in private medical aid systems. Savings can also be made by linking reimbursement of medicines to the Namibia Essential Medicines List (NEMLIST).

It may be worthwhile to review the 50 percent markup on medicines with the view of replacing it with a professional dispensing fee. In the same vein, the practice of dispensing doctors should be discouraged. It will be worthwhile to remunerate solely in the context of the primary professional function.

5. Local Manufacture of Pharmaceuticals

Presently there is only one local pharmaceutical manufacturer in Namibia. The company produces mainly liquid preparations, ointments, and creams.

There is an upbeat feeling in the Ministry of Trade and Industry that local manufacture of pharmaceuticals, particularly focusing on medicines on the NEMLIST, is close at hand. Indeed,

there is an active search for investors. It is important that the Ministry of Trade and Industry and the MoHSS work even closer together to move this agenda forward.

6. Regional Cooperation

Namibia has had a long history of association with the southern African countries and has established trade links with many of them, especially through regional trade arrangements, and in particular with South Africa. There is evidence of recent efforts at expanding the scope of regional trade initiatives.

7. Traditional Medicine

There have been no significant activities in this area except for the preparation of the Traditional Healers Council Draft Bill. Traditional medicine as mentioned in the NMP should focus on medicinal products of plant origin.

8. Monitoring and Evaluation

Monitoring and evaluation of the implementation of the NMP is not optimal. A Pharmacy Management Information System (PMIS) is being developed. Activities are presently limited to surveys of pharmaceutical practice. It is important that a pharmaceutical sector information management system is recognized in the NMP and implemented with data flow from the periphery to the center through the regions. Such a system should provide opportunity for the collection and collation of relevant data using standardized methods that will inform the state of the pharmaceutical sector and provide the prospects for remedial actions, when indicated. Adequate staffing of pharmacists and trained pharmacist's assistants will be crucial to such a system.

Conclusions and Recommendations

Review of the Pocket Manual

Conclusion

The Pocket Manual is a very useful tool in primary health care but is outdated in disease coverage and treatment choices. The review of the Pocket Manual has to be considered in light of the proposed development of comprehensive STGs.

Recommendation

It is recommended that in view of the usefulness of the Pocket Manual and the possible long process of developing comprehensive STGs, the Pocket Manual should be revised to include more current information on health problems and also align treatment choices to the Essential Medicines List.

Development of Comprehensive Standard Treatment Guidelines

Conclusion

There is a clear signal and overwhelming support for the development and use of comprehensive STGs for important health problems for use in both public and private health sectors. The guidelines must be applicable to all levels in the health sector.

Recommendation

It is recommended that as a matter of priority a ministerial standing committee should be set up with a mandate emphasizing one comprehensive STGs document for all health providers in Namibia.

Review of the National Medicines Policy

Conclusion

The elements of the NMP are consistent with those of many developing nations and agree with the format recommended by the World Health Organization. The laws emanating from the policy are comprehensive and cover the major aspects of pharmaceutical sector practice. While aspects of the NMP require review, the delay in issuing the regulations required to implement the Medicines and Related Substances Act based on the 1998 NMP confounds the situation. There are, however, new or outstanding issues to be considered both in the laws and the implementation of the NMP through the NPMP.

Recommendations

Laws and regulations

- MoHSS should expedite action on the finalization of the legislative instruments (regulations) to the law.
- The Ministry of Trade and Industry should work closely with the MoHSS and related ministries to strengthen existing laws to promote local manufacture of pharmaceuticals and medical supplies and also develop the necessary regulations, procedures, and guidelines to take advantage of the TRIPS flexibilities.
- The practice of internet pharmacy should be further investigated and regulations effected if necessary.

Review of National Medicines Policy

- It is necessary to reemphasize in the NMP and its NPMP the search for innovative ways of attracting pharmaceutical manufacturers to Namibia.
- In considering the review of the NMP, the TRIPS agreement and its flexibilities should be included. There is also the need for collaboration between the MoHSS, Ministry of Trade and

Industry, and the Ministry of Justice to initiate the necessary administrative procedure to take advantage of the TRIPS flexibilities.

- The NMP should also reflect regional cooperation in various aspects of pharmaceutical practice in light of new trade agreements entered into and the harmonization of certain procedures in the pharmaceutical sector that will be beneficial to countries in the region.
- The provisions in the NMP regarding herbal medicines should be enhanced to cover conservation of biodiversity and the strengthening of local research institutions to investigate potentially useful herbal medicinal products.

Implementation of National Pharmaceutical Master Plan

- The autonomy of the MCC should be assured by providing MCC with all that is required for efficient operations while maintaining its autonomy from the MoHSS.
- The structure of the NMP Coordination subdivision should be reviewed with the view of enhancing its coordination role.
- Regional and district pharmaceutical services should be strengthened to undertake monitoring and supervisory activities that include the promotion of rational use of medicines.
- The short- and long-term recommendations of the recently submitted draft report on Human Capacity Development Assessment for the Pharmaceutical Service (June 2005) should be considered for priority action (see Annex 4).
- The MoHSS and PSEMAS should develop closer ties and input into activities of NAMAFA in order to align NAMAFA to the NMP.
- Priority should be given to implementing the PMIS that is currently being finalized. Strengthening the NMP Coordination subdivision will facilitate this. Additionally, extra resources need to be allocated to the overall monitoring and evaluation of the NMP.

INTRODUCTION

In 1998 the Ministry of Health and Social Services (MoHSS) of Namibia launched its National Medicines Policy (NMP), which provided comprehensive guidelines and development objectives for both public and private pharmaceutical sectors. In April 2004 the Management Sciences for Health (MSH)/Rational Pharmaceutical Management (RPM) Plus Program was requested to review the NMP of Namibia and related laws and regulations with the view of proposing changes (if any) that would be entered into the revision of Namibia's National Pharmaceutical Master Plan (NPMP). The NMP and the accompanying NPMP were introduced in 1998 and 2000, respectively.

In addition, MSH/RPM Plus was to provide guidance on the review of the Namibia Pocket Treatment Manual for Health Workers and examine the possibility of developing comprehensive standard treatment guidelines (STGs) for Namibia's health sector. The Namibia Pocket Treatment Manual for Health Workers was first published in 1996 and was derived from the more extensive Treatment Manual for Clinics, which was developed and distributed in 1992. Both documents have been overtaken by new information on diseases as well as new and emerging health problems and the third edition of the Namibia Essential Medicines List (NEMLIST). In addition to commenting on the review of the Pocket Manual the MSH/RPM Plus consultancy was also to state the desirability of Namibia having comprehensive STGs and to provide guidance on the feasibility, suitability, and process for the review and development of a comprehensive STGs document.

In the initial interaction with the permanent secretary and the undersecretary of the MoHSS, the expectations arrived at were that the exercise would focus on three main tasks: review of the NMP, updating of the Pocket Manual, and the determination of the desirability of developing a comprehensive STGs document for Namibia. The basis for this position included the dynamic nature of skills and knowledge for treatment choices, frequent changes in staff, and the wide background of medical staff in the country. The MoHSS also indicated a desire to see—

- Comprehensive STGs document that is developed for use by both public and private health services
- Examination of the existing legislation and identifying issues not covered in the legislation
- Suggestions on the formulation of a medicines pricing policy

METHODOLOGY

This report is based on information collected primarily from individual interviews conducted with key informants and group interviews with health officials in the particular health facility or office. Interviewees included staff in the health sector and health partners. Relevant documents were also studied, which included legislations related to the health sector and reports available in hard copy and on the internet.

Focus group discussions (FGDs) were held with health professionals at all levels of the health care delivery structure. The participants were usually made up of a heterogeneous group comprising medical officers, specialists, pharmacists, nurses, and health administrators. The FGDs were held at the following health facilities—

- Eenhana District Hospital (incorporating staff from Engela District and Ohangwena regional management team)
- Oshakati Intermediate Hospital
- Windhoek Central Hospital and Katutura Intermediate Hospital
- Katutura Health Centre
- Onandjokwe Lutheran Hospital

The FGDs were conducted by the lead consultant with the local consultants as documenters. The discussions were based on a guide agreed on by the consultants. At the end of each FGD session a presentation on how Ghana, an African developing country, developed comprehensive STGs (Annex 6) was presented. Electronic copies of the presentation were left at each FGD site on request.

KEY FINDINGS

The findings are presented according to the three main tasks: review of the Pocket Manual, the feasibility of having comprehensive STGs, and review of the NMP.

Annex 1 provides information on the country and the health sector. It also contains information on the status of the implementation of the NMP. Where possible the latest data is compared with an earlier one. The organogram of the MoHSS is shown in Annex 2. The list of persons interviewed is provided in Annex 3 and the list of documents consulted is given in Annex 4.

Review of Pocket Treatment Manual for Health Workers (Pocket Manual)

The Namibia Pocket Treatment Manual for Health Workers was first published in 1996 and was derived from the more extensive Treatment Manual for Clinics, which was developed and distributed in 1992. Its objective was to standardize treatment practices in the country, particularly at the primary health care (PHC) level. The manual has not been revised since its introduction in 1996.

The Pocket Manual has been found to be an especially useful tool in clinical practice for nurses. However, there are various sections that require review as well as incorporation of recent treatment guidelines for malaria, antiretroviral (ARV) treatment, prevention of mother-to-child transmission (PMTCT), tuberculosis (TB), Integrated Management of Childhood Illness (IMCI), and new relevant topics.

Earlier attempts to review the Pocket Manual occurred in 2001/2002, and the last attempt was in 2003. The major problem with reviewing the manual has been the funding needed to carry out the review because, according to a MoHSS official, “it is easier to review specific programme guidelines than a general manual.”

The following subjects were mentioned as important additions to the topics in the Pocket Manual—

- Use of magnesium sulphate for pre-eclampsia
- Use of nevirapine in PMTCT
- New malaria treatment guidelines: using artemisinin-based combination therapy
- Oral manifestation of HIV/AIDS
- Noma or aphtha
- Noncommunicable diseases
- Other emerging health problems

During the MSH/RPM Plus assignment it was revealed that plans are advanced for the review of the Pocket Manual. This would be funded in the context of the PMTCT plan. It appeared the preference was to review the Treatment Manual for Clinics first and then make extracts for the Pocket Manual. In light of the consideration of a comprehensive STGs document, review of the

Treatment Manual for Clinics was found inopportune. However, it would be more realistic to review the Pocket Manual while waiting for the preparation of the comprehensive STGs. This is because health practitioners, particularly nurses at the PHC centers, need the information in the Pocket Manual on hand at the clinics.

