World Inventia Publishers

Journal of Pharma Research

http://www.jprinfo.com/

Vol. 6, Issue 3, 2017 ISSN: 2319-5622 USA CODEN: JPROK3

Review Article

DRUG POLICIES, GUIDELINES, ACTS AND REGULATIONS IN REPUBLIC OF SOUTH AFRICA

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Received on: 19-02-2017; Revised and Accepted on: 22-03-2017

ABSTRACT

A drug policy is the policy, usually of a government, regarding the control and regulation of drugs considered dangerous, particularly those which are addictive. Governments try to combat drug addiction with policies which address both the demand and supply of drugs, as well as policies which can mitigate the harms of drug abuse, and for medical treatment. Demand reduction measures include prohibition, fines for drug offenses, incarceration for persons convicted for drug offenses, treatment (such as voluntary rehabilitation, coercive care, or supply on medical prescription for drug abusers), awareness campaigns, community social services, and support for families. Over the last fifty years, South Africa has developed a medicines regulatory authority with internationally recognized standing. The Medicines Control Council applies standards laid down by the Medicines and Related Substances Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances.

Keywords: *Drug policy, Guidelines, Medicine Control Council.*

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 who 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 [1, 2, 7, 9].

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 [3, 4].

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

1. Health objectives:

- ❖ to ensure the availability and accessibility of essential drugs to all citizens
- ❖ 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.

2.1. 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.

2.2. 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

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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:

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.[5,6]

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 licenses if all registration and Good Manufacturing Practice (GMP) requirements are met. All licenses 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 [10, 11].

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 inspectoral 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:

- 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
- 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"
- Drug promotion and marketing will comply with national criteria, based on the WHO Ethical
- Criteria for Medicinal Drug Promotion
- Marketed traditional medicines will be investigated for safety and quality
- 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:

This aim will be achieved by monitoring and negotiating drug prices and by rationalizing 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, and 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 nonproprietary 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:

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 pediatrician, 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
  - best pharmacokinetic properties
  - has been the best researched
  - the best patient compliance
  - the most reliable local manufacturer

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:

This aim will be achieved by promoting cost-effectiveness in the public sector and by utilizing private sector facilities where appropriate [13, 14].

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.

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 deports regardless of provincial boundaries and will make recommendations to provincial administrations on the need for and sitting 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 [15-17].

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 neighboring 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 [18-20].

7. Rational use of drugs:

AIM:

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.l. Education and Training:

Health personnel: 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 counseling 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.

7.5. 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.

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, and 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. 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

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
9. Research and development
10. Technical cooperation with other countries and international agencies
11. Traditional medicines
12. Monitoring and evaluation
13.Legislation and regulations
14. Case Study in various provinces of South Africa

Case study: A district in the Eastern Cape

The Mt Frere health district in the Eastern Cape has two hospitals and 17 clinics. Only 2 of the 154 professional nurses in the health district have completed the one-year primary health care course, and might therefore be eligible for registration as prescribers. There are no qualified pharmaceutical personnel, and both hospital dispensaries should therefore theoretically be closed when the new legislation becomes effective. How the health authorities and statutory bodies will deal this with is as yet unclear.

SUMMARY AND CONCLUSION

The National Drug Policy (NDP) was launched in 1996, and heralded great changes in the area of drug management in South Africa. However, the legislative process has been rocky, with many of the parliamentary gains cancelled by delaying court action. The greatest success has been the development of Essential Drugs Lists (EDLs) and Standard Treatment Guidelines (STGs) for the Primary Health Care Level and adult and paediatric guidelines for the Hospital Level.

Legislation was again thrown into disarray by the passage in late 1998 of the South African Medicines and Medical Devices Regulatory Authority Act (No 132 of 1998), known widely as the SAMMDRA Act. This Act repealed most of the current Medicines and Related Substances Control Act (No 101 of 1965), bar those sections affected by Act 90. Again, this is an enabling Act, and the premature promulgation of the Act in late April 1999 resulted in a non-functional drug regulatory environment. Attempts to get the High Court to set aside the promulgation were initially unsuccessful, but after the full Bench of the Pretoria High Court heard an appeal, the notice of promulgation was withdrawn.

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 organizations 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.

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 [21].

Recommendations:

There is an urgent need for a review of the National Drug Policy, and the formulation of a plan that highlights short-term, medium-term, and long-term goals/objectives. An inclusive review process will do much to improve the degree of transparency in the development of Drug Policy.

Indicators also need to be defined against which the implementation and impact of the NDP can be measured, which will provide more concrete evidence of the achievement of set goals and objectives.

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How to cite this article:

R. Suthakaran et al. DRUG POLICIES, GUIDELINES, ACTS AND REGULATIONS IN REPUBLIC OF SOUTH AFRICA. J Pharm Res 2017;6(3):35-39.

Conflict of interest: The authors have declared that no conflict of interest exists.

Source of support: Nil