

MINISTRY OF HEALTH AND SOCIAL SERVICES

NATIONAL DRUG POLICY FOR NAMIBIA

Ministry of Health and Social Services
Private Bag 13198
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FOREWORD

The availability of safe and effective drugs is an important condition for well functioning curative and preventive health services. However, their benefit is dependent on accessibility and affordability for people in need as well as on appropriate use by prescribers, dispensers and patients.

In Namibia several laws regulate the dealing with drugs, the most important being the Medicines and Related Substances Control Act. As with other legislation this Act is currently under revision to suit the changed conditions in an independent Namibia.

To guide this revision process as well as the envisaged future role and directions of development of the public and private pharmaceutical sector with respect to the aim of achieving 'Health for all Namibians by the year 2000 and beyond' it was felt necessary to define long term goals and strategies in a comprehensive policy.

This policy takes into account problems particular to Namibia such as existing (regional) inequalities in health status and accessibility to public and private health services; prevailing poverty, and a shortage of qualified human resources. On the other hand problems which also prevail in most other developed and developing countries, such as how to contain the ever increasing costs of medicines, widespread irrational use of drugs, and a lack of unbiased information on drugs for health workers and consumers are addressed.

The National Drug Policy will be accompanied by a National Pharmaceutical Master Plan which will set out in more detail strategies, objectives and inputs needed to implement identified project components. A monitoring system will be put in place to ensure that projects will have the anticipated effects.

In addition, the Ministry of Health and Social Services (MOHSS) will regularly review legislation to ensure that this is in line with the objectives of the policy.

My Ministry urges all stake holders to actively support the principles and objectives contained in this policy document, and to ensure the effective implementation of the policy so as to achieve the wider goal of rendering sustainable quality health care to all Namibians.


Dr. Libertina Amathila
Minister



PREFACE

The National Drug Policy for Namibia provides comprehensive guidelines and development objectives for the Namibian public and private pharmaceutical sectors within the broader framework of the Government's health policy and development plans. In line with WHO recommendations on national drug policies, and considering particular Namibian needs the document is structured as follows:

Section 1 provides some background information on the pharmaceutical sector. This information was collected in early 1996 and assisted in setting priorities.

Sections 2 and 3 state the main policy goals and objectives and outline the policy's key principles.

Sections 4 to 14 deal with the different priority areas of the policy: the legislative and regulatory framework, the selection of essential drugs, the different aspects of drug supply, strategies to achieve rational use of drugs, pricing aspects, drug promotion, human resources development, research and international co-operation, and financing of drug supplies.

Sections 15 and 16 make provision for ensuring implementation, monitoring and evaluation of the policy.

For easy reference a glossary is attached to explain the more specialised expressions used in the document.

The National Drug Policy for Namibia was drafted by the Drug Policy Committee, which was established in 1995 by the former Permanent Secretary of the Ministry of Health and Social Services, Dr Salomon Amadhila. This committee consisted of health professionals from the public and private sectors, and they should be commended for accomplishing a difficult task in a relatively short time.

The first draft of the National Drug Policy was sent out for comments during April and May 1997 to a large number of stakeholders. Their comments provided valuable inputs for the revision of the draft, which was discussed at a national

seminar in December 1997. Here again participants from private and public sectors contributed their valuable time to further improve the document. Particular thanks go to the South African Department of Health, who made it possible for Mrs P Matsoso, Director: Medical Schemes, Supplies and Services, to assist us during this seminar with her valuable experience.

To personally name all of the contributors would be beyond the scope of this document, but I like to stress that only through their joint efforts this policy became a comprehensive document based on broad consensus. Sincere thanks to all of you.

Finally I would like to thank the Namibia Integrated Health Programme and the European Union for supporting the whole process through providing valuable financial and technical assistance.


Dr. Kalumbi Shangula
Permanent Secretary



LIST OF ABBREVIATIONS

CMS	Central Medical Stores
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
INN	International Non-proprietary Name
MCC	Medicines Control Council
MOHSS	Ministry of Health and Social Services
MRA	Medicines Regulatory Authority
Nampol	Namibian Police
NDP	National Drug Policy
NEDLIST	Namibia Essential Drugs List
NGO	Non Governmental Organisation
NPMP	National Pharmaceutical Master Plan
PHC	Primary Health Care
UNDCP	United Nations Drug Control Programme
WHO	World Health Organisation

TABLE OF CONTENTS

FOREWORD	ii
PREFACE	iv
LIST OF ABBREVIATIONS	vi
TABLE OF CONTENTS	vii
1. INTRODUCTION	1
2. POLICY GOALS AND OBJECTIVES	4
3. PRINCIPLES AND KEY POLICY COMPONENTS	4
4. LEGISLATION, REGULATION AND QUALITY ASSURANCE	5
4.1 The Medicines Control Council	5
4.2 Registration of Medicines and Medical Devices	6
4.3 Medicines Control and Inspections	7
4.4 Controlling the Registration of Health Practitioners	8
4.5 Other Quality Assurance Measures	9
5. SELECTION OF DRUGS	11
5.1 The Nedlist	11
5.2 Criteria for Drugs to be included in the Namibia Essential Drugs List (Nedlist).....	12
6. DRUG SUPPLY	13
6.1 Drug Procurement	13
6.2 Donations.....	14
6.3 Drug Storage	14
6.4 Inventory Control	15
6.5 Drug Distribution	15
6.6 Local Drug Manufacture	16
7. RATIONAL DRUG USE	18
7.1 Conferment Of Status	18
7.2 Education and Training.....	18

