health
Department:
Health
REPUBLIC OF SOUTH AFRICA

National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa

Acknowledgements

This guideline was developed through rigorous stakeholder engagement and best practice aligned to the needs of South Africa.

The Affordable Medicines Directorate of the National Department of Health would like to thank the following:

- USAID Global Health Supply Chain Program for the assistance with the guideline;
- Gauteng Provincial Department of Health for the use of content of *Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province*;
- Management Sciences for Health for the use of content of *MDS-3: Managing Access to Medicines and Health Technologies* and;
- all who provided input into this guideline.

13 December 2019

Contents

1. Introduction

The Essential Medicines List (EML) is the approved list of medicines that are defined as satisfying the priority health care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. The Standard Treatment Guidelines (STGs) are the implementation mechanism of the EML, which provide guidance to health care professionals on the use of medicines that appear on the EML and consist of a collection of disorders linked to medicines, background information on the disorder, treatment regimens, as well as other relevant information and are organised per level of care. In South Africa, the STGs and EML are developed and maintained by the ministerially-appointed National Essential Medicines List Committee (NEMLC) which is supported by the Essential Drugs Programme (EDP) of the Affordable Medicines Directorate (AMD) within the National Department of Health (NDoH).

Pharmaceutical and Therapeutics Committees (PTCs) are the primary implementing bodies of medicine-related governance in the provinces, districts and health establishments in South Africa. They are a crucial component of the medicine supply chain as the custodians of medicine governance and the rational selection and use of medicines at all levels of care.

The establishment of the South African STGs and EML were described in the National Drug Policy (NDP) of 1996. The most important pieces of legislation that give effect to the NDP are the Pharmacy Act (53 of 1974, as amended) and the Medicines and Related Substances Act (101 of 1965, as amended). The Good Pharmacy Practice (GPP) standards published in terms of Section 35A of the Pharmacy Act, 1974, and which are legally binding, require pharmacists in institutional (hospital) pharmacies to be involved in all appropriate hospital committees, including the PTC (see 4.3.1 and 4.3.2 of the GPP Regulations). The rules also provide guidelines for the purpose and functioning of these committees. The National Policy for the Establishment and Functioning of PTCs in South Africa was subsequently developed in 2015 to establish the standards for a PTC at all levels of care.

This guideline provides the tools and practical guidance for the implementation of the policy.

1.1. Abbreviations

ADR	Adverse Drug Reaction
AMD	Affordable Medicines Directorate
AMS	Antimicrobial Stewardship
AMR	Antimicrobial Resistance
ATC	Anatomical Therapeutic Chemical
CEO	Chief Executive Officer
DDD	Defined Daily Dose
DDD/TID	Defined Daily Dose per 1000 patient population per day
EDP	Essential Drugs Programme
EML	Essential Medicines List
GPP	Good Pharmacy Practice
HOPS	Head of Pharmaceutical Services
ICD10 Code	International Statistical Classification of Diseases and Related Health Problems (10th Revision) Code
IPC	Infection Prevention and Control
KPI	Key Performance Indicator
MHPL	Master Health Product List
MMDS	Medicine Master Data System
MUE	Medicine Use Evaluation
NDP	National Drug Policy
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee
PHC	Primary Health Care
PTC	Pharmaceutical and Therapeutics Committee
PPTC	Provincial Pharmaceutical and Therapeutics Committee
PRC	Peer Review Committee
RACI	Responsible, Accountable, Consulted, Informed
RMU	Rational Medicine Use
SOP	Standard Operating Procedure
STGs	Standard Treatment Guidelines
TLART	Third Line Antiretroviral Therapy
TORs	Terms of Reference
VEN	Vital, Essential, Necessary

1.2. Definitions

ABC Analysis - The ABC analysis is an inventory categorisation method, used to monitor costs and the rational use of medicines. Items are divided into 3 categories (A, B and C) based on value of usage over a period of time.
The ABC analysis uses the following value classification (using percentage of cumulative value):

- Group A items - 80% of expenditure and an estimated 20% of total items.
- Group B items - 15% of expenditure and an estimated 30% of total items.
- Group C items - 5% of expenditure and an estimated 50% of total items.

Affordable Medicines Directorate (AMD): Directorate within the National Department of Health (NDoH) which is responsible for developing systems to ensure access to essential pharmaceutical commodities through the selection of essential medicines, development of Standard Treatment Guidelines (STGs), awarding and management of pharmaceutical tenders and licensing of persons and premises that deliver pharmaceutical services. The Directorate is also responsible for providing provinces with strategic leadership, a supportive legislative and policy framework and ongoing oversight and monitoring of access to medicines.

Anatomical Therapeutic Chemical (ATC) Code: A code based on the ATC classification system, which divides medicines into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties.[1] The ATC code is designated by the World Health Organization and thus standardised globally.

Defined Daily Dose (DDD): The assumed average maintenance dose per day for a drug (medicine) used for its main indication for treatment in adults. The DDD is assigned per route of administration within an ATC code and is normally based on monotherapy. The DDD provides a fixed unit of measurement of an active ingredient, independent of price and dosage form, enabling monitoring of consumption.[2]

Essential Medicine - A medicine that satisfies the priority health care needs of the population and is selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness.[3] The EML status of a medicine is independent of its pack size but is dependent on its dosage form and indication.

---

[1] World Health Organization. ATC Structure and Principles. (https://www.whocc.no/atc/structure_and_principles/ - accessed 27/10/2017)

[2] World Health Organization Collaborating Centre for Drug Statistics Methodology. DDD Definition and General Considerations. (https://www.whocc.no/ddd/definition_and_general_considera/ - accessed 27/10/2017)

[3] World Health Organization. Essential Medicines and Health Products. (http://www.who.int/medicines/services/essmedicines_def/en/ - accessed 05/02/2017)

Essential Medicines List (EML): The list of medicines determined by the National Essential Medicines List Committee (NEMLC) appointed by the Minister of Health and maintained by the Essential Drugs Programme (EDP) of AMD. The national EML is deemed to satisfy the priority health care needs of the population.

EML Status: The designation of a medicine based on whether or not it is included on the Essential Medicines List (EML or non-EML). These may be further sub-categorised according to NEMLC review status as follows:

- EML medicines may be sub-categorised as:
  - Approved; and
  - Subject to restrictions.

- Non-EML medicines may be sub-categorised as:
  - Not approved
  - For review
  - Not reviewed
  - Under review
  - Not approved – price indicator
  - Other

Formulary: A continually updated list of medicines and related information, used in the diagnosis, prophylaxis, or treatment of disease and promotion of health, to satisfy the needs of the majority of the population served by a particular health establishment/s.

Health Establishment: The whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services[4].

ICD10 Code: The unique identifier based on the International Statistical Classification of Diseases and Related Health Problems (10th Revision) which constitutes a standard diagnostic tool for epidemiology, health management and clinical purposes.[5]

Individual Patient Access: Refers to medicines that may be accessed by clinicians for a specific patient following approval of an application to a PTC where:

[4] Republic of South Africa. 2003. *National Health Act (Act No, 61 of 2003).* Pretoria, South Africa.

[5] World Health Organization. Classifications – International Standard. (http://www.who.int/classifications/icd/en/ - accessed 27.10.2017)

- a medicine needed is not on the formulary of the health establishment where the patient is receiving health care services;
- a patient is referred from another health establishment and requires medicines which are not on the formulary of the receiving health establishment; or
- a medicine needed is on the formulary of the health establishment but requires more control for various reasons e.g. cost or possible irrational medicine use and is designated for individual patient use only.

Level of Care: Categorisation of health establishments according to the type of health care services provided, and aligned with the regulations relating to hospitals published in terms of Section 35 of the National Health Act, 2003 (Act No, 61 of 2003):

- Primary level – Primary Health Care (PHC) clinics and community health centres;
- Secondary level – district and regional hospitals; and
- Tertiary/Quaternary level – tertiary and central hospitals.

*Specialised Hospitals may be categorised as secondary or tertiary/quaternary level.

Master Health Product List (MHPL): A master list of all products that can be procured in the public sector in accordance with a transversal or provincial contract, or on a quotation basis.

Medicine Master Data: The common data that forms the basis for all transactions relating to medicine selection, contracting, supply chain, contract management and use of medicine which helps to ensure that transactions take place in accordance with the requisite rules, governance and protocols and enables interoperability.

Medicine Master Data System (MMDS): The system used to manage all medicine master data.

Medicine Review: A structured, critical appraisal of evidence relating to use of a medicine, based on academic peer-reviewed evidence to determine quality, safety, efficacy and affordability of such medicine, and used to inform policy and decision-making in the selection of medicine.

National Essential Medicines List Committee (NEMLC): The non-statutory, advisory committee appointed by the Minister of Health, responsible for the development and management of the national STGs and EML. The STGs and EML guide clinical practice at all public sector health establishments and inform procurement of medicines in the public sector.

Prescriber Level: The minimum category of prescriber who may prescribe a medicine based on the registration of the prescriber in terms of legislation governing health care professionals, the associated scope of practice, qualifications held, or courses completed and the level of care at which the prescriber

is practising. In addition, some legislation allows for the issuing of permits to enable specific health professionals to examine patients, diagnose, prescribe, dispense or issue medicines.

Prescriber Privilege: The authority provided by a PTC to a specific prescriber or group of prescribers to prescribe a medicine that falls outside the standard applicable prescriber level, but subject to the applicable legislation.

Rational Medicine Use (RMU) - The practice whereby patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period, and at the lowest cost to them and their community.[6]

Standard Treatment Guidelines (STGs): The implementation mechanism of the EML which provides guidance to health care professionals on the use of medicines which appear on the EML and consists of a collection of chapters containing disorder groups, background information on the disorder, treatment regimens, as well as other relevant information.

Therapeutic Class: A group of medicines which have active ingredients with comparable therapeutic effects for a particular indication. Medicines in a therapeutic class may or may not belong to the same pharmacological class, may differ in chemistry or pharmacokinetic properties, and may possess different mechanisms of action, result in different adverse reactions, and have different toxicity, and drug interaction profiles. In most cases, these medicines have close similarity in efficacy and safety profiles, when administered in equipotent doses for a specific indication[7].

VEN Status - The status assigned to a medicine after categorisation of medicines into vital, essential, and necessary, using an analysis and grouping based on its health impact, which enables comparison of medicines of differing efficacy and usefulness. VEN analysis allows medicines of differing efficacy and usefulness to be compared.

- Vital (V): potentially life-saving or crucial to providing basic health services and need to be administered within 24 hours, where no alternative is available. These have significant withdrawal side effects and are of major public health importance. These are medicines that, if not available, will result in a serious medical consequence and/ or serious withdrawal symptoms. They may be medicines to which compliance or adherence is essential.

[6] World Health Organization. The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences. (http://www.who.int/medicines/areas/rational_use/en/ - accessed 05/02/2017).

[7]Gray T, Bertch K, Galt K, Gonyeau M, Karpiuk E, Oyen L, Sudekum MJ, Vermeulen LC; American College of Clinical Pharmacy. Guidelines for therapeutic interchange-2004. Pharmacotherapy. 2005 Nov; 25(11):1666-80.

- Essential (E): effective against less severe but significant forms of disease, but not absolutely vital to providing basic health care. They are medicines that are essential in providing basic health care.
- Necessary (N): used for minor or self-limited illnesses and have questionably efficacy. They are the least important items stocked and may have high cost against marginal therapeutic benefit.

1.3. Purpose of the Guideline

The purpose of this guideline is to provide policy guidance and corresponding tools for use by PTCs. The guideline aims to assist in promoting an outcomes-based approach for good governance and rational selection and medicine use in the functioning of these bodies. It is aimed at standardising functions, roles, and objectives for all PTCs at different levels based on generic Terms of Reference (TORs).

1.4. Scope of the Guideline

The guideline provides principles, standardised procedures and tools, and includes the following areas of functionality:

- Governance, organisational structure and decision-making;
- Formulary management, policies and procedures;
- Rational Medicine Use (RMU) analysis and interventions;
- Stakeholder communication, financial and human resource management; and
- Monitoring and evaluation, including standards and indicators.

1.5. Legislative and Policy Provisions

1.5.1. Constitution of the Republic of South Africa (Act 108 of 1996)[8]

Section 27 of the South African constitution provides "access to health care services" as a basic human right for citizens. As such, all reasonable measures must be taken to ensure that this right is protected, promoted and fulfilled within the limits of available resources.

1.5.2. National Health Act (Act 61 of 2003)[9]

The National Health Act states the requirements 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 address questions of health policy and delivery of quality health care services".

1.5.3. Pharmacy Act (Act 53 of 1974, as amended)[10]

The rules relating to GPP published in terms of the Pharmacy Act 53 of 1974 specify the minimum standards for the selection of pharmaceuticals by institutional pharmacies. In terms of Section 2.4.1:
(a) A Pharmacy and Therapeutics Committee (PTC) must be in place for the selection of pharmaceuticals and the promotion of rational drug use.
(b) A pharmaceutical code list and/or formulary and/or the Essential Drug List must be used as the basis for medicine therapy and the promotion of the rational use of medicine. This system includes a formulary of approved pharmaceutical substances as well as a policy and procedures for the approval and provision of medicine not included in the formulary as required.
(c) The Pharmacy and Therapeutics Committee must be responsible for the formulary.

The GPP Regulations published in terms of Section 35A of the Pharmacy Act, 1974, and which are legally binding, require pharmacists in institutional (hospital) pharmacies to be involved in all appropriate hospital committees, including the PTC (in terms of Section 4.3.2).
In terms of Section of the GPP Regulations, 2.4.1 SELECTION OF PHARMACEUTICALS[11]:
(a) A Pharmacy and Therapeutics Committee (PTC) must be in place for the selection of pharmaceuticals and the promotion of rational drug use.

---

[8] Republic of South Africa. 1996. *Constitution of the Republic of South Africa, Act 108 of 1996.* Pretoria, South Africa.

[9] Republic of South Africa. 2003. *National Health Act (Act No. 61 of 2003).* Pretoria, South Africa.

[10] Republic of South Africa. 1974. *Pharmacy Act (Act No. 53 of 1974).* Pretoria, South Africa.

[11] South African Pharmacy Council. 2010. *Good Pharmacy Practice in South Africa, Fourth Edition.* Pretoria, South Africa.

(b) A pharmaceutical code list and/or formulary and/or the Essential Drug List must be used as the basis for medicine therapy and the promotion of the rational use of medicine. This system includes a formulary of approved pharmaceutical substances as well as a policy and procedures for the approval and provision of medicine not included in the formulary as required.
(c) The Pharmacy and Therapeutics Committee must be responsible for the formulary.
(d) Pharmaceutical usage review programmes must be developed to ensure maximum patient benefit on the most cost-effective basis.

1.5.4. The Medicines and Related Substances Act (Act 101 of 1965)[12]

This Act provides the legislative provision for the regulation of medicines to ensure safety, efficacy and quality.

1.5.5. The Public Finance Management Act (Act 1 of 1999)[13]

This Act is established to "regulate financial management in the national government and provincial governments; to ensure that all revenue, expenditure, assets and liabilities of those governments are managed efficiently and effectively; to provide for the responsibilities of persons entrusted with financial management in those governments; and to provide for matters connected therewith."

1.5.6. National Drug Policy of South Africa, 1996[14]

The NDP requires hospital PTCs to be established and strengthened in "all hospitals in South Africa (both public and private sector) in order to ensure the rational, efficient and cost-effective supply and use of drugs." (Minister of Health. 1996. National Drug Policy for South Africa, section 7.5.). "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".

1.5.7. National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, 2015[15]

The National Policy provides "standards for the establishment of a non-statutory, multidisciplinary, advisory committee, to be called PTCs in all provinces, districts and institutions in South Africa."

---

[12] Republic of South Africa. 1965. *Medicines and Related Substances Act (Act No. 101 of 1965).* Pretoria, South Africa.

[13] Republic of South Africa. 1999. *Public Finance Management Act (Act No. 1 of 1999).* Pretoria, South Africa.

[14] Minister of Health. 1996. *National Drug Policy.* Pretoria, South Africa.

[15] South African National Department of Health. 2015. *National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.* Pretoria, South Africa.

Section 10 of the National Policy for the Establishment and Functioning of PTCs in South Africa specifies the scope of the PTC. In terms of Section 10:

- *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 selection and use activities.*
- *PTCs should strive for excellence in carrying out their duties and support rational use activities for continuous improvement of the health care system. PTC shall act at all times in the best 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 medicines, accountability, participation, rule of law and responsiveness.*

Section 12 of the National Policy for the Establishment and Functioning of PTCs in South Africa specifies the functions of the PTC. In terms of Section 12, the core PTC functions include:

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.*

1.5.8. National Core Standards for Health Establishments in South Africa, 2011[16]

Within the National Core Standards, the Minister of Health identified six priority areas for fast-track improvement: staff values and attitudes, waiting times, cleanliness, patient safety, Infection Prevention and Control (IPC), and availability of medicines and supplies. The NDoH has further identified three fast-

[16] National Department of Health. 2011. *National Core Standards for Health Establishments in South Africa, Domain 3: Clinical Support Services*. Pretoria, South Africa.

track priorities that relate to pharmaceutical services with the expectation that managers oversee compliance for these critical areas. They are:

- *Patient safety and security;*
- *IPC; and*
- *Availability of basic medicines and supplies.*

1.5.9. Affordable Medicines Directorate Policy for the Management of Master Data Relating to Medicine (2019) *In Draft Format*

The AMD Policy for the Management of Master Data Relating to Medicine defines "*the concept of medicine master data in the context of the public sector, and provide guidance in the development, management and use of such master data by stakeholders and systems*."
It describes the contents of the MMDS, including the "*Formulary Management Tool, which enables development, management and use of formularies for all provinces, districts, sub-districts (as applicable) and health establishments. This will allow clean data to inform what medicines should be stocked at a health establishment and data as to the denominator for monitoring and reporting*" by PTCs.

1.5.10. National Guideline for the Development, Management and Use of Formularies (2019) *In Draft Format*

The National Guideline for the Development, Management and Use of Formularies defines "*the concept of a formulary in the context of the provision of health care services in health establishments in the public sector and those in the private sector providing services on behalf of the public sector, and provide(s) guidance in the development, management and use of such formularies at all levels of care. It aims to emphasise the importance of formularies as the basis for the procurement and management of medicine in health establishments to support medicine availability and rational use thereof."*

The Guideline also establishes the hierarchy of formulary development and management based on level of care by mandated PTCs, derived from the national Master Health Product List (MHPL).

2. Categorisation and Purpose of Pharmaceutical and Therapeutics Committees

Pharmaceutical and Therapeutics Committees (PTCs) promote "the rational use of medication through the development of relevant policies and procedures for medication selection, procurement, distribution and use and through the education of patients and staff"[17].

They act as feedback mechanisms between National, Provincial and District Departments of Health, as well as facilities, and are important to strengthen RMU. The PTC is essential for 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"[18].

PTCs should exist at provincial, district, sub-district (where applicable) and health establishment (Regional, Tertiary, Central and District Hospital) level. Decision-making takes place according to a hierarchical structure, as well as across levels of care, as shown in the diagram below. Decisions are made according to the direction of the arrows in the figure.

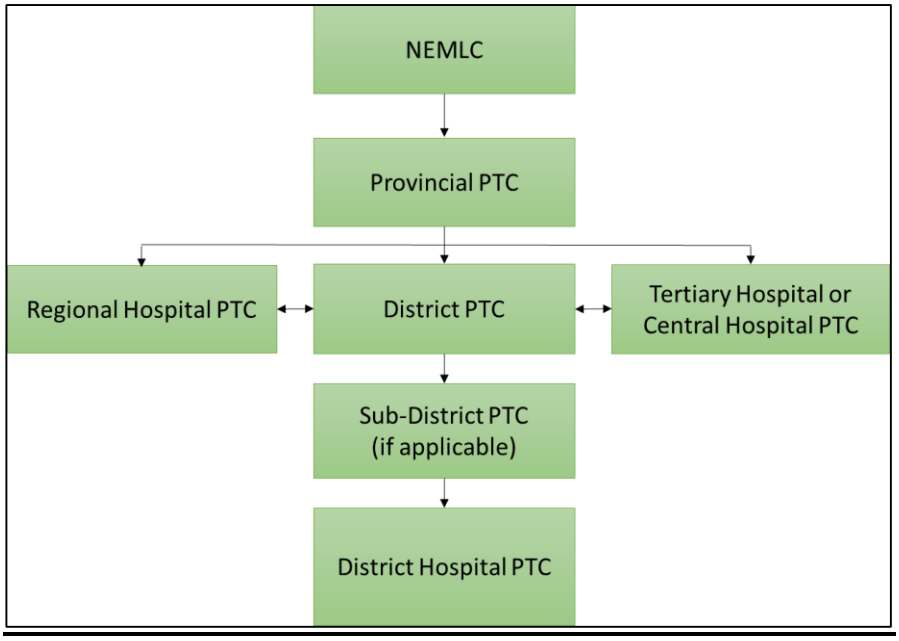

Figure 1: Hierarchy of PTC Decision-Making

[17] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

[18] South African National Department of Health. 2015. *National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.* Pretoria, South Africa.

3. Governance

Governance involves the management of PTCs at the highest level requiring appropriate systems, policies and norms. In order to ensure efficiency in communication and decision-making, meetings should be held according to a defined process, with standing agenda points and attendees. PTC recruitment, selection, appointment and other processes involved in the committee constitution should be clear and transparent, ensuring fairness and equality. PTCs should have clear TORs and policy documents for managing conflicts of interest and confidentiality of members.

3.1. Organisation and Structure

3.1.1. Recruitment of PTC Members

PTC members should be actively recruited with the appropriate skills and to fulfil the range of expertise required in the PTC's TOR. A standard call for applications should be sent to all relevant stakeholders, as per Appendix 1, with an example of a standardised Curriculum Vitae template provided, as per Appendix 2. Applicants are able to apply for membership at the relevant Provincial PTCs, while PTCs for District and Institutional PTCs are nominated, such as by the District Manager or Chief Executive Officer (CEO), Chairperson or member of an existing PTC.

3.1.2. Selection of PTC Members

Members should be shortlisted and recommended to the executive authority which is responsible for the governance of the PTC for appointment, according to the TORs of the PTC, i.e. the CEO for Institutional PTCs, Chief Director: District Health for District PTCs and Provincial Head of Health for Provincial PTCs. An example of a letter of recommendation to the executive authority is included in Appendix 3. The District Chief Director of each district, or other relevant person, within a province should nominate one clinician and one pharmacist from each District PTC to be appointed on the Provincial PTC, taking into consideration the expertise requirements of Provincial PTCs.