Desirability for Comprehensive Standard Treatment Guidelines

Throughout the interviews and FGDs it was found that there is an overwhelming endorsement for the development of comprehensive STGs for the health sector in Namibia. Policies and guidelines are in place for some specific diseases. For example, the Directorate of Special Programmes of MoHSS, which is mandated primarily with the national response to HIV/AIDS, malaria, and TB, has prepared strategic documents for the control of malaria and TB and developed guidelines for the use of artemether-lumefantrine for treatment of malaria, fixed-dose combinations for TB, and guidelines for antiretroviral therapy (ART). These guidelines have been developed in collaboration with the World Health Organization (WHO).

In addition, guidelines for the management of sexually transmitted infections (STIs) and hypertension as well as for IMCI are in existence. The guidelines for hypertension was the initiative of one of the regional health directorates. This is an indication that some local expertise exists for the development of guidelines. The specific disease guidelines were available at most health facilities visited and are introduced during orientation sessions for new clinical staff.

Perceived Advantages

The reasons put forward to support the development of STGs included the fact that most medical officers are being recruited from different countries with different prescribing cultures and the existence of various guidelines on specific health problems. The STGs document is seen as a tool that could save cost through rational prescribing and standardization of treatment. It would also reduce the influence of pharmaceutical sales persons. It was, however, considered important that the Medical Association of Namibia and especially the private sector be involved in the development of the guidelines.

Comprehensive STGs are also seen as a means of addressing concerns about misuse of antimicrobial agents including antibiotics and antimalarial drugs and the prescription of expensive medicines when cheaper but effective alternatives exist.

Some of the doctors interviewed (mainly foreign ones and at one particular health facility), however, were not in favor of comprehensive guidelines, preferring specific disease “stand alone” guidelines for important diseases. Indeed, it was said that guidelines are only good for nurses. It appeared that the doctors who did not favor comprehensive guidelines came from a background where such tools were not used.

Development Process

It was emphasized that the development of the STGs should be a collective effort in broad consultation with all interested parties in both public and private sectors to ensure ownership and adherence to guidelines.

Contents

The treatment guidelines should include symptoms and signs. In addition to common health problems it should cover the major noncommunicable diseases as well as emerging diseases like the haemorrhagic fevers, ebola, and schistosomiasis. Other suggested topics were the management of pre-eclampsia using magnesium sulphate, and extension of the guidelines for malaria treatment to include household management.

Format

It was suggested that the format of the guidelines be practical, step-by-step, and demonstrate a team approach to patient care. The format of guidelines from other countries should also be consulted in formatting the guidelines. It was also suggested that the guidelines be subsequently converted into flow charts and algorithms to enhance their use.

Implementation

It was indicated that postlaunch activities of documents such as guidelines are generally poor and recognized as a challenge. Adherence to the guidelines is also a problem in point. Orientation of new recruits to the guidelines is often not done effectively except for the recent intake of Cuban doctors. It was proposed that perhaps clinical staff should sign an undertaking to abide by the guidelines.

Monitoring and supervision of medical practice is achieved better at the regional level than at the national level. However, managers are busy with many other responsibilities and transportation is a problem. It was also suggested that with a Patient Charter³ in place patients should be educated to recognize their rights.

To deal with some of the expected problems or concerns it was suggested that there also be training of health workers on the STGs to create a critical mass per region so that supervision of use and adherence can be undertaken. Managers of health facilities should also be trained in the use of the STGs so that they can supervise their staff. Enough copies should be made available as the tendency is for clinicians to consider their copies as personal and thereby take them with them at the end of their contract. The high turn over of staff means that copies of the guidelines run out quickly. The need to use the guidelines in orientating new staff was recognized as essential.

³ Government of the Republic of Namibia. July 1998. *The Patient Charter of Namibia*. Windhoek: Ministry of Health and Social Services, Primary Health Care and Nursing Services Directorate.
<<http://www.healthnet.org.na/policiesguidelines/policies/Patient%20Charter.pdf>> (accessed May 1, 2006).

Review of the National Medicines Policy

The current laws in Namibia regarding control of pharmaceuticals, professional health practice, and the draft bill on traditional healers are comprehensive. Review of the major elements of the NMP and the laws related to the pharmaceutical sector raised some issues.

The current NMP was adopted in 1998. The Pharmaceutical Services Division of the MoHSS has oversight of the policy. The three subdivisions of the Pharmaceutical Services Division are: National Medicine Policy Coordination (NMPC), Central Medical Stores (CMS), and Pharmaceutical Control and Inspection (PC&I). The PC&I subdivision also serves as the secretariat of the MCC. The NPMP was developed out of the NMP.

The NMPC is responsible for the coordination of the implementation of the NPMP. The national institutions and agencies it works with include the Ministry of Finance (MoF), the Interim Health Professions Councils, and the professional associations. The NMPC has conducted surveys aimed at assessing trends in medicine use in the public sector and the implementation of the NMP based on the WHO questionnaire⁴ for this purpose

The focus of NMPC activities, however, seems to be more with pharmacy practice than with medical practice. This is particularly so with training activities and the induction of new employees and introduction to the NEMLIST. The introduction of medical staff to the NEMLIST and Pocket Manual depends on the management of the respective health facilities.

Key issues related to the implementation of the NMP are discussed in the following sections.

Regulation and Practice of Health Professions

The regulation and control of the various health professions and their practice is maintained in the acts establishing the different Interim Health Professions Councils.

Interim Health Professions Councils

The Interim Health Professions Councils have only recently been set up in accordance with new laws disseminated by the Parliament of Namibia to control the practice of health professions. The five councils—Nursing, Medical and Dental, Pharmacy, Social Worker and Psychologist, and Allied Health—are autonomous but have one central administration. The legal scope of the councils is the protection of the public. To improve coordination there are discussions to set up a nonstatutory “Joint Council,” which may be formalized in the future through a National Health Bill. With the Allied Health Council Law there will be no need to have new laws establishing councils for any new or additional profession (e.g., homeopathy, acupuncture).

⁴ Brudon, P., J.-D. Rainhorn, and M. R. Reich, ed. 1999. *Indicators for Monitoring National Drug Policies: A Practical Manual* (produced by the WHO Programme on Essential Drugs). 2nd ed. Geneva: WHO.

Nursing Practice

The Interim Nursing Council is the regulatory authority responsible for the practice of nursing. There are three categories of nurses in the country: registered, enrolled, and auxiliary, with the auxiliary nurses being phased out. Nurses are legally authorized to diagnose and prescribe certain medicines in certain circumstances in terms of the Nursing and Medicines Act because of scarce human resources. In the private sector, especially, nurses must have additional qualification and obtain a permit to prescribe. Pharmacotherapy is now incorporated into the training of registered nurses at the university and there are plans to make such graduates eligible for registration as practitioners. The act may require amendment for this to happen. There is also the need to revise the list of medicines that nurses can prescribe. This requirement should be looked at by the “Joint Council” council.

Presently the Interim Nursing Council is looking into several allegations of professional misconduct against nurses. The handling of medicines, particularly narcotic drugs, by paramedics (Emergency Teams and Fire Brigade) is also of concern to the Nursing Council. There are anecdotes of poor accounting for narcotics released to paramedics. The other angle of the concern is that paramedics have not received training at the same level as nurses and yet they are allowed to handle and administer dangerous medicines not authorized by law.

Medical and Dental Practice

The Medical Association of Namibia has a total membership of about 310, although there about 610 medical practitioners in the country. Membership of the Medical Association is not a requirement for registration with the Interim Medical and Dental Council to practice in Namibia. Approximately 70 percent of the membership is in the private sector and the remaining 30 percent is in the public sector.

Pharmacy Practice

The Pharmaceutical Society of Namibia has a membership of about 135 out of some 200 pharmacists registered with the Interim Pharmacy Council. All pharmacies in the private sector are computerized except one at the time of this review. To be registered as a pharmacist one has to apply to the Council and take a law examination as well as a competency in pharmacy practice paper.

Dispensing Physicians

Presently, some physicians dispense medicines as part of their practice. In the current circumstances the question of dispensing physicians was passionately argued on the basis that pharmacy practice is now a simple matter of taking finished packed products off the shelf and dispensing it to patients. The argument was further informed by the fact that assistants with little training do the most dispensing at private pharmacies. It was argued that if persons with such limited backgrounds can dispense medicines surely doctors can too. The new Medicines and Related Substances Control Act makes provision for the registration of dispensers (doctors,

nurses, and pharmacists) after satisfying defined conditions in the act, including situations where the services of pharmacists is not rendered or in proximity.

The pharmacy profession countered the position of physicians by stating that dispensing physicians do not provide full pharmaceutical care as the clinicians are not trained to provide this service. It was emphasized that the practice of pharmacy is a complex practice that comprises a more than dispensing alone—it involves counseling clients, dispensing, follow-up of patients, and clinical pharmacy. The question of profit motivating clinicians to prescribe unnecessary medicines when they are also dispensing was noted as being a real concern in Namibia. The point was also made that refund of medical aid must be directed as the primary function of the practitioner. Published research findings provide evidence indicating a significant level of irrational prescribing among dispensing prescribers. Indeed the Pharmaceutical Society of Namibia (PSN) saw the introduction of STGs as one way of dealing with irrational prescribing under these circumstances.

Continous Professional Development

The acts establishing the health professionals' councils require that continuous professional development (CPD) activities be organized for the membership of the health professional associations. Presently, most CPD sessions are sponsored by the pharmaceutical industry. However, the Medical Association of Namibia, for example, would prefer sessions to be devoid of advertisements and the use of brand names.

A committee involving all the interim health councils is working on establishing a credit system that should be formalized by 2007. The system may be based on the South African system, where professionals get an accreditation number to which credits may be assigned. Health professionals will be expected to gain 60 credit points in the previous two years to be retained on the register. Product launches will not have serious consideration toward credit points. The credit system would be used for registration and retention on the register of the Medical Association of Namibia.

CPD activities may also be taken in the other countries in the subregion and will thus have a subregional perspective. The countries considered for participation are Malawi, Mauritius, Namibia, South Africa, Uganda, and Zambia. Opportunities exist for the inclusion of rational use of medicines and treatment guidelines to the CPD activities.

Traditional/Complimentary Medicine

There is currently no legal basis for the control of the practice and products of traditional medicine. It is increasingly obvious that there is the need to effect the policy considerations in the NMP to streamline practice in this area of health care.

The Traditional Healers Council Draft Bill is under consideration that is intended to control practice of traditional medicine. The activities of traditional or complimentary medicine practitioners is coordinated in the PHC directorate. Traditional medicine practitioners have an association headed by a pastor.