7.3 Drug Information.....	19
7.4 Rational Prescribing	20
7.5 Rational Dispensing	20
7.6 Therapeutics Committees	22
8. DRUG PRICING	23
8.1 Rationalisation of the Pricing Structure	23
8.2 Monitoring and Negotiating Medicine Prices	24
8.3 Promoting the Use of Generic Drugs	24
9. DRUG ADVERTISING, MARKETING AND PROMOTION	25
10. HUMAN RESOURCES DEVELOPMENT	27
11. RESEARCH AND DEVELOPMENT	29
12. TRADITIONAL MEDICINE.....	31
13. TECHNICAL CO-OPERATION WITH OTHER COUNTRIES AND INTERNATIONAL AGENCIES	32
14. FINANCING.....	33
15. POLICY IMPLEMENTATION	34
16. MONITORING AND EVALUATION.....	34
GLOSSARY	36
ANNEX: THE NAMIBIAN POLICY ON PHARMACEUTICAL DONATION.....	40

1. INTRODUCTION

Countries' National Drug Policies normally address all main components which impact on the functioning of public and private pharmaceutical sectors, such as legislation and regulation; drug procurement and distribution; the appropriate use of drugs by health workers and consumers; human resources development; and drug pricing and financing. Strategies to be pursued to achieve the particular aims of these components, however, differ from country to country.

The National Drug Policy for Namibia was developed based on the geographic, demographic, economic and social conditions prevailing in this country, and on the characteristics of the national health sector in general and the pharmaceutical sector in particular.

A document, which was compiled to make the relevant background information available, identified those areas deserving special attention within the Namibian context (Please note, that most of the figures presented below were collected in early 1996.):

1.1 Inequitable access to pharmaceutical services

Out of the 52 private retail pharmacies, 59% are situated in the South Health and Social Services Directorate (comprising Karas, Hardap, Omaheke and Khomas regions), and 31% in the Central Health and Social Services Directorates (comprising Erongo, Kunene and Otjozondjupa regions), mainly in the urban centres. Only 10% (5) of retail pharmacies are located in the Northern Regions where more than 50% of the population lives.

In the public sector, improving geographical access to health services to underserved areas has received priority attention since independence, and some progress has been made. However, a dire shortage of qualified staff still exists. For example, all posts for regional pharmacists in the Northwest Regional Health and Social Services Directorate were vacant in 1996, and consequently

appropriate professional pharmaceutical services and advice could not be ensured.

1.2 A lack of qualified human resources in the public sector

In October 1995, 140 pharmacists were registered with the Pharmacy Board of Namibia, but only 9 of these were working for the public sector. At the same time 22 public sector pharmacist posts were vacant. Fortunately some were covered by volunteer pharmacists. An additional 8 posts were filled with pharmacists from neighbouring countries on restricted period contracts.

This situation makes it very difficult to provide sustainable services of adequate quality.

1.3 Financial Management and Pricing Policies

Budgets for pharmaceutical supplies in the public sector are regularly overspent, which does not necessarily mean, that budgets are too low. Better management and cost consciousness at all levels could reduce overspending without compromising the quality of services. Proper financial management is crucial because the present level over- expenditure cannot be allowed to continue.

Drug prices in the private sector are high, and the percentage mark-up system gives incentives to sell expensive medicines. Private medical practitioners who dispense and thereby sell medicines may be tempted to prescribe inappropriately to increase their income. Information on drug prices and on cheaper generic alternatives is not readily available to the public.

Some of the strategies identified in the policy document had to be developed against this background. These strategies are based on a broad national consensus, and map out a clear course of action for all stakeholders.

2. POLICY GOALS AND OBJECTIVES

The aim of the National Drug Policy is to guide and develop pharmaceutical services to meet the requirements of the Namibian people in the prevention, diagnosis, and treatment of prevailing diseases, using **efficacious, high quality, safe** and **cost-effective** pharmaceutical products. The National Drug Policy will also serve as the guiding document for legislative reforms, human resources planning and development and management improvement.

3. PRINCIPLES AND KEY POLICY COMPONENTS

The guiding principles will be:

- to ensure that the constant **availability** of safe and efficacious drugs is maintained to the Namibian population
- to ensure that the **equitable access** of all citizens to essential drugs is observed and sustained
- to provide essential drugs through the government, private and non-governmental sectors at **affordable prices**
- to promote the **rational use** of drugs through sound prescribing, good dispensing practices, and appropriate usage

4. LEGISLATION, REGULATION AND QUALITY ASSURANCE

Aim: To ensure that medicines reaching the people of Namibia are safe, efficacious, of good quality, and available at affordable prices.

This aim will be achieved through:

- strengthening regulatory and managerial capacity of the Medicines Control Council (MCC)
- streamlining the medicine registration procedure
- controlling the registration of health practitioners
- licensing of private hospitals and health facilities
- enhancing other quality assurance systems

4.1 The Medicines Control Council

The MCC is responsible for the registration of medicine for human and for animal use and for supervising the control of medicines and matters incidental thereto in terms of the Medicines and related Substances Control Act.

The MCC shall be a statutory body accountable to the Minister of Health and Social Services.

The Namibian Government reaffirms its commitment to provide adequate resources, both human and financial, to strengthen and maintain the national medicines regulatory capability.

Fees will be levied for registration and retention of medicines and the fee structure will be reviewed regularly. Funds generated will be retained at the MCC to cover part of the operational costs.

4.2 Registration of Medicines and Medical Devices

Only medicines which are registered in Namibia may be sold unless otherwise approved by the Minister of Health and Social Services in consultation with the MCC.

The criteria for the registration of medicines shall be based on the scientific evaluation of quality, efficacy, safety, therapeutic advantage and cost.