3.1.3. Appointment of PTC Members

Once a decision has been made to appoint a PTC member, a standard appointment letter template should be used to communicate to the prospective member, such as that included in Appendix 4. For a hospital PTC, the PTC member is usually appointed by the CEO of the hospital. In a district, this function is usually performed by the Chief Director: District Health. For a Provincial PTC, a PTC member is appointed by the Provincial Head of Health. The prospective member should provide written acceptance or rejection of such appointment, such as with the template provided in Appendix 5.

3.1.4. Resignation of PTC Member

PTC members have the right to resign at any stage within their term of office. This resignation should be in writing, such as using the template provided in Appendix 6. A template for acceptance of resignation has been provided in Appendix 7, with which the PTC Chairperson or designated official should respond to the resignation.

The membership of a PTC member may be terminated in accordance with the TORs of the PTC, if necessary. A written letter of termination of membership, such as that included in Appendix 8, should be sent to the PTC member.

3.2. Governance Principles and Tools

3.2.1. Terms of Reference for Provincial, District and Institutional PTCs

PTCs should be governed by TORs which, among others, should outline the purpose, authority to act, functions and composition. TORs should be reviewed within a three-year cycle by the Directorate of Pharmaceutical Services and submitted to the accountable person. The accountable person is the Head of Health for Provincial PTCs, Chief Director: District Health for District PTCs and CEO for hospital PTCs. The functions of the PTC should be in line with expertise available and support existing processes.

A Provincial PTC TOR template has been included in Appendix 9, which may be adapted by other levels of PTCs as necessary. The differences in the TORs of different levels of PTCs are highlighted in the table below:

Table 1: Differences Between Provincial, District and Institutional PTCs

Topic	Provincial PTC	District PTC	Institutional PTC
Accountability	Appointed by and accountable to Provincial Head of Health	Appointed by and accountable to Chief Director: District Health (or other relevant person)	Appointed by and accountable to Hospital CEO
Functions – Formulary Management	Provincial Formulary Management Motivation to NEMLC for addition, deletion or amendment of medicine to EML – includes evidence-based medicine reviews	District Formulary Management Motivation to Provincial PTC for addition, deletion or amendment of medicine to Provincial formulary - brief review of efficacy of medicine but full medicine review not required	Institutional Formulary Management Motivation to Provincial PTC for addition, deletion or amendment of medicine to provincial formulary - brief review of efficacy of medicine but full medicine review not required
Functions – Tender Specifications	Estimates based on provincial need	Estimates based on district need	Estimates based on institutional need

Composition of Committee	Ex-officio Members: a) Chief Director: Pharmaceutical Services; b) Head of Pharmaceutical Services (HOPS); c) Manager of the Medical Supplies Depot; and d) NEMLC representative/s Member Expertise: a) Evidence-based medicine; b) Primary level health care services; c) Secondary level health care services; d) Tertiary level health care services; e) RMU; f) Medical supply management; g) Financial management; h) Antimicrobial Stewardship (AMS); i) Bioethics; and j) Medical Academia	Ex-officio Members a) Manager: PHC/ Core Health Services b) Manager: Clinical Support Services, Coordination and Quality Management c) HOPS or delegated official Member Expertise: a) Evidence-based medicine; b) Primary level health care services; c) Secondary level health care services; d) Tertiary level health care services; e) RMU; f) Medical supply management; g) Financial management; h) AMS; i) Bioethics; and j) Expanded Programme on Immunization.	Ex-officio Members a) Hospital CEO; b) Senior Physician; c) Head of Pharmacy Services; and d) Head of Nursing Member Expertise: a) Pharmacist; b) Clinician; c) AMS d) Medical supply management; and e) Financial Management.

3.2.2. Conflict of Interest Policy

Interests of all individuals who could influence the decisions or duties of the PTCs must be identified, declared, assessed and managed. This is intended to, as far as possible, prevent any advice or recommendation made by a committee being challenged on the basis of an actual or perceived conflict of interest of individuals involved. The personal interests of any member or other meeting participant shall not take precedence over the interests of public health.

PTCs should maintain a Conflict of Interest Policy to protect the integrity of the decision-making of the PTC, through the identification, declaration, assessment, management and disclosure of any interest/s of individuals which relate to the work of the PTC. The policy should provide for the management of actual and potential conflict of interest, and where appropriate, recusal or exclusion of individuals from involvement in discussions and/or decision-making.

The AMD Conflict of Interest Policy may be found at http://www.health.gov.za/index.php/national-essential-medicine-list-committee-nemlc/category/520-nemlc-governance-documents, which may serve as a template and be adapted for a PTC Conflict of Interest Policy. Interests must be declared on appointment to a PTC, annually and before each meeting.

3.2.3. Declaration of Confidentiality Guideline

The maintenance of confidentiality by members of PTCs and other meeting participants is key to ensuring that the personal and organisational risk is minimised. Therefore, PTCs should ensure that a Confidentiality Guideline, such as that included in Appendix 10, is maintained and provided to all members and meeting participants. Declaration of confidentiality forms should be signed on appointment to a committee by members and prior to every meeting by non-members

3.3. Decision Making

3.3.1. Different Types of Committee Members

The table below provides details for appointment, voting status and impact on quorum for different types of members:

Table 2: Different Types of Committee Members

Meeting Component	Member	Ex-Officio Member	Co-Opted Member
Appointment	Application or nomination (depending on PTC level)	Nominated due to current job title	Nominated due to expertise
Voting Status	Full voting rights	Full voting rights	No voting rights
Impact on Quorum	Affects quorum	Affects quorum	No impact on quorum
Attendance	Attends all PTC meetings	Attends all PTC meetings	Attends meetings where relevant expertise is required

3.3.2. Meetings

Provincial PTCs should meet quarterly at a minimum. Institutional and District PTCs should try to meet more often than quarterly, i.e. monthly if possible. The appointed members are expected to attend personally (no substitutions) and all apologies must be submitted in writing to the Secretariat. The member will be permitted to participate via teleconference or videoconference at the discretion of the Chairperson. All meeting procedures should take place in line with the TORs of the PTC.

To facilitate the efficiency of meetings, the PTC Secretariat shall:

1) Develop and maintain an annual schedule for the meetings of the Provincial PTC. Invitations to meetings in line with the schedule will be sent timeously before the meeting. Invitations should be sent in writing such as via email using the template provided in Appendix 11. Members are expected to indicate their attendance in writing, such as by using Appendix 12. Apologies for the meetings from members need to be sent to the Secretariat in writing with a reason for non-attendance.

2) Convene and make all the necessary logistical arrangements for the meetings

3) Compile draft minutes of the meeting in consultation with the Chairperson and circulate within 30 working days after the meeting. A minute's template has been included in Appendix 13. The Chairperson will facilitate the discussion around the accuracy on the minutes at the next PTC meeting. Any recommended changes will be discussed at this point. The Chairperson will then ask for a proposer and a seconder for adoption of the minutes, who will both sign the minutes together with the Chairperson.

4) Draft an agenda in consultation with the committee Chairperson. An agenda template has been included in Appendix 14.

A quorum shall be deemed to be one member more than 50 per cent of members. A quorum of members should be present before the meeting can proceed. Other meeting participants who are not appointed members but have been co-opted due to a particular expertise required for a short period of time, are excluded from the calculation and do not form part of the quorum.

Operational plans, such as by using the template in Appendix 15 should be developed and tracked by PTCs in the meetings.

Attendance may be tracked following responses by invitees, using Appendix 16. Quorum may be calculated prior to the meeting using this tool.

4. Core Functions

Core functions include the main activities that the PTC is mandated to perform, in line with its TORs. This includes formulary development and management, the implementation of national policies and procedures, RMU analysis and interventions, as well as procurement. The functions of the PTC should be in line with expertise available.

4.1. Rational Medicine Use

4.1.1. The Rational Medicine Use Cycle

RMU is the practice whereby patients receive medicines 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.[19] RMU should follow a cyclical path from examination (measuring existing practices and awareness of the STGs and EML), diagnosis (identifying RMU problems and causes), treatment (designing and implementing interventions to change behaviour) follow-up (measuring changes and outcomes). This cycle is depicted in the figure below.

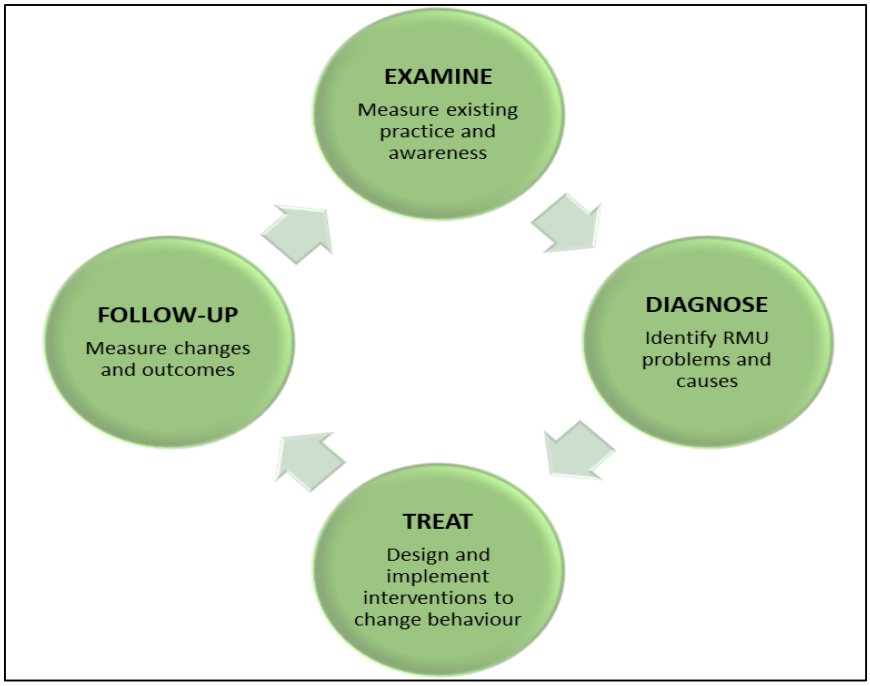

Figure 2: The Rational Medicine Use Cycle[20]

[19] World Health Organization. The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences. (http://www.who.int/medicines/areas/rational_use/en/ - accessed 05/02/2017).

[20] Adapted from: World Health Organization. 2003. *Drug and Therapeutics Committees: A Practical Guide*. Geneva, Switzerland.

Suboptimal medicine use results in inefficiencies, significant opportunity costs and poor health outcomes e.g. Antimicrobial Resistance (AMR) and an increased risk of Adverse Drug Reactions (ADRs). In the medium to long-term, the irrational use of medicines results in wasted resources and has a direct negative impact on sustained availability of medicines. In the short term, inappropriate prescribing including misuse and polypharmacy, has a direct impact on the availability of the right medicines for patients.

To support improved RMU, information approximating consumption and where available, patient level data, should be collected and analysed to review the distribution of consumption relative to treatment guidelines and expected demand volumes. Pharmaco-epidemiological approaches should be implemented to generate actionable insights about medicine effects in target population groups, informing planning for future health needs. Interventions should be designed and implemented by PTCs to support positive prescriber, health provider, patient behaviour and safety.

4.1.2. Sources of RMU Data

Sources of RMU data include the following:

- Procurement data e.g. Warehouse Management System from the depot or any applicable Stock Management System
- Supplier-provided data
- Demographic data e.g. Stats SA (www.statssa.gov.za), District Health Information System population estimates
- Health service utilisation and indicator data e.g. National Health Laboratory Service data
- Stock-outs e.g. National Surveillance Centre Dashboards
- Dispensing data e.g. electronic dispensing systems, manual dispensing records
- Prescribing data e.g. chronic medicine dispensing, manual prescription records
- Donation data, especially when medication is donated for a certain programme e.g. fluconazole for cryptococcal meningitis
- Commercial data sources e.g. IQVIA data which represents the private sector use as well
- Information directly from the patient as to what medication was consumed or gathered prospectively or retrospectively from medical and pharmacy records as part of a medicines use review.

These data sources will be used to not only monitor the use of medicine, but to map current health needs, as well as to conduct statistical, predictive forecasting to describe expected future health needs. Where there are information gaps, these should be highlighted in order to guide future surveillance, and research. In order to complete the medicine value chain, Health Needs Assessments using this data should be performed to influence medicine selection in the development of formularies.

4.1.3. Identifying medicine use problems – Aggregate Data

4.1.3.1. Anatomical Therapeutic Chemical Classification (ATC)

The Anatomical Therapeutic Chemical (ATC) classification is a code related to the ATC classification system, which divides the medicines into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties.[21] ATC codes, guidelines for assignment and other reference data may be found at www.whocc.no.

There are 14 main anatomical/pharmacological groups, which are provided below:

A: Alimentary tract and metabolism;
B: Blood and blood forming organs;
C: Cardiovascular system;
D: Dermatologicals;
G: Genito-urinary system and sex hormones;
H: System hormonal preparations, excluding sex hormones;
J: Antiinfectives for systemic use;
L: Antineoplastic and immunomodulating agents;
M: Musculo-skeletal system;
N: Nervous system;
P: Antiparasitic products, insecticides and repellents;
R: Respiratory system;
S: Sensory organs; and
V: Various.

Active substances are classified in a hierarchy with five different levels. An example is provided below in Table 3:

Table 3: ATC Hierarchy

A	Alimentary tract and metabolism (1st level, anatomical main group)
A10	Drugs used in diabetes (2nd level, therapeutic subgroup)
A10B	Blood glucose lowering drugs, excl. insulins (3rd level, pharmacological subgroup
A10BA	Biguanides (4th level, chemical subgroup)
A10BA02	Metformin (5th level, chemical substance)

[21] World Health Organization Collaborating Centre for Drug Statistics Methodology. ATC Structure and Principles. (https://www.whocc.no/atc/structure_and_principles/ - accessed 27/10/2017)

4.1.3.2. Defined Daily Dose

The Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is assigned per route of administration within an ATC code and is normally based on monotherapy. The DDD provides a fixed unit of measurement independent of price and dosage form, enabling monitoring of consumption.[22]

Usage

DDD allows medicine use to be measured in a simplified manner and for comparisons to be made both locally and internationally. This system allows standardised comparison between usage of products with different dosing regimens. Different populations may be used for comparison, therefore the DDD per 1000 patient population per day (DDD/TID) should be divided by the population number to determine DDD per 1000 patient days per person to ensure standardised comparison.

How to Perform a DDD Analysis?

The example below presents a step-wise approach on how to calculate the DDD:

***EXAMPLE*: Paracetamol use in Hospital X**

- Solid dosage form: 500mg tablet; 10 tablets per pack
  - 5 packs were issued for a specified time period
- Liquid dosage form: 120mg/5ml; 100ml bottle
  - 30 packs were issued for a specified time period
- Injection dosage form: 10mg/ml; 100ml vial
  - 20 packs were issued for a specified time period
- The DDD for paracetamol is 3 grams[23] (3000 mg) for all dosage forms
- Bed occupancy for Hospital X was 40. Specified time period under review was 28 days.

Step 1: Calculate DDD per pack

	SOLID DOSAGE FORM	LIQUID DOSAGE FORM	INJECTION DOSAGE FORM
Calculation	= (Strength value*pack size) / DDD value (in mg)	Note: the strength value is *x* mg per *y* ml, therefore the strength (*x*)	Note: the strength value is *x* mg per *y* ml, therefore the strength (*x*)

[22] World Health Organization Collaborating Centre for Drug Statistics Methodology. DDD Definition and General Considerations. (https://www.whocc.no/ddd/definition_and_general_considera/ - accessed 27/10/2017)

[23] World Health Organization Collaborating Centre for Drug Statistics Methodology. ATC Structure and Principles. (https://www.whocc.no/atc/structure_and_principles/ - accessed 8/11/2019)

		needs to be divided by the volume (*y*) = ((Strength value*pack size(ml))/y)/DDD Value (mg)	needs to be divided by the volume (*y*) = ((Strength value*pack size(ml))/y)/DDD Value (mg)
Example	DDD per pack = $\frac{500mg*10tablets}{3000mg}$ = 1.67 per pack	120mg/5ml: thus strength = $\frac{120mg}{5ml}$ = 24mg/ml DDD per pack = $\frac{24mg/ml*100ml}{3000mg}$ = 0.8 per bottle	10mg/ml: thus strength = $\frac{10mg}{1ml}$= 10mg/ml DDD per pack = $\frac{10mg/ml*100ml}{3000mg}$ = 0.33 per vial

Step 2: Calculate the DDDs issued:

	SOLID DOSAGE FORM	LIQUID DOSAGE FORM	INJECTION DOSAGE FORM
Calculation	DDD issued = DDD per pack * Quantity issued	DDD issued = DDD per pack * Quantity issued	DDD issued = DDD per pack * Quantity issued
Example	Note: Use DDD per pack from step 1 DDD issued = 1.67*5 packs = 8.35	Note: Use DDD per pack from step 1 DDD issued = 0.80*30 packs = 24	Note: Use DDD per pack from step 1 DDD issued =0.33*20 packs = 6.6

Step 3: Decide which level of care is needed (e.g. Provincial or health establishment level)

- Provincial level: DDD per 1000 population per day (DDD/TID) is recommended
  - The denominator in this instance would be the uninsured population (for public sector) for the relevant province. This is available from South African Health Review (available from www.hst.org.za).
- Hospital level: DDD per 100 patient days **or** bed days is recommended
  - The patient day **or** bed day should be defined and used consistently (e.g. patient bed occupancy calculated from the 'midnight census').
- Patient day or bed day information:
  - Bed occupancy data can be extracted from the District Health Information System.

3.1. Health establishment level: Calculate DDD per 100 patient days or bed days:

	SOLID DOSAGE FORM	LIQUID DOSAGE FORM	INJECTION DOSAGE FORM
Calculation	DDD per 100 bed days = (DDD issued/Patient days (for period under analysis)) *100	DDD per 100 bed days = (DDD issued/Patient days (for period under analysis)) *100	DDD per 100 bed days = (DDD issued/Patient days (for period under analysis)) *100
Example	Note: Use DDD issued from step 2 DDD per 100 bed days = (8.35/40) *100 = 20.88 ***Round off to 21***	Note: Use DDD issued from step 2 DDD per 100 bed days = (24/40) *100 = 60	Note: Use DDD issued from step 2 DDD per 100 bed days = (6.6/40) *100 = 16.5 ***Round off to 17***
What this means:	This provides an estimate of the therapeutic intensity. This can be interpreted as follows:		
	21% of in-patients received 1 DDD of oral paracetamol (in the form of a tablet) every day.	60% of in- patients received 1 DDD of oral paracetamol (in the form of a syrup) every day. *NOTE*: DDD is an indication of use in adults, so this must be taken into consideration when reviewing paediatric formulations.	17% of in- patients received 1 DDD of oral paracetamol (in the form of an injection) every day.

3.2. Provincial level: Calculate the DDD per 1000 population per day (DDD/TID)

	SOLID DOSAGE FORM
Example: Province Y used 10 000 packs of enalapril 5mg tablets (28 tablets/pack). According to the South African Health Review, Province Y had an uninsured population of 258 000 people during this time period. The time period measured was 28 days. The DDD for enalapril is 10mg.	

4.1.3.3. ABC Analysis

The ABC analysis is an inventory categorisation method, used to monitor costs and the rational use of medicines. Items are divided into 3 categories (A, B and C) based on value of usage over a period of time. Items in the A category have the highest cost for relatively few items (the Pareto

principle states that 80% of overall consumption value accounts for 20% of all items). In contrast, C items are those with the lowest consumption value and the most items. Category B items are the interclass items. These 3 categories are not static and are specific to usage patterns in the analysis being performed.

ABC analysis informs medicines prioritisation at National Level, formulary decisions at provincial and district level, as well as contracting. For example, non-EML items used in large volumes may be put on contract by the NDoH to ensure cost-effectiveness. Provincial ABC analysis should be conducted annually and reported to the NDoH to inform Health Needs Assessment at both national and provincial level.
The NDoH ABC online tool uses the following value classification (using percentage of cumulative value):

- Group A items - 80% of expenditure and an estimated 20% of total items;
- Group B items - 15% of expenditure and an estimated 30% of total items; and
- Group C items - 5% of expenditure and an estimated 50% of total items.

Usage

Class A medicines may be highlighted as important for review, due to cost implications and possible cheaper alternatives. They have the highest potential for savings and may also help to prioritise resources for forecasting, procurement and stock control due to the high value and corresponding implications for shortage, overstocking or expiry.

How to Perform an ABC Analysis?

The ABC analysis can be applied to procurement data or to consumption data. Procurement data could be retrieved from the depot or pharmacy stores to determine where money was spent and what the top cost drivers are. Consumption data could be retrieved from a dispensing system to determine which medicines where used in larger quantities by patients.

1. List all medicines purchased over a defined period;
2. List unit cost per medicine;
3. List quantity of each medicine purchased;
4. Calculate the total rand value of each medicine;
5. Calculate total rand value for all medicines combined;
6. Calculate percentage of total rand value for each medicine;
7. Arrange the medicines in descending order according to percentage of total value;
8. Calculate cumulative percentage of total rand value for each medicine;
9. Categorise into Group A, B and C
   (A = 80% of cumulative expenditure, B = 15% of cumulative expenditure, C = 5% of cumulative expenditure);
10. Plot cumulative percentage of total rand value against percentage of items; and
11. Monitor Class A medicines for possible cheaper alternatives, accuracy of forecasting, frequency of ordering, good stock management and rational use.

An example of an ABC analysis is presented below in Table 4:

Table 4: Example of ABC Analysis of 10 Medicines

Description as per Contract	Price	Quantity Awarded	Value	Percentage (%) of total value	Cumulative % of total value	Category
Tenofovir, Emtricitabine & Efavirenz 300/200/600mg 28 Tablet	122.53	19400000	2377082000	66.32	66.32	
Vaccine Rotavirus, 1 Dose	105.26	3555587	374261088	10.44	76.76	A
Efavirenz 600mg 28 Tablet	48.55	7484800	363387040	10.14	86.90	
Beclomethasone Diproprionate 200mcg 200Dose Inhaler	61.19	2690080	164605995	4.59	91.49	
Enalapril 20mg 28 Tablet	7.43	9038094	67153038.4	1.87	93.36	B
Enalapril 10mg 28 Tablet	4.51	13664676	61627688.8	1.72	95.08	
Ampicillin 500mg/Vial 1 Vial	8.42	6837587	57572482.5	1.61	96.69	
Efavirenz 200mg 84 Capsule	58.58	960000	56236800	1.57	98.26	
Factor Vii 100000IU/vial 1 Unit	12347.4	4049	49994622.6	1.39	99.65	
Omeprazole 20mg 28 Tablet	9.54	1310255	12499832.7	0.35	100.00	C
Total	**12773.41**	**64945128**	**3584420588**	**100**		

Table 5: Example of Summary ABC Analysis of 1154 Medicines

Category	A	B	C	Total
Number of Items	159	491	504	1154
Percentage of all items	13.78	28.60	57.45	100
Value of Annual Consumption	27492017641	5176142260	1727160128	34395320029
Percentage of Annual Consumption	79.93	15.05	5.02	100

4.1.3.4. VEN Analysis

In a VEN analysis, medicines are divided, according to their health impact, into vital, essential, and necessary categories. It is used to set priorities for selection, procurement and use based on significance of a medicine in a population. Vital medicines are of importance to ensure accurate forecasting, medicine supply and inventory management. VEN analysis allows medicines of differing efficacy and usefulness to be compared and re-categorisation should take place frequently based on changing needs of a population. VEN may be used against an ABC analysis to compare actual usage with priorities

Vital (V): potentially life-saving or crucial to providing basic health services and need to be administered within 24 hours, where no alternative is available. These have significant withdrawal side effects and are of major public health importance. These are medicines that, if not available, will result in a serious medical consequence and/ or serious withdrawal symptoms. They may be medicines to which compliance or adherence is essential.

