

MINISTRY OF HEALTH AND SOCIAL SERVICES

**NATIONAL PHARMACEUTICAL
MASTER PLAN**

Directorate: Tertiary Health Care and Clinical Support Services
Division: Pharmaceutical Services
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FOREWORD

In my speech launching the National Drug Policy for Namibia in November 1998, I pointed out the importance of this policy for the overall goal of our health sector, namely to ensure accessibility to and affordability of quality health services to the people while using resources effectively and efficiently.

In addition, I noted the challenge ahead of implementing this policy: that the National Pharmaceutical Master Plan which had to be developed should consider how best to implement the different policy strategies by ensuring that realistic targets are set and resources are used efficiently for the benefit of all Namibians.

The development of this plan has taken longer than anticipated which was mainly due to constraints with regard to available human resources. However, the time was spent productively. The document on hand is a comprehensive guide on which strategies and activities will be applied to reach the policy aims in the different fields, and when, by whom and at what cost implementation will be effected.

Like other strategic planning documents currently being prepared for different sectors of my Ministry, the plan covers a period of five years, and therefore fits well with the overall planning efforts.

It is my wish that all actors involved in implementing the first National Pharmaceutical Master Plan will do so with full commitment and enthusiasm, and it is my hope that our partners in development will take it on to provide technical and / or financial assistance for some of the projects contained in the plan.

Let us all ensure that in five years from now we can proudly single out the implementation of this plan and consequently the implementation of the National Drug Policy for Namibia as a success story.

Dr. Libertina Amathila
Minister

PREFACE

The National Drug Policy for Namibia was launched in late 1998, and as required by this policy, I subsequently appointed a committee to draft the National Pharmaceutical Master Plan.

The National Pharmaceutical Master Plan should be seen as a document to facilitate and ensure implementation of the strategies defined in the National Drug Policy, which aim at reaching the specified development goals of the private and public pharmaceutical sectors in our country.

The planning document is organised along the chapters of the National Drug Policy covering the main areas of

- drug legislation, regulation, and quality control
- drug selection
- drug supply
- the rational use of drugs by health workers and the general public
- drug pricing in the private sector
- human resources development
- research and development
- traditional medicine
- technical co-operation, and
- financing of drug supplies, particularly in the public sector

An introductory part informs the reader about the approach adopted, the summarised budget estimates, and structures to be used to monitor progress and effects of plan implementation.

Annexes I and II contain the detailed planning schedules, and the corresponding Gantt charts.

I would like to ensure the implementers my fullest support for the huge task lying ahead. The recent creation of the Sub-division: National Drug Policy Co-ordination under the Division: Pharmaceutical Services as part of our Ministry's restructuring exercise will surely contribute to successful implementation. This new sub-division's staff will find it a challenging task to be not only involved in practically planning and carrying out certain activities but also to be in charge of overall monitoring.

I would also like to appeal to the private sector to actively support the Ministry in activities aimed at improving sustainable accessibility to their pharmaceutical services, which already play a big role in the country's health sector.

Finally, I would like to commend the committee members who developed this National Pharmaceutical Master Plan for an excellent job done. My thanks also go to the Namibia Integrated Health Programme and the European Commission for technical and financial support provided.