Marketing authorisation (registration) of a medicine can only be effected if the procedures, standards and facilities for manufacturing of the medicine are approved.

Registration status shall be granted for a limited period, subject to renewal upon review.

The MCC will provide / disseminate information to health care professionals and the general public about medicinal products which have been registered.

The registration process shall be streamlined by:

- defined registration requirements for generic products (interchangeable multi - source pharmaceutical products) which focus on proof of the quality of the product and adherence to Good Manufacturing Practices (GMP).
- establishing a fast-track registration procedure for essential drugs needed to be procured by the public and private sectors.
- computerisation of the medicine registration system and the exchange of such information with Medicines Regulatory Authorities (MRAs) in the region on a strictly confidential basis.
- adoption of internationally acceptable standards for medical devices and disposable items.

4.3 Medicines Control and Inspections

Medicine legislation and regulations will be supported by an adequate and effective medicines control inspectorate which will form part of the MCC Secretariat.

The inspectorate will collaborate and co-operate closely with the National Drug Control Commission and especially with agencies of the Ministry of Home Affairs (the Drug Enforcement Unit; Nampol), the Ministry of Finance (Directorate of Customs and Excise), the Ministry of Trade and Industry, and health profession boards/councils.

Pharmacists and other competent persons may also be authorised to perform certain inspections after receiving the necessary in-service training.

All premises, places, vehicles, vessels, and aircrafts where medicines including veterinary medicines are sold, will be subject to inspection.

GMP inspections at local or foreign pharmaceutical manufacturing plants will be carried out in collaboration with inspectors from other MRAs.

Psychotropic substances and narcotic drugs control will conform with the requirements of international drug control treaties to which Namibia is signatory.

A permit system for the importation and exportation of medicines will be established. Only holders of import permits will be allowed to import medicines and all consignments of medicines crossing the border will be checked against a current list of registered importers or exporters. Final sellers of medicines will only buy medicines from registered importers or producers in Namibia.

Individuals entering Namibia may be allowed to import limited quantities of medicines prescribed for them for their own use.

A medicines surveillance laboratory linked to the MCC will be established. The services of other quality control laboratories in the country and the region will be made use of if required.

4.4 Controlling the Registration of Health Practitioners and Health Facilities

All practitioners must be registered with the relevant professional boards/councils or authorised by the Minister to practice.

All private hospitals and health facilities must be licensed by the Ministry. Pharmaceutical wholesalers and manufacturers must be licensed by the MCC.

Medical practitioners and nurses in private practice with proven competency in dispensing medicines may be issued with a licence by the licensing authority to dispense medicines in the absence of adequate pharmaceutical services.

Pharmacists and nurses in private practice with proven competence in diagnosis and prescribing may be given a licence by the licensing authority to prescribe certain specified medicines in the absence of adequate medical services.

These licences and other licences issued by the MCC will be reviewed annually.

Pharmacy ownership will not necessarily be restricted to registered pharmacists. A pharmacy operation must however always be under the continuous personal supervision of a pharmacist.

Therapeutic alliances (group practice) between different health care professionals for the purpose of providing cost-effective high quality health care for the benefit of the patient will be encouraged.

4.5 Other Quality Assurance Measures

Medicines advertising and marketing will have to comply with national criteria based on WHO's Ethical Criteria for Medicinal Drug Promotion.

The MCC will co-operate closely with medicines information centres in the Southern African Region and the WHO Collaborating Centre for International Drug Monitoring in the monitoring and reporting of adverse drug reactions.

A drug information and adverse reaction monitoring unit linked to the MCC will be established to co-ordinate adverse reaction reporting and to manage data collection, analysis and dissemination.

Manufacturers and/or their representatives in Namibia are required to keep records of all adverse reactions reported to them and submit such reports to the MCC.

Suppliers of branded drugs will be required to label their product packages and containers with the generic name of the drug at least the same size as, and displayed adjacent to, the trade name. Special permission may be granted for deviation.

The MCC will collaborate closely with other MRAs in the region, the National Botanical Research Institute and the Traditional Practitioners Board to identify and investigate traditional medicines. Efforts will be made for traditional medicines to be tested for safety, efficacy and quality and ultimately be included in a Traditional Medicines Pharmacopoeia for the Southern African Region in order to be used to maximum advantage in organised health care.

Retail and wholesale trade in medicines (Schedule 1 and higher) will be confined to registered premises only. The licensing authority is mandated to register these medicine outlets.

Premises where non-prescription Schedule 0 medicines are sold will be inspected by the MCC.

5. SELECTION OF DRUGS

Aim: To ensure that the essential drugs incorporated in the Namibia Essential Drugs List (Nedlist) are suitable for the appropriate treatment of prevailing diseases and that drug needs at different levels of the health care system are met.

5.1 The Nedlist

An essential drugs list committee will be established to maintain the Nedlist and monitor its implementation. The committee will consist of health care professionals from the pharmacy, medical and nursing disciplines. Members shall have a good knowledge of pharmaceutical products, prevailing morbidity and mortality patterns and public health concepts and they should represent primary, secondary and tertiary health care. In addition, adequate representation of all regions shall be ensured. The committee is to be appointed by the Minister of Health and Social Services. The committee may consult other professional bodies, pharmaceutical manufacturers and consumer agencies. Other persons may be co-opted on an ad hoc basis when necessary.

Drugs will be selected by their international non-proprietary name (INN) or generic name to reduce costs and hence total health expenditure.

The resulting Nedlist will be comprehensive and provide a list of pharmaceutical products, including the dosage forms and strengths available at various levels in the health care system, and will be made available to all health workers in Namibia.