The draft bill defines traditional healers as herbalist, traditional birth attendant, faith herbalist, diviner herbalist or diviner. The bill sets up the Traditional Healers Council and ascribes to it all the necessary authority under the MoHSS for the regulation of the practice of traditional healers.

While the draft bill makes reference to CPD, its role in research into traditional medical practice is not clear. Some research into local herbs for medicinal purposes has been undertaken at the University of Namibia. Reports on such research are to be deposited with the Health Research Unit of the MoHSS. Unfortunately these could not be verified during the review exercise. However, a MEDLINE® and Google Scholar (<http://scholar.google.com/>) search show some publications on herbal plants in Namibia, but there are no laboratories in the country to undertake safety and efficacy testing of herbal medicines.

It was pointed out during interviews that the use of herbal medicines should be “encouraged” and efforts made to bring them into mainstream practice as there are potentials for the treatment of some of the common diseases. It was pointed out that the practice of traditional medicine, at the moment, is not subject to litigation as opposed to clinic/hospital practice.

Traditional Medical Practitioners advertise their expertise in the local newspapers. They contravene the Medical and Dental Act by stating that they treat certain diseases, while they are not registered as practitioners. On the other hand, there is no legal requirement regarding the advertisement of specific diseases.

Pharmaceutical Regulation

The Medicines Control Council

The MCC has been established by law. Although it has autonomous status the secretariat is formed by the PC&I subdivision. The Registrar of Medicine is also the Chief Pharmacist for PC&I in the Pharmaceutical Services Division. This situation creates a conflict with his position as the Registrar of Medicines.

The MCC has a membership of 12 and the responsibility of regulating medicines for human use. A gap has been identified in the new Medicines Act regarding veterinary medicines, which is being considered for amendment before implementation. The MCC does not concern itself with the regulation of food supplements and cosmetics.

Presently the secretariat of the MCC is located within the Pharmaceutical Services Division and shares staff with the Division. The need for the independence of the MCC secretariat from the Pharmaceutical Services Division is paramount to the function of the MCC. At the moment the budget of the MCC is held by the Pharmaceutical Services Division. In addition, the MCC secretariat needs the requisite staffing, space, and facilities to make it function as per the law. Even with the limited staff available to it there is still the frustration of multiple responsibilities of the key staff members. These factors threaten the autonomy of the MCC.

Registration of Medicines

There was no Namibian medicines register at independence (March 21, 1990). A call for registration of all products in circulation resulted in the registration of 3,000 products in South Africa for automatic registration. Approximately 2,400 of these products have been registered with a backlog of about 1,200. RPM Plus has provided technical assistance to clear the backlog. Computerization of the registration process using the WHO sponsored software, SIAMED, has not been found useful. The software was described by a MoHSS official as “not user-friendly and human resource intensive.”

A registration fee of 60.00 Namibian dollars (NAD) and an annual retention fee of NAD 20.00 are required. This retention fee is not pursued as there are no mechanisms to remind companies or enforce the payment due to workload. Publicizing registered products is a legal requirement that seeks to inform the general public about approved medicines. There are plans to post the decisions of the MCC with regard to registration of medicines on the government website.

Inspection

The inspectorate function of the Pharmaceutical Services Division of the MoHSS covers all facilities as well as the premises of foreign manufacturers wanting to register their products in Namibia. There is only one post for an inspector in MoHSS, a limitation that is problematic for the Division making it difficult to effectively carry out this important function.

Quality Surveillance Laboratory

This essential laboratory has been set up and equipped. Again, the staffing of the facility is inadequate.

Post-marketing Surveillance and Pharmacovigilance

There are no definite activities in this area.

Pharmaceutical Donations

Guidelines for donations have been established and in force. However, there have been hardly any donations in recent times as the guidelines are strictly implemented.

Counterfeit Medicines

There have been no reports of this to the MCC.

Pharmaceutical Advertisement and Promotion

Literature produced and distributed by pharmaceutical companies is a major source of information on medicines for pharmacists and medical practitioners in Namibia. There is no active effort to control advertisement, although the law requires that pharmaceutical

advertisements are approved by the MCC. Promotion of pharmaceuticals is usually carried out by pharmaceutical companies through the launching of products and CPD sessions. There are suggestions that aspects of the International Federation of Pharmaceutical Manufacturers and Associations code of ethics and the WHO guidelines on pharmaceutical promotion are breached. There are reports of pharmacists and doctors being influenced by pharmaceutical companies for the prescription or dispensing of their products.

Traditional medicine practitioners advertise their services in the newspapers without apparent clearance from the MCC. There is a need to work with newspapers to control this act. It was observed by some of the interviewees that enforcement of the law on pharmaceutical advertisement in Namibia is poor and the MCC called for strengthening of the regulatory authority to deal with the practice.

Internet Pharmacy

The MCC is concerned about the increasing trade in pharmaceutical products over the internet involving pharmacies in Namibia. This is a practice where prescriptions from outside Namibia are served by Namibian pharmacies over the internet, resulting in the Namibian government subsidizing medicines for specific diseases outside the country. The trade is usually in antiretroviral medicines, psychotropic medicines, and any medicines that can be procured at a cheaper cost in Namibia.

Public Sector Pharmaceutical Management

The CMS is under the Pharmaceutical Services Division of the MoHSS. It has responsibility for procurement, storage, and distribution of medicines and related supplies for the MoHSS and faith-based hospitals. The CMS supplies to two regional medical stores in the Northeastern and Northwestern parts of the country and also directly to health facilities mainly in the central and Southern parts of the country not reached by the regional medical stores.

Quantification

Quantification is done for periods of one or two years and is based on consumption. This method is, however, not suitable for ARVs due to the changing epidemiology of the disease. Therefore, for ARVs, projections are made based on the scaling-up morbidity method.

Procurement

The method of procurement in Namibia is by international competitive tender. There is only one local manufacturer of pharmaceuticals that produces liquids and creams, and as a result the vast majority of medicines have to be either imported or bought off the shelf from local distributors of imported medicines. The MoHSS expenditure on pharmaceuticals is 8.00 U.S. dollars (USD) per capita. The average international price obtained for regular procurement for a set of indicator medicines in 2003 was 101 percent. The small size of the pharmaceutical market also contributes to the high average price. When there is an order outside the normal tender process, the “buy out” price is usually higher.

Distribution

The CMS has its own fleet of vehicles and runs a six week schedule of delivery. The CMS distributes to two regional medical stores and other health facilities not covered by the regional medical stores.

Inventory Control

A computerized inventory control system—SYSPro™—has been installed and is operational at the CMS and two regional medical stores. It is used to create replenishment reports that guide the distribution of medicines and supplies. The government’s policy is that there shall be no stock-outs at the CMS level. When stock-outs occur at the CMS it is usually because of operational constraints rather than lack of funds. However, stock-outs do occur particularly at the district level. These are mainly due to poor inventory control rather than the existence of budget ceilings that affect acquisition of medicines. The no stock situation in some of the regions was further explained to result when stock ordered by pharmacist’s assistants is reduced before the order is sent to the CMS because of shortage of funds in the region. This practice is, however, not condoned by the Pharmaceutical Services Division as it increases the need for interim orders and expenditure on transport as well as increasing “no stocks” in health facilities.

CMS Concerns

The CMS perceives modernization of its transport fleet as an important requirement for effective performance of its function of distribution. It would also want to institutionalize proper quantification methods to inform procurement, ensure the availability of medicines in all regional medical stores to cut down the six week cycle, and shorten the reorder cycle for the regional medical stores, to improve availability in the facilities they serve. Another major constraint of the CMS is the lack of well trained staff with appropriate skills.

Essential Medicines List

The Namibia Essential Drugs List (formerly NEDLIST, now NEMLIST) was originally derived largely by specialists. There is now a committee that draws up the list. It remains medicine-oriented and the therapeutic classification does not follow the WHO therapeutic classification system. The NEMLIST also does not make reference to the WHO Model List of Essential Medicines (EML). The list therefore is not in a form that makes for easy comparison with other national EMLs. The NEMLIST was first published in 1995 and has been revised to its third edition (1995, 1999, and 2003). Medicines on the list are in international nonproprietary name. The current edition has 398 medicines.

Rational Use of Medicines

Many of the activities listed in the NPMP under rational use of medicines (RUM) have been initiated mainly through a subdivision of NMP. Implementation, however, has not been comprehensive due to staffing problems at headquarters and in the regions. Unimplemented activities include appropriate use of medicines at the community level, establishment of a Drug Information Centre, and the instituting of a pharmacovigilance program. The subdivision has also undertaken serial RUM indicator studies across the country that provide information on progress or changes in the indicators.

Opportunities exist in the implementation of CPD activities by the Interim Professional Health Councils and the proposed comprehensive STGs to improve rational use of medicines. The concept of essential medicines is part of preservice curricula of health staff training in Namibia, comprising mainly nurses and pharmacist's assistants. The dissemination of the regular national surveys on rational use of medicines may also assist in increasing awareness of the problems or achievement of the various interventions being pursued. It is important that the coordination role of NMPC predominate over implementation of interventions. In the long-term each district and region should have a pharmacist who will also be the focal person to promote rational use of medicines in the region and liaise with the office of the NMPC.

The promotion of the rational use of medicines is a major responsibility of the NMPC subdivision in the Pharmaceutical Services Division. The NMPC subdivision has conducted workshops and carried out surveys based on the WHO medicine use indicators to support RUM activities. There is the need to encourage and resource regional and district health management teams to institutionalise activities aimed at improving medicine use.

The Interim Professional Health Councils support the promotion of RUM through the incorporation of the essential medicines concept and the rational use of medicines concept in the curricula of the training institutions for nursing and pharmacy. The councils ensure a certain minimum requirement in the curriculum and the training institutions may add on to this. There is opportunity to promote the rational use of medicines through the councils, as CPD is a requirement for all the councils as enshrined in the Parliament of Namibia acts. In the private sector the Namibian Association of Medical Aid Funds does not organize CPD activities for its providers and has no plans to pursue such activities.

Opportunities exist for the MoHSS to liaise with the professional health associations and introduce the concept of the RUM and training in the use of STGs in the CPD program of the associations. The MoHSS could also write articles on other relevant topics for publication in the newsletter of the health associations, for example, the Epistola of the Medical Association of Namibia.

Therapeutic Committees

The permanent secretary of the MoHSS issued an order for the establishment of Therapeutic Committees (TCs) in all health facilities. The importance of TCs was related to poor prescribing habits, especially polypharmacy and the problem of expatriate doctors and their different

prescribing cultures. According to MoHSS officials, “...the country is not short of medicines but it is the way we use them.” Concern was also expressed about vaccines that were supplied with short expiry dates (especially for immunization campaigns).

