

National Drug Policy for South Africa

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ACKNOWLEDGEMENTS

So many persons and organisations participated in the development of the National Drug Policy, that to attempt to list them would stand the risk of leaving out some of the contributors. Suffice it to say that the policy was developed following a recommendation of the National Drug Policy Committee, which was established by the Minister of Health, Dr N.C. Dlamini Zuma, in September 1994, and reported to the Minister in November 1994. The NDP is also based on the report of that committee, whose terms of reference were necessarily limited to specific issues, but which, nevertheless, formed a solid basis for further development of the policy. Based on this report, a discussion document was put together and presented at a National Drug Policy Consultative Workshop which was convened in June 1995, and which was attended by representatives of the nine provinces, professional bodies and representative organisations of key role players in health care. Following this workshop, comments were received which were incorporated into the policy document.

The contributions of all those who participated in the process are acknowledged with sincere thanks.

The Department of Health is also indebted to the World Health Organisation's Action Programme on Essential Drugs, which helped with comments and extensive editing.

1. Preface

1.1 Process

The NDP presented in this document is the culmination of a number of steps, one of the first of which was the compilation, in 1993, of a draft National Pharmaceutical Policy. This original policy was not widely circulated at the time, nor was active discussion encouraged.

The second step followed the establishment of a democratically-elected and internationally recognized government in mid-1994. A Drug Policy Committee was appointed by the Minister of Health with the following terms of reference:

1. Develop a pricing plan for drugs used in South Africa in the public and private sectors.
2. Develop a plan to ensure that drugs are tested and evaluated for effectiveness in the South African context of treatment using epidemiological approaches.
3. Develop an Essential Drugs List to be used in the public sector and prepare treatment guidelines for the health personnel.
4. Develop specific strategies to increase the use of generic drugs in South Africa.
5. Prepare a plan for effective procurement and distribution of drugs in South Africa, particularly in the rural areas.
6. Investigate traditional medicines.
7. Rationalise the structure for Pharmaceutical Services.

The 1994 NDP Committee compiled and presented a report on its findings, with recommendations, to the Minister of Health in November 1994. The Department of Health then disseminated a discussion document based on these recommendations as a basis for consultation and discussion with stake-holders, health care providers and patients.

Consultative workshops were held in June 1995 with key role players, who included officials of the provincial health departments, representatives of the pharmaceutical industry, professional organisations, the departments of Trade and Industry and Finance, academics and statutory bodies. Valuable input was received from the World Health Organisation's Action Programme on Essential Drugs during and after the workshops. Following the workshops, a wide range of comment was received. These steps facilitated the formulation of a number of clearly-defined components which have been incorporated in the policy.

1.2 Use of the NDP document

This document will serve the health care needs of South Africa in the following ways:

1. It offers a clear description of the approach by which pharmaceutical services in the country will

be managed.

2. It offers guidance to stake-holders, including health care providers, suppliers of goods and services, and governmental and non-governmental agencies of ways in which they can contribute to achieving the policy's main aim.
3. It follows a clear and logical system for reducing inefficiency and waste and improving efficiency and effectiveness through the development of an adequate pharmaceutical infrastructure.
4. It facilitates the design, production and implementation of appropriate programmes for human resource development in health care.

1.3 Implementation of the National Drug Policy for South Africa

In order to achieve optimal use of limited resources the National Drug Policy will be coordinated and supervised by a comprehensive programme, the South African Drug Action Programme (SADAP), established within the Department of Health. This Programme will coordinate and support provincial activities and strategies, together with the complimentary roles of the different parties and stakeholders. The Programme will also have responsibility for policy monitoring and evaluation.

2. Introduction

Health care delivery in South Africa, until the recent process of democratisation and universal franchise, was characterized by a two-tier system of:

1. private health care funded by medical schemes, which covered up to 20% of the country's population, the vast majority of whom were from the white section of the population;
2. a public sector which was characterized by fragmentation (no less than 14 health authorities), a resultant irrational use of resources, poor working conditions and inadequate infrastructure.

Although South Africa spent 6.66% of its GNP on health care in 1992/93, a breakdown of this figure between private and public expenditure shows that public sector expenditure accounted for only 3.44% of GNP, with the private sector taking up 3.22%. Put differently, the private sector was responsible for 48.5% of total health care expenditure in 1992/93. Disparities between the public and private sectors are further illustrated by the fact that in 1990 the private sector was responsible for 80% of the country's total expenditure on drugs, although 60-70% of the total volume of pharmaceuticals was consumed in the public sector.