The Nedlist will be reviewed and updated regularly in line with the Standard Treatment Guidelines, and new drugs will be introduced only if they offer a distinct advantage over previously selected drugs.

The Nedlist will serve as the guideline for public sector drug procurement, the development of a national drug formulary, and the training of health workers.

It will also serve as a guideline for drugs to be reimbursed under the Government Medical Aid Scheme.

5.2 Criteria for Drugs to be included in the Namibia Essential Drugs List (Nedlist)

The selection of drugs will be based on the following criteria:

- the drugs must meet the health needs of the majority of the population.
- sufficient scientific data must be available to prove the safety and efficacy of any such product.
- selection will be based on the evaluation of benefit, cost and safety.
- products containing a single pharmacologically active ingredient will be preferred. Combination products may be included where they have been shown to promote patient compliance or where the ingredients act synergistically.
- when two or more drugs have similar safety/efficacy profiles, selection will be based on the evaluation of cost of the treatment regimen and potential patient compliance.

6. DRUG SUPPLY

Aim: To ensure that essential drugs of high quality are available in adequate quantities to meet the health needs of the population in all parts of the country at the lowest possible cost.

6.1 Drug Procurement

Procurement of drugs for the public and private sectors will be limited to items registered for use in Namibia, unless otherwise approved by the Minister in consultation with the MCC.

Drug procurement for the public sector will be carried out by Central Medical Stores (CMS), based on an international tender system. Evaluation and adjudication of tenders will be conducted by the respective tender committees and final approval given by the Tender Board of Namibia. In emergencies, or where circumstances dictate otherwise, drugs may be procured through direct buying from suppliers, by quotation in compliance with Tender Board Regulations, or by price negotiations.

Drugs will be procured by INN or generic name based on the Nedlist. Drugs not on the Nedlist may be procured for specific patients using a standardised procedure.

The WHO Certification Scheme for Pharmaceutical Products moving in the International Commerce will be used to expedite evaluation and procurement of essential drugs.

Preference in procurement will be given to Namibian registered companies in terms of prevailing tender preferences and eligibility will be carefully evaluated.

Procurement will also be directed towards manufacturers in preference to wholesalers, distributors and trading houses.

However, notwithstanding these preferences, in order to make the best possible use of available funds, procurement will continue to be aimed at securing the lowest price for a product of acceptable quality.

The MOHSS will actively encourage improved procurement efficiency by ensuring the adequate provision of suitably qualified personnel and facilities for CMS and by supporting the computerisation of procurement operations which will include the development of a market intelligence capability.

6.2 Donations

Drug donations must comply with the Namibian Policy on Pharmaceutical Donations (Annex) and donated drugs must meet all the following criteria:

- be certified by the MRA of the exporting country according to the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in the International Commerce.
- be included in the Namibia Essential Drugs List, or a similar prototype
- have at least 12 months shelf life remaining
- be labelled in English.

All medicines donated to the public sector shall be channelled through the CMS and should not be sent directly by donors to the institutions.

6.3 Drug Storage

The MOHSS will endeavour to ensure the provision and regular maintenance of adequately sized, suitably constructed and equipped storage facilities at every level in the decentralised public sector drug distribution system.

The quality of stored drugs will be checked regularly at all levels in the private and public sectors to ensure that

they have not deteriorated under the storage conditions prevailing at each location, and to ascertain the adequacy and suitability of the storage facilities. Checking and monitoring will be performed by the pharmaceutical personnel in charge of the storage facilities and by delegates of the MCC.

The professional skills of pharmacists and pharmacist's assistants or technicians are vital to the efficient and successful operation of a drug storage and distribution system. The Government will therefore ensure that adequate numbers of suitably trained pharmaceutical personnel are recruited to run and maintain public and private sector facilities.

6.4 Inventory Control

The MOHSS will strive to improve and standardise inventory control procedures at all levels of the public drug supply system. Minimum and maximum stock levels will be introduced and systematic stock rotation ensured.

Proper procedures will be implemented to assure accountability at all levels.

Suitable computerised inventory control methods and equipment will be introduced at central and lower levels and staff trained in their use at the earliest feasible opportunity.

The MOHSS will introduce and maintain systematic, practical and accurate procedures for the estimation and regular reporting of drug consumption at all levels so that these data can be used in the compilation of estimates for national drug procurement needs and for monitoring drug expenditure.

6.5 Drug Distribution

Drugs will continue to be distributed through the public, parastatal, and private sectors. CMS is responsible for the distribution of drugs to the public health sector according to the Nedlist.

The Government will endeavour through the MOHSS to maximise co-ordination between the different sectors in the transportation and distribution of essential drugs, particularly to less accessible areas of the country.

The MOHSS will strive to provide adequate and appropriate transportation and communication facilities and the personnel necessary to maintain an efficient public sector distribution system.

The MOHSS will ensure that the decentralisation of the public sector distribution system is rationally and efficiently implemented.

The MOHSS will institute an efficient and practical system for the identification, collection and redistribution of excess stocks of drugs and medical supplies.

Expired, damaged or banned drugs will be disposed off in a way which precludes their use by any person, and with minimal environmental pollution.

The MOHSS will encourage the establishment and extension of private pharmaceutical services to underserved communities.

6.6 Local Drug Manufacture

The Government will stimulate the interest of national drug manufacturing companies in the bulk production of drugs on the Nedlist by giving them preference in procurement and by using other incentives available for industrial development.

The Government will encourage the development of associated industries such as raw materials, glass, plastics, paper, aluminium, etc. involved in the production and packaging of essential drug products.

The Government will seek and encourage collaboration with other states within the region in the production of raw materials and finished bulk essential drugs to

minimise duplication and to optimise the range of products and the use of resources.