Dr. Kalumbi Shangula
Permanent Secretary

LIST OF ABBREVIATIONS

CE	Continuing Education
C/E	Cost effectiveness
CMS	Central Medical Stores
Chief Med Sup	Chief Medical Superintendent / Division: Hospital Support
CP: CMS	Chief Pharmacist: Central Medical Stores
CP: NDP	Chief Pharmacist: National Drug Policy Co-ordination
CSO	Central Statistics Office
D: Finance & RM	Director: Finance & Resource Management
D: P,P & HRD	Director: Policy, Planning & Human Resources Development
D: PHC & NS	Director: Primary Health Care & Nursing Services
D: THC & CSS	Director: Tertiary Health Care & Clinical Support Service
DD...	Deputy Director
DD: PhSs	Deputy Director: Pharmaceutical Services
DD: RCU	Deputy Director: Regional Co-ordination Unit
DIC	Drug Information Centre
Div ...	Division ...
Div PI	Division: Planning
ED	Essential Drugs
EDL	Essential Drugs List
EDLC	Essential Drugs List Committee
FEFO	First Expiry - First Out
FIFO	First In - First Out
GIS	Geographical Information System
GRN	Government of the Republic of Namibia
HF	Health Facility
HMIS&RC	Health Management Information System & Research Co-ordination
HP	Hospital Pharmacist
HR	Human Resources
HRD	Human Resources Development
HW	Health Worker
IC	Inventory Control
IDCT	International Drug Control Treaties
IEC	Information, Education and Communication
KAP	Knowledge, Attitudes and Practice
MAN	Medical Association of Namibia
MCC	Medicines Control Council
MLS (NIP)	Medical Laboratory Services (Namibia Institute of Pathology)
MoHSS	Ministry of Health and Social Services
MoJ	Ministry of Justice
MoT&I	Ministry of Trade and Industry
MRA	Medicines Regulatory Authority

MS	Medical Superintendent
MWTC	Ministry of Works, Transport and Communication
NDP	National Drug Policy
Nedlist	Namibia Essential Drugs List
NHTC	National Health Training Centre
NIHP	Namibia Integrated Health Programme
NPMP	National Pharmaceutical Master Plan
P...	Pharmacist
PA	Pharmacists' Assistant
PB	Pharmacy Board
PF	Pricing Forum
PHC	Primary Health Care
PMO	Principal Medical Officer
PS	Permanent Secretary
PSC	Public Service Commission
PSN	Pharmaceutical Society of Namibia
QSL	Quality Surveillance Laboratory
RDU	Rational Drug Use
RC	Research Committee
RHSWO	Regional Health and Social Welfare Officer
RMT	Regional Management Team
RP	Regional Pharmacist
S&T	Subsistence and Travel (allowance)
SM	Stock Management
SOP	Standard Operating Procedure
T&P	Tenders & Procurement
TB	Tender Board of Namibia
TC	Therapeutics Committee
UNAM	University of Namibia
US: HCS	Under Secretary: Health Care Services
WHO	World Health Organisation
WS	Workshop
WTO	World Trade Organisation

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1. Introduction

The National Drug Policy (NDP) for Namibia was launched in November 1998, after having been approved by Cabinet. The policy addresses identified problems and priority areas for development of the public and private pharmaceutical sectors. Clear strategies are laid down determining how to achieve the stated policy objectives.

To facilitate policy implementation the requirement of formulating and adopting the National Pharmaceutical Master Plan (NPMP) is included in the second last section of the NDP. This plan should determine in more detail how the policy objectives will be achieved, which activities to be done by whom, when, and with what funds and resources.

It should also serve as a project document to facilitate the soliciting of financial and technical co-operation funds where required.

In September 1998 the Permanent Secretary appointed seven staff members of the Ministry of Health and Social Services (MoHSS) and one technical assistant to serve on the committee to draft the NPMP. The Deputy Director: Pharmaceutical Services was to be the committee's chairperson.

The existing NPMP is the result of many meetings held by this committee during the past 2 years. In addition, input from various public and private sector stake holders was sought during a one day seminar in April 2000. The revised NPMP was then approved by the Ministry's policy making bodies, and plan implementation can now begin.

All sectors and divisions concerned will have to incorporate the NPMP activities into their annual plans. In many cases this will require a more detailed formulation and timing of projects.

At national level the Sub-division: National Drug Policy Co-ordination in the Directorate: Tertiary Health Care and Clinical Support Services (THC & CSS) will oversee the implementation of the NPMP. This sub-division will also be responsible for technically supporting operational levels.

2. Approach

The NPMP was developed in line with the eleven main chapters of the NDP, i.e. chapters four to fourteen, except that the NDP section on 'Drug Advertising, Marketing, and Promotion' was incorporated into the section on 'Legislation, Regulation, and Quality Assurance'.

Annex I contains the main planning document, detailed objectives, expected results, strategies, activities, responsible staff, required resources, required budgets, and timing of projects for the ten areas. Annex II consists of the corresponding Gantt charts and provides a comprehensive overview of the distribution of activities over the next five years, and the related budget requirements.