Essential (E): effective against less severe but significant forms of disease, but not absolutely vital to providing basic health care. They are medicines that are essential in providing basic health care, the quantity of which determines whether an alternative is available in sufficient quantity.

Necessary (N): used for minor or self-limited illnesses and have questionably efficacy. they are the least important items stocked and may have high cost for marginal therapeutic benefit.

Use of a VEN Analysis

Vital and essential medicines should be given priority with limited human and financial resources for selection, procurement and use. Forecasting of vital medicines should be as accurate as possible and orders should be more frequent, with good stock management, strategic interventions such as split tender and buffer stock to avoid stock shortages. Therapeutic duplications should be minimised for “N”

items.

How to Conduct a VEN Analysis?

1. List all medicines available;
2. Determine occurrence of the target condition each medicine is used to treat;
3. Determine severity of the target condition each medicine is used to treat;
4. Determine therapeutic effect of the medicine; and
5. Use Table 5 to classify each medicine as Vital (V), Essential (E) or Necessary (N).

The table below illustrates the World Health Organisation sample guideline for VEN categories[24]:

Table 6: Sample Guidelines for VEN Categories[10]

Characteristic of the drug and target condition	Vital	Essential	Necessary
Occurrence of target condition			
% of population affected	Over 5	1-5	Less than 1
Average number of patients treated per day in average health establishment	Over 5	1-5	Less than 1
Severity of target condition			
Life-threatening	Yes	Occasionally	Rarely
Disabling	Yes	Occasionally	Rarely
Therapeutic effect of drug			
Prevents serious disease	Yes	No	No
Cures serious disease	Yes	Yes	No
Treats minor, self-limited symptoms and conditions	No	Possibly	Yes
Has proven efficacy	Always	Usually	May or may not

Example of VEN Analysis

An example of the results of a VEN analysis of Tenofovir 300 mg tablets for HIV is provided in the table below:

[24] World Health Organization. Drug and Therapeutics Committees – a Practical Guide (http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf - accessed 02.05.2017)

Table 7: VEN Analysis for Tenofovir

Characteristic of the drug and target condition	Vital	Essential	Necessary
Occurrence of target condition			
% of population affected	Over 5	1-5	Less than 1
Average number of patients treated per day in average facility	Over 5	1-5	Less than 1
Severity of target condition			
Life-threatening	Yes	Occasionally	Rarely
Disabling	Yes	Occasionally	Rarely
Therapeutic effect of drug			
Prevents serious disease	Yes	No	No
Cures serious disease	Yes	Yes	No
Treats minor, self-limited symptoms and conditions	No	Possibly	Yes
Has proven efficacy	Always	Usually	May or may not

RESULT: VITAL

Application of ABC and VEN Analyses

A comparison of applications of the ABC and VEN analyses is provided in the following table:

Table 8: ABC and VEN Applications Comparison

	ABC Analysis	VEN Analysis
Selection	• Reviewing Class A medicines may uncover high-use for items with a lower-cost alternative is available • Assist in identifying expenditure on non-formulary items or non-EML medication	• Vital and essential medicines are given priority when funds are limited • Role of out of stocks when buying out items not on formulary • Greater focus on vital and essential EML items • Contract management – selection of suppliers
Procurement	• Determine order frequency • Monitoring order status, particularly of Class A items as unexpected shortage can lead to expensive emergency buy-outs • Monitoring procurement priorities	• Greater focus on vital and essential items • Supplier selection • Monitoring safety stock • Monitoring orders
Distribution	• Monitoring shelf-life for Class A items to minimise waste caused by expired medicines • Performing stock-take • Improving security or control of Class A items	• System to replenish vital and essential items are different from the necessary items
Use	• Perform MUEs on high usage items where overuse or underuse are expected • Prescriber preferences may be highlighted • Minimise losses by evaluating expiry dates	• Review usage • Stock control • Identify use of necessary items

Limitations of ABC and VEN Analyses

The ABC analysis primarily focuses on how much of an item was consumed and the monetary value attached to it. However, in a health establishment there are vital items which are life-saving medicines that may be found in either the 'B' or 'C' category and may be overlooked. These items may have a low impact on the budget or minimum consumption and still requires monitoring to prevent an out of stock situation. A limitation of a VEN analysis as a standalone tool is that it

assists with prioritising medicines according to usage, but it does not quantify the amount spent on each item. This therefore highlights the need to conduct an ABC/VEN matrix analysis to optimally evaluate expenditure and procurement practices to facilitate higher level decision making.

The ABC/VEN Matrix Tool

A combination of the ABC/VEN matrix can be beneficially employed to develop more meaningful control over the expenditure and procurement practices at institutions. The ABC/ VEN Matric Tool is provided in the table below:

Table 9: ABC/ VEN Matrix Tool

	V	E	N
A	AV	AE	AN
B	BV	BE	BN
C	CV	CE	CN

ABC Analysis	VEN Analysis	Category	Matrix	Definition
A and B	Vital (V)	Category 1a	AV,BV	This category contains vital medicines that are high to moderate with respect to number of items and/or related expenditure.
C	Vital (V)	Category 1b	CV	This category contains vital medicines that are low in expenditure. These items may most likely expire.
A	Necessary (N)	Category 2	AN	This category contains necessary medicines that are high with respect to number of items and related expenditure. These items may be evaluated for irrational medicine use.
A, B and C	Essential (E)	Category 3	AE, BE, CE	This category contains essential medicines that are high, moderate and low with respect to number of items and related expenditure.
B and C	Necessary (N)	Category 4	BN, CN	This category contains necessary medicines that are moderate to low with respect to number of items and related expenditure.

The benefits of the matrix are that it may:

- Identify expenditure on necessary medicines and to promote discussion with relevant PTCs. This is especially relevant for the AN category;
- Flag medicines that are inappropriately used;

- Flag medicines that are most likely to expire (For example category CV); and
- Prioritising focus on vital medicines and potentially minimise stock-out risks.

4.1.4. Identifying medicine use problems – Individual level studies

4.1.4.1. Indicator Studies

Indicator studies involve collection of data pertaining to defined criteria to identify medicine use. This data may show areas of improvement needed but is limited to patient-level analysis and not a wider aggregate data. Indicator studies provide a standardised simple method to data reporting.

The indicators provide information on medicine use, prescribing habits and patient care. Indicator studies may be used to:

1. Identify problems with RMU and treatment practices;
2. Indicate performance over time;
3. Provide motivation and show progress; and
4. Show impact of an intervention.

World Health Organization Indicators for Primary Health Care Facilities[25]

Prescribing indicators:

1. Average number of medicines per encounter;
2. Percentage of medicines prescribed by generic name;
3. Percentage of encounters with an antibiotic prescribed;
4. Percentage of encounters with an injection prescribed; and
5. Percentage of medicines prescribed from EML or formulary.

Patient care indicators:

1. Average consultation time;
2. Average dispensing time;
3. Percentage of medicines actually dispensed;
4. Percentage of medicines adequately labelled; and
5. Patients' knowledge of correct doses.

Health establishment indicators:

1. Availability of essential medicines list or formulary to practitioners;
2. Availability of STGs; and
3. Availability of key medicines.

[25] World Health Organization. 1993. How to Investigate Drug Use in Health Facilities: Selected Drug Use Indicators (WHO/DAP/93.1).

Complementary medicine use indicators:

1. Percentage of patients treated without medicines;
2. Average medicine cost per encounter;
3. Percentage of medicine cost spent on antibiotics;
4. Percentage of medicine cost spent on injections;
5. Percentage of prescriptions in accordance with treatment guidelines;
6. Percentage of patients satisfied with the care they receive; and
7. Percentage of health facilities with access to impartial medicine information.

Correct sample size and sampling technique for different intended analyses is key.

Example

On analysis of a health establishment, a designated PTC member assessed prescriptions generated over a period of one month according to the "Prescribing Indicators" listed above. She found the following results:

1. Average number of medicines per encounter = 3;
2. Percentage of medicines prescribed by generic name = 20%;
3. Percentage of encounters with an antibiotic prescribed = 5%;
4. Percentage of encounters with an injection prescribed = 2%; and
5. Percentage of medicines prescribed from EML or formulary = 20%.

Results 2 and 5 alarmed the PTC member, stimulating an educational intervention where the member trained the nurses and doctors within the health establishment about the importance of adherence to the health establishment's formulary, as well as the need to prescribe according to generic name.

After the intervention, the PTC member analysed prescriptions generated over the next 3 months to establish effectiveness of the intervention.

The following results were found:

1. Average number of medicines per encounter = 3;
2. Percentage of medicines prescribed by generic name = 100%;
3. Percentage of encounters with an antibiotic prescribed = 5%;
4. Percentage of encounters with an injection prescribed = 2%; and
5. Percentage of medicines prescribed from EML or formulary = 100%.

She was pleased to see that her intervention had been successful, and she continued to monitor the indicators to assess rational prescribing in the health establishment.

4.1.5. Identifying medicine use problems – In-depth Investigation

4.1.5.1. Medicine Use Evaluation (MUE)

A Medicine Use Evaluation (MUE) is an ongoing, systematic, criteria-based program of medicine evaluations that will help ensure appropriate medicine use. If therapy is determined to be

inappropriate, interventions with providers or patients will be necessary to optimise pharmaceutical therapy.

An MUE is used to define standards of care and thresholds for RMU. It is used to assess whether prescribing is in line with STGs. MUEs are used to monitor prescribing and prepare appropriate interventions to correct misuse of medicines. Irrational medicine use may include polypharmacy, ADRs, treatment failure, more that 10% expenditure on Non-EML medicines, excessive expenditure on Class A medicines or other misuse. Triggers for an MUE to be conducted may be derived from safety warnings, ADR reports, recommendations from PTC members, ABC analyses, VEN studies or ATC Analyses. Indicators and criteria for an MUE are highly individualised depending on the scope of the analysis.

The World Health Organization recommends the following steps to perform an MUE:

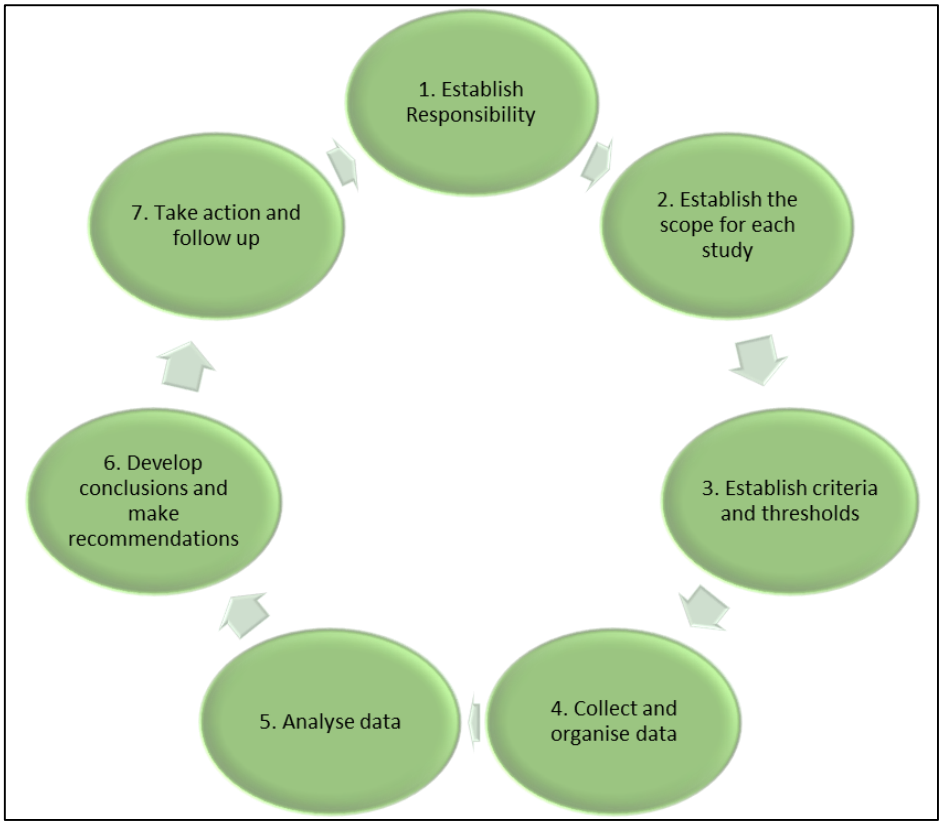

Figure 3: Steps to Performing an MUE

To illustrate how to conduct an MUE, an example has been included in italics for an MUE conducted at a health establishment.

1. **Establish Responsibility**

Responsibility for conducting of an MUE should be mandated in accordance with the TORs of a PTC. For example, the PTC or PTC sub-committee of a health establishment should have an annual plan to conduct MUEs. A technical lead should be assigned.
Example: The Responsible Pharmacist of the hospital was assigned responsibility of conducting an MUE for use of a medicine, over a period of 3 months.

2. Develop Scope of Activities

Firstly, the medicine use problem needs to be identified. Methods to identify medicine use problems include an ABC or VEN analysis, DDD analysis, ADR reports, medication error reports, antibiotic sensitivity results, procurement studies, hospital and primary care clinic indicator studies, patient complaints or feedback, and staff feedback.

Many medicine use problems may be identified and will then need to be prioritised according to those medicines with the greatest potential for misuse e.g.:

- High volume or price;
- Low therapeutic index or high incidence of ADRs;
- Injections, antimicrobials and other focus medicine groups;
- Medicines used for off-label indications and high-risk patients; and
- Medicines undergoing evaluation for possible inclusion in a formulary.

Choosing the MUE in this manner will also enable the MUE to have more impact. The scope should be kept narrow to include only the most important MUE criteria. A selection matrix can also be used to prioritise the medicine use problem.
Example:

Table 10: Example of Developing an MUE Scope

Medication	*High Use*	*High Cost*	*High Risk*	*Problem Prone*	*Total Score*
Paracetamol	*1*	*0*	*0*	*0*	*1*
Ertapenem	*1*	*1.5*	*1*	*0*	*3.5*
Warfarin	*0.5*	*0*	*1*	*2*	*3.5*
Albendazole	*3*	*0*	*0*	*1*	*4*

Key:
High Use refers to medicines with the greatest volume being utilised.
High Cost refers to medicines with the greatest procurement cost.
High Risk refers to the safety or side-effect profile of that item.
Problem Prone refers to medicines with a risk in either the administration or prescribing of that medicine.

Thus, albendazole with the highest overall score was chosen for the MUE.

3. Establish Criteria

Criteria used should be from reliable evidence-based literature sources and, where possible, the National STGs. To simplify the review process, 3 to 5 indicators should be used. These may include:

- Process Indicators – indications, dose, quantity dispensed, preparation and administration of medicine, laboratory monitoring, contraindications, drug interactions, patient education and counselling.
- Outcome Indicators – clinical outcomes such as stabilised blood glucose and fewer asthma attacks, decreased hospitalisation, improved quality of life of the patient.
- Pharmacy Administration Indicators – correct costing, accurate billing and dispensing records, use of generics or therapeutic equivalents, formulary use and quantity dispensed

Example:

Indicators and criteria were developed for albendazole use, based on the South African PHC STGs:

Table 11: Example of Developing MUE Criteria

Indicator	***Criteria***
Indication	*Helminthic Infestation, Tapeworms* *Sandworm*
Dose	*Children under 2 years – 200 mg daily* *Children over 2 years and adults – 400 mg daily*
Duration	*3 days*
Health Education	*Health education about adequate preparation and cooking of meat (for Tapeworm)*

4. Define and Establish Thresholds

A threshold needs to be determined for each criterion, Results achieved below the threshold will warrant corrective action. This is usually set at 90 to 95%, depending on the indicator, and is an important step in the MUE to establish how strictly the defined criteria should be adhered to, depending on the importance of the indicator.

Example:

Table 12: Example of Defining MUE Thresholds

Indicator	***Criteria***	***Threshold***
Indication	*Helminthic Infestation, Tapeworms* *Sandworm*	*95%*
Dose	*Children under 2 years – 200 mg daily*	*95%*

	Children over 2 years and adults – 400 mg daily	
Duration	*3 days*	*90%*
Health Education	*Health education about adequate preparation and cooking of meat (for Tapeworm)*	*90%*

5. Collect Data and Organise Results

Prospective studies are performed as prescribing or dispensing is being performed, which enables an intervention if necessary. Examples include indication, dose, duration of therapy, dosage form and route of administration, potential interactions, appropriate selection, therapeutic substitution and quantity dispensed.

Retrospective studies are performed after prescribing or dispensing has been performed, such as with chart reviews, prescription records and laboratory records, which allows a more flexible review period. Examples include laboratory monitoring, high use of Class A medicines, ADRs and patient outcomes.

Example:

Prescribing and dispensing data involving albendazole was collected over the period of 3 months at the health establishment. Patients were also interviewed when albendazole was prescribed, after prescribing and dispensing took place.

6. Analyse Data

Results are tabulated against indicators and compared. Data should be analysed at least quarterly. If the threshold is not met, an intervention may be necessary.

Example:

Table 13: Example of MUE Data Analysis

Indicator	***Criteria***	***Threshold***	***Results***
Indication	*Helminthic Infestation, Tapeworms* *Sandworm*	*95%*	*100 out of 100 patients had albendazole prescribed for the correct indication*
Dose	*Children under 2 years – 200 mg daily* *Children over 2 years and adults – 400mg daily*	*95%*	*99 out of 100 patients had correct dose*
Duration	*3 days*	*90%*	*88 out of 10 had medicine prescribed for 3 days. 12 out of 10 had medicine*

			prescribed as one stat dose.
Health Education	*Health education about adequate preparation and cooking of meat (for Tapeworm)*	*90%*	*Only 9 out of 20 patients interviewed cited being counselled on adequate preparation of meat.*

7. **Develop Recommendations and Plan**
   Results are presented to the relevant stakeholders, including the PTC, and appropriate recommendations for intervention are proposed, for example:
   - Education (letters to practitioners, in-service education, workshops);
   - Implementation of medicine order forms or prescriber restrictions; and
   - Formulary changes.

   Example:

   A plan was developed to include in-service education and workshops for clinicians on the appropriate use of albendazole, as well as health education required to be provided to patients. Training was conducted over a period of one month, prior to the next MUE conducted.

8. **Conduct MUE Follow-Up**
   Long-term follow-up is important to ensure correction of the irrational medicine use. An MUE should be on-going. Feedback is important and educational, managerial and regulatory interventions may be needed to improve RMU.

   Example:

   A follow-up assessment was conducted after training was concluded and a report prepared and shared with management and clinicians, following which another MUE was planned for the next quarter.

4.1.6. Strategies to Improve Medicine Use – Managerial

Managerial interventions may be used to improve the rational use of medicine. These include the use of audit plans and providing feedback thereof, the implementation of local protocols that are used to provide further restrictions to the STGs, as well as the use of access controls for individual patient use or other restrictions on EML medicines.

4.1.8.1. AUDIT AND FEEDBACK

An audit is a managerial intervention that has been proven to successfully improve medicine use. MUEs are a common method of audit, with an analysis being performed to identify medicine use problems, then repeated according to an ongoing, structured plan to serve as an intervention to drive RMU. MUEs may assess processes or treatment outcomes.

An example of a MUE audit plan as outlined in the “Identifying Medicine Use Problems” is provided below:

Medicine Use Evaluation Plan for Albendazole

Place:

Date:

Person Conducting Audit:

Criteria Used:

Process indicators based on the South African PHC STGs.

Data Collection Method:

Prospective study of patient consultation observation.

Indicator	Criteria	Threshold	Results
Indication	Helminthic Infestation, Tapeworms Sandworm	95%	100 out of 100 patients had albendazole prescribed for the correct indication
Dose	Children under 2 years – 200 mg daily Children over 2 years and adults – 400 mg daily	95%	99 out of 100 patients had correct dose
Duration	3 days	90%	88 out of 10 had medicine prescribed for 3 days. 12 out of 10 had medicine prescribed as one stat dose.
Health Education	Health education about adequate preparation and cooking of meat (for Tapeworm)	90%	Only 9 out of 20 patients interviewed cited being counselled on adequate preparation of meat.

Recommendations and Plan:

- Education of practitioners should take place, including letters to practitioners that will be sent and displayed on the health establishment notice board.
- In-house workshops on the use of the STGs

Schedule of Follow-Up Audits:

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
Training	X			X			X		
Audit		X			X			X	
Analysis		X			X			X	
Report and feedback			X			X			X

4.1.8.2. FORMULARY RESTRICTIONS

Restrictions may be placed on medicines to ensure better control over use, while maintaining access where rational need exists. Examples of these as outlined previously in the PTC Guideline include:

- Individual Patient Access; and
- EML (restricted).

4.1.8.3. TREATMENT PROTOCOLS

Treatment protocols are local guidelines attached to a medicine by a relevant PTC that inform the treatment regimen used when prescribing the medicine to a patient. These guidelines are used in addition to the National STGs and should not replace them. An example of this protocol would be for the use of a non-EML medicine for which a National STG is not attached. These should follow the same format of the National STGs on the MMDS.

4.1.7. Pharmacovigilance and patient safety

The World Health Organization defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”.[26] Pharmacovigilance is a crucial element of RMU that ensures feedback to the medicines regulator, the South African Health Products Regulatory Authority (SAHPRA), pharmaceutical companies, as well as the NDoH. This enables a feedback loop to allow trends to trigger regulatory and selection decisions on medicine use.

Pharmacovigilance is the responsibility of all healthcare professionals, including doctors, dentists, pharmacists, nurses and other health professionals. Unusual adverse effects are especially important to be reported, as these may trigger safety concerns in the wider population. It is the responsibility of the PTC to ensure education of healthcare professionals on the monitoring and

[26] World Health Organization. Essential medicines and health products: Pharmacovigilance. (https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/ - accessed 08/02/2019).

reporting of ADRs and product quality problems. Education on the importance of pharmacovigilance should be performed, including the importance of reporting even if all facts about a case or direct correlation with medicine are not known. PTCs should discuss ADRs and product quality problems in meetings, as well as any safety concerns raised by SAHPRA, and report on consolidated ADRs and product quality problems in line with the indicators listed in Section 7. ADRs should be a standing agenda item at PTC meetings.