All production facilities will be regularly inspected by the Medicines Control Inspectors to ensure compliance with GMP guidelines.

Provided that local demand is adequately covered, the Government will promote the exportation of pharmaceutical products, especially within the region, through the provision of appropriate export incentives.

7. RATIONAL DRUG USE

Aim: To promote rational prescribing, dispensing and use of drugs by all health workers and to encourage and support the informed use of drugs by the community.

The aim will be achieved through:

- the provision of strict guidelines on the authorisation of prescribers and dispensers.
- encouraging and supporting a team approach to patient care.
- promoting and encouraging uniform and systematic case management in all of Namibia.
- encouraging appropriate training and continuing education for all health personnel and the education of the community in relation to drug use.
- providing for and ensuring that all drug related information is up to standard as well as strictly controlling how and where drugs are marketed.

7.1 Conferment Of Status

Ensuring and promoting Namibian public health and safety shall be the guiding principle in the consideration of any and all conferment of dispenser and/or prescriber status.

7.2 Education and Training

Health Personnel

Curricula of all educational programmes for health personnel shall be developed, assessed and revised to ensure sufficient exposure to the concepts of primary health care, team approach, essential drugs and rational drug use including non-drug therapies, communication

and patient counselling, in addition to the conveyance of adequate diagnostic and prescribing skills.

Professional Boards/Councils in liaison with the MOHSS shall be charged with the approval, supervision and monitoring of education programmes for members of their profession.

The Community

The MOHSS shall seek the collaboration of the Ministries of Education and Culture and Youth and Sport, Local Authorities, the mass media and other relevant partners including NGOs and adult literacy programmes and co-ordinate an educational programme, aimed at promoting an informed attitude towards drugs and their effects, in the community and in schools. A more cautious countenance towards advertising and commercial information, responsible self-prescribing and the confidence to interact effectively with health care providers will be promoted.

7.3 Drug Information

Health Personnel

The MOHSS shall establish drug information centre(s), collaborate with existing information resource centres, and/or support independent centres, which in their turn shall have the prime responsibility of collecting, examining, compiling and disseminating validated drug information.

A national drug information bulletin or newsletter will be compiled and circulated to provide drug information and to promote appropriate prescribing practices.

The Community

The MOHSS, through primary health care shall

- educate the community on drug use and provide easy access to objective information on drugs, their benefits, risks and limitations.
- form partnerships with various sections of the community, inter alia, Government, academic institutions, industry, associations and the media for the purpose of promoting the rational use of drugs, disease prevention, healthy lifestyles and nutrition and for providing guidance on self-diagnosis and self-treatment.
- provide feedback information on operational research findings to other partners in order to effect desired changes in drug consumption habits in the community.

7.4 Rational Prescribing

Prescribing by generic name will be actively encouraged and promoted.

The MOHSS will monitor and evaluate prescribing practices in both the public and private sectors in order to ensure the provision of efficient and cost-effective prescribing.

Standard Treatment Guidelines will be defined in a manual which will be disseminated to all health professionals.

The Standard Treatment Guidelines will guide the drug selection process for the Nedlist.

All health personnel involved in the diagnosis, prescribing and dispensing of drugs, will receive adequate theoretical and practical training on the use of the manual.

7.5 Rational Dispensing

All prescriptions will be dispensed and labelled using generic or approved names. The MOHSS will strive to

improve dispensing practices by ensuring the provision of adequate packaging and labelling materials and by promoting the use of pre-packed courses of therapy for the treatment of common conditions in all types of health institutions.

The MOHSS shall assist, in co-ordination with other interested parties, in the preparation of a cross-index of generic and proprietary names for all drug products on the market.

The *minimum* information on a prescription label shall consist of:

- name of pharmacy or practice
- date of dispensing
- the name of the patient
- the generic name of the drug or the brand name if the medicine consists of two or more active ingredients
- the strength of the active ingredients
- the quantity of medicine dispensed
- the complete dose regimen in written and/or graphic form
- cut off date on use ('use before ..')

Dispensing by persons other than pharmacists, pharmacy technicians or pharmacist's assistants shall be performed only by holders of a valid dispensing licence or as otherwise authorised by the Minister of Health and Social Services.

Inspectors of Medicines as appointed under the Medicines and Related Substances Control Act will make regular inspections of premises where dispensing operations are performed to ensure that the provisions of

the Act, in relation to the granting and renewal of dispensing licences, are being satisfied in all respects.

In the private sector pharmacists may substitute prescribed brand name products with equivalent generic drugs if not expressly stated otherwise by the prescriber. Before dispensing the pharmacist must inform the patient about available cheaper generic alternatives.

A list of products which may not be substituted shall be compiled and disseminated by the MCC.

7.6 Therapeutics Committees

Hospital therapeutics committees will be encouraged in all hospitals, (both public and private) to ensure the rational, efficient and cost-effective supply and use of drugs.

In particular the MOHSS shall provide for the establishment of therapeutics committees at directorate, regional and institutional levels.

The committees will, inter alia, be responsible for:

- assisting in the assessment of drug and medical supplies requirements for the respective levels
- assisting in the assessment and monitoring of expenditure on drugs and medical supplies
- monitoring of the use of the Standard Treatment Guidelines and overall drug utilisation
- provision of relevant and up-to-date drug utilisation information for prescribers and dispensers
- planning for measures to be employed in case of drug shortages
- the establishment of treatment protocols in line with national policies

- approval of requests for the purchase of non Nedlist medicines
- co-ordination of reports of suspected drug related adverse events and reporting of such events to the next higher level (MCC)

8. DRUG PRICING

Aim: To ensure that drug prices are reasonable, and affordable for the consumer.