In developing the NPMP, only those activities and related resource requirements which are not part of the normal operations of the respective directorates, divisions, management teams, institutions etc., were included. For example, if activities require travelling of staff within Namibia, related subsistence and travelling allowances are not costed. These will have to be budgeted for under the respective directorate or regional plans.

The annual budget for pharmaceutical supplies for public sector institutions is also not included in the costing. This budget estimate amounts to approximately N\$ 70 Million per year at current prices and consumption figures. It has to be noted that **availability of sufficient funds for health institutions to purchase appropriate quantities of pharmaceutical supplies is an important precondition for the successful implementation of the NDP and NPMP.** Many activities and projects under the NPMP do, however, aim at appropriate drug supply management and drug use by prescribers and patients, and thereby support efficient use of public funds.

In some cases similar activities and projects are listed in different sections of the NPMP. Budgetary and resource implications are then listed in one section only, and cross references to this section are provided at the appropriate places.

3. Summary of budget estimates for implementation of the NPMP

NPMP Budget Estimates in N\$						
POLICY COMPONENT	99/00	00/01	01/02	02/03	03/04	TOTAL
Legislation & Regulation	375,000	332,500	292,500	682,500	192,500	1,875,000
Drug Selection	11,000	53,500	23,500	13,500	23,500	125,000
Drug Supply	3,017,000	2,857,000	2,872,000	2,790,000	2,772,000	14,308,000
Rational Drug Use	2,000	106,000	75,000	135,000	55,000	373,000
Drug Pricing	0	210,000	140,000	20,000	20,000	390,000
Human Resources Development	150,000	202,000	199,000	194,000	199,000	944,000
Research & Development	0	20,000	50,000	20,000	20,000	110,000
Traditional Medicine	0	0	10,000	10,000	95,000	115,000
Technical Co-operation	0	0	0	0	0	0
Drug Financing	0	0	0	0	150,000	150,000
GRAND TOTALS:	3,555,000	3,781,000	3,662,000	3,865,000	3,527,000	18,390,000

N.B.: These budget estimates are based on additional expenditure arising through the implementation of the NPMP. They exclude estimated expenditure for pharmaceutical and medical supplies of approximately N\$ 70 Million/year as well as other ongoing operational and personnel expenditure.

Approximately 70% of the estimated budget (N\$ 13 Million) is related to costs resulting from construction of new and renovation of existing medical stores.

The remaining N\$ 5.4 Million is mainly earmarked for expenditure related to training activities in Namibia and the region, production of information and training material, attendance of conferences and meetings, and short term consultancy services.

Funds for long term technical assistance are not included in the budget estimates. Most probably these will have to be provided by development co-operation partners. In case a decision for commercialisation of Central Medical Stores (CMS) will be made during the plan period, additional funds will be required, e.g. transfer of assets including stock, and capitalisation of the trade account.

With a few exceptions, the NPMP does not specify the sources of required funds. Different development partners will have to be approached in order to ensure funding for the projects. Some costs, particularly those related to construction and feasibility studies, might be included in the development budget submissions.

4. Legislation, regulation, and quality assurance

In order to ensure that a **fast and effective registration system** is in place, activities will concentrate on streamlining registration procedures, including the implementation of a computerised registration system and increased co-operation with other Medicines Regulatory Authorities (MRAs).

In addition, training of MCC members will be implemented to increase capacity and skills.

Giving increased autonomy to the MCC will be investigated at the end of the planning period.

The **effectiveness of the monitoring system** will be improved by activities aimed at strengthening the inspectorate, operationalizing the Medicines Quality Surveillance Laboratory, and by the implementation of regulations on advertising and marketing.

Media campaigns will aim at involving the public in the monitoring process.

A drug information centre will be established to provide unbiased information to health workers and the public, and to serve as the focal point for post marketing surveillance activities.

The **sale of medicines** and medical devices will be effectively regulated by multisectoral efforts directed at controlling imports and at the implementation of requirements of the international drug control treaties.

Revised acts and updated regulations will ensure that health practitioners and facilities are registered and licensed where appropriate.