Guidance on ADR reporting is available on https://www.sahpra.org.za/Publications/Index/1.

4.2. Formulary Management

Formularies should be managed according to the National Guideline for the Development, Management and Use of Formularies[27]. A formulary was defined in the *National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa*, available at http://www.health.gov.za/index.php/affordable-medicines/category/544-pharmaceutical-and-therapeutics-committees as a list of medicines that is approved for use in the healthcare system by authorised prescribers and dispensers.[28] This definition has been developed further, with the revised definition referring to *'A continually updated list of medicines and related information, used in the diagnosis, prophylaxis, or treatment of disease and promotion of health, to satisfy the needs of the majority of the population served by a particular health establishment/s.'*

The PTC is mandated to manage the formulary, however, it is imperative that the individual controlling procurement finances should sign off on the formulary to acknowledge approval. For institutional formularies, this would be the CEO, for district formularies, the Chief Director: District Health and for provincial formularies, the Head of Health. Health Needs Assessments should be conducted to determine the selection of medicines to be included in a formulary using data as specified in Section 4.3.2. Formulary development and management follows a hierarchical approach based on the level of care according to the figure below. The arrows represented the direction of decision-making:

[27] South African National Department of Health. 2019. *National Guideline for the Development, Management and Use of Formularies.* Pretoria, South Africa.

[28] National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, 19 January 2015

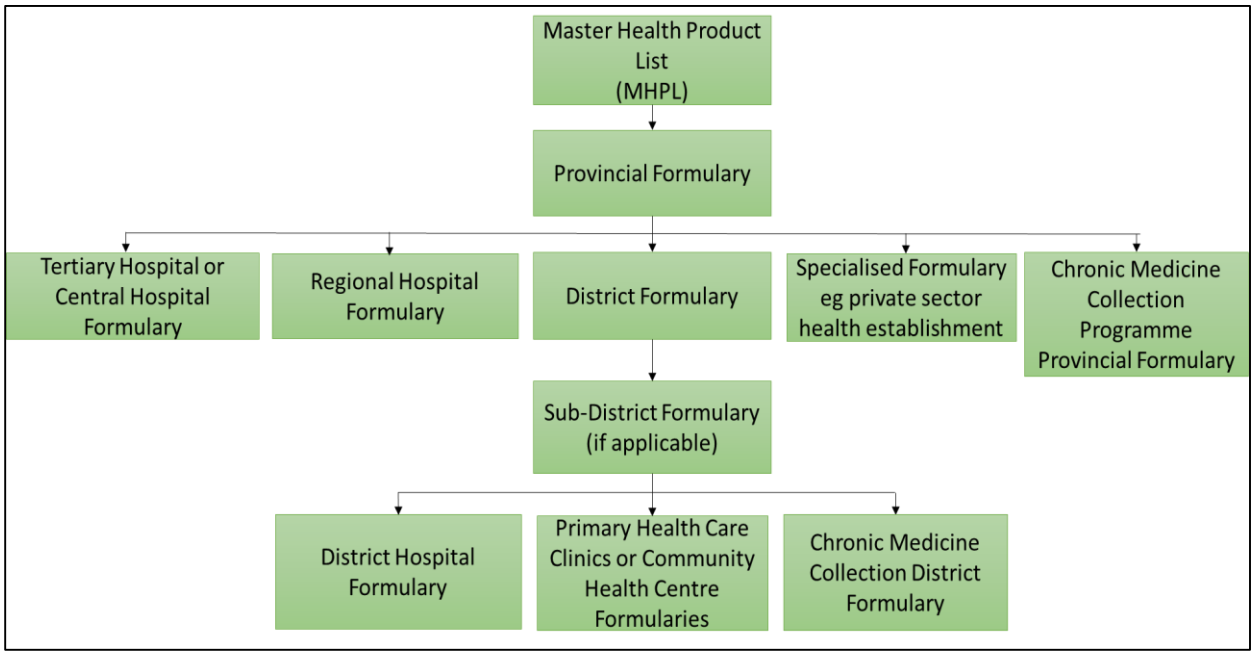

Figure 4: Hierarchy of Formulary Development and Management

PTCs should develop a formulary aligned to treatment guidelines and protocols subjected to robust evidence-based interrogation and consideration of cost implications, according to the SOP on Formulary Develop, Management and Use, attached as Appendix 17. In the case of Essential Medicines, guidelines for use should be aligned to the STGs. However, in the case of medicines that are non-EML, guidelines for use should be developed by the PTC. Before formulary updates can be implemented at a clinical level, there must be assurance that adequate supply of the relevant medicines has been secured, and patients will not face interruptions to treatment. This requires careful alignment of planning between selection, contracting and supply chain processes by PTCs prior to changes to formularies.

The national STGs and EML are determined by the NEMLC and managed and implemented by the EDP. The ministerially-appointed Expert Review Committees for Primary, Secondary and Tertiary level of care, are technical Sub-Committees of the NEMLC. They conduct the review of the STGs and EML taking into consideration clinical need, as well as evidence of efficacy, quality, safety, affordability and implications for practice. This review process is managed and implemented by the EDP. All EML medicines should be available at the relevant level of care based on the package of services provided at a particular health establishment/s.

4.2.1. Development and Maintenance of Local Formularies

4.2.1.1. Individual Patient Use

Applications for individual patient use may be submitted by the relevant treating clinician to the applicable PTC on an approved application form (Appendix 19). In cases where a medicine which is not on the formulary of the health establishment is required for the treatment of a particular patient, or the medicine required is already indicated on the formulary of the health establishment

for 'individual patient use' only, the application must include a motivation providing reasons as to why the medicine is needed for the patient in question. Applications for individual patient access may be for a medicine on the EML at a higher level of care, or for a non-EML medicine. If the application is for a non-EML medicine, the application must also include evidence of efficacy and safety in similar groups of patients, for a similar indication with cost-effectiveness and affordability also being taken into consideration.

An application for use of a Special Access (EML – subject to restrictions) medicine may only be initiated at the tertiary/quaternary level of care by an appropriate specialist for the indication or under the supervision of an appropriate specialist at a lower level of care. Applications should be for a course of therapy, with the period for authorisation being determined to suit the relevant condition or medicine after which date, a motivation for continued use of the medicine (including progress reports, where applicable) should be submitted to the relevant PTC. Patients who meet the predefined criteria as stated by NEMLC will be considered for eligibility on receipt of the required application and motivation. The cost implication to the National Tertiary Services Grant will also be taken into account.

Scenarios for the application of Individual Patient Use (Appendix 19) and corresponding sections of the application form that should be used are provided below:

Table 14: Scenarios for Individual Patient Use

Section to Complete	1. Patient Details	2. Current medical details and Medical History	3. Clinical Summary	4. Motivation with Evidence	5. Cost Effectiveness and Clinical Efficacy	6. Application and Approval Details
EML medicine to be available at lower level of care	Yes	Yes	Yes	Yes – evidence of appropriate prescriber available, diagnosis etc.	No	Yes
Non-EML Medicine	Yes	Yes	Yes	Yes – diagnosis etc.	Yes	Yes
PTC pre-approved Individual Patient Access	Yes	No	No	Yes – evidence that patient meets	No	Yes

				defined criteria		
Special Access (EML – subject to restrictions)	Yes	No	No	Yes – evidence that patient meets defined criteria	No	Yes
Down-referral	As above – a detailed referral letter and prescription from referring health establishment is required to contain the above information.					

4.2.2. Third Line Antiretroviral Applications

An access programme was initiated by the NDoH to provide access to Third Line Antiretroviral Therapy (TLART) for patients that have failed second line treatment, and to provide an appropriate, individualised regimen based on each patient's particular resistance pattern, an access programme was initiated by the NDoH. TLART is indicated in patients who have Protease Inhibitor (PI) resistance as identified via genotyping. A recommendation is formulated by the clinical status of the patient together with the results of the genotyping test.

Upon confirmation of PI resistance through genotyping, the clinician is required to submit an application for TLART to the Peer Review Committee (PRC) at the NDoH. The application form approved by the PRC indicates mandatory fields for the clinician to complete. The completed form is then submitted to the Secretariat (EDP) on TLART@health.gov.za, available from http://www.health.gov.za/index.php/affordable-medicines/category/524-third-line-antiretrovirals. To ensure visibility of the request for TLART amongst relevant stakeholders, the ARV or relevant pharmacist and Institutional PTC Secretariat should be copied into the email, as well as their original email requests included on the TLART application form.

Subsequently, the PRC provides a treatment recommendation based on pre-defined algorithms. PTCs not to be involved in the application process. However, once approval has been provided by the PRC, the medicine should be made available by the PTC on an Individual Patient Basis. A separate application for Individual Patient Access need not be made to the PTC if the approval is provided from the NDoH, in order to avoid delay in access, as this should be automatically applied. PTCs should have sight of the committees that are responsible for TLART and track expenditure of the approved TLART medicines.

4.2.3. Motivation for addition, deletion or amendment of medicine on the EML

The South African public health sector operates in a resource-limited environment, where the health care demands are continually growing. Whilst new medicines entering the South African market hold the potential for improved health outcomes, they may also introduce an additional cost to the health system. Their availability introduces challenges for priority setting, resource allocation, and patient care choices. Funders. clinicians and administrators in the public health system need to choose between treating a disease or preventing it in the first place, alternative interventions for a given disease or treating one disease as opposed to another. In order to make these complex choices, the best available evidence must be used for medicine review, to ensure an approach that is systematic, unbiased, and transparent.

As such, PPTCs may motivate for the addition, deletion or amendment of a medicine (or appeal of a selection decision) on the EML using the approved application form along with evidence (Appendix 18). The motivation process should ensure a high-quality medicine review that takes into account disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. Examples of medicine reviews are available on http://www.health.gov.za/index.php/standard-treatment-guidelines-and-essential-medicines-list

4.2.4. Developing and reviewing treatment guidelines and protocols

Local treatment guidelines should be developed for medicines not available in the National STGs but present on the formulary. Local guidelines should include ICD10 code and all of the information required in the Clinical Setup module of the MMDS.

4.3. Implementation of Medicine-Related Policies and Procedures

4.3.1. Therapeutic Interchange Policy

The National Therapeutic Interchange Policy, available from http://www.health.gov.za/index.php/national-essential-medicine-list-committee-nemlc, enables the prescribing of a medicine instead of a medicine that was originally prescribed, provided that both medicines are from the same therapeutic class. These therapeutic classes have been designated by NEMLC with the criteria that none of the members of the class offer any significant benefit over the other members of the class for a specific indication. Therapeutic interchange by prescribers should be considered in the case of stock-outs, and will affect procurement and the supply chain.

According to the National Therapeutic Interchange Policy, it is the responsibility of PTCs to:

- Timeously facilitate communication of policies around designation of medicines into therapeutic classes from the Department of Health to relevant stakeholders;
- Implement and oversee processes to facilitate the switch from one member of the therapeutic class to another, and minimise confusion or risks for patients; and
- Put processes in place for the monitoring and reporting of adverse events and medication errors and ensure that these processes are followed.

4.3.2. Antimicrobial Resistance National Strategy Framework; One Health Approach, 2018-2024

AMR, or the ability of a microorganism to withstand treatment with an antimicrobial medicine, is a significant and multifaceted public health problem and a direct threat to human and animal health, food security and the continued use of available antimicrobials. The societal and financial costs of treating antimicrobial resistant infections in humans and animals will place a significant human and economic burden on society and compromise food security.

Sixty percent of the human pathogens come originally from animals and therefore it is clear that AMR poses a serious global threat to both animal and human disease treatment. From an animal health perspective antimicrobial agents are essential tools for protecting animal health and welfare, and also contribute to satisfying the increasing world demand for safe food of animal origin. A return to appropriate, targeted antimicrobial use in humans, animals and the environment is critical to conserve the antimicrobial armamentarium.

The AMR National Strategy Framework[29] provides a structure for managing AMR among humans and animals to limit further increases in resistant microbial infections, and improve the health of the population.

The strategic framework consists of five strategic objectives:

- **Strategic objective 1**: Strengthen, coordinate and institutionalise interdisciplinary and intersectoral efforts through national and provincial One Health governance structures which encompasses human, animal, and environmental health experts.

- **Strategic objective 2:** Diagnostic Stewardship to improve the appropriate use of diagnostic investigations to identify pathogens and guide patient and animal treatment and antimicrobial management whilst strengthening quality laboratory systems for the detection of disease.

- **Strategic objective 3**: Optimise surveillance and early detection of AMR and antimicrobial use to enable reporting of local, regional, and national resistance patterns to optimise empiric and targeted antibiotic choice.

- **Strategic objective 4**: Enhance IPC and biosecurity to prevent the spread of resistant microbes to patients in healthcare settings and between animals, farms and countries. Reduced use of antimicrobials by disease prevention and community measures include wide-reaching vaccination programmes, improvements in water and sanitation, and improved biosafety.

- **Strategic objective 5**: Promote appropriate use of antimicrobials in human and animal health through AMS practices and controlled access to antimicrobials to ensure availability.

[29] South African National Department of Health. 2019. *Antimicrobial Resistance National Strategy Framework; One Health Approach, 2018 - 2024.* Pretoria, South Africa.

Under Sub-objective 5.2: Institutionalise antimicrobial stewardship in human health, AMS is highlighted as a key method to help correct inappropriate use through protocols, structures and interventions. This may include:

1. AMS Committee or structure to function in every Health Establishment and district aligned within the overarching clinical leadership functions.
2. AMS Teams in every institution to actively oversee appropriate prescribing and optimise antimicrobial use. Composition of an AMS team will vary depending on setting and availability of expertise. A Departments of Health and Agriculture, Forestry and Fisheries for the Republic of South Africa: Antimicrobial Resistance National Strategy Framework 2018 – 2024 Page 17 of 22 prescribing physician and pharmacist are the ideal core members of an AMS team. Outreach and support by experts may be sought to advise and train teams.
3. Provision, use and monitoring of protocols such as formulary restrictions, pre-authorisation of antimicrobials, monitoring the use of national prescribing guidelines such as the STGs and EML, and development of local treatment guidelines based on health establishment resistance data.
4. Expenditure on antimicrobials

AMS is therefore a key function of PTCs. AMS committees can either be a subcommittee of the PTC or other relevant standing Committee (for example, Quality Assurance) or a separate committee on its own, at the discretion of the Provincial Head of Health. Whichever option is implemented in the province, the PTC should develop and maintain a mechanism for regular interaction with and feedback from the AMS committee. AMS should be a standing item on the agenda of PTC meetings and should form an essential part of the RMU cycle in line with the strategic framework.

The governance of AMS committees should be in line with the “Guidelines on Implementation of the Antimicrobial Strategy in South Africa” available from http://www.health.gov.za/index.php/antimicrobial-resistance.

4.3. Procurement and Medicine Availability

4.4.1. National Surveillance Centre Dashboards

The National Surveillance Centre (http://ndohsurveillancecentre.dedicated.co.za) provides visibility of medicine availability Key Performance Indicators (KPIs) at health establishment, district, provincial level and supplier level. Medicine availability dashboards and related reports are refreshed using data collected by the Stock Visibility System, RxSolution, Warehouse Management Systems and the respective electronic stock management systems in use by suppliers. The dashboard reports aim to provide healthcare professionals, supply chain managers and PTCs with updated information to enable evidence-based decision making to support medicine supply management and ensure reliable medicine availability. This includes identification and mitigation of supply-chain issues, as well as the effective implementation of stock-out escalation protocols. Various dashboard and report views are available and are

designed to serve different purposes. An example of the national medicine availability dashboard which measures the KPIs relating to the NDoH's strategic objectives is provided below:

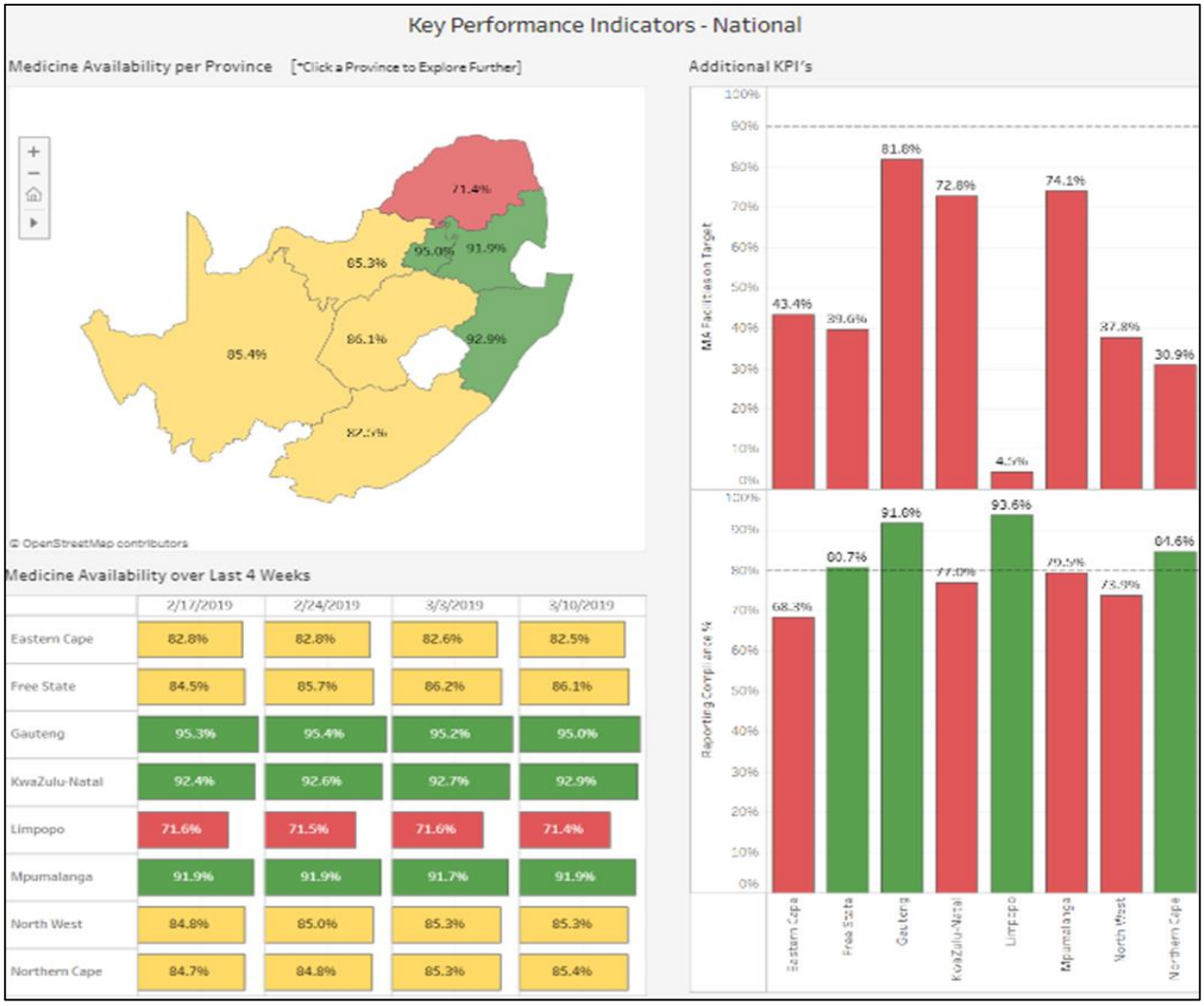

Figure 5: National Surveillance Centre Dashboard Example

Examples of report views that should be monitored include:

- KPI Dashboard – indicating performance against medicine availability KPIs;
- Reporting Compliance – indicating health establishment compliance to minimum reporting requirements as set out in the KPI dictionary;
- Items Out of Stock – indicating medicines with zero stock on hand at various levels; and
- Item Level Availability – enabling monitoring of priority medicines.

PTCs should monitor the dashboards at least weekly to monitor and identify supply interruptions at health establishments, such as items out of stock, below minimum level or average stock levels. If necessary, PTCs should make use of the escalation protocol to manage these challenges

locally and escalate those issues which cannot be resolved at health establishment or district level. The root cause of identified challenges can then trigger the implementation of corrective and preventive interventions where necessary. Interventions may include the following:

- Review and update of the health establishment customised formulary;
- Correction of master data or stock availability related data;
- Movement of stock between facilities;
- Recommendation of use of alternative pack sizes or dosage strengths;
- Recommendation of therapeutic alternatives/interchange (in close collaboration with the EDP at NDoH); and
- Training and capacitation of stock managers to ensure correct application of medicine supply management principles (as per SOPs).

4.4.2. Stock-Out Escalation Protocol

PTCs are key stakeholders in the stock-out escalation process, in order to provide therapeutic alternatives where supplier constraint issues occur to avoid adverse patient outcomes. If a medicine stock-out is reported at a health establishment, the following steps should be followed to manage the stock-out by facilities, in line with the generic National Stock Out Escalation Protocol, which should be tailored according to provincial processes and needs:

1. Verify if there are any other medicines affected and compile a comprehensive list of affected items (for example utilise SVS reported data to facilitate);
2. Confirm with the relevant PTC whether the affected medicine(s) should be part of the formulary;
3. If the medicine(s) should not be on the formulary, the formulary should be adjusted to remove the medicine;
4. If the medicine should be on the formulary and there are known supplier challenges that will affect supply, the Institutional PTC should consider therapeutic alternatives, together with the EDP;
5. If there are no therapeutic alternatives, the issue should be escalated in accordance with the escalation protocol to the Sub-District, District or Provincial PTC as applicable;
6. Once escalated to the Sub-District or District PTC, the sub-district of district formulary should first be reviewed and the issue should be escalated to the Provincial PTC only if no therapeutic alternatives are available, in line with the escalation protocol; and
7. Once escalated to the Provincial PTC, the formulary should first be reviewed and the issue should be escalated to the Improved Medicine Availability Team at the AMD for action only if no therapeutic alternatives are available, in line with the escalation protocol.

4.4.3. Tender Specification Review

Provincial PTCs (unless this function is performed by another pre-existing structure within the province) are expected to take part in the awarding of National tenders for medicines. Estimates

of quantities are requested from the Provincial PTCs during the Bid Specification process. Provincial PTCs should call on their members at different levels of care to assist in the finalisation of specifications, therapeutic classes and estimates to ensure that specifications are in line with practical implementation requirements. Alignment with provincial formularies should be considered.

4.4. Pharmaceutical Expenditure Planning and Monitoring

PTCs are key to the planning, monitoring and efficient use of pharmaceutical expenditure, which is critical to ensuring the sustainability of the health system and provision of services. Various methods may be used to monitor expenditure, which should influence selection, procurement and use of medicines. PTCs have the mandate to balance of making the right medicine available to the right patient at the right time with the limited financial resources that are available within the public healthcare system.