It was observed that TCs are not well developed at the health facility level. The reasons given included no support for supervision, lack of pharmacists at health facilities, and the busy schedule of health providers making it difficult for them to meet. However, two regions have managed to establish a TC in each district hospital as well as at the regional level and several other districts have TCs that are functioning to some degree.

Human Resources Development

The lack of qualified staff poses the leading threat to the development of the pharmaceutical sector in Namibia. The situation affects pharmacists and pharmacist’s assistants. In addition there are disparities in the distribution of the pharmacy professionals within the public sector and between the public and private sectors. About 80 percent of pharmacists are in the private sector. Those in the public sector are found in the larger health facilities. Other health professionals are also affected; there are about 700 vacant posts in the MoHSS. The difficulties faced in filling these vacancies are related to availability of qualified persons, freezing of some posts, and budget cuts. The staffing situation is worsened by the Ministry embarking on new programs without hiring additional staff, absenteeism, and death from HIV/AIDS (including the pool from which new staff will be derived).

The implications for quality health care and in particular, the ARV program, include increased work load and unplanned shifting of tasks within requisite training; for example, pharmacist’s assistants doing the work of pharmacists, and nurses covering for doctors. Although some needs are being addressed by recruitment through support from The President’s Emergency Plan for AIDS Relief team in Namibia and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), it is questionable if this assistance is sustainable.

Human resources development in the MoHSS is vested in the Human Resources Development Division. Staffing in the MoHSS is limited and even worse in the pharmaceutical sector. The categories of personnel under the purview of the division are doctors, pharmacists, pharmacist’s assistants, registered nurses, and enrolled nurses. The dire situation of human resources availability was reinforced by nearly all persons interviewed. The severe human resources problem was highlighted focusing on the lack of doctors, pharmacists, and medical technologists. The point was made that no projections exist for these staff—contrary to information provided by the HRD Division and the NMP Coordination subdivision. The vacancy rate for doctors, nurses, and pharmacists was given as 40, 25, and 50 percent respectively.

It was repeatedly mentioned by many of the interviewees, particularly those in the United Nations organizations, that there was lack of human capital in the health sector. Many of the doctors in the country are expatriates and are found in the public sector. Namibian doctors tend to be in the private sector.

Training of pharmacists and medical doctors start at the University of Namibia (only for those who do not meet the entry requirements for South African universities) and is completed in South Africa. The National Health Training Centre also runs preservice trainings for pharmacist's assistants, radiography assistants, environmental health assistants and enrolled nurses, and in-service training sessions on PMTCT, Integrated Management of Adolescent and Adult Illness (IMAI), VCT, and ART.

The expected response to the shortage of pharmacists is to train more Namibian pharmacists; however, the situation is confounded by the lack of high school graduates interested in pharmacy, poor public image of pharmacists, and a highly competitive labor market with a shift from public to private health sector (where the working conditions and compensation are better).

There is also a shortage of nurses in the public health sector. Currently plans are advanced to recruit nurses from Kenya and also from the Southern African Development Community countries to meet national requirements. This, however, takes a long time because of the delays in obtaining work permits. In addition, several positions in the public sector have been frozen and reactivation takes a long time to occur.

Table 1 shows the vacancies that exist in the MoHSS for various categories of health workers. Table 2 shows a summary of staff losses by reason for 2002/2003 and 2003/2004.

Table 1. Health Worker Vacancies in the MoHSS

Category	Approved Posts	Posts Filled by Namibians		Posts Filled by Non-Namibians		Total Posts Filled		Volunteers		Vacancies	
	N	N	%	N	%	N	%	N	%	N	%
Physiotherapists	29	4	13.8	2	6.9	6	20.7	6	26.1	23	79.3
Pharmacy interns	2	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0
Pharmacists	46	5	10.9	16	34.8	21	45.7	10*	21.7	25	54.3
Pharmacist's assistants	80	60	75	0	0.0	60	75	0	0.0	20	25
Health inspectors	67	23	34.3	5	7.5	28	41.8	2	5.1	39	58.2
Environmental health assistants	82	36	43.9	0	0.0	36	43.9	0	0.0	46	56.1
Dentists	20	5	25.0	5	25.0	10	50.0	4	40.0	10	50.0
Social workers	147	73	49.7	4	2.7	77	52.4	2	2.9	70	47.6
Medical interns	32	9	28.1	17	53.1	26	81.3	0	0.0	6	18.8
Doctors	286	59	20.6	112	39.2	171	59.8	43	37.4	115	40.2
Medical specialists	47	20	42.6	13	27.7	33	70.2	1	7.1	14	29.8
Enrolled nurses	2487	1900	76.4	0	0.0	1900	76.4	0	0.0	587	23.6
Registered nurses	2071	1538	74.3	9	0.4	1547	74.7	0	0.0	524	25.3
Orthodontists	4	2	50.0	1	25.0	3	75.0	0	0.0	1	25.0
Radiographers	48	20	41.7	9	18.8	29	60.4	4	21.1	19	39.6
Radiography assistants	40	32	80.0	0	0.0	32	80.0	0	0.0	8	20.0
Orthopaedic technologists	10	9	90.0	0	0.0	9	90.0	0	0.0	1	10.0
Orthopaedic technicians	26	26	100.0	0	0.0	26	100.0	0	0	0	0.0

Source: Government of the Republic of Namibia. October 2005. HRD Division Annual Report 2004/05 and Subdivision of National Medicines Policy Coordination. Windhoek: MoHSS.

* This figure excludes Cuban pharmacists volunteers and extra pharmacists to staff establishments employed by CDC, MSH, FHI, and GFATM.

An area of marked concern is the human resources deficiency in the pharmaceutical sector. Although outward movement of health professionals (brain drain) is not a major problem, the human resources base is poor, as there is about a 50 percent failure rate for entrance into tertiary education. There is also the social and public image of the pharmacist mitigating the enrollment for training in pharmacy. Of the 48 posts in the MoHSS for pharmacists at the time of the interviews, only 14 posts were filled, 4 of which are filled by Namibians. The majority of pharmacists (over 80 percent) are in the private sector.

Table 2. Summary of Staff Losses by Reason for 2002/2003 and 2003/2004

Reason	2003–2004		2002–2003	
	Number of Staff	% of Total Staff Losses	Number of Staff	% of Total Staff Losses
Resignations	224	42.5	82	35.3
Death	93	18	63	26
Retirement	65	12.3	38	16
Transfer to other government unit	92	17.5	28	12
Medical discharge	35	6.6	11	5
Dismissal	18	3.4	12	2.1
Total	527	100	234	100

Source: Government of the Republic of Namibia. July 2004. HRD Division Annual Report. Windhoek: Director of Policy, Planning, and HRD, MoHSS.

The effect of the situation on all categories of staff in the MoHSS was emphasized. The situation has an effect on the quality of service provided at health facilities. These effects include increased work load and use of underqualified staff. For example, pharmacist's assistants are doing the work of pharmacists and nurses are covering for doctors.

The government has implemented government-sponsored training programs to address the problem of the shortage of doctors and pharmacists. However, there is a real risk that the trainees will move to the private sector when they qualify.

Another factor that mitigates against government-sponsored training of pharmacists is that the beneficiaries cannot be bonded; this is considered to be against their human rights. There is therefore the need to enforce the contract between the beneficiaries and the Ministry of Education to serve a period or give the trainees a provisional registration until they have completed an agreed service period.

The MoHSS is using The President's Emergency Plan for AIDS Relief Program, GFATM, and other funding sources to support employment by importing expertise and providing supplemental staff. This is in the face of frozen posts and a decrease in health spending. There is great concern as to the sustainability of this intervention. Table 3 shows the situation in the pharmaceutical sector, where a total of 48 health workers are provided through development partners.

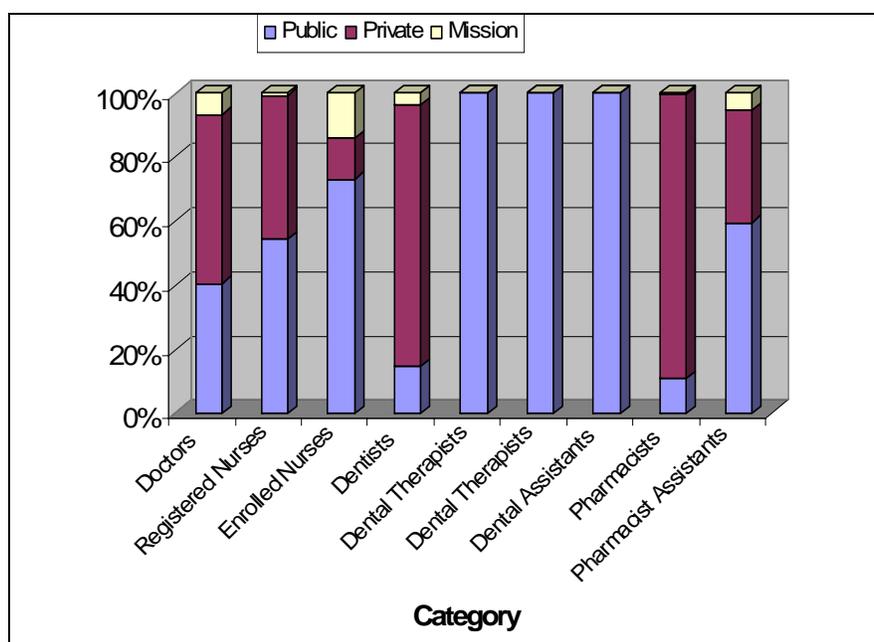
Table 3. Public Sector Pharmaceutical Staff Provided Through Development Partners

Source	Cadre	Number
CDC	Pharmacist	10
	Pharmacist's assistant	0
GFATM	Pharmacist	1
	Pharmacist's assistant	3
Cuban volunteers	Pharmacist	20
MSH	Pharmacist	9
	Pharmacist's assistant	2
	Quality Surveillance Laboratory manager	1
	Pharmacist's assistant training course tutor	1
	Advisor	1

Source: Government of the Republic of Namibia. 2005. Subdivision National Medicine Policy Coordination.

Inequality in the distribution of health personnel is a national problem. The removal of incentives for working in under-served areas (which was in place until 1995) has also contributed to the shift from the public to the private sector.

Figure 1 shows the distribution of registered key health staff (2004/2005) between the three major service providers: public, private, and mission facilities.



Source: Government of the Republic of Namibia. HRD Division Annual Report for Financial Year 2004/2005. Windhoek: MoHSS.