The pharmaceutical sector, as a component of the health sector, reflected its deficiencies, most notably the lack of equity in access to essential drugs, with a consequent impact on quality of care. Furthermore, rising drug prices, already high in international terms, gave increasing cause for concern, as did evidence of irrational use of drugs, losses through malpractice and poor security, and cost-ineffective procurement and logistic practices.

Most of these problems are interlinked. The Government of South Africa decided to tackle them systematically through the development and implementation of a National Drug Policy that would be consonant with and an integral part of the new National Health Policy, which aims at equity in the provision of health care for all.

The goal of the National Drug Policy is to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers.

The specific objectives of the National Drug Policy are as follows:

2.1 Health objectives

- ! to ensure the availability and accessibility of essential drugs¹ to all citizens

¹ Essential drugs are drugs that are required to treat the majority of conditions that are prevalent in a country in a cost-effective and efficient manner. The concept does not imply that no other drugs are useful, but that these drugs are the most needed for the health care of the majority of the population. They should therefore be available at all times, in adequate amounts and in the proper dosage forms.

- ! to ensure the safety, efficacy and quality of drugs
- ! to ensure good dispensing and prescribing practices
- ! to promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information
- ! to promote the concept of individual responsibility for health, preventive care and informed decision making.

2.2 Economic objectives

- ! to lower the cost of drugs in both the private and public sectors
- ! to promote the cost-effective and rational use of drugs
- ! to establish a complementary partnership between Government bodies and private providers in the pharmaceutical sector
- ! to optimize the use of scarce resources through cooperation with international and regional agencies.

2.3 National development objectives

- ! to improve the knowledge, efficiency and management skills of pharmaceutical personnel
- ! to reorientate medical, paramedical and pharmaceutical education towards the principles underlying the National Drug Policy
- ! to support the development of the local pharmaceutical industry and the local production of essential drugs
- ! to promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector.

The text of the policy covers the key issues under the following components: legislation, including regulation, registration, inspection, quality control and quality assurance; pricing; selection; procurement and distribution; rational drug use; human resources development; research and development; technical cooperation with countries and international agencies; traditional medicines; monitoring and evaluation. The underlying aim and objective of each component are given together with the principal policy strategies.

The policy is an expression of commitment by the Department of Health, as well as a guide to action. It will be accompanied by an appropriate action plan.

3. Legislation and regulations

AIM

**To ensure that drugs reaching patients are safe, effective
and meet approved standards and specifications**

This aim will be achieved through strengthening the Medicines Control Council (MCC), rationalising drug registration, controlling the registration of practitioners and the licensing of premises, enhancing the inspectorate and laboratory functions, and promoting other quality assurance measures.

3.1 Medicines Control Council

The MCC will have monetary autonomy and be allowed to retain revenue, but will be accountable to the Minister of Health. Funds will be generated from registration and retention fees and licensing renewals, supplemented by government funding. The fee structure will be reviewed regularly. Funds will be used for: MCC running costs, drug evaluations, drug testing, improvement and expansion of the MCC infrastructure including computerization of the administrative procedures, and training programmes.

The MCC will review legislation and regulations in order to support the objectives of the NDP and liaise frequently with relevant departments and organizations active in the implementation of the policy, e.g. the NDP Consultative group, the SADAP and governmental procurement and distribution agencies.

The Medicines Control Council will play a prominent role in facilitating the harmonisation of drug regulation and control in Southern Africa. This process will include: sharing of review decisions and exchange of evaluation reports without compromising confidentiality; adoption of criteria for drug evaluation and for Good Manufacturing Practice (GMP); and promoting the use of the WHO Certification Scheme for the Quality of Pharmaceuticals moving in International Commerce.

3.2 Registration of drugs and supplies

Only drugs which are registered in South Africa may be imported, produced, stored, exported and sold. All companies which wish to register products for marketing in the country will be issued with licences if all registration and Good Manufacturing Practice (GMP) requirements are met. All licences will be reviewed periodically.

The current drug registration procedure will be adapted to meet needs within the policy framework. Formal procedures for registration, based on quality, efficacy and safety will be upgraded through introduction or strengthening of:

- ! a five-year re-licensing system for drugs
- ! computerization of the evaluation system
- ! an evaluation report exchange system with reputable regulatory bodies in other countries
- ! prioritization of registrations, based on need
- ! fast-track procedures for essential drugs

! norms and standards for registration of medical devices.