4.5.1. Non-EML USE

Non-EML medicines are a necessary mechanism to ensure equitable access to medicines for patients. However, taking into account the rigorous process through which medicines are evaluated for inclusion onto the EML, the use of Non-EML medicines should be limited due to financial and efficacy implications of their overuse.

Non-EML medicines with the sub-category of “reviewed but not approved” should as far as possible not form part of a formulary, as these have been evaluated through the NEMLC selection process and have been designated to not form part of the EML. The overall expenditure on Non-EML medicines should not exceed 10% of the overall expenditure for all medicines of a health establishment, district or province. This includes expenditure on equitable share and conditional grants.

4.5.2. Pharmaceutical expenditure vs budget

The budget should be informed by strategic goals and external factors, such as policy changes. Expenditure tracking capabilities should be well developed and in real time, using electronic systems where available. The PTC should monitor and advise on procurement of medicines not contained on the formulary due to its implication on the budget.

PTCs should also ensure that adequate resources are available to cater for functional needs of the committee. PTCs should ensure that their resource plan is comprehensive and easy to implement at provincial and district level. The resource plan should be aligned to strategic needs and include operational budgets and staffing. PTCs should also advise health facilities on resource planning and management at both provincial and district level.

PTCs should analyse the major cost-drivers using procurement data to inform selection and formulary decisions, as well as to advise on procurement decisions. An ABC analysis may be used to determine the major cost-drivers by volume or value. For example, class A items should be ordered more often and in less quantities to reduce inventory-holding costs. Inventory management and storage monitoring should be prioritised for class A items, to minimise wastage.

Reduction in use where cheaper alternatives are available should be prioritised. For this, therapeutic category analysis may be used to choose the most cost-effective medicine for a particular indication.

VEN status may be used to enhance this analysis and influence selection and procurement decisions. For example, vital and essential medicines should be given priority in selection where funds are limited. Order monitoring of these medicines should be given priority and safety stock should be higher for these items to avoid stock-outs.

PTCs must ensure that cumulative pharmaceutical expenditure against budget does not deviate by more than 10%, as indication in the Pharmaceutical Services Dashboard Manual. Cumulative expenditure includes expenditure on equitable share and conditional grants, while donations are excluded.

5. Communication and Relationship Management

Communication across the health system should follow a hierarchical two-way path. This process should ensure that the available expertise is used for clinical decision-making to the benefit of the majority of the population. Communication should take place between different stakeholder groups to inform decision-making, according to the figure below:

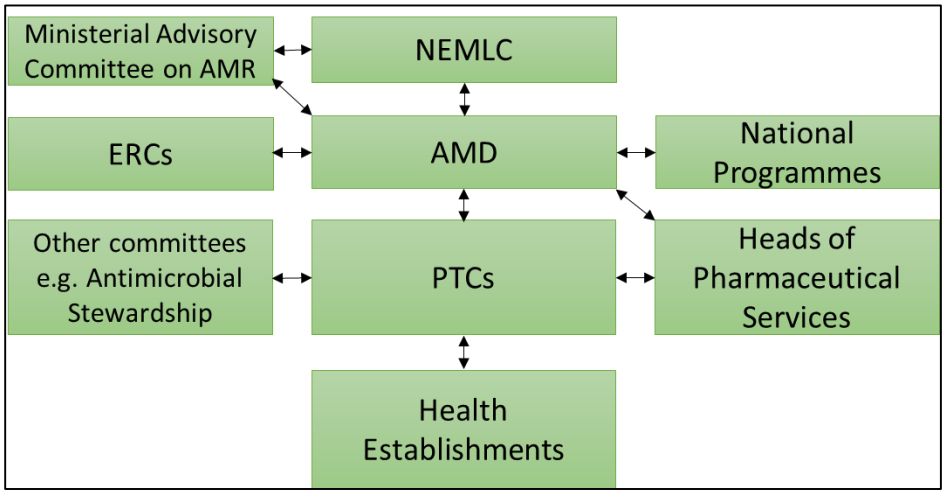

Figure 6: Communication Diagram

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 health care professionals of issues related to medicine management. Communication from the PTC should be signed by the Chairperson.

5.1. Communication Objectives

Effective and open communication is critical to the success of the PTC. The key objectives for PTC communication include the following:

- Define stakeholder communication roles and responsibilities;
- Provide accurate and timely information about the PTC and its deliverables;
- Establish coordinated information flow and task completion for PTC;
- Provide feedback on the review of the STGs;
- Communicate PTC progress; and
- Ensure a consistent message is delivered at all times.

As part of the communication and engagement activities, training sessions or workshops may be conducted with the different stakeholders to update them on any changes such as new policies, operating procedures, guidelines, processes and system changes that have been developed.

5.2. Stakeholder Identification and Engagement

Through the identification of stakeholders and engagement planning, appropriate management strategies should be developed to effectively engage all PTC stakeholders. The engagement plan should communicate and influence all relevant internal and external PTC stakeholders with the purpose of creating alignment, buy-in and commitment from key stakeholders that have a high influence on the success of the PTC.

Stakeholders should be classified into a "RACI" chart or matrix describing their level of involvement in PTC decisions – whether they are responsible (R), accountable (A), should be consulted (C) or should be informed (I). An example of this is provided in the table below:

Table 15: PTC RACI Chart Example

Stakeholder Group	RACI Classification
Hospital CEO, Chief Director: District Health and Provincial Head of Health	(R) Responsible
PTC Chairperson and Vice-Chairperson	(A) Accountable
PTC Members	(A) Accountable
HOPS	(A) Accountable
EDP	(C) Consult
District and Institutional PTCS	(C) Consult
Other Committees e.g. AMS	(C) Consult
Healthcare Professionals	(I) Inform
Clinical Societies	(I) Inform
Patient Advocacy Groups	(I) Inform

Stakeholder groups should be categorised so that appropriate attention can be given to each group according to the level of engagement needed. A highly engaged stakeholder is pivotal for clearing obstacles, refining and making recommendations for the successful implementation of the PTC. As the implementation progresses, the level of engagement should shift from key stakeholders to the broader PTC stakeholder groups. Stakeholder mapping should be followed by analysis and engagement planning, then engagement, according to the figure below:

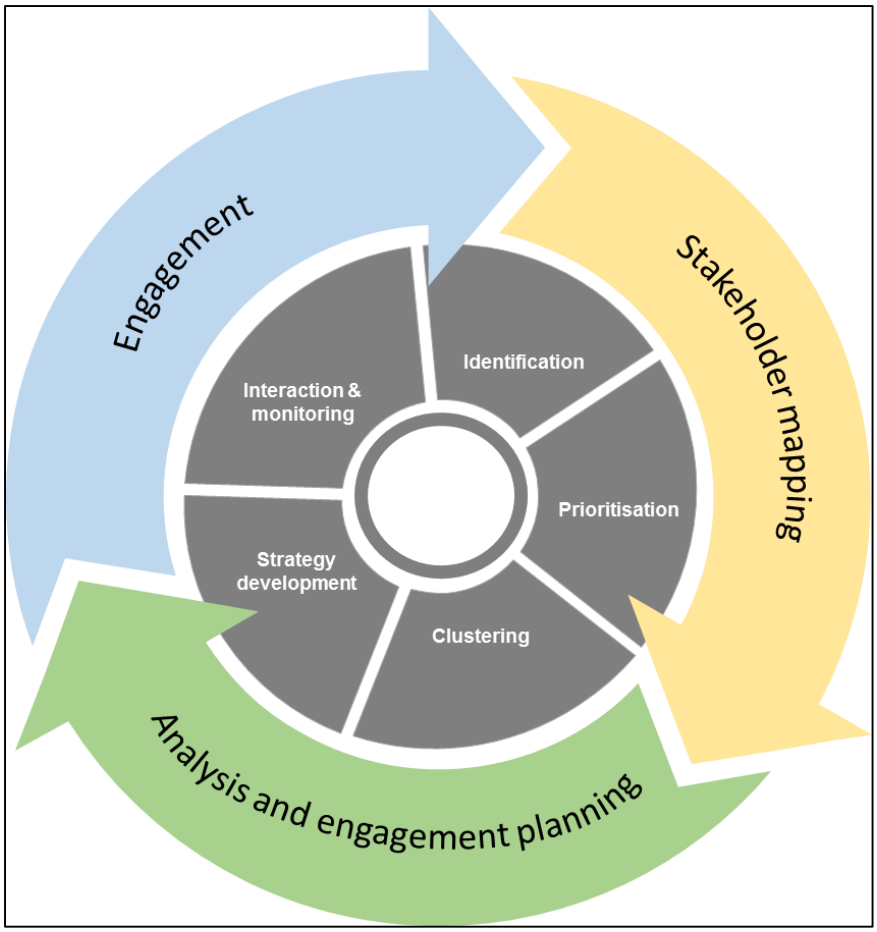

Figure 7: Stakeholder Mapping and Engagement Process Flow

5.3. Communications approach

The PTC communications approach should stem from various communication methods. The communication methods should be developed in terms of meeting the internal stakeholders needs as well those of external stakeholders, with a variety of different communication methods and formats used. The following formats have been highlighted as those which will be most used in the PTC:

Table 16: PTC Communication Methods

Communication method	Description
Written Communication	Refers to either writing or typing out information, facts, and figures in order to share information or ideas and includes emails fax, instant messages, official letters, newsletters, bulletins, circulars and other electronic written messaging. It can be either formal or informal.
Oral or verbal communication	Verbal communication is central to the sharing of information in a work environment. In context, it is often a difficult method of communication to employ given the different geographic locations of staff, different languages and different cultures. It remains the best way of ensuring common understanding and building relationships.
Electronic Communication	In the context of the PTC, electronic communication refers to sharing of information, email notifications, agenda, minutes, meeting invitations, teleconferencing, and videoconferencing.
Visual Communication	This refers generally to the sharing of ideas and information that are displayed in a visual format. It is used to express both simple and complex concepts in a diagrammatic fashion or in a layout that is short and engaging.

The figure below depicts the interdependency of different types of communications in bringing about sustainable change and adoption of the PTC process.

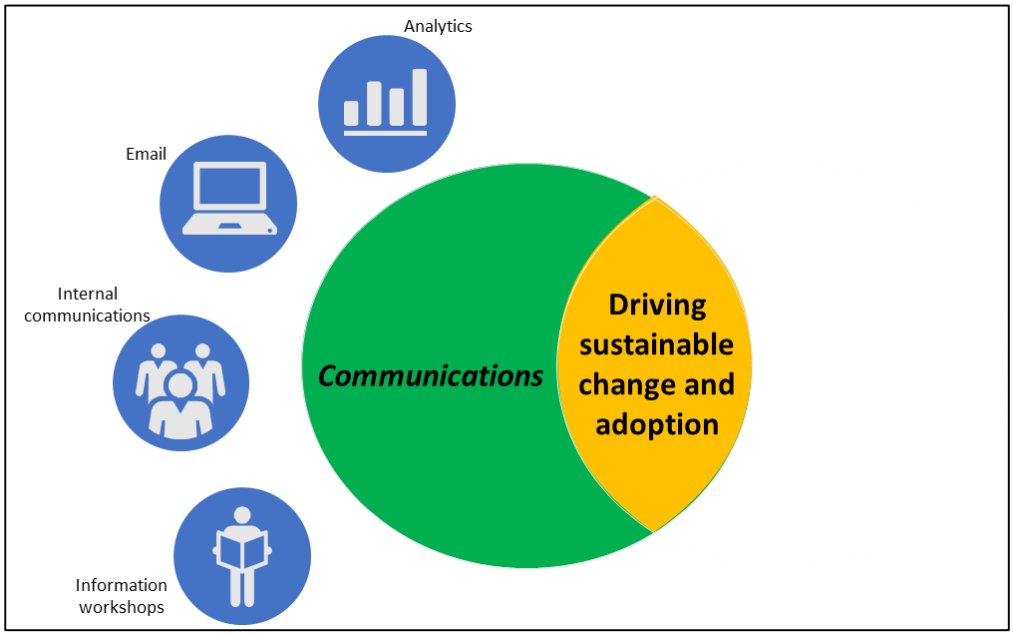

Figure 8: Different Types of PTC Communication

Depending on the type of communication needed with each stakeholder group, there are common methods of communication that may be used by the PTC. These are listed in the table below:

Table 17: Most Common Methods of Communication with Stakeholders

Stakeholder Group	Most Common Method of Communicating (as required)
PTC Chairperson and Vice-Chairperson	Written and electronic
PTC Members	Written and electronic
Head of Pharmaceutical Services	Written and electronic
EDP	Written and electronic
District and Institutional PTCS	Written and electronic
Other Committees e.g. AMS	Written and electronic
Healthcare Professionals	Written, electronic, oral and visual

Clinical Societies	Written, electronic, oral and visual
Patient Advocacy Groups	Written, electronic, oral and visual

6. Human Resource Management

Human resource management within PTCs is important to ensure that the required range of expertise and technical skills to fulfil its mandate.

6.1. Training and Capacity Building

Training is an essential function of PTCs, to enable the implementation of new information and guidelines, as well as a key intervention to improve the rational use of medicine. In order to achieve set objectives, training may be covered through a blended approach, with training scope linked to appropriate training method. PTC members should be actively engaged to build their skill sets and knowledge areas through a variety of training options.

Examples of training methods and scope are provided in the figure below:

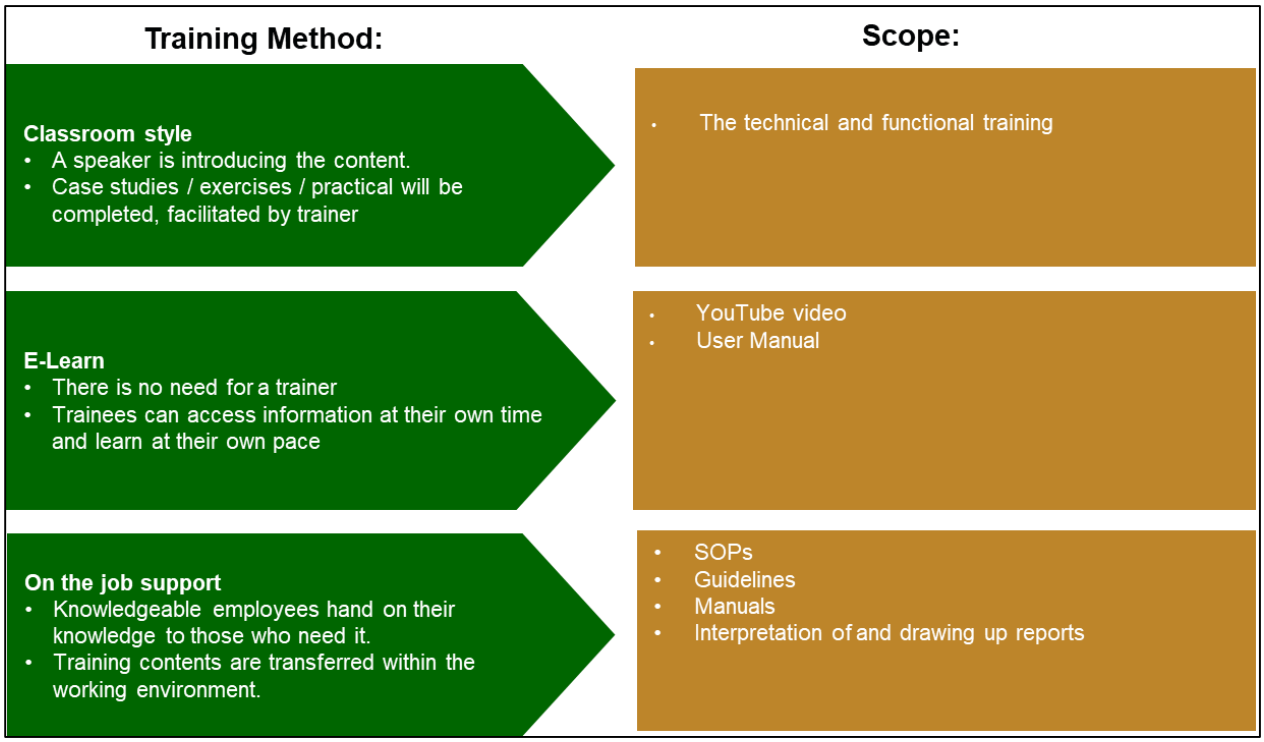

Figure 9: Examples of Training Methods and Scope

A standard learning design consists of 7 steps, as below:

1. **Scoping**
   This starts with the definition of the target audiences. Based on the learning needs analysis (including change impact and task analysis) the learning plan can be developed.

This plan includes an overview of the learning needs, target audiences, the learning strategy and the needed capacity and planning for design and delivery.

2. **High Level Design**
   Based on the learning plan the high level designs of the learning programmes can be developed. The templates for learning materials should also be developed. Also the training schedule should be defined in this step.

3. **Learning Materials**
   The next step is to develop all learning materials based on the defined learning objectives, high level designs of the learning programmes and the templates. Both trainer as participant materials should be developed.

4. **Trainer Preparation**
   When the learning materials are reviewed and adjusted, the preparation of the trainers should take place during a "train the trainer" programme. A complete walk through of the detailed learning programmes and all materials should take place in order to realise full preparedness of the trainers to deliver the learning programmes successfully.

5. **Learning Programme**
   The learning programme should be delivered following the three phase approach: pre-learning, formal learning programme and on the job support. All formal learning courses should be followed by a post training assessment to ensure training achieved was effective and achieved the set objectives.

6. **Evaluation**
   The learning programmes should be evaluated by both the trainers and the participants in order to define the effectiveness and define needed adjustments for further roll-outs. A post training report should be compiled to inform future training.

7. **Logistics**
   The execution of training logistic activities should be carried out during the learning development and delivery process. This includes: reservation of locations, invitation of participants, arrangement of resources required, printing of learning materials and development of evaluation forms.'

6.2. Administrative Support

The PTC Secretariat should be provided with training to ensure the roles and responsibilities of the Secretariat and PTC are understood, in line with the TORs. The Secretariat should be capacitated to ensure that functions are able to be efficiently carried out, including communication and meeting administration. It should be understood that although the Secretariat is the administrative unit of the PTC, it is more importantly the key driver of the PTC's activities, and

members of the Secretariat should be experts in PTC processes in order to educate other PTC members.

PTC members should be actively engaged with the health facilities to assist with administrative task management, especially at provincial level. Incident reporting and pharmacovigilance should be actively used and immediately addressed.

6.3. Retention

The retention of PTC members with the necessary skills that are scarce and valued is vitally important for PTCs to fulfil their purpose. PTC members should be encouraged to seek real-time feedback from their supervisors as well as co-workers. Retention strategies can be adopted in order to create a positive employee morale, help create a positive working environment and increase staff commitment to the PTC, as per the figure below:

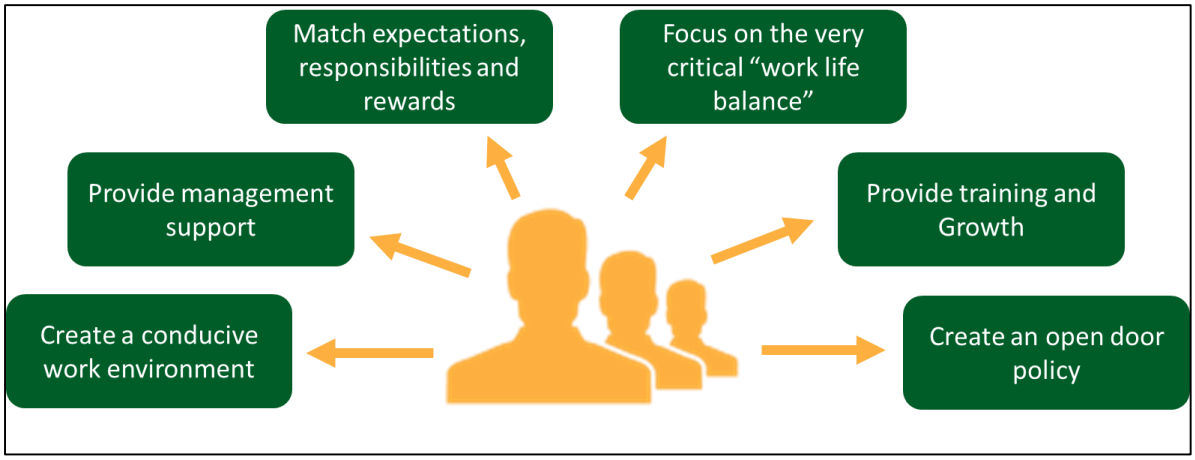

Figure 10: Member Retention Strategies

1. Conducive Work Environment

It is critical that PTC members are comfortable in their working environment and that all members are treated fairly. Communication should flow easily, with members being provided with the necessary resources with which to fulfil their mandate.

2. Provide Management Support

The Chairperson, Secretariat and other support staff to the PTC should be equipped with the necessary skills and techniques to enable their effectiveness in their role. Soft skills are just as important as technical expertise when managing a team such as a PTC.

3. Match Expectations, Responsibilities and Rewards

Dissatisfaction and resignation may occur when expectations of members are not clear from the outset. Members should be provided with explanation to the TORs for the PTC and their

corresponding responsibilities. Members should receive recognition for their efforts where possible, such as through email communication to their superiors.

4. Work Life Balance

It is important to recognise that PTC members are skilled, busy professionals who, although need to be committed fully to the PTC, may require to be excused from meetings occasionally for personal matters as they arise.

5. Training and Growth

Individuals join any organisation to give their best, to learn and grow. Frequent training of PTC members to enable professional growth and skills development is crucial for better retention.

6. Open Door Policy and Communication

It is important for the Chairperson, Secretariat and other PTC support staff to have an open door policy when it comes to concerns or complaints by members of the PTC. Issues should be dealt with confidentially and fairly to ensure that PTC members feel they have a pathway of communication with the PTC leadership.

6.4. Succession Planning

PTCs should proactively help facilities to establish a strong succession planning process, involving robust mentorship and leadership development programs available to staff. Succession planning is important to ensure that diversity in experience and thought is established and maintained within the PTC, as well as for continuity of the work performed by the PTC.

7. Monitoring and Evaluation

The monitoring and evaluation of PTC activities and impact provides an important feedback mechanism to ensure relevance. PTCs may be evaluated based on indicators developed against the functions and scope of its activities. The balance of maintaining adequate confidentiality where necessary, with the need for transparency in decision-making is key for stakeholder buy-in and relationship management.

