

**National Policy for the Establishment and Functioning of  
Pharmaceutical and Therapeutics Committees in  
South Africa  
19 January 2015**

Version 1.0 CONFIDENTIAL



**health**

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Department:  
Health  
**REPUBLIC OF SOUTH AFRICA**

## 1. FOREWORD

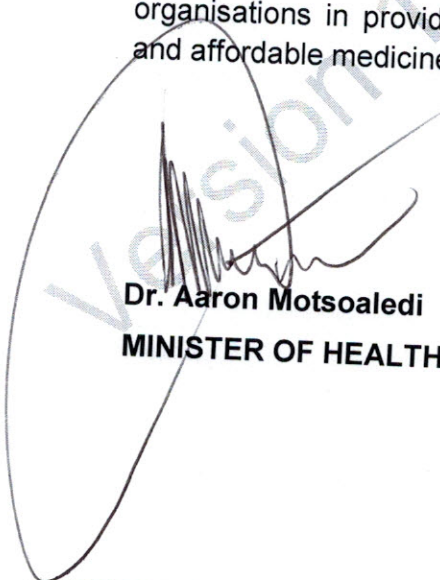
I am proud to present the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.

Medicine management requires the involvement of many different disciplines. A forum is needed to address medicine use problems whereby the efforts of different disciplines are co-ordinated towards achieving an efficient healthcare delivery system.

According to the World Health Organization<sup>1</sup> (WHO) rational medicines use requires that, "Patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time, and at the lowest cost to them and their community". The National Department of Health has adopted WHO's approach to the promotion of rational medicines use<sup>2</sup> and has identified the establishment of Pharmaceutical and Therapeutics Committees (PTCs) as the core intervention to target the various threats to the efficient use of resources.

However, the lack of a policy detailing the standards for the structure, role and functions of PTCs has led to an overall poor involvement of PTCs in the promotion of an effective medicine management system. Acknowledging the need to provide guidance and standards to PTCs to enhance their functionality, the Department of Health developed the National Policy for the Establishment and Functioning of PTCs in South Africa.

This policy is a framework for PTCs to effectively support health care organisations in providing equitable access to safe, effective, cost-effective and affordable medicines and quality care to all citizens in the country.



**Dr. Aaron Motsoaledi**  
**MINISTER OF HEALTH**

<sup>1</sup> WHO, 1985 Conference of Experts on the Rational Use of Drugs.

<sup>2</sup> WHO, Medicines, The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences, [http://www.who.int/medicines/areas/rational\\_use/en/](http://www.who.int/medicines/areas/rational_use/en/) (accessed 19 January 2015).

## 2. INTRODUCTION

It is my pleasure to introduce the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.

Appropriate medicine use is a function of medicine availability. The goal of the South African Government, as expressed in the South African National Drug Policy<sup>3</sup> (NDP), is to “ensure an adequate and reliable supply of safe, cost-effective (medicines) of acceptable quality to all citizens of South Africa and the rational use of (medicines) by prescribers, dispensers and consumers”. To achieve this goal, there should be a system to effectively manage medicines.

A Pharmaceutical and Therapeutics Committee (PTC) provides a forum for all relevant role players, from prescribers to dispensers, to contribute to an efficient medicine management system. PTCs shall ensure that all medicine-related activities are founded on sound governance principles. This in turn shall ensure the availability of appropriate, safe, effective and cost-effective medicines to improve the quality of therapeutic care in the South African health sector.

The National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa is intended to provide guidance on the organisation and operation of PTCs. This policy is intended for use both in the public and private sectors. The implementation of the policy at all healthcare organisations will be facilitated by a comprehensive guidance document.

It is our fervent wish that all relevant stakeholders will embrace this policy.



**Ms Precious Matsoso**

**DIRECTOR GENERAL: HEALTH**

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<sup>3</sup>National Department of Health. 1996. *National Drug Policy for South Africa*, section 2, p3.

### **3. ACKNOWLEDGEMENTS**

The contributions of all those who participated in the process are acknowledged with sincere thanks, among them are Dr Terence Carter, Deputy-Director General: Hospital, Tertiary services and Human Resources Development; Dr Janette Hunter, Deputy-Director General: Primary Health Care; Dr Anban Pillay, Deputy-Director General: Health Regulations and Compliance; Pharmaceutical Services National Health Council Technical Subcommittee; National Essential Medicines List Committee; Essential Drug Programme; and the Systems for Improved Access to Pharmaceuticals and Services (SIAPS).

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## 5. ABBREVIATIONS

EML	Essential Medicines List
NDoH	National Department of Health
NDP	National Drug Policy
PTC	Pharmaceutical and Therapeutics committee
RMU	Rational Medicine Use
TOR	Terms of Reference
WHO	World Health Organization

## 6. DEFINITIONS

- **Equity:** Equity is impartial or just treatment, requiring that similar cases be treated in similar ways.
- **Essential medicines:** Essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.<sup>4</sup>
- **Evidence based medicine:** Evidence based medicine is a process of independent and objective decision making based on consideration of objective data with integration of best research evidence (external) with clinical expertise (internal) and patient values.
- **Formulary:** A formulary is a list of medicines that is approved for the use in the health care system by authorised prescribers and dispensers.
- **Governance:** Governance is the strengthening of organisational structures for appropriate decision making, authority and oversight.
- **Good governance:** Good governance is characterised by equity, transparency, evidence based medicine, accountability, participation, rule of law and responsiveness.
- **Medicine management system:** A medicine management system is a set of practices and policies related to the selection, procurement, distribution and use of medicines.