5. Drug selection

The **Nedlist will be appropriately managed** by implementing activities to ensure competency and functionality of the Essential Drugs List Committee (EDLC). In addition, the concept of essential drugs will be included in health workers' training curricula and introduced to all health workers who received training outside Namibia.

The **selection of essential drugs** will follow accepted standards and procedures. After agreement on applicable standards is reached, the EDLC members will receive the required training. In addition, information sources will be identified and made available.

6. Drug supply

6.1 Drug procurement

The **public sector drug procurement system will work efficiently**. This will be achieved by a broadened supplier base and market intelligence. Quality control measures will be implemented to ensure quality of purchased supplies.

In order to achieve a **rational quantification of drug needs** at national level, appropriate quantification methods will be identified, necessary training provided and data collected and analysed.

At CMS staff in the procurement section will be trained to ensure availability of knowledge and skills.

The possible **transformation of CMS into a commercialised agency** will be thoroughly investigated and resulting recommendations implemented.

6.2 Drug donations

Procedures that have already been developed should be enforced to ensure that all agencies and departments **comply with the Namibian Policy on Drug Donations**.

Statistics on donations will be kept at a designated point at national level. These statistics will include estimated values of donations so that these can be included in any costing of pharmaceutical supplies and budget exercises.

6.3 Drug storage

Drugs will be appropriately and securely stored. Medical stores will be renovated and staff receive the required training. Security guidelines will be developed and implemented for all levels.

Quality assurance measures aimed at maintaining quality of stored drugs will be implemented. These will include visual and physico chemical inspections, and adherence to specific storage requirements.

6.4 Inventory control

Adequate supplies (quantities and types) will be available at all health facilities. To achieve this a standardised inventory management system will be developed and implemented. The CMS computerised system will be installed where appropriate. Trainers and users will be trained in the use of the inventory management system. The performance of the system will be regularly monitored using relevant indicators.

6.5 Drug distribution

Appropriate transit conditions between medical stores and users will be ensured by training staff, minimised transit times, and appropriate packaging material.

The transport system will be more efficient. This will be achieved by improved transport management. In addition, the most cost effective transport alternative will be investigated and recommendations implemented (e.g. wholly or partially out-sourcing of transport from CMS to the regions).

The drug distribution system will become more **responsive to local demand** by the establishment/refurbishment of regional sub stores. Districts will receive required support to implement a decentralised distribution system.

To **increase accessibility to private pharmaceutical services**, appropriate incentives will be provided. In addition, legal provision for ownership of pharmacies by non-pharmacists (subject to prescribed conditions) will be made.

6.6 Local drug manufacture

Communication channels with the relevant ministries will be established in order to explore possibilities for incentives for the local manufacture of essential drugs.

In addition, the issue of compulsory licensing of production of patented essential drugs will be examined.

The quality of locally manufactured drugs will be regularly tested at the Quality Surveillance Laboratory (QSL).

7. Rational drug use

Appropriate drug prescribing will be promoted by training and regulatory measures.

Training will aim at prescribers at all levels. Principles of rational prescribing will be included in training curricula and prescribers will be enabled to evaluate scientific articles in order to establish a system of evidence based prescribing. Refresher courses will also be planned for prescribers in the private sector.

Treatment guidelines for hospitals will be developed (evidence based) and implemented, and therapeutics committees established at different levels.

Prescribing habits will be regularly monitored at all levels in order to be able to suggest corrective measures where appropriate and to evaluate their impact.

Similarly **good dispensing practices** will be promoted by relevant training activities. In addition, existing acts and regulations will be amended to allow generic substitution in the private sector, and licensing of dispensing medical practitioners.

CMS and health workers in charge of pharmacies will be encouraged to ensure availability of sufficient packaging, labelling, and dispensing materials, and a study to investigate costs and benefits of course of therapy packs will be carried out.

Appropriate drug use by the public will be encouraged. Based on studies on drug usage by communities, public education campaigns will be developed and implemented. These will include teaching of modules on appropriate drug use in formal and in-formal education.

Counselling of patients by dispensers will be improved by providing communication training to dispensing health workers.