7.1. Standards and Indicators

Indicators may be used to measure PTC performance. The following types of indicators may be used to evaluate a PTC:

1. Process Indicators – measure whether planned activities took place
2. Output Indicators - performance of a set of activities that a PTC is expected to carry out
3. Outcome Indicators – how well change has been achieved as a result of PTC activities

The following indicators were developed in line with the functions and scope of activities defined in this PTC Guideline, as detailed in the table below. Where a target is not included, the PTC should aim for improvement in the indicator from the last period of review.

Table 18: Indicators of PTCs

Number	Indicator	Target
PROCESS INDICATORS		
Governance		
PR1	Does the PTC have TORs that have been updated in the last 5 years?	Yes
PR2	Does the PTC have a defined place within the applicable level of organisational structure with clear authority and accountability?	Yes
PR3	Does the PTC have Confidentiality Declarations signed at the time of appointment, as well as Declaration of Interest Policies that are signed at every meeting?	Yes
PR4	Are potential conflicts of interest of members managed in accordance with the applicable policy? Is it suitably captured in the minutes of the meeting?	Yes
PR5	Is there a process for monitoring of ADRs and product quality complaints?	Yes
PR6	Does the PTC consist of membership and expertise in accordance with its TORs?	Yes

PR7	Does the PTC meet at least quarterly and in accordance with its TORs?	Yes
OUPUT INDICATORS		
Governance		
P1	What is the average attendance of PTC members at meetings?	50% + 1
P2	Is an agenda prepared before every meeting in accordance with the TORs?	Yes
P3	Are minutes circulated within 30 days after a PTC meeting, in accordance with the TORs?	Yes
Core Functions		
P4	Does the PTC have a formulary developed on the Medicine Master Data System (MMDS) that has been reviewed in the last quarter?	Yes
P5	Has the current formulary been signed off by the CEO?	Yes
P6	Is a health needs assessment performed prior to formulary review, such as by using an ABC analysis?	Yes
P7	Are motivations for medicines for individual patient use completed with required evidence?	Yes
P8	Are all Third Line Antiretroviral Therapy (TLART) applications approved by the NDoH Peer Review Committee (PRC)?	Yes
P9	Are motivations for addition, deletion or amendment of a medicine on the EMLs sent using the appropriate application form including evidence?	Yes
P10	How many quantitative analyses identifying medicine use problems performed in the last 3 months e.g. Defined Daily Dose (DDD), ABC Analysis, Indicator studies, Medicine Use Evaluation (MUE)?	3
P11	How many qualitative analyses identifying medicine use problems performed in the last 3 months e.g. Focus Group Discussion, In-Depth Interviews, Structured Observations, Structured Questionnaires?	3
P12	How many educational interventions to improve medicine use were performed in the last 3 months?	3
P13	How many managerial interventions to improve medicine use were performed in the last 3 months?	3

P14	Are all Adverse Drug Reactions (ADRs) encountered reported to the South African Health Products Regulatory Authority (SAHPRA) on the appropriate form?	Yes
P15	Percentage of prescriptions developed in accordance with the STGs	
Pharmaceutical Expenditure		
P16	Are no more than 10% of formulary items Non-EML (i.e. either not reviewed or under review by NEMLC)?	Yes
P17	Does cumulative pharmaceutical expenditure of non-EML medication fall within 10% of the budget?	Yes
P18	Is the PTC aware of medicines expenditure against budget?	Yes
Communication and Relationship Management		
P19	Does the PTC have a matrix of stakeholders that have been classified as responsible, accountable, should be consulted or should be informed?	Yes
Human Resource Management		
P20	Does the PTC have an annual training plan to develop capacity?	Yes
P21	What is the percentage annual turnover of PTC members?	10% or less
Transparency and Reporting		
P22	Does the PTC have 100% reporting compliance to the National Pharmaceutical Services Dashboard?	Yes
OUTCOME INDICATORS		
O1	What proportion of PTC decisions were made using clinical and economic evidence?	
O2	Growth in annual medicine expenditure compared to growth in population estimate, as per StatsSA data? This is calculated as follows: $\frac{\text{expenditure-current year}}{\text{expenditure-previous y}} / \frac{\text{public sector population size-current year}}{\text{public sector population size-previous y}}$	
O3	What is the average percentage availability of antimicrobials in the institution/ district/ province (as applicable) according to the National Surveillance Centre?	

O4	What is the average percentage availability of medicines in the institution/ district/ province (as applicable) according to the National Surveillance Centre?	

7.2. Transparency and Reporting

Institutional PTCs should send minutes of their PTC meetings and supporting documentation to their respective Sub-district or District PTC (if applicable), as well as Provincial PTC, at least quarterly.

Sub-District and District PTCs should send minutes of their meetings and supporting documentation to their respective Provincial PTC and institutions at least quarterly.

National Pharmaceutical Services Dashboard reports, including supporting documentation, should be completed by Provincial PTCs quarterly in accordance with the National Provincial Pharmaceutical Services Dashboard Manual. Should the Pharmaceutical Services Dashboard not be functional at this time, formularies should be emailed in an excel format to SAEDP@health.gov.za.

Provincial PTCs should send an annual report to the Head of Department and to other relevant provincial stakeholders.

Provincial PTCs may request information as needed from their respective districts, sub-districts and institutions to enable monitoring of PTC performance.

Appendix 1: Notice of Call for Application to The X Pharmaceutical and Therapeutics Committee

The X Department of Health calls for the application of suitably qualified individuals for appointment to the X Pharmaceutical and Therapeutics Committee (PTC). The PTC is a non-statutory, advisory, committee constituted in terms of the National Drug Policy (1996) and appointed by the [Executive authority] for a period of three years in order to ensure the rational, efficient and cost-effective supply and use of medicines.

The Pharmaceutical and Therapeutics Committee (PTC) promotes the rational use of medication through the development of relevant policies and procedures for medication selection, procurement, distribution and use and through the education of patients and staff.

The PTC acts as a feedback mechanism between National, Provincial and District Departments of Health, as well as facilities, and is important to improve rational medicine use. The PTC is essential for 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.

Section 12 of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa specifies the functions of the PTC 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.*

Individuals are eligible for appointment if they are South African citizens who currently work within the jurisdiction of X and have expertise in at least one of the following areas:

a) Evidence-based medicine;
b) Primary level health care services;
c) Secondary level health care services;
d) Tertiary level health care services;
e) Rational Medicine Use;
f) Medical supply management;
g) Financial management;
h) Antimicrobial Stewardship;
i) Bioethics; and

j) Medical Academia.

In order to appoint a suitably experienced committee, it is essential that all applicants have the relevant qualifications and expertise.

Nominees should note that the Provincial Department of Health reserves the right to verify details submitted and to subject candidates to the necessary security clearance. Correspondence will be limited to selected candidates only. No late applications will be accepted.

Interested persons are requested to submit a brief *Curriculum Vitae* (using the standard format provided) by e-mail to:

[Name]
[Telephone No.]
[E-mail Address]

It would be appreciated if nominations can be received by [Date]. Your co-operation in this regard is appreciated.

Kind regards

[Name]
[Date]
[Designation]
[Institution]

Appendix 2: Standardised Curriculum Vitae Template

1. Personal details:

Title: Mr/Mrs/	
Name and Surname	
Date of Birth	
Contact information	Tel no:
	Mobile no:
	Email Address:
	Preferred method of contact: Telephone ☐ Email ☐ Text Message ☐
	City of Residence:
	Physical Address:

2. Academic and Professional Qualifications:

Year	Institution	Qualification and field of study

3. Health Professional Council:

4. Relevant past and current work experience:

Area of Relevant Expertise	Mark Applicable (X)	Number of Years of Experience	Position Held	Organisation / Institution	Sector (public/ private/ NGO/ Academia/ Other)
Evidence-based medicine	☐				
Primary level health care services	☐				
Secondary level health care services	☐				
Tertiary level health care services	☐				
Rational Medicine Use	☐				
Medical supply management	☐				
Financial management	☐				
Antimicrobial Stewardship	☐				
Bioethics	☐				
Medical Academia	☐				

5. Current Employment - Public/ Private/ NGO/ Academia/ Other (please specify):

Organisation/ Institution	Position	Sector	Full time/ Part time

6. Other relevant Medicine Selection Committee experience (e.g. PTC, NEMLC)

Name of Committee	Term of Office

7. Publications:

Publication Date	Journal Title	Publication Title

8. Contactable References:

Name	Institution	Contact Details

Signature: _____ Date: _____

Appendix 3: Letter of Request to the Executive Authority

Dear X,

LETTER OF REQUEST TO THE [EXECUTIVE AUTHORITY] TO APPROVE THE APPOINTMENT OF INDIVIDUALS TO SERVE ON THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

INTRODUCTION

The purpose of this letter is to request the [Executive Authority] to:

- Approve the appointment of individuals to serve on the X Pharmaceutical and Therapeutics Committee (PTC) for a period of three years from the date of approval;
- Sign the appointment letters.

PTCs promote "the rational use of medication through the development of relevant policies and procedures for medication selection, procurement, distribution and use and through the education of patients and staff"[30].

They act as feedback mechanisms between National, Provincial and District Departments of Health, as well as facilities, and are important to improve rational medicine use. The PTC is essential for 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"[31].

The appointment of a new PTC is required due to [REASON].

DISCUSSION

Functions of the Provincial PTC should be carried out in line with the National Pharmaceutical and Therapeutics Committees Guideline, as informed by the National Policy for the Establishment and Functioning of PTCs. Section 12 of the National Pharmaceutical and Therapeutics Committees Guideline and National Policy for the Establishment and Functioning of PTCs specifies the functions of the PTC 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

[30] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

[31] National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, 19 January 2015

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[4].

According to the Terms of Reference of the X PTC. The committee shall consist of members appointed by the Head of the Department of Health, including the following ex-officio members with full voting rights:

- Chief Director: Pharmaceutical Services (Chairperson);
- Head of Pharmaceutical Services in the province;
- Manager of the Medical Supplies Depot; and
- NEMLC representative/s.

Areas of expertise of the remaining members should include a minimum of the following:

- Evidence-based medicine;
- Primary level health care services;
- Secondary level health care services;
- Tertiary level health care services;
- Rational Medicine Use;
- Medical supply management;
- Financial management;
- Antimicrobial Stewardship;
- Bioethics; and
- Medical Academia.

The following is a summary of applicants recommended for appointed:

Table 1: Summary of Applicants Recommended for Appointment

Name	Area of Relevant Expertise	Number of Years of Experience	Position Held	Organisation/ Institution	Sector (public/ private/ NGO/ Academia/ Other)

(Refer to Annexure B for detailed information regarding applicants recommended for appointment)

Please find included in support of this letter:

- Annexure A: Summary of all applicants for the X PTC;
- Annexure B: Summary of applicants recommended for appointment to the PTC; and
- Annexure C: Appointment Letters for the X PTC for signature by the [Executive Authority].

CONCLUSION

It is therefore recommended that the [Executive Authority]:

- Approves the appointment of individuals to serve on the X PTC, for a period of three years from the date of approval; and
- Signs the appointment letters.

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 4: Letter of Appointment

[ADDRESS]

Dear X

LETTER OF APPOINTMENT TO THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

On behalf of the X Department of Health, I have the pleasure of informing you of your appointment onto the X Pharmaceutical and Therapeutics Committee (PTC) for a period of three years from the date of approval.

Section 12 of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa specifies the functions of the PTC 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.*

The details of the next PTC meeting will be communicated in due course.

Members are subject to the provisions and procedures surrounding Conflict of Interest and Confidentiality applicable to that of the PTC, and are expected to abide by the PTC's Terms of Reference. The Terms of Reference, Declaration of Interest and Confidentiality documents will be communicated to you on commencement of your Term of Office.

Please kindly indicate your acceptance or rejection of this appointment using the attached template. Your technical and professional input to the PTC will be appreciated.

Kind regards

[NAME]

[DATE]

[POSITION]

[INSTITUTION]

Appendix 5: Letter of Acceptance or Rejection

[ADDRESS]

Dear X.

ACCEPTANCE/ REJECTION OF APPOINTMENT TO THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

I, _____ hereby **accept/ decline** the appointment to the X Pharmaceutical and Therapeutics Committee (PTC), for a period of 3 (three) years from the date of approval.

(If accepting) I have read, understood and accepted the Terms of Reference, Declaration of Interest and Confidentiality documents. I understand that the PTC reserves the right to terminate my appointment if any false information is supplied.

I fully understand the commitments required for participation in the PTC, as set out in the Terms of Reference.

_____

[NAME]

_____

[DATE]

_____

[WITNESS 1]

_____

[WITNESS 2]

Appendix 6: Letter of Resignation

[ADDRESS]

Dear X,

LETTER OF RESIGNATION FROM THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

This serves as notice of my resignation from the X Pharmaceutical and Therapeutics Committee (PTC) as of [DATE]. The reasons for my resignation include the following:

- [REASON]
- [REASON]
- [REASON]

I would like to thank you for the opportunity to serve on the PTC and wish the committee well for the future.

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 7: Letter of Acceptance of Resignation

[ADDRESS]

Dear X,

LETTER OF ACCEPTANCE OF RESIGNATION FROM THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

On behalf of the X Pharmaceutical and Therapeutics Committee (PTC), I would like to acknowledge your resignation and to thank you for your commitment and contribution as a member of the PTC.

Your expertise and input has been of great value and the PTC wishes you well in your future endeavours.

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 8: Letter of Termination of Membership

[ADDRESS]

Dear X

LETTER OF TERMINATION OF MEMBERSHIP FROM THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

On behalf of the X Pharmaceutical and Therapeutics Committee (PTC), this serves to inform you of the termination of your membership from the PTC. The reasons for the termination of your membership, in line with the Terms of Reference of the PTC, are as follows:

- [REASON]
- [REASON]
- [REASON]

The PTC would like to thank you for your contribution and wish you well in your future endeavours.

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 9: Terms of Reference for the X Provincial Pharmaceutical and Therapeutics Committee

1. Abbreviations

ADR	Adverse Drug Reaction
AMD	Affordable Medicines Directorate
AMR	Antimicrobial Resistance
DDD	Defined Daily Dose
EML	Essential Medicines List
HOPS	Head of Pharmaceutical Services
IPC	Infection Prevention and Control
KPI	Key Performance Indicator
MUE	Medicine Use Evaluation
NEMLC	National Essential Medicines List Committee
PTC	Pharmaceutical and Therapeutics Committee
RMU	Rational Medicine Use
STGs	Standard Treatment Guidelines
TLART	Third Line Antiretroviral Therapy
TORs	Terms of Reference
VEN	Vital, Essential, Necessary

2. Purpose of the Provincial PTC

The Pharmaceutical and Therapeutics Committee (PTC) promotes "the rational use of medication through the development of relevant policies and procedures for medication selection, procurement, distribution and use and through the education of patients and staff"[32]

[32] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

The PTC acts as a feedback mechanism between National, Provincial and District Departments of Health, as well as facilities, and is important to improve rational medicine use. The PTC is essential for 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"[33].

3. Accountability of the Provincial PTC

The Provincial PTC is appointed by the Head of the Provincial Department of Health or person to whom this function was delegated, and will provide him or her with annual reports regarding its various functions as determined by the Terms of Reference (TORs). Reports are required to be produced in line with requirements set out in the National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.

To this end, the Provincial PTC will establish indicators to gauge its performance. All policies and formularies emanating from the Provincial PTC's work will be submitted to the head of Department of Health for approval prior to implementation.

4. Authority to Act

4.1. Constitution of the Republic of South Africa (Act 108 of 1996)[34]

Section 27 of the South African constitution provides "access to health care services" as a basic human right for citizens. As such, all reasonable measures must be taken to ensure that this right is protected, promoted, and fulfilled within the limits of available resources.

4.2. National Health Act (Act 61 of 2003)[35]

The National Health Act states the requirements 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 address questions of health policy and delivery of quality health care services".

4.3. Pharmacy Act (Act 53 of 1974, as amended)[36]

The rules relating to GPP published in terms of the Pharmacy Act 53 of 1974 specify the minimum standards for the selection of pharmaceuticals by institutional pharmacies. In terms of Section 2.4.1:

(a) A Pharmacy and Therapeutics Committee (PTC) must be in place for the selection of pharmaceuticals and the promotion of rational drug use.

---

[33] National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, 19 January 2015

[34] Republic of South Africa. 1996. *Constitution of the Republic of South Africa (Act No. 108 of 1996).* Pretoria, South Africa.

[35] Republic of South Africa. 2003. *National Health Act (Act No. 61 of 2003).* Pretoria, South Africa.

[36] Republic of South Africa. 1974. *Pharmacy Act (Act No. 53 of 1974).* Pretoria, South Africa.

(b) A pharmaceutical code list and/or formulary and/or the Essential Drug List must be used as the basis for medicine therapy and the promotion of the rational use of medicine. This system includes a formulary of approved pharmaceutical substances as well as a policy and procedures for the approval and provision of medicine not included in the formulary as required.

(c) The Pharmacy and Therapeutics Committee must be responsible for the formulary.

5. Goal of the PTC

The PTC should be committed to the governance of an effective medicine management system to provide equitable and reliable access to medicines and quality care while making the best use of available resources[37].

6. Functions

Functions of the Provincial PTC should be carried out in line with the National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, as informed by the National Policy for the Establishment and Functioning of PTCs.

Section 12 of the National Pharmacy and Therapeutics Committees Guideline and National Policy for the Establishment and Functioning of PTCs specifies the functions of the PTC 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[4].

This involves the following enabling functions:

6.1. Governance including:

- Development and implementation of policies and procedures for recruitment,

[37] National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa, 19 January 2015

selection, appointment, resignation and termination of membership of PTC members;
- Implementation and review of TORs for Provincial, District and Health Establishment PTCs;
- Development of policies and implementation of governance procedures to manage Conflict of Interest and Declaration of Confidentiality; and
- Decision-making at PTC meetings and activity planning.

6.2. Formulary Management, applying evidence-based medicine review and pharmaco-economic principles based on safety and quality, efficacy, cost-effectiveness and affordability, including:
- Development and maintenance of formularies on at least a quarterly basis, including the review of applications for non-EML medicines and applications for individual patient use in accordance with the National Guideline for the Development, Management and Use of Formularies and Affordable Medicines Directorate Policy for the Management of Master Data Relating to Medicine;
- Motivation for addition, deletion or amendment of medicines on the EML through the development of peer review mechanisms and evidence-based medicine reviews to the National Essential Medicines List Committee (NEMLC); and
- Developing, reviewing and implementing national and provincial treatment guidelines and protocols.

6.3. Implementation and review of National medicine-related policies and procedures, including therapeutic interchange and the implementation of the Antimicrobial Resistance (AMR) One Health National Strategy Framework through governance, monitoring and stewardship of antimicrobial use.

6.4. Developing and implementing systems to promote Rational Medicine Use (RMU) including:
- Identifying medicine use problems, such as through Defined Daily Dose (DDD) analysis, ABC Analysis, Indicator Studies and Medicine Use Evaluations (MUEs);
- Understanding medicine use problems through focus group discussions, in-depth interview, structured observations and questionnaires;
- Developing and implementing strategies to improve medicine use, such as through education, audits, clinical pharmacy programmes and treatment protocols; and
- Monitoring pharmacovigilance and patient safety.

6.5. Monitoring medicine availability using the National Surveillance Centre Dashboards and assisting with efficient procurement systems to ensure minimisation of stock-outs in line with National Stock Out Escalation Protocol.

6.6. Reviewing tender specifications and providing forecast estimates based on provincial need for the tender process.

6.7. Developing and implementing mechanisms for effective and efficient communication and relationship management with stakeholders

6.8. Expenditure planning and monitoring, including non-EML use and pharmaceutical expenditure as compared to budget.

6.9. Human resource management, including training and capacity building, administrative support, retention and succession planning.

6.10. Monitoring and evaluation against standards and indicators, ensuring transparency and reporting according to relevant timelines.

7. Monitoring and Reporting

7.1. The Provincial PTC is granted authority to request health establishment and district reports that enable it to carry out its functions. These reports must remain confidential and be used solely for the intended purpose.

7.2. Reporting by the Provincial PTC should be performed in line with requirements set out in the National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa.

8. Composition of the Provincial PTC

8.1. The committee shall consist of members appointed by the Head of the Department of Health, including the following ex-officio members with full voting rights:

a) Chief Director: Pharmaceutical Services;
b) Head of Pharmaceutical Services (HOPS) in the province;
c) Manager of the Medical Supplies Depot; and
d) NEMLC representative/s.

8.2. Areas of expertise of the remaining members should include a minimum of the following:

a) Evidence-based medicine;
b) Primary level health care services;
c) Secondary level health care services;
d) Tertiary level health care services;
e) RMU;
f) Medical supply management;
g) Financial management;
h) Antimicrobial Stewardship;
i) Bioethics; and
j) Medical Academia.

8.3. The Provincial PTC and its subcommittees may co-opt persons from specific specialties as they deem necessary, to assist in the finalisation of a matter on the agenda. Such co-opted persons shall have no voting powers.

8.4. Other members of the NEMLC or its technical committees may serve on the Provincial PTC as technical advisors, when required.

8.5. The table below provides details for appointment, voting status and impact on quorum for different types of members:

Table 1: Different Types of Committee Members

Meeting Component	Member	Ex-Officio Member	Co-opted Member
Appointment	Application or nomination (depending on PTC level)	Nominated due to current job title	Nominated due to expertise
Voting Status	Full voting rights	Full voting rights	No voting rights
Impact on Quorum	Affects quorum	Affects quorum	No impact on quorum

9. Appointment Period

9.1. Members, excluding ex-officio members as mentioned above, shall be appointed to a term of three years and the Head of Department of Health may, after due consideration, extend the term beyond the three-year cycle.

9.2. A member may be re-appointed for two consecutive terms (of a three-year cycle), after which time, the member will need to submit a new full application to be appointed onto the PTC. This does not apply to ex-officio members, who will remain as members during their term in office.

9.3. Vacancies will be reviewed in line with the skills base requirements, and appointments will be made when necessary.

10. Termination of Membership and Leave of Absence

10.1. Membership will be terminated when:

- the Head of Health, in the public interest, terminates the membership;
- a member resigns from the PTC, in writing;
- a member does not attend 2 meetings consecutively, without tabling an apology with reasons;
- a member is suspended for misconduct by his/her employer or statutory council; or
- a member fails to adhere to the TORs set out in this document.

10.2. Members should inform the Secretariat in writing of a leave of absence prior to a meeting; in the case of sabbatical leave, the members should inform the Chairperson three months in advance.

11. Code of Conduct and Conditions of Membership

11.1. Members are expected to:

- avail themselves for meetings, punctually and for the whole of the scheduled meeting time;
- indicate their unavailability to attend any meeting in writing to the Secretariat, in good time;
- act with the highest professional and ethical standards at all times;
- contribute to debate in an informed, rational and evidence based way and take decisions solely in the interest of the public;
- bring their relevant experience and expertise to the PTC;
- make full, and considered and unbiased contributions to the debates and decision decision-making processes of the PTC;
- facilitate communication of the call up notices through the relevant administrative structures and provide technical support in preparing submissions;
- regard the views expressed by individual members of the PTC as confidential;
- respect and value each member's expertise, perspective and contribution;
- make decisions together and take joint responsibility for them;
- be informed and prepared for the meeting by reading the agenda and papers; and
- state all potential conflicts of interest and recuse him/herself as appropriate.