This aim will be achieved by rationalising the drug pricing system, by monitoring and negotiating drug prices, and by promoting the use of generic drugs.

8.1 Rationalisation of the Pricing Structure

The percentage mark-up system as it is currently applied in Namibia to determine the price of medicines, creates incentives for selecting more expensive items to be prescribed and dispensed.

The link between the price of the item and the income of the prescriber or the dispenser and thus incentives to dispense high priced (brand name) products will be removed by developing and implementing a fee system. In addition, the right to dispense will be restricted to pharmacists wherever possible.

The wholesale and retail percentage mark-up systems will be replaced with pricing systems based on fixed professional fees (retail) or fee-for-service (wholesale) plus the cost of the medicine.

Accurate data on the pharmaceutical market in Namibia including private households' expenditure on drugs will be compiled and analysed to monitor the effects of pricing policies.

8.2 Monitoring and Negotiating Medicine Prices

Drug prices will be monitored at all stages (manufacturer, wholesaler, retailer) of the distribution process.

Negotiations between Government and the private sector shall prevent unreasonably high prices. Internal and external reference prices will guide this process.

There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers and retailers.

Mechanisms to regularly inform the public about drug prices will be implemented.

A system which will give negotiating power to the local distribution industry in view of drug manufacturers, will be developed in collaboration with other Ministries.

8.3 Promoting the Use of Generic Drugs

The use of interchangeable multi-source pharmaceutical products to reduce medicine cost and expenditure will be promoted through the implementation of appropriate incentives.

In addition, promoting the use of generic names will also contribute to a sound system of procurement and distribution, drug information, and rational drug use at every level of the health care system.

9. DRUG ADVERTISING, MARKETING AND PROMOTION

Aim: To ensure that advertising and promotion of drugs is of high professional standard and in the interest of the public.

National ethical criteria for drug promotion and advertising will be established and published for distribution to all interested parties.

Labelling and advertising for drugs must be based on scientifically established evidence in line with approved package inserts and be in good taste.

Drug promotional activities must be in line with national drug policy objectives. In this respect, whenever the brand name of a drug is used in any form of promotional or educational material, including radio advertising, the generic name of the drug must be given due prominence.

Advertising must be educational in purpose and in the case of public advertising, restricted to non-prescription Schedule 0 medicines.

Accepting that medicines are not ordinary commodities of trade, and that their sale and supply requires the involvement of a pharmacist or other health professional, advertising campaigns shall be directed to health professionals rather than the public.

Thus promotion and advertising of Schedule 1 and higher medicines will be restricted to professional medical, pharmaceutical, dental, veterinary or nursing publications.

Promotion in the form of financial or material benefits shall not be offered to or sought by health care practitioners to influence them in the prescribing and dispensing of drugs.

Scientific studies and surveillance must not be misused as a disguised form of promotion. Drugs used in clinical trials will be identified by a code number and not by name.

No advertisement for a medicine may contain a statement which deviates from the evidence submitted in the application for registration, where such evidence has been accepted by the MCC.

Drug advertising aimed at, or involving the inappropriate use of children will not be permitted.

Medicines control inspectors will carefully monitor drug advertising and promotional activities to ensure that they conform with the national ethical criteria. Members of the public and health professionals will be encouraged to report suspect advertisements to the MCC.

10. HUMAN RESOURCES DEVELOPMENT

Aim: To build capacity and develop expertise among health workers who are to implement the different elements of the drug policy.

The aim will be achieved through:

- the conducting of an analysis of staffing needs and requirements (medium and long term) in both the public and private sectors.
- the development of a pharmacists' training programme for the country, and the development of a comprehensive and relevant curriculum for pharmacists, which will focus in particular on the principles of PHC, the concepts of essential drugs and rational use of drugs, and drug management.
- the strengthening and continuation of the training programme for pharmacist's assistants, including the review and updating of their curriculum to ensure inclusion of appropriate aspects of prescribing, dispensing, rational drug use and drug management.
- the development and implementation of a systematic and comprehensive programme of in-service training and continuing education focusing on inter alia aspects of quality assurance, legislation and regulatory procedures, drug control and management.
- the collaboration with relevant Professional Boards/Councils and the University of Namibia (UNAM) to ensure inclusion of the essential drugs concept, rational drug use, cost considerations and other issues of this policy in all health workers' curricula.

Analysis of career opportunities and mobility especially for pharmacists will be conducted with a view to improve

conditions of service. Those coming from under-served, remote areas will enjoy preference in receiving government bursaries for studies in pharmacy and medicine. Mechanisms will be put in place to ensure that the country benefits from such training.

A suitable career structure will be designed to attract and retain pharmacists and pharmacist's assistants for the public sector.

11. RESEARCH AND DEVELOPMENT

Aim: To identify and support operational research and development activities, which will facilitate the achievement of the objectives of this policy.

The Government will encourage the development of multi-disciplinary research and the training of research personnel in the relevant areas of interest.

Areas of health research which are particularly important for this policy are:

- health systems research to measure the impact of this policy and its main components
- behavioural research on prescribing and dispensing problems at different levels of the health system
- research on the economics of drug supply and utilisation
- research on social and cultural aspects of drug use, self-medication, acceptability and utilisation of drug supply systems, and attitudes of drug consumers

Clinical trials on medicines will be carried out with the approval of the MCC and the ethical committee of the MOHSS in compliance with WHO guidelines on Good Clinical Practice (GCP). Clinical studies are to be conducted in terms of the Declaration of Helsinki.

Exploratory and developmental research into local raw materials as sources for new drugs will be encouraged in order to achieve the objective of increased local production of essential drugs through the promotion of local manufacturing capability.