Figure 1. Distribution of registered key health staff (2004/2005) between public, private, and mission facilities.

To shift the imbalance in the distribution of the pharmacists in favor of the public sector, there will need to be improved remuneration and attention given to work load. Opportunities exist in the public sector for career fulfillment as in joining ward rounds, patient counseling, and other clinical activities.

Regional Cooperation

Namibia has had a long history of association with the southern African countries and has established trade links with many of them, especially through regional trade arrangements, and in particular with South Africa. There is evidence of recent efforts at expanding the scope of regional trade initiatives.

Trade-Related Aspects of Intellectual Property Rights

Namibia was expected to be TRIPS compliant on the date the team visited the Ministry of Trade and Industry. The bill is in place but yet to be placed before parliament. The draft bill had been extensively circulated for comment to various international agencies including the World Trade Organization, WHO, and the African Regional Industrial Property Organization (ARIPO), as well as local stakeholders. The plan is to include the TRIPS Agreement flexibilities to protect public health in national legislation.

Namibia is also speeding up the preparation of legislation to be in line with the World Intellectual Property Organization (WIPO) and the ARIPO agreements. Despite the historical ties with the Republic of South Africa and the close trade relations with ARIPO, South Africa is not a signatory to ARIPO. This may have implications for subregional transactions.

There is also an act in place for the setting up of a Competition Commission. This is necessary for the implementation of the TRIPS agreement.

The Republic of South Africa is assisting Namibia in the establishment of a Standards Body to ensure that imported and locally manufactured goods meet required set standards. This is an important activity that can promote interregional trade in pharmaceuticals if a common standard is applied to commodities in the region.

Patents

The existing law on patents is an act inherited from South Africa (passed in 1916). The patent register is not computerized, making it difficult to obtain information on pharmaceuticals on the patent register. This information is required by the MoHSS when it wants to take advantage of the TRIPS flexibilities.

As part of Namibia's Vision 2030⁵ it is expected that the country will become a major exporter. The country is opening up to the rest of the world and decreasing its dependence on South Africa. Examples of these efforts include the Trans Kalahari Highway, the Maputo Corridor, and the establishment of more Air Namibia regional and international routes. It is important that necessary plans be made to take advantage of the trade agreements Namibia is signatory to.

It will also be pertinent for the Ministry of Trade and Industry and the Ministry of Justice/Attorney General's office to work closely with the MoHSS to outline the administrative arrangements required for taking advantage of the provisions of the TRIPS agreement and develop a standing protocol for the generation of government use and compulsory licensing documents.

Pricing of Pharmaceuticals

Public Sector Pharmaceutical Pricing

There are no tariffs or markup on medicines procured for the public health sector. The MoHSS absorbs the cost of transportation. Medicines are supplied to public health facilities at the price procured by the CMS.

Private Sector Pharmaceutical Pricing

The pricing of medicines in the private sector was previously based on wholesalers' price with a markup while different prices could be negotiated for bulk purchase. However, a Single Exit Price (SEP) was set up in negotiation with the South African Government and wholesalers (InterPharma Data Systems). The prices are fixed regardless of quantity purchased. All pharmacies in Namibia are computerized except one and this makes implementation of medicines prices consistent. Prices are determined as SEP + 50 percent SEP, as markup + 15 percent VAT, plus a dispensing fee of NAD 2.50 per item. For ARVs a flat fee of NAD 75.00 is charged per item per prescription. For medicines classified as expensive life saving medications a fee of 10 percent the SEP per item is applied.

In late 2004 the Namibia Maximum Price List (NMPL) was set up in collaboration with the medical aid companies. The NMPL is not the average price but rather a subjective price, determined by taking into consideration the range of prices available for a certain item. The NMPL states the maximum price the medical aid fund will refund. The NMPL encourages use of generic medicines and results in significant savings to patients.

⁵ Government of the Republic of Namibia. 2004. *Namibia Vision 2030: Prosperity, Harmony, Peace and Political Stability*. Windhoek: Office of the President, National Planning Commission. <<http://www.npc.gov.na/vision/vision2030.htm>> (accessed May 1, 2006).

Medical Aid Schemes

Public Sector

Health financing for public servants is managed by the PSEMAS, which has a membership of 122,000. PSEMAS is owned by the public employees and subsidized by the government. It operates as a private scheme for all public servants and their dependants but is not mandatory. Rules and benefits are determined by the Office of the Prime Minister. The MoF acts as the coordinator/administrator on the financial part. The MoHSS is the advisor on the medical part. Claim administration is outsourced to private administrators who have a contract with service providers.

PSEMAS does not abide by reimbursement based on the NEMLIST and there is no “capping” or ceiling on the amount of refund for prescriptions. PSEMAS pays 95 percent of medication costs and the patient pays the remaining 5 percent of the price of medications prescribed by a recognized service provider. Where a PSEMAS member attends a provider not registered with PSEMAS and the member cannot pay the bill, the member may apply to PSEMAS and 95 percent of the cost may be borne by PSEMAS and the other 5 percent by the member. About 40 to 50 percent of the insurance cost is attributable to medicines. The NMPL is a private sector driven list that ensures a level playing field in medicine costs. The NMPL forms the basis for reimbursement for medicines in the public sector.

There have been attempts to limit items on a prescription to a maximum of five except with justification, but this is being opposed by the Pharmaceutical Society of Namibia. There is the need to educate scheme managers on the benefits of the NEMLIST and the STGs. There is also no ceiling on reimbursement of AIDS treatment as exists in the private sector and this imposes financial strains on the public health system.

Private Sector

The NAMAF is a statutory body constituted by the Medical Aid Funds Act (1995) under the Namibia Financial Institutions Supervisory Authority. It has responsibility for all medical aid funds in Namibia except the PSEMAS. About 14 percent of the population of Namibia is on a medical aid scheme. Of these about 10 percent are on private schemes and the remaining 4 percent are on PSEMAS.

Accreditation of members is based on the laws and regulations of the specific profession. The practices are monitored against a background of benchmarks set by the fund. Outliers are usually informed of their position and encouraged to conform.

The NAMAF has defined tariffs that it uses to reimburse services including pharmaceuticals. Payment is guaranteed in 30 days. The NAMAF sets the prices for all medical aid funds. The SEP is the determinant of the price paid by patients for medicines. There are current negotiations with the PSN to establish a new scheme for reimbursement, based on a professional fee rather than 50 percent markup.

The medicines on MedScheme's reimbursement list are determined by a TC and do not follow the NEMLIST. Pricing is based on the NMPL. Generic substitution is allowed except for medicines with a narrow therapeutic window or medicines that have no substitutes. The private medical aid funds set a limit for ARV treatment. One insurer has an annual limit of NAD 25,000.00.

Traditional Medicine

The NAMAf does not reimburse use of traditional medicine because their products are not registered and there is no formal body to deal with. Some medical aid funds have fixed limits for complimentary and alternative medicines.

High Cost of Medicines

Factors that contribute to the high cost of medicines include dispensing physicians who maximize their profits by obtaining their medicines directly from manufacturers or give medicine samples to patients for a fee. Other factors were the absence of control on the rational use of medicines and the abuse of patient follow-up (a practice where patients attending for review of their health problems are treated as new cases and medications are prescribed for conditions that may be a consequence of an earlier visit). Medical aid funds charge 8 percent of entire subscriptions as their administrative cost. This was considered to be too high and a drag on the system.

It was noted that profit for manufacturers, wholesalers and pharmacists have been cut in an effort to decrease medicine costs, but the administrative costs applied by medical aid funds has not been decreased. It was considered not reasonable to expect intermediaries to reduce prices as smaller pharmacies will suffer financially. It was also pointed out that distributors are allowed to charge a single digit percent logistic fee and this covers free delivery to the door step. However, certain medicines, like antimalarials, do not attract the logistic fee.

Public-Private Partnership

The suggestion that the private medical practitioners buy their medicines from the CMS or set up cooperatives with the Pharmaceutical Society as a means of maintaining reasonable medicine costs that can be passed on to patients was considered reasonable.

Local Manufacture of Pharmaceuticals

Presently there is only one local pharmaceutical manufacturer in Namibia. The company produces mainly liquid preparations, ointments, and creams. The private sector in Namibia considers that the pharmaceutical market is too small for a capital intensive activity like pharmaceutical manufacture. Regional cooperation is seen as a possible solution but this will require a common certification or reciprocal recognition and common scheduling of medicines for the region. This will have the advantage of cheaper medicines in Namibia.

The Ministry of Trade and Industry, on the other hand, has a different view. It views the opinion of the private sector on the low capacity for local manufacture as being based on false assumptions and a marketing ploy. It was stated that the NEMLIST is comprehensive to cover national needs. It was also indicated that the size of the market goes beyond the borders of

Namibia as there are infiltrations into Namibia from its Eastern and Northern borders for health care.

The Ministry saw the establishment of three medium-sized plants as feasible. These plants will focus on the production of items on the NEMLIST in addition to others. Discussions are ongoing about the conditions for the establishment of the pharmaceutical plants. Some of the conditions will be a five-year contract that will provide coverage of 30 percent of the public market plus participation in distribution. In addition to the fixed 30 percent of the public market and participating in a distribution network, other incentives include competing on local tenders. It was felt that participation in distribution will serve as a catalysts for the CMS to be more efficient. As part of the package it is also proposed that there will be no tariffs on manufacturing inputs and assistance will be provided to expedite skills development and waste management.

In pursuing this agenda, the Ministry will bring to bear its regulations and guidelines as enshrined in the Environmental Law, as environmental assessment is mandatory prior to the establishment of any industry.

The need to develop traditional herbal medicines was seen as a national priority and an interministerial committee on it exists. Three potential plants have been identified, including Devil's Claw, that can be developed. The need to have conservation of biodiversity vis-à-vis promotion of local development and manufacture of herbal medicines and the export of plants for the same purpose was emphasized. The absence of firm statements regarding utilization of indigenous knowledge in health in the NMP was identified as a challenge.

Standards

Namibia has no national standards body. There is a bill ready for Parliament that seeks the establishment of a standards organization for the country. In the meantime, international standards apply and there is a responsible office in the Ministry of Trade and Industry.

NEXT STEPS

Review of the Pocket Manual

The Pocket Manual should be revised and updated to reflect current management of health problems—in particular the IMCI, IMAI, PMTCT, VCT, and ARV services as a result of the increased need for these services at the periphery.

The review of the Pocket Manual has to be considered in light of the proposed development of comprehensive STGs.

In view of the usefulness of the Pocket Manual and the possible long process of developing comprehensive STGs, the Pocket Manual should be revised to include more current information on health problems and also align treatment choices to the EML.