11.2. Under no circumstances may an individual member, except the Chairperson, represent the views and decisions of the PTC with stakeholder groups.

11.3. Members are subject to prescribed provisions and procedures surrounding conflict of interest and confidentiality as specified in the National PTC Guideline.

11.4. There should be no influence within the Provincial PTC by the pharmaceutical or equipment industry. This includes sponsorship of meals or meeting venues of the PTC meetings. Names of members on this committee should be kept confidential as well as all discussions. Minutes of the meeting should therefore not reflect individual names when items are discussed.

11.5. Committee members shall not use the name of the committee in any publication, meeting, negotiation, or promotion without prior approval of the Head of Department of Health.

11.6. Members may not nominate representatives to attend meetings in their absence.

12. Establishment of Subcommittees and Task Teams

12.1. The Provincial PTC, in the execution of its functions, may constitute subcommittees or task teams by means of establishment of specific TORs.

12.2. The following are examples of subcommittees that can be established in accordance with the TORs:

- Formulary Review;
- RMU;
- Procurement Advisory;

- Safety and Quality (including ADR monitoring);
- Antimicrobial Stewardship; and
- Other sub-committees as determined by the PTC e.g. mental health.

12.3. Such subcommittees shall be under the leadership of and chaired by a Provincial PTC member or such other person designated by the Provincial PTC, who shall ensure compliance with the TORs.

12.4. No member or group shall have authority to amend or alter the TORs, adopt any action contrary to the committee, remove any member, or take any action on behalf of the Provincial PTC.

12.5. Any member of any group may be removed by the Provincial PTC whenever the best interests of the committee or the state will be best served by such removal.

12.6. Each subcommittee shall appoint its own Chairperson and Secretariat from amongst its members.

13. Chairperson of the Committee

The Chairperson of the Committee shall:

13.1. Play a leadership role in developing and implementing an effective Provincial PTC and sound policies and procedures;

13.2. Implement sound policies and procedures;

13.3. Possess a comprehensive knowledge of the selection, procurement, management, and rational use of medicines;

13.4. Foster open, fair and collegial discussion among all committee members while maintaining focus on the issues at hand, arriving at consensus;

13.5. Upon arrival at consensus, summarise the decision and call for members to propose and second the adoption of the motion;

13.6. If a consensus cannot be reached, the final decision on how to resolve the matter will reside with the Chairperson;

13.7. Facilitate the development and maintenance of policies and guidance documents with advice and consultation from all relevant stakeholders;

13.8. With the assistance of the Secretariat, finalise all Provincial PTC documents for submission to the Head of Department of Health;

13.9. Have respect for committee members from diverse backgrounds, perspectives, and sources of expertise and promote a culture of respect among committee members and key

stakeholders;

13.10. Conduct the scheduled meetings in accordance with the annual schedule; and

13.11. Hand over to Vice-Chairperson if unavailable for any reason

14. Secretariat

The Secretariat shall:

14.1. Develop and maintain an annual schedule for the meetings of the Provincial PTC. Invitations to meetings in line with the schedule will be sent timeously before the meeting;

14.2. Convene and make all the necessary logistics arrangements for the meetings;

14.3. Advise the Provincial PTC on policy, administrative and regulatory matters;

14.4. Compile draft minutes of the meeting in consultation with the Chairperson:

- Draft minutes will be circulated within 30 working days after the meeting;
- The Chairperson will facilitate the discussion around the accuracy on the minutes at the next PTC meeting. Any recommended changes will be discussed at this point. The Chairperson will then ask for a proposer and a seconder for adoption of the minutes, who will both sign the minutes together with the Chairperson.

14.5. Coordinate and facilitate any research required for the Provincial PTC to perform its functions;

14.6. Compile relevant documents to be tabled at the Head of Department meetings; and

14.7. Maintain information regarding the performance of the Provincial PTC.

15. Agenda

15.1. A draft agenda will be determined by the Secretariat and finalised in consultation with the Chairperson of the committee.

15.2. Standing items of the Agenda include the following:

- Welcome and apologies;
- Declaration of Conflict of Interest and Confidentiality;
- Adoption of previous minutes;
- Matters arising;
- Activity plan progress;
- Feedback on previous NEMLC and/or other PTC meetings;
- Formulary Management;
    - Motivations for addition, deletions and amendments
    - Medicine reviews

    - Individual Patient Access review (including TLART)
- Rational Medicine Use;
    - DDD Analysis, ABC analysis, indicator studies, MUEs reports
    - Qualitative analysis reports
    - Educational Interventions reports
    - Safety, quality assurance, and ADR reports
- Feedback on AMR trends and antimicrobial stewardship conducted;
- Tender specification review (if applicable);
- Expenditure Planning;
    - Non-EML use
    - Pharmaceutical Expenditure vs Budget
- Medicine supply management, including availability and stock-outs;
- Other matters arising; and
- Way Forward (Actions, responsibility and timelines).

16. Urgent Matters

The committee will appoint members who, together with the Chairperson, shall constitute the executive committee. Urgent matters will be attended to by the executive committee and then ratified by the full PTC at the next meeting.

The following will be considered as urgent matters:

16.1. When public health may be compromised if a medicine is not added or removed from the Provincial Formulary;

16.2. Resistance to an antimicrobial agent or safety concerns with a medicine listed on the Provincial Formulary have become evident; and

16.3. Urgent Individual patient access applications;

17. Attendance at Meetings

17.1. The Provincial PTC shall meet at least quarterly.

17.2. The appointed members are expected to attend personally (no substitutions) and all apologies must be submitted in writing to the Secretariat. The member will be permitted to participate via teleconference at the discretion of the Chairperson.

18. Voting and Quorum

18.1. A quorum shall be deemed to be one member more than 50 per cent of members. A quorum of members should be present before the meeting can proceed. Other meeting participants who are not appointed members are excluded from the calculation and do not form part of the quorum.

18.2. All business of the Provincial PTC shall be transacted by motion or resolution, which

may be made by any member in attendance, including the Chairperson, and shall require a seconder.

18.3. Voting on motions or resolutions shall be by a show of hands, unless a member asks that the roll be called and that the vote of each member be recorded.

18.4. Each member of the Provincial PTC shall have one vote on each matter submitted to a vote of the committee. The Chairperson shall be a voting member of the committee.

18.5. A majority of 80 per cent of those voting shall be considered a quorum which is required for all matters.

18.6. When a member recuses himself or herself from participating on any matter, that person will not be counted for purposes of determining a quorum.

18.7. The Secretariat will extract the relevant information and decisions and then circulate for implementation.

18.8. A non-quorate meeting will not be able to take any decisions.

19. Communication Strategy

Communication between the Provincial PTC, Heads of Pharmaceutical Services, National Department of Health's Affordable Medicines Directorate and other PTCs is crucial to ensure rational medicine selection and use, as well as effective implementation of decisions.

Communication will follow a two-way pathway according to the below figure:

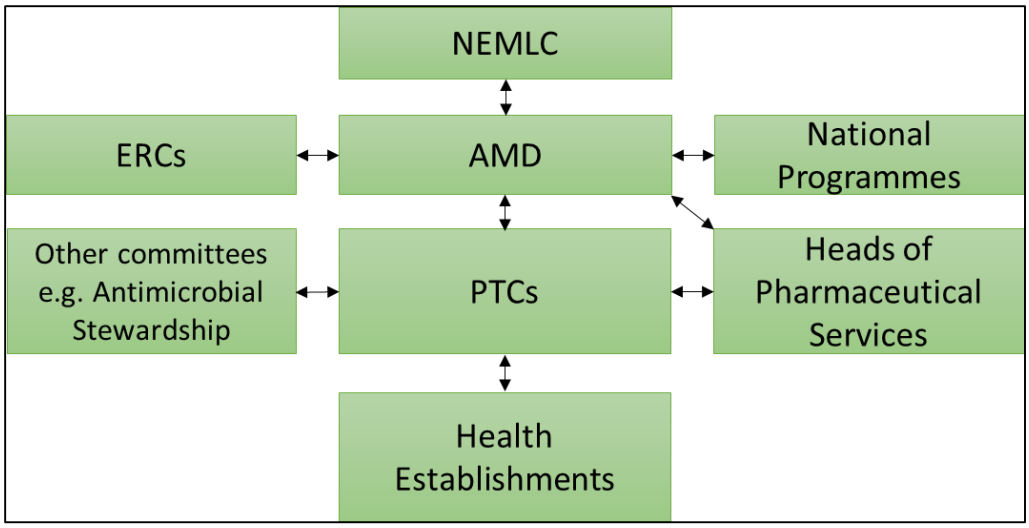

Figure 1: Provincial PTC Communication Diagram

Key:
AMD – Affordable Medicines Directorate (National Department of Health)
ERCs – Expert Review Committees (National Department of Health)
NEMLC – National Essential Medicines List Committee (National Department of Health)

Amendment of Terms of Reference of the X Provincial PTC

TORs should be reviewed within a three-year cycle by the Directorate of Pharmaceutical Services and submitted to the Head of Department of Health for ratification and approval.

The TORs of the Provincial PTC were duly adopted at the meeting of the Provincial PTC on the

_____(day) of _____(month), _____(year)

Signed by

……
Chairperson **Date**

Approved by

……..

Head of Department of Health

Appendix 10: Pharmaceutical and Therapeutics Committee Confidentiality Guideline

A guideline for individuals involved in the work of the X Pharmaceutical and Therapeutics Committee

1. Purpose of Guideline

This Confidentiality Guideline outlines the principles and process to be followed by all individuals involved in the work of the X Pharmaceutical and Therapeutics Committee to declare confidentiality in a clear, comprehensive, and efficient manner.

Confidentiality and transparency are not mutually exclusive and a balance needs to be struck between managing risk whilst maintaining the appropriate degree of transparency required for sound technical decision-making and protection of constitutional rights.

A risk is any event that affects the performance and viability of the PTC and/or its external stakeholders. In terms of leaked information, the risk broadly translates into:

- loss of credibility
- decisions are made externally based on draft material
- reluctance of members to participate in the process and/or loss of momentum of the review
- negative impacts upon the procurement processes
- negative business consequences for various parties including suppliers

This code of practice guides the Chairperson, Secretariat and members of the X Pharmaceutical and Therapeutics Committee and any other individual present at a X Pharmaceutical and Therapeutics Committee working or involved with the X Pharmaceutical and Therapeutics Committee work, as to the circumstances in which they should maintain confidentiality regarding the decisions of the committee and its source documents.

2. Definitions

Commercial entity means any commercial company, organisation, individual, group or association that has or may have a direct or indirect interest in the decisions and work undertaken by a committee, and includes legal or natural persons who (i) own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant commercial entity; (ii) are controlled by; or (iii) are under common control of a

commercial entity. This includes for profit as well as non-profit entities, as well as researchers and research organisations such as universities.

Confidential business information is commercial or financial information considered to be confidential because disclosure may:

1. Impair an individual or commercial entity's ability to obtain necessary information in the future; or
2. Cause substantial harm to the competitive position of the individual or commercial entity which provides the information.

External stakeholders are all stakeholders that have not been designated as internal or who have been granted access to the documentation in terms of a resolution of the X Pharmaceutical and Therapeutics Committee

Internal stakeholders are those subcommittees or task teams constituted by the X Pharmaceutical and Therapeutics Committee with established terms of reference.

Member refers to all individuals appointed to X Pharmaceutical and Therapeutics Committee.

Meeting participant means an individual temporarily included and/or co-opted, as well as observers or any other individuals attending any meeting of a committee.

Proprietary information is information or data belonging to an owner or proprietor, who may have exclusive rights to the manufacture and sale of a specific item.

Sensitive information is information or data in which disclosure, loss, misuse, alteration, or destruction may adversely affect national security or other government interest.

Trade secret is any formula, pattern, device, or information that is used in business which provides a competitive advantage.

2.3 Related Documents

- X Pharmaceutical and Therapeutics Committee Terms of Reference
- X Pharmaceutical and Therapeutics Committee Conflict of Interest Policy

3. SCOPE OF THE GUIDELINE

This code of practice applies to the Chairperson, Secretariat and members of the X Pharmaceutical and Therapeutics Committee. It also applies to any other individual present at a committee meeting or involved with the committee work.

4. INFORMATION THAT IS CONSIDERED CONFIDENTIAL

The document is intended as a guide to the types of information and situations which should remain confidential. Where a committee member or other meeting participant is uncertain as to whether information should be disclosed to an external stakeholder, he or she should seek guidance from the Chairperson of the committee or Secretariat. Alternatively, the interested party should be referred to the National Department of Health's information officer appointed in terms of PAIA and the relevant manual published by this officer. Further guidance as to implementation of PAIA such as grounds for refusal can be found at http://www.doj.gov.za/paia/paia.htm.

Different types of confidential information can be envisaged and may include, but is not limited to:

1. Identity of a developer or reviewer of a technical document;
2. Proprietary information that is supplied to or contained within the committee; and
3. Trade secrets, confidential business information or other sensitive information pertaining to the National Department of Health or another commercial entity.

Leaked information is any information that an individual has access to which is not in the public domain. This includes all documents that are actively being reviewed by the X Pharmaceutical and Therapeutics Committee or National Department of Health, unless approved for external consultation as contemplated in the terms of reference. In its resolution of acceptance of a technical document, the committee should declare the level of confidentiality. For documents approved for consultations, the scope of the consultation should be specified.

5. RISK OF LEAKED OR DISCLOSED CONFIDENTIAL INFORMATION

Disclosure of an individual's identity poses certain risks which include;

- Exposure of the PTC's processes to potential undue pressures from external stakeholders and parties with vested interests which may:
  - Discredit the objectivity and impartiality of the review process.
  - Introduce conflict of interests
- Lack of willingness to participate in future PTC activities.

Leaked or disclosed confidential information may also result in:

- Prolonged PTC processes through the introduction of subjective information by individuals with a vested interest prior to the finalisation of the evidence based consensus process;
- Providing a competitor with a business advantage to a potential supplier in which case it would be considered a trade secret;
- A negative impact upon the Department of Health's ability to generate competition and obtain the best price for commodities;
- Have a negative impact upon the Department of Health actualising a public health outcome; and
- A document being implemented as policy prior to finalisation of the consensus seeking process.

6. POSITION OF THE CHAIRPERSON

The Chairperson of the committee is the individual responsible for compiling information to be communicated to the information officer for disclosure in terms of any approved PAIA application. The Chairperson may consult with the Secretariat or the X Pharmaceutical and Therapeutics Committee in the compilation of such documentation. The affected committee should be informed of such disclosure and should be furnished with a copy for their reference.

The nature, but not necessarily the details of communication with internal and external stakeholders, should be declared as part of the proceedings of the affected committee. In meetings with stakeholders on technical matters, the relevant Chairperson of the technical committee will act as the spokesperson supported by any member of the committee who has agreed to such a meeting and members of the Secretariat.

The Secretariat may meet with stakeholders to discuss matters that are of a procedural or administrative nature or to clarify a technical matter which requires expertise available in the Secretariat provided that the member of the Secretariat has been present in the relevant deliberations.

7. MANAGEMENT OF CONFIDENTIALITY RESTRICTIONS

For the purposes of confidentiality, restrictions refer to information being disclosed verbally, electronically or as a hard copy.

Committee members and other meeting participants should be provided with a copy of the confidentiality guideline and upon review must sign a confidentiality agreement on appointment, and at each committee meeting using the format provided in **Appendix 10a.**

The Secretariat will provide the member or other meeting participant with the guideline and ensure that the confidentiality agreement has been received upon appointment for members and at meeting for non-members.

All source documentation must comply with relevant copyright provisions and should remain confidential unless approved by the committee. During the review strict confidentiality must be maintained on all draft documents until consensus have been reached by the committee that such a document may be released for consultation or public consumption. A member may consult with experts in accordance with the committee's terms of references and in consultation with the committee. Where such consultation requires the disclosure of any significant sections of technical documents, the recipient must sign a confidentiality agreement using the format provided in **Appendix 10a.** When the restriction is lifted, the expert should be informed of such.

The maintenance of confidentiality requires procedural safeguards. Final minutes tabled at committees should not identify the names of individuals, although the working version may have transient reference to individuals using initials in order to track contributions that are outstanding. Although the minutes adopted by the committee may have residual reference to these initials, their removal is considered mandatory and administrative before finalisation.

All materials related to the review process must be stored in a secure manner to prevent unauthorised access. They must be transmitted using secure carriers and technologies. When documentation is no longer required, it must be destroyed using a secure method such as burning or shredding or returned to the Secretariat for destruction.

When a member or other meeting participant is faced with a request for information by an external stakeholder which he or she feels has merit or is in the interest of public health, they should consult the Chairperson of the relevant committee, unless the aforementioned has delegated such powers.

A copy of the confidentiality guideline should be available to any member of the public who expresses an interest in accessing information or where they are of the opinion that the agreement has been transgressed.

Directives and provisions within this guideline remain in force not only during a committee member's term of office, but also after the termination of services with the X Pharmaceutical and Therapeutics Committee for a period of three years unless otherwise specified.

8. HANDLING OF UNWARRANTED DISCLOSURE OF CONFIDENTIAL INFORMATION

A determination should be made as whether the disclosure was:

1. Outside of the provisions of this guideline;
2. Inadvertent; or
3. Clearly in disregard of this guideline.

Discussion should be lead with respect to the harm or potential harm such a disclosure may have held for the review process, individuals who have contributed or the government.

Based on the nature of the disclosure of information, the Chairperson, in consultation with the committee, may rule that the member:

1) Reviews the guideline, discusses its provisions with the Chairperson and signs a new confidentiality agreement;
2) The member takes corrective measures in order to prevent further inadvertent disclosures; and/ or
3) The member is excluded from participation of meetings and/or consultation.

9. Promotion of Access to Information Act

The Promotion of Access of Information Act or 'PAIA" Section 32(1)(a) of the Constitution of the Republic of South Africa Act, No. 108 of 1996 provides that everyone has a right of access to any information held by the state and any information held by another person that is required for the exercise or protection of any rights. The Promotion of Access to Information Act, No. 2 of 2000 is the national legislation which was enacted to give effect to the constitutional right of access to information.

Any member of the public may utilise the avenue of the Promotion of Access of Information Act ("PAIA"), provided such requests are reasonable and have been made in compliance with the administrative procedures that makes provisions for such access.

10. RECORD OF AGREEMENT

The Secretariat should keep a record of Declaration of Confidentiality documents signed and action taken on the unwarranted disclosure of confidential information.

11. PUBLICATION

Information regarding this guideline and agreements with members may be made available to third parties if compelled in terms of the Rules of Court pursuant to litigation or by virtue of the provisions of the Promotion of Access to Information Act, 2000 (Act 2 of 2000). The latter requires the protection of personal information and contains procedures which require consultation with the person to whom the information relates. Therefore, in the event of compulsory disclosure, this will not take place without prior consultation with the affected party.

APPENDIX 10a: DECLARATION OF CONFIDENTIALITY

[X Pharmaceutical and Therapeutics Committee]

I hereby declare that:

1. I have taken cognisance of the provisions in the X Pharmaceutical and Therapeutics Committee Confidentiality Guideline;
2. I understand that I may not divulge any information of whatever nature, which I have obtained or may obtain by virtue of my official duties, to any unauthorised person, whether verbally or in writing, without prior approval of the Head of Department of Health or an official duly authorised by him/her;
3. I understand that the above-mentioned directives and provisions remain in force not only during my term of office, but also after the termination of my services with the X Pharmaceutical and Therapeutics Committee for a period of three years unless otherwise specified; and
4. I am fully aware of the serious consequences which may result from breaking or violating the above-mentioned directives and provisions.

Name	Signature	Date

Appendix 11: Invitation to Attend Meeting

Dear X

INVITATION TO ATTEND THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE MEETING

You are invited to attended the following X Pharmaceutical and Therapeutics Committee Meeting:

Date:

Time:

Venue:

Please kindly confirm your attendance by [DATE]. If you are unable to attend, please kindly indicate the reasons for this. Please send correspondence to [NAME] on [EMAIL ADDRESS].

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 12: Response to Invitation to Attend Meeting

[ADDRESS]

Dear X

RESPONSE TO THE INVITATION TO ATTEND THE X PHARMACEUTICAL AND THERAPEUTICS COMMITTEE MEETING

Thank you for the invitation to attend the following X Pharmaceutical and Therapeutics Committee Meeting:

Date:

Time:

Venue:

A) I would like to cordially accept the invitation and confirm my attendance.
B) Unfortunately, I will not be able to attend the meeting due to the following reasons:

- [REASON]
- [REASON]
- [REASON]

Kind Regards,

_____

[NAME]

_____

[POSITION]

_____

[DATE]

Appendix 13: Meeting Minutes Template

X Pharmaceutical and Therapeutics Committee Meeting Minutes **Date:** **Time:** **Venue:** Minutes Taken By:	
Attendees:	
Name	**Organisation**
Apologies:	
Name	**Organisation**
Absentees:	
Name	**Organisation**
Items Discussed:	
No.	**Item**
1	Welcome and apologies
2	Declaration of Interest and Confidentiality
3	Adoption of Previous Minutes • Proposer: • Seconder:
4	Matters arising
5	Activity plan progress
6	Feedback on other NEMLC and/ or PTC meetings
7	Formulary Management • Motivations for additions, deletions and amendments from formulary • Medicine reviews

8	Individual Patient Access review (including TLART)
9	Rational Medicine Use • DDD Analysis, ABC analysis, indicator studies, MUEs reports • Qualitative analysis reports • Educational Interventions reports • Safety, quality assurance, ADR reports
10	Status of antimicrobial resistance trends and antimicrobial stewardship conducted
11	Tender specification review (if applicable)
12	Expenditure Planning • Non-EML use • Pharmaceutical expenditure vs budget
13	Medicine supply management, including availability and stock-outs
14	Other matters arising
15	Way Forward (Action, responsibility and timeframes):
16	Next PTC Meeting to be held: • Date: • Time: • Venue:

*For each Item discussion, the following should be considered where applicable:

- Decisions made
- Action to be taken and due date

Appendix 14: Meeting Agenda Template

X Pharmaceutical and Therapeutics Committee Meeting Agenda Date: Time: Venue:			
Attendees:			
Name		**Organisation**	
Agenda Items:			
No.	**Time**	**Agenda Item**	**Discussion Lead**
1		Welcome and apologies	
2		Declaration of Interest and Confidentiality	
3		Adoption of Previous Minutes	
4		Matters arising	
5		Activity plan progress	
6		Feedback on other NEMLC and/or PTC meetings (other levels of PTCs related to the applicable PTC - Provincial, District or Institutional)	
7		Formulary Management • Motivations for additions, deletions and amendments from formulary • Medicine reviews	
8		Individual Patient Access review (including TLART)	
9		Rational Medicine Use • DDD Analysis, ABC analysis, indicator studies, MUE reports • Qualitative analysis reports • Educational Interventions reports • Safety, quality assurance, ADR reports	
10		Feedback on antimicrobial resistance and antimicrobial stewardship • Antimicrobial consumption data • Antimicrobial Surveillance Patterns • IPC feedback • Provincial antimicrobial resistance dashboards	

		• Antimicrobial stewardship performed	
11		Tender specification review (if applicable)	
12		Expenditure Planning • Non-EML use • Pharmaceutical expenditure vs budget	
13		Medicine supply management, including availability and stock-outs	
14		Other matters arising	
15		Way Forward (Actions, responsibility and timeframes)	

Appendix 15: Operational Plan Template

X Pharmaceutical and Therapeutics Committee

Operational Plan for [DATE]

Objectives of the PTC

As per the terms of reference, the main objectives of the PTC shall be to (insert as per TOR):

1.
2.
3.