As funds devoted for research are limited, priority will be given to major pharmaceutical problems encountered in

the country. Research funding will aim to support operational research comprehensively.

As problems of drug supply and utilisation affect many countries, the Government will promote the exchange of research findings with other countries and with international agencies such as WHO and will encourage and support the participation of local drug researchers and research institutions in international drug research activities.

12. TRADITIONAL MEDICINE

Aim: To promote and ensure the safe and appropriate use of traditional medicines.

A national database of indigenous plants with proven or alleged medicinal value will be compiled. These plants will be screened for toxicity.

Investigations will be carried out to determine health conditions that can be treated effectively with traditional medicines.

Marketed traditional medicines will be registered and regulated.

Traditional Healers will be required to register with a board/council and to comply with a Code of Ethics and Practice.

13. TECHNICAL CO-OPERATION WITH OTHER COUNTRIES AND INTERNATIONAL AGENCIES

Aim: To make optimal use of human and financial resources by ensuring that possible technical co-operation and harmonisation are investigated, promoted and implemented.

The aim will be achieved through strengthening and broadening ongoing bi- and multi-lateral technical co-operation and through establishing new links. Possible areas of co-operation include (but are not limited to) the following:

- evaluation and registration of medicines
- development of standard dossiers for essential generic drug formulations.
- drug information
- drug quality surveillance and GMP inspections.
- adverse drug reaction monitoring and reporting
- human resources development and training
- implementation of International Drug Control Treaties.
- research and development
- traditional medicine identification, investigation and documentation
- co-ordination of response to emergency situations

The guidelines and recommendations of the WHO, United Nations Drug Control Programme (UNDCP) and other relevant organisations on technical co-operation will be adopted and implemented wherever appropriate.

14. FINANCING

Aim: To ensure that sufficient funds are mobilised to sustainably finance national drug needs.

The Government will endeavour to provide adequate budgets for essential drugs and ensure that funds are used efficiently to maximally benefit the Namibian people.

Budgeting guidelines will be developed to ensure the equitable allocation of funds.

The devolution of financial control to lower levels will be one long-term strategy to improve efficient use of funds.

Drugs for preventive and promotive health care services e.g. immunisation, family planning, ante-natal care, etc. will be provided free of charge at public health facilities.

Existing fees for the treatment of out- and in-patients will be revised regularly to be in line with the costs of providing such services. Efforts will be made to ensure that those individuals who can afford to pay for their treatment and drugs are charged the full cost.

The possibility of employing user fees to partly cover drug costs will be evaluated.

The development of compulsory health insurance will be further investigated.

15. POLICY IMPLEMENTATION

Aim: To ensure efficient and effective implementation of the National Drug Policy.

A National Pharmaceutical Master Plan (NPMP) will be formulated and adopted to ensure that the policy is put into practice. This master plan will define objectives, broad strategies and activities as well as budgets and timing.

On the basis of the NPMP priority areas will be defined and translated into concrete short term action plans with defined activities, budgets, time tables, responsible persons, expected outcomes and indicators.

16. MONITORING AND EVALUATION

Aim: To ensure that the policy is implemented efficiently and that selected strategies and activities serve the objectives.

Indicators for monitoring the implementation and effects of the National Drug Policy will be defined.

A monitoring system will be developed to ensure regular data collection and analysis.

The efficiency and effectiveness of the policy will be evaluated at specified time intervals. Strategies and activities will be adjusted if necessary.

The focal point for co-ordinating planning, implementation and monitoring of the policy will be the Essential Drugs Programme in the Ministry of Health and Social Services.

GLOSSARY

Adverse drug reaction: a response to a pharmaceutical product which is harmful and unintended and that occurs at doses normally used or tested in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Declaration of Helsinki: Recommendations guiding medical practitioners and other clinicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly in Helsinki, Finland, 1964, and amended in 1975, 1983, and 1989.

Ethical Criteria for Medicinal Drug Promotion: Criteria prepared by an international group of experts to give manufacturers, distributors, the promotion industry, prescribers and consumer groups a framework to ensure that promotional practices are in keeping with acceptable ethical standards (WHO, 1988)

External reference prices: the price of identical or comparable drugs like the one under consideration in other countries or on the world market.

Fast-track registration procedure: a system to prioritise and expedite the processing of applications for registration of pharmaceutical products.

Generic name: a unique name identifying a particular pharmaceutical substance. Generic names are officially assigned by national drug nomenclature commissions and nowadays mostly conform to those assigned by the WHO programme on the selection of international non-proprietary names (INN)

Generic products: Products marketed under a non-proprietary or generic name rather than a proprietary or brand name, often at a cheaper price.

Good Clinical Practice (GCP): a standard for clinical studies which encompasses the design, conduct, monitoring,

termination, audit, analyses, reporting and documentation of the studies, and which ensures that the studies are scientifically and ethically sound, and that the clinical properties of the pharmaceutical product under investigation are properly documented. Further defined in WHO Technical Report Series, No. 850, 1995: Guidelines for good clinical practice for trials on pharmaceutical products.

Good Manufacturing Practices (GMP): Pharmaceutical quality assurance system which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. Further described in WHO Technical Report Series No. 823, 1992: Good manufacturing practices for pharmaceutical products.

Health practitioners: any person registered or authorised to practise a health profession under the Allied Health Services Act, 1993; Medical and Dental Professions Act, 1993; Pharmacy Profession Act, 1993; or Nursing Professions Act, 1993.

Interchangeable multi-source pharmaceutical products: pharmaceutical products from different manufacturers with the same active ingredient and in the same dosage form, which have the same therapeutic effect as the reference product.