Special attention will be given to the needs of health providers in primary health care environments. This step may include rescheduling of certain drugs to improve patient access to appropriate treatment.

3.3 Registration/licensing of practitioners and premises

Only practitioners who are registered with the relevant Council and premises that are registered and/or licensed in terms of the Medicines and Related Substances Control Act (No 101 of 1965) may be used for the manufacture, supply and dispensing of drugs. Medical practitioners and nurses will not be permitted to dispense drugs, except where separate pharmaceutical services are not available. In such instances/situations where dispensing by doctors and nurses has to take place, such persons will be in possession of a dispensing licence issued by the Medicine Control Council. Criteria for the granting of such licences will include *inter alia*, the application of geographical limits. Special concessions will be granted with regard to certain categories of providers such as occupational health services.. Proven competency of such persons to dispense drugs will be by virtue of the successful completion of a suitable training programme. All licences will be reviewed and renewed annually. These inspection functions will be delegated to the provinces.

The retail trade in drugs will be confined to a licenced place for the sale of drugs, which by virtue of its staffing can provide a comprehensive pharmaceutical service. Where it is deemed to be in the interests of the public, and provided that comprehensive pharmaceutical care is ensured, ownership of pharmacies by lay persons and other health care professionals will be considered. Where non-pharmacist ownership is permitted, it will still be expected that the pharmacy be under the full-time management and supervision of a registered pharmacist.

Uniform norms and standards pertaining to the dispensing of drugs by different service providers will be incorporated into one set of regulations. The conditions pertaining to the retail sale of pharmaceuticals will be adapted to local conditions and will meet the requirement of rational, effective and safe drug supply.

3.4 Inspection

Drug legislation and regulations will be supported by an adequate and effective drug inspection service, under the direction of the MCC. Most inspection functions (e.g. inspection of government depots, hospital stores, private pharmacies, dispensing doctors and nurses) will be devolved to provincial authorities, with a few specialized inspectorial functions (e.g. inspection of manufacturing facilities and wholesale premises) retained at the national level. The MCC will set guidelines for provincial inspection services.

The number of inspectors will be increased, and in-service training programmes will be strengthened.

3.5 Drug quality control laboratory

A national drug quality control laboratory, linked to the MCC, will be established. The present system of contracting with universities will be retained until such a facility is available.

Formal relations with the South African Bureau of Standards will be maintained.

3.6 Quality assurance

The following measures, additional to those already described, will apply:

- M** Guidelines for donated drugs, to follow WHO guidelines for drug donations. Donated drugs will
 - match the health needs of the country and hence appear on the Essential Drugs List
 - be compatible with overall government policy
 - be of appropriate quality, efficacy and safety
 - be accompanied by appropriate legal and administrative documents
 - be reviewed through the MCC fast track procedure
- M** Clinical trials of drugs will be carried out in compliance with Good Clinical Practice Guidelines and the WHO "Model list of items to be included in a clinical trial protocol"
- M** Drug promotion and marketing will comply with national criteria, based on the WHO Ethical Criteria for Medicinal Drug Promotion
- M** Marketed traditional medicines will be investigated for safety and quality
- M** Norms and standards will be set for medical devices and disposable items which appear on an Essential Equipment List. These items will also be evaluated.

4. Drug pricing

AIM

**To promote the availability of safe and effective drugs
at the lowest possible cost**

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

4.1 Rationalization of the pricing structure

- ! A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmacoeconomists, representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives.
- ! There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals.
- ! A non-discriminatory pricing system will be introduced and, if necessary, enforced.
- ! The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee.
- ! All drugs at the primary care level will be supplied free of charge. At the secondary and tertiary levels a fixed affordable co-payment for drugs supplied by the State will be levied. A system of exemption will be established for patients without the resources to meet such payment to ensure that they are not deprived of treatment.
- ! A data base will be developed to monitor the cost of drugs in the country in comparison with prices in developing and developed countries.
- ! Price increases will be regulated.
- ! Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.

4.2 The use of generic drugs

The use of interchangeable multi-source pharmaceutical products (IMPP), using the international non-proprietary name (INN), or generic name, is a recommended step to reduce drug costs and expenditure. It also contributes to a sound system of procurement and distribution, drug information and rational use at every level of the health care system.