Development of Comprehensive Standard Treatment Guidelines

- Move from disease specific treatment guidelines to comprehensive STGs.
- Establish a standing committee with ministerial oversight to develop STGs.
- Establish a secretariat within the subdivision of NMPC to support the standing committee.
- Pull together all guidelines available in the public sector, including hospital developed guidelines, by a committee comprised of credible physicians, surgeons, pharmacists, and nurses; consult guidelines from other developing countries.
- Identify sources of funding and technical assistance for the activities of the standing committee.
- Select treatments based on evidence and conform to WHO criteria for selecting essential medicines for pharmaceutical selection; technical assistance may be sought from WHO and MSH.
- Use STGs to inform the development of a Namibia Essential Medicines List.
- Use experience of other African developing countries to guide the process of developing the treatment guidelines.
- Use presentation on the how the STGs of Ghana was developed as a guide.

Review of the National Medicines Policy

The elements of the NMP are consistent with those of many developing nations and agree with the format recommended by WHO. The laws emanating from the policy are comprehensive and cover the major aspects of pharmaceutical sector practice. While aspects of the NMP require review, the delay in issuing the regulations required to implement the Medicines and Related Substances Act based on the 1998 NMP confounds the situation. There are, however, new or outstanding issues to be considered both in the laws and the implementation of the NMP through the NPMP.

Legislation

MoHSS should expedite action on the finalization of the legislative regulations to the law.

The Ministry of Trade and Industry should work closely with the MoHSS and related ministries to strengthen existing laws to promote local manufacture of pharmaceuticals and medical supplies and also develop the necessary regulations, procedures, and guidelines to take advantage of the TRIPS flexibilities.

The practice of internet pharmacy should be further investigated and regulations effected if necessary.

- For efficient performance of the Interim Health Professions Councils, legislative instruments may have to be provided to formalize the concept of a “Joint Council” as an administrative mechanism.
- The acts concerning nursing practice may require amendment to allow certain trained categories of nurses (graduates trained in pharmacotherapy) to prescribe identified medicines and continue prescription for stabilized chronic disease patients.

Comment: This will allow patients to go for refills nearest to home and improve adherence for most chronic disease medicines, particularly ARVs. This is also in line with the decentralization and task shift ideas of the IMAI. Decentralization of prescription rights should be a major recommendation and the scheduling of medicines should also reflect the same. There are also issues with the access to palliative care medicines as part of Home Based Care kits.

- Institute a training plan leading to the certification of paramedics and other emergency personnel on the use of narcotic substances and other resuscitating medicines.
- The Traditional Healers Bill should have a section dealing with conduct of research into herbal medicines and verification of claims.
- The Traditional Healers Bill should also consider the establishment of a national institution for research into plant medicine.

- The matter of dispensing clinicians in the context of containing costs of medicines and promoting rational use of medicines should be reviewed and a legislative instrument established to control it.
- Enact legislation on internet pharmacy.
- Develop legislation of modalities for the utilization of the flexibilities of TRIPS.
- Develop a standing protocol for the generation of government use and compulsory licensing documents.

Pharmaceutical Regulation

The autonomy of the MCC should be assured by providing MCC with all that is required for efficient operations while maintaining its autonomy from the MoHSS.

The structure of the NMP Coordination subdivision should be reviewed with the view of enhancing its coordination role.

Regional and district pharmaceutical services should be strengthened to undertake monitoring and supervisory activities that include the promotion of rational use of medicines.

The short- and long-term recommendations of the recently submitted draft report on Human Capacity Development Assessment for the Pharmaceutical Service (June 2005) should be considered for priority action (see Annex 4).

The MoHSS and PSEMAS should develop closer ties and input into activities of the NAMAFA to align the NAMAFA to the NMP.

Priority should be given to implementing the Pharmacy Management Information System that is currently being finalized. Strengthening the NMP Coordination subdivision will facilitate this. Additionally, extra resources need to be allocated to the overall monitoring and evaluation of the NMP.

- The MCC should be adequately resourced in terms of a separate budget, space, equipment, and personnel to carry out its responsibilities; the secretariat should also be removed from the Pharmaceutical Services Division to ensure the MCC its autonomy.
- Considering the constraints of staff and space, consideration may be given to outsourcing some of the functions of the MCC (for example, maintaining the registration database), seeking technical assistance from international agencies like the WHO, MSH, The President's Emergency Plan for AIDS Relief, etc., as well as embarking on intensive programs to build the necessary capacity (for example, training in dossier review and Good Manufacturing Practice inspection) to carry out its mandate.

- Provide resources to enable complete review and completion of medicines registration and linking to the patent registration procedures in the Ministry of Trade and Industry.
- Establish a national pharmacovigilance system.
- Strengthen the control of advertisement of traditional medical practice and traditional medicines in the media.

Public Sector Medicines Management

- Extend the experience gained in the quantification, inventory management, and distribution of ARVs to the general medicines management process at the national, regional, and district levels. This should include training and resources to perform adequately.
- Reorganize the EML committee by broadening the membership to include representatives of all categories of medical staff. Train EML committee members on critical appraisal skills.
- The selection and therapeutic classification of medicines on the EML should follow the WHO criteria.
- Strengthen the present institutional arrangements for the promotion of rational use of medicines; promote closer collaboration with the interim professional councils and the professional associations.
- Implement the directive of the permanent secretary on the establishment of TCs at all health facilities. However, technical support in the establishment and responding to the responsibilities of TCs should be made available.
- The Coordination subdivision of NMPC should be strengthened with staff and other required resources for it to carry out its coordinating role efficiently.

Human Resources Development

It is recognized that there is severe deficiency in human resources in the pharmaceutical sector that is influenced by complex factors including the effects of the HIV/AIDS epidemic in Namibia. In addition, while brain drain is not a major problem, the human resources base is poor as a result of a relatively high failure rate for entrance into tertiary institutions.

- Efforts should be made to improve conditions of service in the public sector to attract young people into the pharmacy profession.
- The Government of Namibia should reconsider the process of reactivating frozen posts to make it more efficient, especially for the pharmaceutical sector.
- The current system of using donor funds to pay for positions in the health sector is not sustainable and alternate approaches have to be explored.

Pricing of Pharmaceuticals

Pricing of medicines has been through a stable mechanism that works well in the private sector, but it is relatively expensive. The cost of medication treatment is also affected by inappropriate prescribing, dispensing physicians, and aggressive detailing by pharmaceutical firms. The public service suffers from a higher cost of treatment because its medicine reimbursement is not tied to the NEMLIST.

- The MoHSS should work closely with PSEMAS and the NAMAF to streamline medicine prices.
- PSEMAS should use the NEMLIST as the basis for its medicines reimbursement scheme.

Local Manufacture of Pharmaceuticals

It is necessary to reemphasise in the NMP and its NPMP the search for innovative ways of attracting pharmaceutical manufacturers to Namibia.

In considering the review of the NMP, the TRIPS agreement and its flexibilities should be included. There is also the need for collaboration between the MoHSS, the Ministry of Trade and Industry, and the Ministry of Justice to initiate the necessary administrative procedure to take advantage of the TRIPS flexibilities.

The NMP should also reflect regional cooperation in various aspects of pharmaceutical practice in light of new trade agreements entered into and the harmonization of certain procedures in the pharmaceutical sector that will be beneficial to countries in the region.

The provisions in the NMP regarding herbal medicines should be enhanced to cover conservation of biodiversity and the strengthening of local research institutions to investigate potentially useful herbal medicinal products.

- The MoHSS must take advantage of the commitment of the Ministry of Trade and Industry to promote and establish local pharmaceutical manufacturing companies and work together to achieve this mutual objective.
- Improve on the operations of the Patent Office by providing electronic documentation facilities to facilitate efficient retrieval of information for processing applications seeking implementation of the TRIPS flexibilities.

Regional and International Cooperation

- Build on the existing efforts to promote regional cooperation to enhance trade and professional relations particularly in the health sector.

It is advised that these recommendations should be accommodated within the NMP, updated, and reviewed at a workshop by all stakeholders and subsequently adopted as a reviewed NMP, which

will be signed by the Minister to become the new NMP. Subsequently, the new NPMP should be developed from the revised NMP.

Annex 5 provides provisional costing for the implementation of the major activities recommended in this report. It is provided only as a guide and may be enhanced based on local knowledge and practices.

ANNEX 1. NAMIBIA NATIONAL MEDICINES POLICY INDICATORS

BACKGROUND INFORMATION

Population data

BG1: Total population 1.83 Million (2001 census)

BG2: Average annual growth of the population 2.6% (2001 census)

BG3: Percentage of the total population living in urban areas (NDHS 2000)

Residence	Female	Male
Urban	41.2%	44.4%

BG4: Life expectancy (years) = 43.9years (2005 IDB Summary Demographic Data for Namibia, <http://www.census.gov/cgi-bin/ipc/idbsum?cty=WA>)

Economic data

BG5: GNP per capita

2003

GDP per capita (constant 1995 USD) 2250.3

Source: World Development Indicators,

<http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/AFRICAEXT/NAMIBIAEXTN/0,,menuPK:382319~pagePK:141132~piPK:141109~theSitePK:382293,00.html>

GDP - per capita: Purchasing power parity - \$7,300 (2004 est.)

Source: <http://www.cia.gov/cia/publications/factbook/geos/wa.html>

BG6: Average annual rate of inflation

Inflation rate 4.2% (2004 est.)