Internal reference prices: The price of pharmaceutical products on the home market, containing the same active ingredient/s or belonging to the same therapeutic class as the product under consideration.

International non-proprietary name (INN): the shortened scientific name of a pharmaceutical substance assigned by the WHO programme on the selection of INNs. Except for older substances generic names assigned by national authorities are nearly always identical with INNs.

Licensing authority: general name for any statutory body delegated by the Government to register health practitioners and to regulate their professional practice.

Medicines Control Council: a council charged by the Government with matters relating to the control of medicines

according to the Act, for example registration of medicines and inspection of manufacturing premises.

Medicines Regulatory Authority: general name for an institution charged in any country with the registration and control of pharmaceutical products.

Medicines surveillance laboratory: a laboratory where pharmaceutical products can be analysed to ensure their compliance with quality standards.

National Drug Control Commission: a commission consisting of members of different Ministries and NGOs which is charged amongst others with the prevention of drug misuse and abuse (including alcohol and tobacco), and the treatment and rehabilitation of addicts.

Pharmacopoeia: a publication issued by an authorised national or international commission which specifies quality standards and other properties of pharmaceutical substances and dosage forms (e.g. the United States Pharmacopoeia (USP); the European Pharmacopoeia).

Registration of medicines: the process of registering medicines to be allowed to be sold on the market. This is usually done by the MRA, and includes evaluation of safety, efficacy and quality of the pharmaceutical product. Conditions of sale will also be specified during this process, e.g. on prescription only.

Sell (medicines): means sell by wholesale or retail in public and private sectors and includes import, offer, advertise, keep, expose, transmit, consign, convey, deliver, supply, or dispense whether receiving direct payment or not.

Synergistic: describes the interaction of two or more drugs to produce a certain effect, different from that observed when administering each drug separately.

Team approach: the co-operation of health workers with different qualifications in the management of a patient aimed at improving the quality of care.

Therapeutic advantage: a significant improvement of efficacy or safety of one pharmaceutical product over another of the same therapeutic class seen in daily practice.

Therapeutic alliances: the co-operation of health workers with different qualifications in a private practice to increase accessibility to and quality of services provided. Also referred to as 'group practice'.

User fees: out of pocket payment for services and goods by the patient. They can either be co-payments or designed to cover the full costs of e.g. a treatment course.

WHO Certification Scheme for Pharmaceutical Products moving in the International Commerce: a tool to ensure quality of pharmaceutical products first adopted by the World Health Assembly in 1975. The Scheme has been revised twice since then and the latest version offers importing countries information about the status of the pharmaceutical product, the status of the manufacturer of the pharmaceutical product, the quality of individual batches of the exported pharmaceutical product, and product information as approved in the country of export.

ANNEX: THE NAMIBIAN POLICY ON PHARMACEUTICAL DONATION

- 1. Before a donation is sent to Namibia, the recipient should be contacted by the potential donor (or vice versa) in order to establish the need for such medicines at that time.**

This is meant to prevent overstocking of items already in stock, while the recipient continues to suffer from shortages of essential drugs.

- 2. Before such donation comes to Namibia, the necessary import authorisation must be granted for each item to be donated, after completing the prescribed form which can be obtained from:**

**Ministry of Health and Social Services
Secretariat of the Medicines Control Council
Private Bag 13366
Windhoek
Harvey Street
Tel. No. 203 9111, Fax (061) 227607**

- 3. All donated medicines must be registered in the countries of origin, and such registration numbers should be indicated on the import authorisation form.**
- 4. Authorisation to import donations can be done only if the medicines concerned are manufactured in conformity with the guidelines on Good Manufacturing Practices (GMP) and certified according to the WHO Certification Scheme On the Quality of Pharmaceutical Products Moving in International Commerce.**

In order to guard against fake or substandard products, we must rely on the assurance granted through this scheme.

- 5. Donations must consist only of medicines of known good quality which are included in the 'list of essential drugs' supplied by the recipient, or on the Ministry of Health and Social Services' Essential Drugs List which is obtainable from the above address.**

It is expected that donors would respect the National Drug Policy and hence aim at the implementation of its components, one of which is the provision of only medicines which are considered to be necessary in the treatment of diseases afflicting most people in Namibia.

6. All medicines coming into Namibia should be labelled by their generic or international non-proprietary name (INN) and in English language.

The INN's are internationally known and understood in any country where Roman script is used. Also, receiving the same medicines (active ingredient) under different brand names is confusing to local health personnel and is potentially dangerous. Furthermore, it is a waste of the donor's resources if medicines come here and they end up being wasted because the language on the packages is not familiar to Namibia's health personnel.

7. All donated medicines should have a shelf-life of at least one year after the estimated arrival into Namibia, and should be sent in quantities previously agreed upon between the donor and the recipient.

This is because there may be a logistic problem in distribution, which may cause the medicines to reach the users late. For example, the medicines delivery system currently practised in Namibia's public health service is based on a two monthly schedule, and does therefore not allow for immediate distribution. Also, the climate can shorten the actual shelf-life of pharmaceuticals. Furthermore, the minimum shelf-life requirement facilitates planning for future supplies and avoids overstocking and possible wastage.

8. If medicine is sent to the same place or programme regularly, it is highly appreciated if the strength and dosage of such medicine could remain constant.

The reason for this is that health workers at different levels of the health care system have been trained to use medicines in relation to a particular dosage and strength, and treatment schedules have been developed accordingly. Also, health workers with insufficient training in making necessary calculations to modify schedules may end up giving wrong dosages.

9. For donations targeted for big health facilities, large quantity packaging units are preferred to the small-quantity ones.

These are less bulky, and therefore easier and cheaper to handle.