- ! The availability of generic, essential drugs will be encouraged through the implementation of incentives that favour generic drugs and their production in the country.
- ! The policy will aim at achieving generic prescribing in both the public and private sectors. Until this aim is achieved, generic substitution will be allowed, through legislation, in the public and the private sector. It will be incumbent on the pharmacist, prior to dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that substitution takes place with the patient's full understanding and consent.
- ! Patients have the right to make informed decisions concerning their own health, including a choice for generic drugs.
- ! A regularly updated list of products that cannot be substituted will be prepared and disseminated by the MCC.

5. Drug selection

AIM

To promote the rational choice of drugs and associated items to be used in South Africa, in accordance with the Essential Drugs concept

This aim will be achieved through the development of an Essential Drugs Programme, which will include an Essential Drugs List and standard treatment guidelines.

A National Essential Drugs List Committee (NEDLC), appointed by the Minister of Health, will be responsible for the selection of drugs to be used in the public sector. The Committee will be composed of experts in all spheres of medical and pharmaceutical practice, including clinical pharmacists and pharmacologists, medical specialists, a paediatrician, professional nurses from community practice, medical practitioners involved in primary care practice, a member of a drug information centre, a member of the clinical committee of the Medicines Control Council, a health professional involved in drug management training and representatives of the provincial EDL committees. Additional members may be co-opted on an ad-hoc basis. Consultations will be undertaken with all interested parties.

The NEDLC will draw up and periodically review a National List of Essential Drugs using generic names. This list will be prepared for three levels of health care providers, namely primary contact, secondary and tertiary hospital care. The list will be reviewed every two years. It will be distributed to all health workers in the country.

The selection of drugs on the National Essential Drugs List will be based on the following criteria:

- ! must meet the health needs of the majority of the population
- ! sufficient proven scientific data must be available regarding the effectiveness of any such product
- ! products should have a substantial safety and risk/benefit ratio
- ! the aim, as a general rule will be to include, as far as possible, only products containing single pharmacologically active ingredients. Combination products may, as an exception, be included where patient compliance becomes an important factor or two pharmacologically active ingredients are synergistically active in a product
- ! when two or more drugs are equivalent in the above respects, preference will be given to those which have:
 - the best cost advantage
 - has been the best researched
 - the most reliable local manufacturer
 - best pharmacokinetic properties
 - the best patient compliance

The national list of essential drugs will be used as a foundation for:

- ! the basic health care package of the National Health System for Universal Primary Care
- ! procurement and use of drugs
- ! standard treatment guidelines and training in rational prescribing
- ! drug information to health care providers, including a national formulary
- ! support to the national pharmaceutical industry
- ! drug donations.

The list may also be used as a model for medical aid schemes.

In exceptional circumstances, drugs outside the essential drugs list may be requested for specific patients. A standardized procedure for such requests will be developed. Care will be taken to ensure that a minimal portion of the drugs budget is spent on such drugs. These drugs will be included on a supplementary list for that facility, drawn up and regularly reviewed by the Pharmacy and Therapeutics Committee of the facility concerned.

6. Procurement and distribution

AIM

To ensure an adequate supply of effective and safe drugs of good quality to all people in South Africa

This aim will be achieved by promoting cost-effectiveness in the public sector and by utilizing private sector facilities where appropriate.

6.1 Financing

The objective is to develop a system of joint responsibility between the government and the patient for the financing of drugs. However, in line with National Health Policy, the government will ensure that essential drugs are available to all people in need. To this end, drugs will be provided free of charge at the point of service at the primary care level.

The annual budget for procurement of drugs in the public sector will be based on proper quantification of estimates based on the population served, morbidity and related to consumption data.

6.2 Procurement

The objective is the maintenance of a system which will ensure that medical supplies will be procured at the best possible prices.

The public sector coordinating body for procurement (COMED) will be strengthened. Price negotiations for the procurement of essential drugs and medical supplies for the public sector will be undertaken at the national level, using national and international tendering. After contracts have been awarded provincial authorities will purchase drugs directly from suppliers.

All public sector institutions will procure essential drugs through the public sector tender system. In the long term this system will be extended to NGOs and the private sector. The system for issuing and administering the tenders will be computerized and standardized. A system for supplier performance monitoring will be established; information from this system will be used in the adjudication of new drug supply contracts.