(consumer prices):

Source: <http://www.cia.gov/cia/publications/factbook/geos/wa.html>

HEALTH INFORMATION

Health status data

BG7: Infant mortality rate (per 1,000 live births) 1992 – 57, 2000 - 38

BG8: Maternal mortality rate (per 100,000 live births) 1992 – 225, 2000 - 271

BG9: Top five causes and rate of infant morbidity

UNDER 1yr Morbidity (rate per 1000 discharges from Paediatric wards)

	2001-02	2004-05
Diarrhoea / GE	217	279
Pneumonia	208	204
Malaria	171	115
Other Respiratory disease	53	80
Bronchitis / bronchiolitis	34	
Malnutrition		24

BG10: Top five causes and rate of infant mortality

Rate per 1000 deaths	1999	2004/05
Pneumonia	242	253
Premature Birth	182	79
GE	109	143
Slow Foetal Growth		92
AIDS	88	57
Malnutrition	71	
Other Perinatal Period		57

BG11: Top five causes and rate of adult morbidity

Rate per 1000 in 5yrs and older	1997/98	2001
Malaria	201	265
ENTM	118	
Musculo-skeletal/Neuro	113	100
Other respiratory		92
Other diagnosis	112	
Other Skin		72
ARI	94	
Trauma / Injury		65

BG12: Top five causes and rate of adult mortality

Deaths all ages

Rate per 1000 deaths	2001	2003/04
HIV/AIDS	234	200
Diarrhoea/GE	165	123
Pulmonary TB	152	117
Malaria	134	90
Pneumonia	108	92

Human resources

BG23: Total number of pharmacists

	2000	2004
Employed by MoHSS	22	20
Namibian in MoHSS	8	6
Extra in MoHSS	2	28
Registered with Ph Board	Unknown	193

BG24: Total number of pharmacy technicians or other aides/assistants

	2000	2004
Employed by MoHSS	Unknown	60
Extra in MoHSS	Unknown	7
Registered with Ph Board	Unknown	81

Number of drugs

BG31: Total number of drugs on the national essential drugs list (in INN)

	1 st edition 1995	3 rd edition 2003
	426	398

Legislation and regulation

ST1: Is there an official national drug policy document updated in the past 10 years? YES

Essential drug selection and drug registration

ST12: Is there a national essential drugs list (EDL)/formulary using INN officially adopted and distributed countrywide? Yes

ST13: Is there an official drug committee whose duties include updating the national essential drugs list (EDL)? Yes

ST14: Has the national essential drugs list (EDL)/formulary been updated and distributed countrywide in the past five years? Yes – 1st edition 1995, 2nd edition 1999, 3rd edition 2003

Pricing policy

ST37: Are drug prices regulated in the private sector? YES Namibian Maximum Price List

ST38: Is there at least one major incentive for the private sector to sell essential drugs at low cost?

Yes the NMPL

ST39: Is the total margin used by wholesalers and retailers less than 35% of the CIF price? No; Retailers add 50% plus VAT 15%

ST40: Is there a system for monitoring drug prices? Yes

ST41: Are essential drugs under INN or generic name sold in private drug outlets? Yes

Information and continuing education on drug use

ST42: Is there a national publication (formulary/bulletin/manual, etc.), revised within the past five years, providing objective information on drug use? No

ST43: Is there a national therapeutic guide with standardized treatments? Not comprehensive – only some diseases

ST44: Is the concept of essential drugs part of the curricula in the basic training of health personnel? - yes

ST45: Is there an official continuing education system on rational use of drugs for prescribers and dispensers? Not yet

ST46: Is there a drug information unit/centre? No

ST47: Does the drug information unit/centre (or another independent body) provide regular information on drugs to prescribers and dispensers? N/A

ST48: Are there therapeutic committees in the major hospitals? Yes (?Oshakati)

ST49: Are there public education campaigns on drug use? Not comprehensive – so far used pharmacy week for public education campaigns – with pharmacy staff providing health education, posters being displayed and radio talks

ST50: Is drug education included in the primary/secondary school curricula? Not as far as we know

Essential drug selection and drug registration

PR8: Value of drugs from the national essential drugs list (EDL) procured in the public sector, out of total value of drugs procured in the same sector. 100%

PR9: Number of drugs from the national essential drugs list (EDL) prescribed, out of total number of drugs prescribed (*).

Refer to 3rd Medicine Use survey – 91% according to Nedlist – i.e. on Nedlist and prescribed at appropriate level

PR10: Number of drugs from the national essential drugs list (EDL) sold, out of total number of drugs sold(*). No survey to date in private sector

PR11: Number of locally manufactured drugs sold in the country from the national essential drugs list (EDL), out of total number of drugs from the national essential drugs list (EDL). ??

Information and continuing education on drug use

PR33: Number of prescribers having direct access to a (national) drug formulary, out of total number of prescribers surveyed (*). –

3rd medicine Use survey 2001:

The **Treatment Manual for Clinics** was available in 84% of facilities with the lowest result from referral hospitals, only half of which had this reference available.

The **Pocket Treatment Manual** was available in 89% of facilities; again the lowest availability was in the referral hospitals.

All **National Policies** (ARI, CDD, Malaria, STD and TB) were available in 61% of facilities, with availability decreasing according to increasing level of care.

PR34: Number of training sessions on drug use for prescribers in the last year, out of average number of training sessions organized in the past three years. Unknown

PR35: Number of prescribers who have attended at least one training session in the last year, out of total number of prescribers surveyed (*). Unknown

PR36: Number of issues of independent drug bulletins published in the last year, out of average number of issues of independent drug bulletins published per year in the past three years.

None

PR37: Average number of copies of independent drug bulletins sent to prescribers, out of total number of prescribers.

None

PR38: Amount spent on public education campaigns on drug use, out of total amount spent on public health education campaigns.

2005 – Spent approx NAD 60,000 on pharmacy week to raise awareness of role of pharmacist in HIV/AIDS treatment and general education re safe medicine use.

OUTCOME INDICATORS

Availability of essential drugs

OT1: Number of drugs from a basket of drugs available in a sample of remote health facilities, out of total number of drugs in the same basket (*).

97 – 89%

99 – 93%

2001 – 93% - or 92% not expired

OT2: Number of drugs at the lowest price from a basket of drugs, out of total number of drugs in the same basket (*).

No survey to date in private sector

Affordability of essential drugs

OT3: Average retail price of standard treatment of pneumonia, out of the average retail price of a basket of food (*).

No survey to date in private sector

OT4: Value of a basket of drugs, out of the value of the same basket with the cheapest drugs (*).

No survey to date in private sector

Quality of drugs

OT6: Number of drugs beyond the expiry date, out of the total number of drugs surveyed(*).

% of key drugs expired = 0.7%

Rational use of drugs

OT7: Average number of drugs per prescription (*).

There has been a steady increase from 2.49 (1997 survey) to 2.55 (1999 survey) to 2.72 (2001 survey).

OT8: Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed (*).

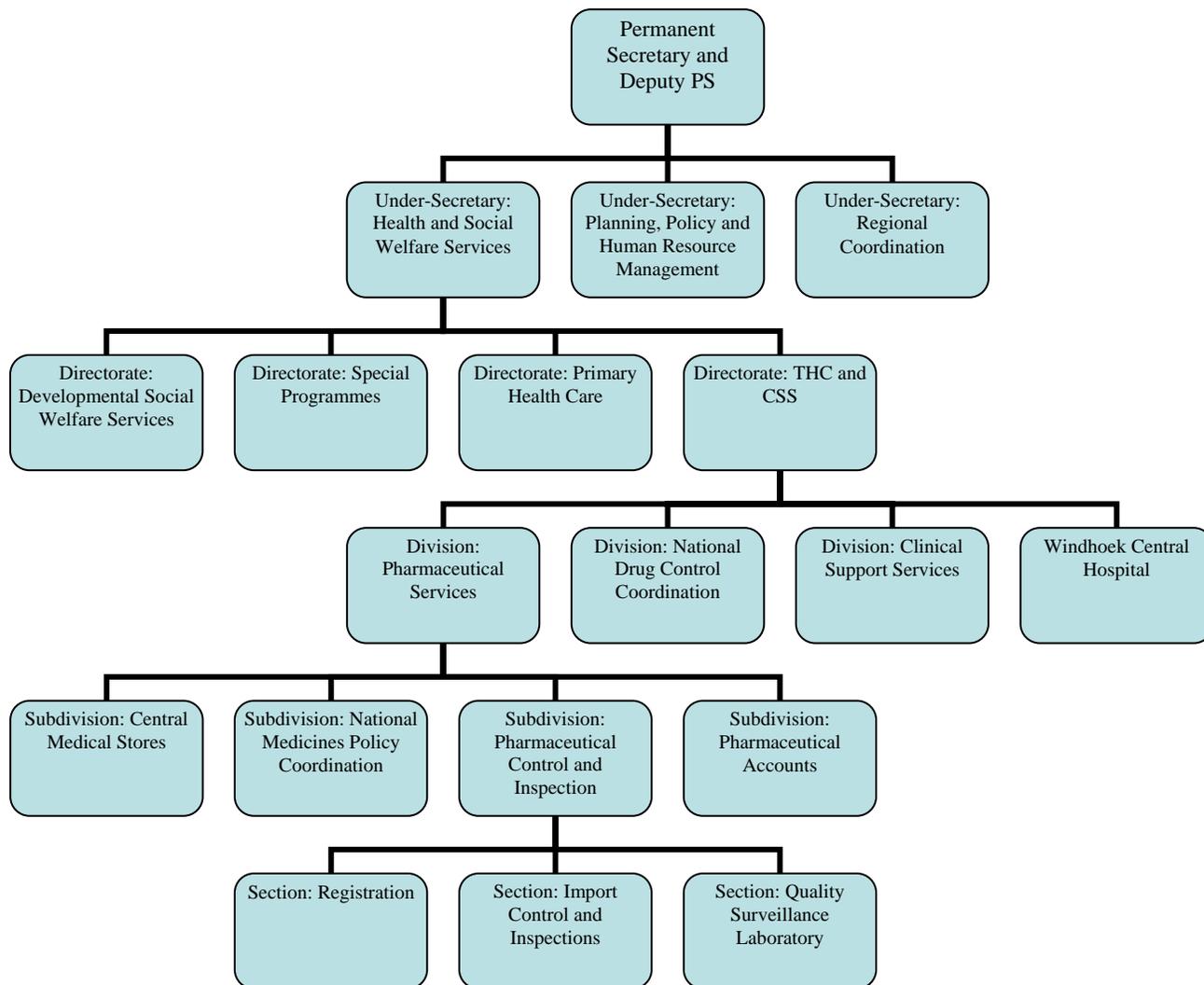
2001 – 9%

1999 – 7%

OT9: Number of children under five with diarrhoea receiving anti-diarrhoeal drugs, out of the total number of children under five with diarrhoea surveyed (*). Not assessed

OT10: Number of drugs from the national essential drugs list among the 50 best selling drugs (EDL), out of the 50 best selling drugs in the private sector.
No survey to date in private sector

ANNEX 2. ORGANOGRAM OF THE MOHSS



ANNEX 3. LIST OF PERSONS INTERVIEWED

Ministry of Health and Social Services

Executive Management

Dr. K. Shangula Permanent Secretary, MoHSS
Ms. K. Mutirua Under-Secretary, MoHSS

Pharmaceutical Services Division

Johannes Gaeseb Acting Deputy Director; Chairperson, TRIPS Subcommittee
P. W. Rite MCC Secretariat, Medicines Registration
Acting Chief Pharmacist PC&I, MoHSS
Ruigu Njiriri Pharmacist, Medicines Registration, PC&I
Lazarus M. Indongo Medicines Inspector
Ms. Jennie Lates Pharmaceutical Management Advisor, NMP
Coordination, MoHSS