Objective information on drugs will be available through the **drug information centre**. This centre will provide information to prescribers, dispensers, and the public on request. In addition, a regular newsletter on pharmaceuticals will be produced and distributed.

8. Drug pricing

The **pricing structure** in the private sector will be rationalised based on evaluation of existing practices and cost structures. In consultation with all stakeholders a pricing system considering public health and private sector concerns will be developed and implemented, including necessary legislative changes.

A pricing forum representing public and private sectors will be established to discuss issues pertaining to the subject.

The public will be informed regularly about drug prices so that consumers can make better informed decisions.

In order to achieve increased access to low cost quality pharmaceuticals the **use of generic drugs** will be promoted by identifying and implementing appropriate incentives, and by conducting workshops for peers to encourage prescribing by generic names.

9. Human resources development

Adequate pharmaceutical staff should be available at all levels. To achieve this, a sufficient number of bursaries will be negotiated based on proper needs analysis.

Requirements for pharmacy curricula satisfying the country's needs will be established and study places at appropriate training institutes negotiated.

Training of pharmacist's assistants will continue based on human resources plans. The training curriculum will be updated.

To ensure that available professional **staff is equitably distributed** within the country, appropriate systems will be developed and implemented.

Staff involved in pharmaceutical management **will be competent**. Based on an evaluation of strengths and weaknesses of current services, training programmes for pharmaceutical staff will be developed and implemented.

Training needs of practising pharmacists and prescribers (public and private sectors) will be assessed in consultation with the professional boards and societies, and appropriate continuing education programmes designed and implemented.

10. Research and development

Relevant **research activities** will be **promoted**. Seminars to discuss research questions and findings will be held. Research results will be included in management reports and presented at international conferences.

Guidelines to evaluate research proposals (especially clinical trials) will be developed and implemented.

A searchable computerised research database will be made available through the Internet.

Research funding will be facilitated by discussions with funding agencies. Feed-back to funding agencies will be ensured.

11. Traditional medicine

Access to information on traditional medicine will be improved by purchasing reference material, publication of relevant information, and research and discussion with collaborating partners.

Plants will be tested for efficacy and toxicity and the drug information centre and researchers will contribute to the compilation of a regional (Southern African) pharmacopoeia.

Legislative reform will aim at ensuring **competency of traditional practitioners**. This will include the development and implementation of a code of conduct in collaboration with various stake holders.

Exploitation of safe and effective medicinal plants for the benefit of the population will be promoted. Communities will be encouraged to engage in commercial plant cultivation. Furthermore, the trade of raw materials and processed goods will be facilitated.

The **safety** of marketed traditional medicines will be ensured through legislative reform and post marketing surveillance.

12. Technical co-operation

Technical co-operation will be strengthened through improved communication within the Ministry and between the Ministry and agencies.

13. Drug financing

Budgeting guidelines for pharmaceuticals will be developed and implemented and staff oriented towards financial control.

A system of equitable classification of private and state patients including the respective fees to be paid will be established. The aim is to recover actual costs from private patients.

Benefits and disadvantages of charging user fees for pharmaceuticals will be evaluated, and a feasibility study, investigating the issue of compulsory health insurance schemes will be conducted.

14. Implementation, monitoring, and evaluation

The NPMP will be implemented in the form of more specified annual work plans. These work plans will be drafted by the sub-division: NDP Co-ordination and discussed at the annual pharmacists' meetings to ensure that operational levels incorporate relevant activities in their annual plans. In addition, the relevant private sector players will be consulted where plans ask for their involvement.

The sub-division will also be responsible to select relevant indicators for monitoring the implementation process and expected and unexpected outcomes. The selection of these indicators will be based on all available sources (such as the WHO publication 'Indicators for Monitoring National Drug Policies'). Indicators suggested in these publications might be

modified to suit the particular Namibian context. Based on the above a comprehensive data collection and analysis plan will be developed. Available data already collected in 1996 and 1998 will also be used when documenting change occurring over time.

The sub-division will compile annual progress reports, detailing state of plan implementation, outcomes and impact of activities as compared to the originally expected results. Revisions to the NPMP might then be recommended if appropriate.

At the end of the plan period a revision of the NDP will take place involving all stake holders.