A computer system will be developed to record drug purchases by provincial authorities and other organizations, in order to improve the forecasting of annual needs. To facilitate this, all institutional purchases will be channelled through the depots, either for ex-stock deliveries or merely for recording purposes. Provincial administrations will be requested to adopt the use of standardised COMED or compatible systems. This includes the use of the National Codification System and the participation in national tenders for EDL and Essential Equipment List (EEL) items.

National tender prices will be monitored and compared with international prices. Preference will be given to national manufacturers. Notwithstanding this preference, procurement will aim at securing the lowest available prices for products of defined specifications. The government will thus reserve the right to consider procurement on the international market, which includes the options of parallel importation and purchasing on the international generic market.

Drug procurement and distribution for the public sector will be limited to drugs on the national list of essential drugs, and to products registered for use in South Africa. A fast-track registration procedure will be established for products which are procured solely for the public sector.

Tenders will be called for by generic name only. As much as possible, drugs will be procured in patient-ready packs; in other cases repacking will be done by provincial depots. Preference will be given to products labelled solely by generic name; in all other cases the generic name must be printed immediately above or under the trade name, in a letter type at least as large as that of the trade name.

The award process for tenders will be transparent and conducted in the terms recommended by the Tender Board.

6.3 Storage and safeguarding of drugs in the public sector

The objective is to ensure the maintenance of quality and security of drugs and medical supplies in storage from the time of receipt into stock up to the time of issue to the patient.

Provincial authorities will be assisted in drafting long-term plans for the rationalization and upgrading of depots, including plans for the reconstruction or replacement of existing facilities. The Directorate of Procurement will determine the geographic areas covered by existing depots regardless of provincial boundaries and will make recommendations to provincial administrations on the need for and siting of additional storage facilities.

Standard Operating Procedures (SOPs) will be developed with practical guidelines to cover all administrative procedures to manage and control effectively the storage and distribution of drugs and medical supplies, including methods to define minimum and maximum stock levels, guidelines on systematic stock rotation and handling of expired and obsolete stock. These SOPs will be used for training and supervision of staff and will be updated regularly.

Appropriate functional staffing structures for public sector depots and institutional stores will be defined to include the correct rank, occupational class and personnel establishment levels.

Effective and standardized security systems will be developed and implemented in all public sector depots.

The turn-over of drugs and medical supplies will be monitored with the aid of a systematic and practical information gathering process. This information will be used to determine the quantities to be procured.

6.4 Distribution

The objective is to ensure the prompt, efficient, timely and equitable distribution of essential drugs and medical supplies to all health care institutions.

Provinces will make their own distribution arrangements to ensure that drugs and medical supplies are distributed in the most cost-effective manner. Where appropriate, provincial authorities may contract distribution to the private sector.

The distribution of drugs and medical supplies to public sector health facilities will take place at least once per month but preferably more often.

Computerized inventory control systems will be established in all hospital pharmacies and clinics. These systems will be linked to computerized inventory control systems in the depots.

The use of accredited private sector providers in the distribution of drugs and medical supplies to patients in the public sector will be expanded where necessary. The supply of drugs to patients with chronic illnesses, referred patients and national disease control programmes, will be included in this system.

Ownership of pharmacies by non-pharmacists will be permitted in areas with inadequate pharmaceutical services, and where it is clearly not for personal gain. It will also be permitted in the case of private and mine hospitals, and to facilitate group practices. Such pharmacies will remain under the management and full-time supervision of a registered pharmacist.???

Prescribing of drugs above schedule 2 by pharmacists, except as provided in the regulations of the Medicines and Related Substances Control Act (101 of 1965), will not be permitted. Similarly, prescribing by nurses will only be in accordance with the provisions of Act 101 of 1965.

The distribution of cold-chain items, such as vaccines, will be the responsibility of public sector depots, according to guidelines of the EPI Review Committee.

6.5 Local manufacture of drugs

The objective of the policy is to stimulate the national pharmaceutical industry to manufacture and market drugs on the National List of Essential Drugs, and to promote national self-sufficiency in the production of these drugs.

The national pharmaceutical manufacturing industry will receive a maximum 15 per cent price preference as recommended by the World Bank in the awarding of public sector drug tenders, provided they comply with the State Tender Board regulations and conditions.

Inspections will be carried out regularly by the inspectorate of the MCC in order to ensure compliance with Good Manufacturing Practices.

The export of locally manufactured drugs, particularly essential drugs, will be encouraged, especially to neighbouring countries.

6.6 Disposal of expired and unwanted drugs

The objective is to ensure that all unwanted and expired drugs, medical supplies and associated waste are disposed of promptly, efficiently and safely.