Sub-Division: Central Medical Stores

Joseph Ngidari Pharmaceutical Management Advisor, MSH/RPM
Plus

Directorate: Special Programme

Dr. Goraseb Deputy Director, Directorate of Special Programmes

Centres for Disease Control/Namibia

Dr. Tom Kenyon Director, CDC/Namibia

Directorate: Policy, Planning and Human Resource Development

Mrs. B. Katjivena Director of Policy, Planning and Human Resources
Development
Mrs. C. Usiku Deputy Director, Human Resources Development

Directorate: Primary Health Care

Mrs. M Nghatanga Director, PHC
Ms. H Auala Head, Family Health Division
Ms. D Diergaardt SHPA, Noncommunicable Diseases
Mr. C. T. John Programme Officer, Oral Health

Katutura Health Centre

Dr. Olga Khokevitch District Medical Officer
Ms. F. Alvarez Pharmacist
Dr. L Fiss Medical Officer

Regional Health Directorate, Oshana

Dr. Hamataa	Regional Director
Mr. M. Kweba	Chief Pharmacist Oshana Region

Other Organizations

USAID

Ms. Kirk Lazell	HIV/AIDS Officer, USAID/Namibia
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World Health Organization

Dr. Custodia Mandlhate	WHO Country Representative
Dr. Alamerew T. Desta	Medical Officer

Chair of Medicines Control Council

Dr. I. Shipanga	Chairperson, MCC
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Medical Association of Namibia

Dr. E. Maritz	President
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Pharmaceutical Society of Namibia

Mrs K Brockmann	PSN Secretary
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Namibian Association of Medical Aid Funds (NAMAF)

Mr. Wessels Africanus	Health Care Advisory Coordinator, NAMAF
Mr. Tiaan Serfontein	Managing Director, Medscheme

Public Service Employees Medical Aid Scheme (PSEMAS)

Mr. Shiimbi	Director of Administration, MoF
Ms. Kauaria	Financial Advisor

UNICEF

Dr. Tesfaye Shiferaw	Health and Nutrition Project Officer
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GEKA Pharmaceuticals/Interim Pharmacy Council

Mr. Willie Van Wyk, MD	Geka Pharmaceutical; Chairperson, Interim Pharmacy Council
Ms. Cheryl Erasmus	Pharmacist

Namibia Institute of Pathology Ltd.

Mrs. T.K Angola	CEO
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Pama Pharmacy, Oshakati

Dr. Kondjeni Kafidi	Director
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Interim Health Professions Councils

Mrs. E. Barlow Registrar

Ministry of Trade and Industry and the Patent Office

Andrew Ndishishi Permanent Secretary

Daniel Nghidinua GM, Investment Promotion and Projects

Ruben Amaambo Assistant Manager, Investment Promotion and Projects

Riundja A Kaakunga Deputy Director, Internal Trade
(Weights, Measures, and Standards)

Steve Motinga Director, Industrial

Petrus Quawanga Economist, Industrial Planning

Mr. T. S. Andima Registrar, Ministry of Trade and Industry

ANNEX 4. LIST OF DOCUMENTS STUDIED

Aboagye-Nyame, F., L. Akhlaghi, and V. Dias. 2004. *Assessment of the Public Sector Pharmaceutical Supply System of Namibia, November 2003*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

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Management Sciences for Health. 2006. *Human Capacity Development Assessment for the Pharmaceutical Services, Ministry of Health and Social Services, Namibia: Strategies to Scale Up HIV/AIDS Program with an Emphasis on Antiretroviral Treatment* (in preparation).
Extracted recommendations and HRD data from final draft report, June 8, 2005. Arlington, VA: Management Sciences for Health.

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ANNEX 5. PROVISIONAL COSTING OF PRIORITY ACTIVITIES

Costing of Priority Activities for the Review of the NMP, Pocket Manual, and Development of STGs

No.	Activity	Subactivities	Costing	Comments
1	Review of the NMP	Develop draft on the consultant's review	MoHSS staff time	
		Circulate NMP consultant's review draft for comments	MoHSS staff time	
		Stakeholders workshop on review of NMP	NAD 80,000	
		Final NMP draft reviewed	MoHSS staff time	
		Approval of reviewed NMP	MoHSS staff time	
		Development of NPMP workshop	NAD 80,000	
		Printing of the reviewed NMP and the NPMP	NAD 25,000	
		2	Review of the Pocket Manual	Constitution of the review committee
Constitution of editorial team/secretariat	MoHSS staff time			
Development of the review guidelines workshop (agreement on purpose, content, structure, and format)	NAD 40,000			
Review committee harmonization meeting	NAD 80,000			
Editorial team workshop/presentation of draft to review committee	NAD 80,000			
Approval of the reviewed Pocket Manual	MoHSS staff time			
Production of the reviewed Pocket Manual (4,000 copies)	NAD 25,000			
Launch workshop	NAD 60,000			
Distribution of the reviewed Pocket Manual	NAD 10,000			

No.	Activity	Subactivities	Costing	Comments
3	Development of comprehensive STGs	Constitution of the STGs committee	MoHSS staff time	Permanent secretary will constitute
		Constitution of editorial team/secretariat	MoHSS staff time	
		Development of the STGs committee guidelines workshop (agreement on purpose, content, structure, and format)	NAD 120,000	
		Field visits by STGs committee	NAD 60,000	
		STGs committee harmonization meeting	NAD 80,000	
		Editorial team workshop/presentation of draft to STGs committee and HIV/AIDS, TB, malaria, IMCI, etc., program managers	NAD 80,000	
		Approval of the comprehensive STGs	MoHSS staff time	
		Development of the NEMLIST	NAD 40,000	
		Production of the comprehensive STGs (10,000 copies)	NAD 25,000	
		Printing of the NEMLIST	NAD 10,000	
		Launch workshop	NAD 80,000	
		Distribution of the comprehensive STGs	NAD 10,000	

ANNEX 6. POWERPOINT PRESENTATION ON PROCESS OF DEVELOPING STGS IN GHANA

Essential State Functions in the Pharmaceutical Sector

- ✓ Policy Making
- ✓ Drug Regulation
- ✓ Professional Standards
- ✓ Access to essential drugs
- ✓ Rational Use of Drugs
 - ✓ Availability and dissemination of unbiased information
 - ✓ Continuing education
 - ✓ Patient and public education

National Drug Policy

Why have one?

The existence of a written NDP document is a sign of awareness of the problems facing a country in the pharmaceutical sector. It forms a basis for planning and implementation of the components of the NDP

Treatment Guidelines

- "Lists the preferred drug and non-drug treatments for common health problems experienced by people in a specific health system".
- "Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances"

Basis of STGs

- Treatment of diseases may have many different approaches
- Large number of drugs to choose from
- Different backgrounds of practitioners
- Applying the most effective treatment benefits both the patient and the health care system

Key Features

- Simplicity
- Credibility
- Same standards for all levels
- Drug supply based on standards
- Introduced in pre-service training
- Dynamic - regular updates

Developing Treatment Guidelines

- Target priority conditions
- Base on local disease factors
- Coordinate with special programs
- Use fewest drugs necessary
- Evidence-based selection

Developing Treatment Guidelines

- ✓ Choose cost-effective treatments
- ✓ Use essential drug selection criteria
- ✓ Involve respected clinicians
- ✓ Consider patient perspective

Criteria for Selecting Treatment

- Disease Pattern
- Treatment facilities
- Personnel - training and experience
- Financial Resources
- Genetic, Demographic and Environmental factors
- Selection based on valid scientific evidence - efficacy and safety; quality (bioavailability) and stability

Mandate From ICD/MoH

- One national treatment guidelines.
- Incorporate all the elements of the previous guidelines plus the suggested inclusion of therapeutic objectives and also key laboratory tests.
- The manual will co-exist with programme specific guidelines but will essentially not deviate from them, information content-wise.
- The guidelines would also constitute or provide a basis for in-service training.

Steps in the STG Review Process

- Upgrade/Revise "Treatment Guidelines for Middle Level Personnel" to hospital practice level
- Draft additional topics
- Selection of the Group of Experts
- Preparation of documents on
 - evidence-based selection of treatment
 - criteria for selection of Essential Drugs
 - A conflict of interest document

Steps in the STG Review Process

- Review by Expert Group
 - Composition of Teams
 - Identify and draft additional topics
 - Agree on format
- Editorial Committee
- Final Review by Expert Group

Steps in the STG Review Process

- Final Draft
- Field Testing
- Final Editing and submission to publisher
- EDL Review Committee

Steps in the EDL Review Process

- Collated comments from the regions, teaching hospitals etc.
- Extract drugs mentioned in STG
- Constitute EDL Review Committee
- Revision of EDL

Levels of Evidence

- Evidence obtained from meta-analysis of randomised control trials - Ia
- Evidence obtained from at least one randomised control trial - Ib
- Evidence obtained from at least one well-designed controlled study without randomisation - IIa
- Evidence obtained from at least one other type of well-designed quasi-experimental study - IIb

Levels of Evidence

- Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies - III
- Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities - IV

Grades of Recommendations

A

Requires at least one randomised control trial as part of body of literature of overall good quality and consistency addressing the specific recommendation (Evidence levels Ia, Ib)

Grades of Recommendations

B

Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation (Evidence levels IIa, IIb, III)

Grades of Recommendations

C

Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV)

Disadvantages of STGs

- Inaccurate guidelines will provide the wrong information
- Guideline development and maintenance takes much time and effort
- Higher-level practitioners may be stifled in their practice
- May give false sense of security

Advantages

- For Patients
 - consistency among prescribers
 - most effective treatments prescribed
 - improved drug supply
- For Providers
 - provides expert consensus
 - provider can concentrate on diagnosis
 - quality of care standard
 - basis for monitoring and supervision

Advantages

- For Supply Management Staff
 - performance standard for drug supply
 - allows pre-packs of common items
 - drug demand more predictable
- For Health Policy Makers
 - funds used more efficiently
 - assess and compare quality of care
 - therapeutic integration of special programs

Implementation

- Official launch
- Initial training
 - Pre-qualification
 - Post-qualification
- Reinforcement training
- Monitoring of the use of the guidelines
- Supervision

Summary

- Treatment Guidelines are a time-honoured system to improve patient outcomes and to improve efficiency within the health care system
- Only evidence-based medicine concepts should be used in preparation of guidelines
- Provides standardized guidance to practitioners
- Formulary management will have only limited impact if the drugs are used incorrectly



● “Doctors are men who prescribe medicines of which they know little, to cure diseases of which they know less in human beings of whom they know nothing”

● Voltaire (1694-1778)