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<sup>4</sup>[http://www.who.int/medicines/services/essmedicines\\_def/en/](http://www.who.int/medicines/services/essmedicines_def/en/) (accessed 13/02/2014)

- **Rational medicine use:** The rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.<sup>5</sup>
- **Transparency:** Transparency means that the degree of disclosure to reach agreements, dealings, practices and transactions is open to verification.

## **7. PURPOSE OF THE POLICY**

The purpose of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa is to provide standards for the establishment of a non-statutory, multidisciplinary, advisory committee, to be called Pharmaceutical and Therapeutics Committee (PTC) in all provinces, districts and institutions in South Africa.

## **8. GOAL OF PTC**

The PTC shall be committed to the governance of an effective medicines management system to provide equitable and reliable access to medicines and quality care while making the best use of available resources.

## **9. POLICY AND LEGISLATIVE FRAMEWORK**

9.1 The Constitution of South Africa (Constitution) guides the substantive content of all laws and policies through its Bill of Rights. The Constitution provides for health policy and practices that respond to the needs of South Africans. In terms of Section 27 of the Constitution access to health care in itself is a basic human right. All reasonable measures must be taken to ensure that this right is protected, promoted, and fulfilled within the limits of available resources.

9.2 The National Health Act (Act 61 of 2003) provides the framework for a structured uniform health system within South Africa. The Act specifically provides for the establishment of “a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must

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<sup>5</sup> [http://www.who.int/medicines/areas/rational\\_use/en/](http://www.who.int/medicines/areas/rational_use/en/) (accessed 11/03/2014)

address questions of health policy and delivery of quality health care services”.

9.3 The Medicines and Related Substances Act (Act 101 of 1965), as amended, provides the legislative framework to ensure that medicines are safe, efficacious and of good quality.

9.4 The Public Finance Management Act (Act 1 of 1999) ensures that all revenue, expenditure, assets and liabilities of all levels of governments are managed efficiently and effectively and provides for the responsibilities of persons entrusted with financial management to support, among others, sustainable access to health care and medicines.

9.5 The Companies Act, Act 71 of 2008 provides the regulatory framework to promote the efficient and responsible management of companies taking into consideration the principles of good governance.

9.6 The National Drug Policy (NDP)<sup>6</sup> provides for the establishment of hospital and therapeutics committees at institutional level as one of the key elements to achieve its 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”.

## **10. SCOPE OF THE PTC**

PTCs shall have an oversight of the medicines management system in all provinces, districts and institutions in South Africa.

PTCs shall evaluate, advise and educate on all medicine-related activities.

PTCs should strive for excellence in carrying out their duties and continuous improvement of the health care system. PTC shall act at all times in the best

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<sup>6</sup>National Department of Health. 1996. *National Drug Policy for South Africa*, section 7, p17



interest of the public, not inflicting harm, maintaining patient confidentiality and ensuring fair treatment.

The PTC will be guided by the characteristics of good governance which include (but is not limited to) equity, transparency, evidence based medicine, accountability, participation, rule of law and responsiveness.

## **11. STRUCTURE**

PTCs will be established by, and be accountable to, the organisation's executive authority.

The PTC's position in the organisation must be clearly articulated to enable enactment of its decisions through appropriate management structures.

PTCs will have formalised reporting structures that form part of the organisation's governance framework.

The membership of the PTC should include a range of expertise and skills to reflect its scope and functions.

PTC members will be appointed by the organisation's executive authority for a fixed period of time based on the Terms of Reference (TOR).

PTCs must have TOR aligned with this policy and approved by the organisations executive authority.

The TOR should provide for a documented basis for making future decisions and developing a common understanding of the goal, scope and functions of the PTC and its authority to act.

The TOR will describe the structure, organisation and operation of the committee so that all members are clear about their roles and responsibilities.

## **12. FUNCTIONS**

The PTC shall perform core functions considered necessary to achieve its goal.

The activities implemented by the PTC must be guided by the core functions; it will be the responsibility of the PTC to prioritise activities according to the local context. The PTC will have an operational plan guiding the implementation and monitoring of its activities.

The core PTC functions shall be as follows:

- a) To participate in the development and review of medicine-related policies and procedures and to advise on their implementation in support of good governance.
- b) To evaluate and select essential medicines for the formulary on an on-going basis to support equitable access to medicines
- c) To participate in the development and review of treatment guidelines and protocols and to advise on their implementation.
- d) To monitor and investigate medicine use.
- e) To design interventions and to support their implementation to promote rational medicine use among health care professionals and patients.
- f) To monitor and investigate matters related to the safety and quality of medicines and to advise on the implementation of preventative and corrective action.
- g) To advise on and support sound practices for effective procurement, distribution and storage of medicines.
- h) To advise on the pharmaceutical budget, analyse the expenditure and make recommendations for the implementation of appropriate control measures.

## **13. COMMUNICATION**

The communication across the health system should follow a hierarchical two way path. This process should ensure that the available expertise is

used for clinical decisions making to the benefit of the majority of the population.

PTCs shall establish a communication framework to ensure that all issues related to medicine management are communicated timeously and effectively to internal and external stakeholders.

The PTC shall be responsible for informing all health care professionals within their organisation of issues related to medicine management.

#### **14. MONITORING AND EVALUATION**

The PTC shall monitor and evaluate its functioning against its annual operation plan; when deemed necessary the PTC shall implement corrective measure to improve its efficiency.

#### **15. RESOURCES**

The organisation's executive authority shall ensure the availability of appropriate resources to support the optimal functioning of the PTC under their responsibility.

In order to effectively and efficiently assume its functions, the PTC should have the authority to request access to adequate data from any relevant stakeholder within its constituency.