The Department of Health, in cooperation with the private sector and in consultation with the state medical

depots, will ensure that appropriate methods are applied for the removal and disposal of expired and returned stock, medical supplies and medical waste. Where possible returned non-expired stock and reusable items will be redistributed.

The Government will ensure through legislation that the removal and/or disposal of drugs, medical supplies and medical waste takes place in such a manner that is neither harmful nor dangerous to the community or environment.

Authorized inspectors will carry out regular inspections to ensure that the disposal of unwanted items takes place according to prescribed guidelines, which will carry a penalty for infraction.

7. Rational use of drugs

AIM

To promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the community

This aim will be achieved through appropriate training, the provision of scientifically validated drug information for professionals and the community, the establishment of hospital therapeutic committees, good dispensing practice and an enhanced role for the pharmacist, and control of commercial marketing practices.

7.1 Education and Training

Health personnel (see also 8. Human resource development)

The objective is to ensure that all health personnel involved in diagnosis, prescribing and dispensing of drugs receive adequate theoretical and practical training.

The core curricula of all educational programmes for medical, paramedical and pharmaceutical personnel will be assessed and, if necessary, revised by the relevant statutory councils to ensure sufficient exposure to the concepts of primary health care and essential drugs, the rational use of drugs, including non-medicinal therapies, and patient counselling and communication.

A systematic and comprehensive programme of continuing education will be developed and implemented.

All such initial and continued training will be developed and assessed in collaboration with health personnel at all levels.

General public

The Department of Health will collaborate with other bodies responsible for school, adult literacy and other educational programmes to integrate into the curriculum basic education that will lead to a better appreciation of the benefits and limitations of the role of drugs in health care. Care will be taken to develop among the general public a more critical attitude to advertising and commercial information, responsible self-prescribing, and confidence to interact effectively with health care providers.

7.2 Drug information

The objective is to ensure the provision of practical and scientifically validated information on the correct handling and rational use of drugs to health personnel at all levels, including community pharmacists, as well as to patients and the general public.

Information for prescribers and dispensers

Scientifically validated information on drugs will be collected, compiled and disseminated by supporting and/or establishing independent Drug Information Centres, which will also assist with drug surveillance.

Regularly updated standard treatment protocols for treatment of common conditions with essential drugs will be produced by the Department.

The Department will also produce an annual national formulary of essential drugs for distribution to all health care providers and dispensers. This publication will include guidelines to good dispensing and prescribing, together with information on drug interactions.

Information for patients and the general public

The public will be provided with access to objective, validated and practical information on drugs and their proper use, written in lay language, and including appropriate self-diagnosis and treatment.

Information for the public on subjects including disease prevention, limited self-diagnosis, appropriate and inappropriate self-medication and suitable alternative non-medicinal treatment, and communication with health care providers, will be promoted through all available communication media.

A partnership among government, industry, health workers, professional associations, the public/consumers and academic institutions will support this campaign.

Research on social and cultural factors which influence medicines usage will be encouraged. This activity will facilitate subsequent interventions to alter attitudes and beliefs which are found to contribute to the irrational use or non-use of drugs, and to prioritize and tackle problems of misuse which are identified as being particularly serious.

7.3 Appropriate prescribing

The objective is to ensure that all drugs are prescribed by generic name in accordance with recommended standard treatment protocols and the Essential Drugs List. At primary level prescribing will be competency, not occupation, based.

The Department of Health will collect, evaluate and disseminate systematic data on drug utilization to monitor and act on policy adherence.

7.4 Dispensing

The objective is to ensure that all drugs are dispensed according to regulations and good dispensing practice.

Dispensing will be in accordance with the principles already stated in section 4.2.

7.5 Hospital therapeutic committees

The objective of the policy is to establish and strengthen Pharmacy and Therapeutic Committees in all hospitals in the country (both public and private) in order to ensure the rational, efficient and cost-effective supply and use of drugs.

These therapeutic committees will consist of at least a senior pharmacist, a senior nurse, a senior financial officer and senior clinicians or their nominated representatives in their absence.

Their terms of reference will include responsibility for:

- ! the accurate estimation, prompt procurement and optimal storage and supply of drugs and medical supplies
- ! the compilation and preparation of a hospital formulary
- ! cost-effective drug use
- ! proper staff establishments to carry out these functions.

7.6 The role of pharmacists

Although all health care providers and the public are involved in the rational use of drugs, WHO has recommended a special role for pharmacists, particularly in quality assurance and in the safe and effective administration of drugs. Pharmacists will be in a strong position to promote the rational use of drugs through their extensive knowledge.

Pharmacists, particularly those in the community, have a central community educational role in instructing patients in the correct use of drugs. Professional associations will be encouraged to develop coordinated programmes to facilitate and further this role.

Pharmacists will be involved in a multi-disciplinary approach to the rational utilization of drugs. Greater cooperation between pharmacists and other health professions within communities and hospitals will be promoted to facilitate consensus regarding the choice of drugs and treatment protocols. They also have a critical role to play in primary health care and preventive health services.

Pharmacies will be required to have available scientific sources of reference. They will also require access to additional essential information from a central drug information system.

The policy will also aim at expanding and standardizing the training of pharmacy technicians and other pharmaceutical support personnel. Pharmacy technicians will be prepared for certain tasks in hospital pharmacies under the supervision of pharmacists, and for managing drug supply in primary care clinics

under the indirect supervision of a district pharmacist.

7.7 Advertising and marketing of drugs

The objective is to ensure that advertising and marketing of drugs shall be in keeping with the National Drug Policy, and in compliance with national regulations, as well as with voluntary industry standards. All promotion-making claims shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. Promotional material shall not be designed to disguise its real nature. 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 prescription of drugs. Scientific and educational activities shall not be deliberately used for promotional purposes.

Ethical criteria and guidelines for the promotion and advertising of drugs will be established, widely disseminated and strictly enforced. The Ethical Criteria for Medicinal Drug Promotion adopted by the World Health Assembly (WHA) and the Pharmaceutical Manufacturers Association (PMA) Codes of Marketing Practice will be considered in the development of the national criteria (See also section 3.1).

Issues related to pharmaceutical promotion and comparative independent sources of drug information will be included as a core component of all curricula of the health and pharmaceutical professions.

8. Human resources development

AIM

To develop expertise and human resources to support the successful implementation of the policy and to promote the concepts of essential drugs and rational drug use and ensure their adoption throughout the country

The aim will be achieved by strengthening drug management systems and improving the quality of service in drug supply; improving inspection services and quality assurance for drugs and their rational use; training pharmaceutical support staff so that deficiencies in the distribution chain will be eliminated and transforming training institutions so that they produce health care professionals who function effectively and efficiently in meeting the country's health care needs. Current anomalies in conditions of service will be corrected. Incentives will be introduced to encourage practitioners to move to under serviced areas.

Appropriate training programmes will be designed and implemented to address specific needs as outlined below. Programmes will be implemented at two levels: institutional and in-service training. With regard to institutional training, the curricula and syllabi of the training institutions will be appropriately modified to produce suitably qualified and motivated health workers. In-service training programmes will be developed and implemented to address on-the-job requirements of the respective groups. The priority training needs for various categories of staff follow.

Medical doctors:

1. Introduction to the principles of the national drug policy
2. Standard treatment guidelines and essential drugs in effective prescribing
3. Rational use of drugs
4. Managing decentralized health care systems
5. Management information systems.

Nurses:

1. Introduction to the principles of the national drug policy
2. Standard treatment guidelines and essential drugs in effective prescribing (in cases of role substitution when medical doctors are not available)
3. Rational use of drugs
4. Managing decentralized health care systems
5. Management information systems.
6. Introduction to dispensing (in cases of role substitution when pharmaceutical personnel are not available)
7. Managing drug supplies in clinics (in cases of role substitution when pharmaceutical personnel are not available).

Pharmacists:

1. Introduction to the principles of the national drug policy
2. Standard treatment guidelines and essential drugs in effective prescribing
3. Rational use of drugs
4. Managing decentralized health care systems
5. Management information systems.
6. Drug supply management
7. Hospital pharmacy administration
8. Pharmacoepidemiology
9. Pharmacoeconomics
10. Principles of pharmaceutical care.

Pharmacy support staff (pharmacy technicians):

1. In-service basic training for registration purposes
2. Introduction to principles of the national drug policy
3. Introduction to concepts of essential drugs
4. Managing drug supplies.

Training of this cadre will be standardized and accelerated. The anomaly which exists between the training and career structure for these workers will be corrected.

Health service managers and pharmaceutical depot managers:

1. Introduction to principles of the national drug policy
2. Introduction to concepts of essential drugs
3. Drug supply management
4. Management information systems.

All training will be skills-based, so that workers will contribute to effective health care delivery at their functional level.

Statutory councils and boards will be encouraged to introduce a requirement for continuing competence as a basis for periodical renewal of registration.

The above training programmes will be coordinated by the Department of Health to ensure optimal utilisation of resources.

9. Research and development

AIM

To promote research that will facilitate the implementation, monitoring and evaluation of the National Drug Policy and/or meet the health care needs of the country

9.1 Operational research

The aim will be achieved through the Department of Health supporting important areas of operational research* that can promote the successful implementation of the National Drug Policy. The findings of such research will be used to make necessary adjustments in strategy and to ensure that policy objectives are achieved.

Research will focus particularly on the following areas:

- ! the impact of the National Drug Policy and its core principles on health service systems and delivery
- ! problems related to prescribing and dispensing at different levels of the health system
- ! the economics of drug supply and use
- ! socio-cultural aspects of drug use, including self-medication, acceptability and use of supply systems, and knowledge, attitudes and practices of users of drugs.

9.2 Drug research and development

Research aimed at alleviating common diseases and complaints will be encouraged, eg the development of new, less toxic, more effective and more stable drugs and vaccines for existing conditions.

Note: * Operational research aims to identify the best methods of selecting, procuring, distributing and using drugs. It should be carried out in partnerships among policy makers, service providers, universities, research institutes and other NGOs, and consumers. It should lead to practical and cost-effective measures and should underpin management decisions.

10. Technical cooperation with other countries and international agencies

AIM

To ensure that all relevant forms of technical cooperation are investigated and promoted to maximise the effective use of limited resources.

The aim will be achieved through ongoing technical cooperation with international agencies, such as the WHO, and the maintenance and strengthening of this cooperation.

Possibilities for further international and regional collaboration will be systematically identified.

Cooperation, particularly in the following areas, will be encouraged and supported:

- ! evaluation of drugs
- ! regional procurement systems and the exchange of information on pharmaceutical supply sources
- ! quality control
- ! computerization of stock control and drug registration
- ! production and formulation of drugs
- ! transfer of appropriate technology
- ! research and development
- ! training and human resources development
- ! studies on drug utilization
- ! exchange of drug information
- ! emergency situations, such as epidemics and disasters.

The guidelines and recommendations of the World Health Organization will be followed wherever possible.

11. Traditional medicines

AIM

To investigate the use of effective and safe traditional medicines at primary level

The aim will be achieved through the encouragement of traditional healers to work more closely with the formal health care sector, although this will not necessarily be aimed at making them part thereof. The appropriate traditional healers' organisations will be encouraged to compile and develop a "Code of Practice".

Traditional healers will be encouraged to cooperate with other workers in the formal health sector, particularly in programmes such as immunization monitoring and AIDS management.

Traditional medicines will be investigated for efficacy, safety and quality with a view to incorporating their use in the health care system.

Marketed traditional medicines will be registered and controlled.

A national reference centre for traditional medicines will be established. Functions will include:

- ! development of a national database of indigenous plants that have been screened for efficacy and toxicity
- ! testing for toxicity and efficacy
- ! compiling a national formulary of Medicines Control Council approved "essential traditional medicines"
- ! propagation of medicinal plants.

12. Monitoring and evaluation

AIM

To support the successful implementation of the National Drug Policy through establishing mechanisms for monitoring and evaluation of performance and impact that will identify possible problems and effective strategies

The aim will be achieved through coordination, supervision, monitoring and evaluation of the implementation of the National Drug Policy by the Department of Health.

Indicators for monitoring the National Drug Policy will be compiled and will form part of the National Health Information System. These indicators will conform to internationally agreed standards, e.g. WHO. Information from different provinces, directorates and sections will be integrated in the system.

Progress in National Drug Policy implementation will be monitored at regular intervals.

A full evaluation of the National Drug Policy will take place every three years.

Systems for monitoring of the private sector and, to a limited extent, international pharmaceutical markets will be developed and implemented.

13. Concluding remarks

A comprehensive National Drug Policy has been developed for South Africa. It covers the wide range of activities which contribute to the effective production, supply, storage, distribution and use of medicines. Its successful implementation depends on a commitment to its principles by all role players and stake holders. This commitment must go beyond lip service to include active participation in the process of initiation, review and modification to ensure that the people of South Africa receive the drugs they need at a cost that they and the system as a whole can afford.