Rationale behind the operational plan

Outcomes

Outcome indicators

Outputs

Output indicators

Operational Plan Gantt Chart

Activities	Q1	Q2	Q3	Q4
Summary activity 1				
Activity 1.1				
Activity 1.2				
Activity 1.3				
Summary activity 2				
Activity 2.1				
Activity 2.2				
Activity 2.3				
Assess impact of activity 1				

Appendix 16: Attendance Tracker

X Pharmaceutical and Therapeutics Committee Meeting

[DATE]

No.	Title	Initial	Surname	[MEETING DATE 1] Response	[MEETING DATE 2] Response	[MEETING DATE 3] Response	[MEETING DATE 4] Response
1				[ATTENDING/ APOLOGIES/ NO RESPONSE]	[ATTENDING/ APOLOGIES/ NO RESPONSE]	[ATTENDING/ APOLOGIES/ NO RESPONSE]	[ATTENDING/ APOLOGIES/ NO RESPONSE]
Total invitations sent							
Total attending							
Total apologies							
% ATTENDING = [total attending] x 100 / [total invitation sent]							
Quorum Reached (Yes/ No)							

NOTE: Quorum is reached when % ATTENDING = 50% + 1 person

Appendix 17: Standard Operating Procedure for the Development and Management of a Formulary by Pharmaceutical and Therapeutics Committees (PTCs)

INSTITUTION	National Department of Health
DEPARTMENT	Affordable Medicines Directorate
PURPOSE OF SOP	To provide guidance on how to develop and manage a formulary
VERSION	1

FUNCTIONAL ROLES AND RESPONSIBILITIES

Pharmaceutical and Therapeutics Committees (PTCs) - Develop formularies based on national and local mandates on the MMDS; Manage formularies taking into consideration changes to the STGs and EML and local context; Constantly update formularies and manage additions, deletions and amendments; Communicate and implement formulary changes, including phase in and out of medicines on the formulary.

Prescribers, Dispensers and Inventory Managers - Provide input to PTCs with respect to the addition of an item/s to a formulary, the deletion of an item/s from a formulary or any other amendments thereto.

DEFINITIONS

Formulary – A continually updated list of medicines and related information, used in the diagnosis, prophylaxis, or treatment of disease and promotion of health, to satisfy the needs of the majority of the population served by a particular health establishment/s.

Medicine Master Data - The common data that forms the basis for all transactions relating to the core functions of AMD namely medicine selection, contracting, supply chain, contract management and use of medicine which helps to ensure that transactions take place in accordance with the requisite rules, governance and protocols and enables interoperability.

Medicine Master Data System (MMDS) - The system used to manage all medicine master data.

PRINCIPLES

Hierarchy of Formulary Development and Management

Formulary development and management follows a hierarchical approach based on the level of care according to Figure 1 below:

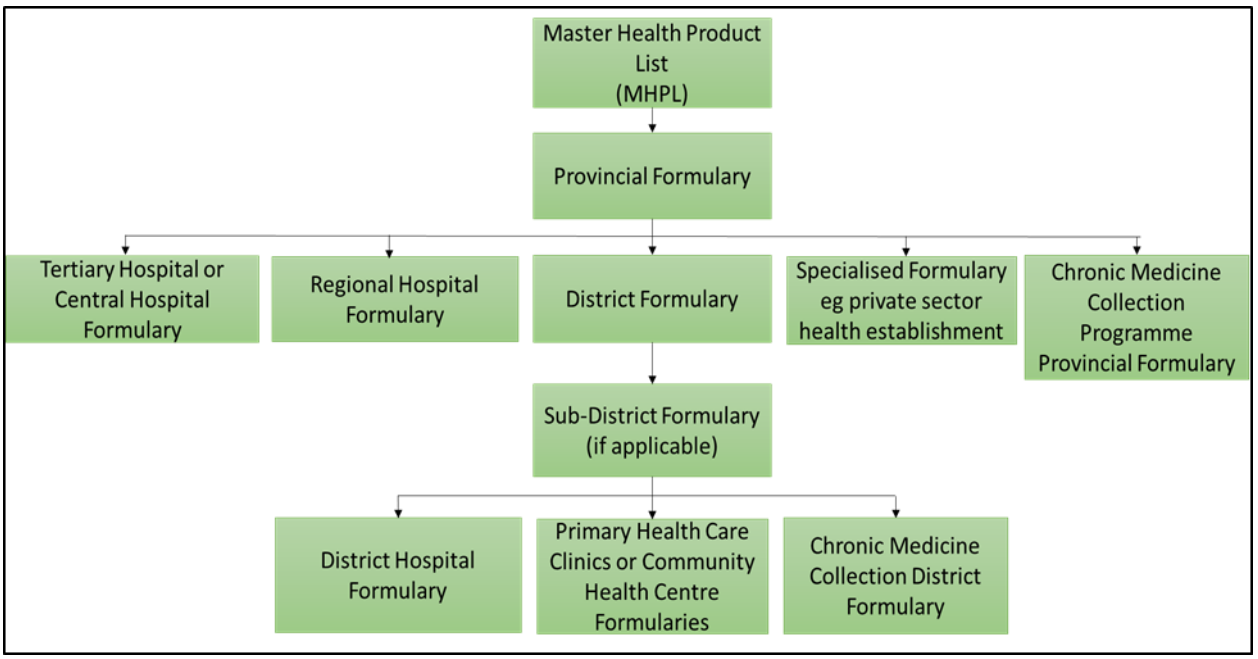

Figure 1: Hierarchy of Formulary Development and Management

When considering whether to add a medicine to a formulary, effectiveness, safety, cost-effectiveness and affordability must be evaluated using a structured, evidence-based approach.

ONLY 10% of medicines on the formulary should be non-EML. Medicines that are designated as non-EML (reviewed but not approved) should not form part of a formulary.

Prescriber privilege may be assigned to a prescriber for which authority is given by the PTC to prescribe a medicine that falls outside of the standard applicable prescriber level.

Applications for medicines designated as “EML – subject to restrictions” should be evaluated by PTCs on individual basis as to whether the application fits the criteria defined only. Evaluation for cost effectiveness and clinical efficacy does not need to occur due to the review undergone by NEMLC.

PROCEDURE

Formulary Development	
1.	Analyse the list of EML medicines on the Medicine Master Data System (MMDS) and add all EML medicines that are used for the package of services available to the formulary.
2.	If a non-EML medicine is to be included in the formulary, analyse the MMDS to determine if the medicine is present as non-EML (not reviewed) or non-EML (under review) on the formulary of the level of care above, or on the MHPL (as applicable according to level of the PTC). a. If not present on the formulary of the level above, submit an application to add a non-EML medicine to the PTC controlling the formulary of the level above using the Technical Review Form included in the PTC Guideline. b. If not present on the MHPL, submit an application to the EDP to add a medicine to the MHPL, using the template included in the PTC Guideline (Provincial PTC only).
3.	Select medicines to be included as non-EML (not reviewed) or non-EML (under review) from the MMDS.
4.	Assign prescriber privilege to any applicable medicines on the formulary.
5.	Circulate the formulary for review by relevant stakeholders including PTC members and healthcare professionals. Educate relevant stakeholders on the purpose of the formulary, reasons for specific medicine choices and importance of adherence to it when prescribing, dispensing and ordering medicine.
6.	Finalise the formulary following stakeholder feedback and publish on the MMDS.
Formulary Management	
7.	Update the formulary at least every quarter, or on an adhoc basis when there is an urgent change to the EML.
8.	Review changes to the EML on the MMDS.
9.	For medicines that have been removed from the EML and changed to non-EML (reviewed but not approved), consult with relevant stakeholders to remove these off the formulary.
10.	Medicines being removed from a formulary should be phased out carefully, with thorough consultation with affected stakeholders including prescribers, to ensure that treatment of patients is not adversely affected.
11.	Review all non-EML medicines to determine whether they may be removed and replaced by a medicine on the EML.

12.	Review additions to the EML and add to the formulary if aligned with the package of services.
13.	Allow motivation by healthcare professionals to add non-EML medicines to the formulary, through application together with clinical evidence using the Technical Review Form included in the PTC Guideline. Once the Technical Review Form has been approved by the Provincial PTC, it should then be escalated to EDP for consideration at NEMLC.
14.	If clinical evidence is sufficient and budget allows, add the medicine to the formulary according to Step 3 and 5 above.
15.	Repeat Steps 6 and 7 above.
Individual Patient Access	
16.	Allow applications for Individual Patient Access to be submitted to the PTC on the approved form (Appendix 19 of the PTC Guideline). Evaluate on individual basis whether the application fits the criteria defined in the Formulary Guideline.
17.	Consider cost-effectiveness and affordability of the medicine to treat the individual patient.
18.	If a medicine is approved for Individual Patient Access, apply to the EDP to add the medicine to the MHPL and mark as “Individual Patient Access” on the formulary in the MHPL. If the application is rejected, provide feedback as to the reasons for this.
EML Subject to Restrictions (Special Access)	
19.	Allow applications for Special Access (indicated at “EML – subject to restrictions”) to be submitted to the PTC on the approved form, such as that included in the PTC Guideline.
20.	The PTC should either approve or reject the application, including reasons if the patient does not meet the criteria.

AUTHORISATION OF SOP

REVISION NO	REVISION DETAILS	DEPARTMENT NAME	FULL NAME	TITLE	SIGNATURE	DATE	REVISION DATE
1	N/A						

Appendix 18:

National Essential Medicine List

Indicate the Level of Care Medication Review Process

Component:

MEDICINE MOTIVATION:

1. **Executive Summary**

Date:
Medicine (INN):
Medicine (ATC): *http://www.whocc.no/atc_ddd_index/*
Indication (ICD10 code): *http://apps.who.int/classifications/icd10/browse/2016/en*
Patient population:
Prevalence of condition: [article citation AND hyperlinked]
Level of Care:
Prescriber Level:
Current standard of Care:
Efficacy estimates: (preferably NNT)
Motivator/reviewer name(s):
PTC affiliation:

2. **Name of author(s)/motivator(s)**

3. **Author affiliation and conflict of interest details** *[Organisation, Involvement/receipts]*
   http://www.health.gov.za/index.php/component/phocadownload/category/194

4. **Introduction/ Background**
   Contextualisation – why we need it and why alternatives already on EDL are not suitable.

5. **Purpose/Objective i.e. PICO question** [comparison to current standard of care for a specific indication]:
   -P *(patient/population):*
   -I *(intervention):*
   -C *(comparator):*
   -O *(outcome):*

6. **Methods:**
   a. **Data sources** *e.g. Medline, EMBASE, Pubmed, etc.*
   b. **Search strategy** *Cut and paste your search strategy – the idea being that if an update is required at a later stage, the same strategy can be used. Describe briefly what you ended up with – e.g. 14 RCTs, of which 3 were duplicate publications, two observational studies, etc.*
   c. **Excluded studies:** *Describes briefly which you have rejected and why*

Author, date	***Type of study***	***Reason for exclusion***

   d. **Evidence synthesis –**[article citation AND hyperlinked] *Brief (don't get carried away!) critical appraisal of included studies, including key drawbacks (e.g. underpowered, control medication dose too low, etc) Include key objective*

endpoints effect sizes with their confidence intervals and p values. Doesn't need to be too detailed, but should reference the appropriate study, which should ideally be available in full text (a pdf is easiest.)

Author, date	***Type of study***	**n**	**Population**	**Comparators**	**Primary outcome**	**Effect sizes**	**Comments**

e. **Evidence quality:** *You may have said it all under evidence synthesis, but just a line or so on the quality of the whole evidence 'package'.*

7. **Alternative agents:** *List therapeutic alternatives, if they exist, with supporting evidence for comparable dose for this specific indication.*

EVIDENCE TO DECISION FRAMEWORK

	JUDGEMENT	**SUPPORTING EVIDENCE & ADDITIONAL CONSIDERATIONS**
QUALITY OF EVIDENCE	**What is the overall confidence in the evidence of effectiveness?** Confident ☐ Not confident ☐ Uncertain ☐	
BENEFITS & HARMS	**Do the desirable effects outweigh the undesirable effects?** Benefits outweigh harms ☐ Harms outweigh benefits ☐ Benefits = harms or Uncertain ☐	
THERAPEUTIC INTERCHANGE	Therapeutic alternatives available: Yes ☐ No ☐ List the members of the group.	Rationale for therapeutic alternatives included: References:

<table>
<tr><td></td><td>List specific exclusion from the group:</td><td>Rationale for exclusion from the group:

References:</td></tr>
<tr><td>VALUES & PREFERENCES / ACCEPTABILITY</td><td>Is there important uncertainty or variability about how much people value the options?
Minor ☐ Major ☐ Uncertain ☐

Is the option acceptable to key stakeholders?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
<tr><td>RESOURCE USE</td><td>How large are the resource requirements?
More intensive ☐ Less intensive ☐ Uncertain ☐</td><td>Cost of medicines/ month:<table><tr><th>Medicine</th><th>Cost (ZAR)</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table>Additional resources:</td></tr>
<tr><td>EQUITY</td><td>Would there be an impact on health inequity?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
<tr><td>FEASIBILITY</td><td>Is the implementation of this recommendation feasible?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
</table>

Type of recommendation	We recommend against the option and for the alternative ☐	We suggest not to use the option or to use the alternative ☐	We suggest using either the option or the alternative ☐	We suggest using the option ☐	We recommend the option ☐

Recommendation

Rationale:

Level of Evidence:

Review indicator:

Evidence of efficacy ☐ Evidence of harm ☐ Price reduction ☐

VEN status:

Vital ☐ Essential ☐ Necessary ☐

Monitoring and evaluation considerations

Research priorities

References: *Remember to reference the excluded studies. Vancouver style format*

NDoH_EML_Motivation_Technical Review Form_v5.0_2016Oct28

Appendix 19: Individual Patient Access Application

Date
Reference

Annexure C details the sections of the application that must be completed for individual patient access scenarios

Section 1: Patient and Medicine Details					
Patient's Name:		Age:	Gender:		
Weight:		Height:			
Hospital or ID Number:		Patient Contact Number:			
Patient Category:	H0	H1	H2	PHP	
Medical Aid: Yes / No	Medical Aid Name:		Number:		
Diagnosis (ICD10 code and words):					
Current Standard of Care for Diagnosis:					
Medicine (International Non-proprietary Name/ INN): *http://www.whocc.no/atc_ddd_index/*					
Medicine (ATC): *http://www.whocc.no/atc_ddd_index/*					
Dosage Form and Strength/s:					
Level of care:					
Prescriber level:					
Treatment Regimen:					
Duration of Treatment: (in days/ months)					

Section 2: Current Medical Details and Previous Medical History

N.B. This section is only relevant for Non-EML Medicines and EML medicine to be available at lower level of care

	INN	Treatment Regimen	Duration of Treatment
Current medicine therapy:			

	INN	Dosage Regimen	Duration of Treatment
Previous medicine therapy:			

Section 3: Clinical Summary

N.B. This section is only relevant for Non-EML Medicines and EML medicine to be available at lower level of

Section 4: Motivation with Evidence

Section 5. Cost Effectiveness and Clinical Efficacy

N.B. This section is only relevant for Non-EML Medicines

Annexure A provides guidance on how to complete the Medicine Review. The complete medicine review and

5.1 Estimated benefit. Annexure B provides guidance on this section

Effect measure	
Risk difference (95% CI)	
Number Needed to Treat (NNT)	

5.2: Motivating information (Level of evidence based on the SORT system)

A. New product: High quality systematic reviews or peer-reviewed high quality randomised controlled trials (Level I)

Author	Title	Journal ref

B. Comparison product(s): Poorer quality controlled trials or high quality observational studies (Level II)

Author	Title	Journal ref

5.3: Cost-considerations

Type of Cost Consideration performed: *(mark applicable option)*

- Daily cost determination
- Cost minimisation
- Cost-effectiveness analysis

Other relevant cost information if available:

Author	Title	Journal ref

If approved, would a cost saving be effected? If so, please indicate where. (Please tick)	
Duration of hospital stay	
Laboratory tests	
Other diagnostic tests	
Outpatients attendances	
Nursing services	

Section 6: Application and Approval Details

6.1. To be completed by Applicant

Motivation prepared by:

Name	Designation	Signature
		Date

Institution:

6.2. To be completed by Head of Department

Funds available: Yes/No

Approved: Yes/No

Name	Signature
	Date

6.3. To be completed by Chairperson of Institutional PTC

Approved: Yes/ No

Chairperson of Institutional PTC:

Name	Signature
	Date

Annexure A

National Essential Medicine List
Medication Review Process
Component: Individual Patient Access

MEDICINE MOTIVATION:

8. **Executive Summary**

Date:
Medicine (INN):
Medicine (ATC): *http://www.whocc.no/atc_ddd_index/*
Indication (ICD10 code): *http://apps.who.int/classifications/icd10/browse/2016/en*
Patient population:
Prevalence of condition: [article citation AND hyperlinked]
Level of Care:
Prescriber Level:
Current standard of Care:
Efficacy estimates: (preferably NNT)
Motivator/reviewer name(s):
PTC affiliation:

9. **Name of author(s)/motivator(s)**

10. **Author affiliation and conflict of interest details** *[Organisation, Involvement/receipts] http://www.health.gov.za/index.php/component/phocadownload/category/194*

11. **Introduction/ Background**
Contextualisation – why we need it and why alternatives already on EDL are not suitable.

12. **Purpose/Objective i.e. PICO question** [comparison to current standard of care for a specific indication]:
-P *(patient/population):*
-I *(intervention):*
-C *(comparator):*
-O *(outcome):*

13. **Methods:**
    a. **Data sources** *e.g. Medline, EMBASE, Pubmed, etc.*
    b. **Search strategy** *Cut and paste your search strategy – the idea being that if an update is required at a later stage, the same strategy can be used. Describe briefly what you ended up with – e.g. 14 RCTs, of which 3 were duplicate publications, two observational studies, etc.*
    c. **Excluded studies:** *Describes briefly which you have rejected and why*

Author, date	***Type of study***	***Reason for exclusion***

    d. **Evidence synthesis –**[article citation AND hyperlinked] *Brief (don't get carried away!) critical appraisal of included studies, including key drawbacks (e.g.*

underpowered, control medication dose too low, etc) Include key objective endpoints effect sizes with their confidence intervals and p values. Doesn't need to be too detailed, but should reference the appropriate study, which should ideally be available in full text (a pdf is easiest.)

Author, date	***Type of study***	**n**	**Population**	**Comparators**	**Primary outcome**	**Effect sizes**	**Comments**

e. **Evidence quality:** *You may have said it all under evidence synthesis, but just a line or so on the quality of the whole evidence 'package'.*

14. Alternative agents: *List therapeutic alternatives, if they exist, with supporting evidence for comparable dose for this specific indication.*

EVIDENCE TO DECISION FRAMEWORK

	JUDGEMENT	**SUPPORTING EVIDENCE & ADDITIONAL CONSIDERATIONS**
QUALITY OF EVIDENCE	**What is the overall confidence in the evidence of effectiveness?** Confident ☐ Not confident ☐ Uncertain ☐	
BENEFITS & HARMS	**Do the desirable effects outweigh the undesirable effects?** Benefits outweigh harms ☐ Harms outweigh benefits ☐ Benefits = harms or Uncertain ☐	
THERAPEUTIC INTERCHANGE	Therapeutic alternatives available: Yes ☐ No ☐ List the members of the group. List specific exclusion from the group:	Rationale for therapeutic alternatives included: References:

<table>
<tr><td></td><td></td><td>Rationale for exclusion from the group:

References:</td></tr>
<tr><td>VALUES & PREFERENCES / ACCEPTABILITY</td><td>Is there important uncertainty or variability about how much people value the options?
Minor ☐ Major ☐ Uncertain ☐

Is the option acceptable to key stakeholders?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
<tr><td>RESOURCE USE</td><td>How large are the resource requirements?
More intensive ☐ Less intensive ☐ Uncertain ☐</td><td>Cost of medicines/ month:<table><tr><th>Medicine</th><th>Cost (ZAR)</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table>Additional resources:</td></tr>
<tr><td>EQUITY</td><td>Would there be an impact on health inequity?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
<tr><td>FEASIBILITY</td><td>Is the implementation of this recommendation feasible?
Yes ☐ No ☐ Uncertain ☐</td><td></td></tr>
</table>

Type of recommendation	We recommend against the option and for the alternative	We suggest not to use the option or to use the alternative	We suggest using either the option or the alternative	We suggest using the option	We recommend the option
	☐	☐	☐	☐	☐

Recommendation

Rationale:

Level of Evidence:

Review indicator:

Evidence of efficacy	Evidence of harm	Price reduction
☐	☐	☐

VEN status:

Vital	Essential	Necessary
☐	☐	☐

Monitoring and evaluation considerations

Research priorities

References: *Remember to reference the excluded studies. Vancouver style format.*

Annexure B

Cost Effectiveness and Clinical Efficacy

Estimated benefit

- Effect measure: this is the clinical outcome that was reported in the clinical trial such as BP, FEV, $CD_{4,}$ VL etc.
- Risk Benefit: this should be reported in the clinical trial and, in most cases, includes the 95% confidence level (95% CI). Absolute risk reduction, also termed risk difference, is the difference between the absolute risk of an event in the intervention group and the absolute risk in the control group
- Number Needed to Treat (NNT): gives the number of patients who need to be treated for a certain period of time to prevent one event. It is the reciprocal of the absolute risk or can be calculated using the formula below.

Calculations

	Bad outcome	**Good outcome**	**Total patients**
Intervention group	*a*	*c*	*a + c*
Control group	*b*	*d*	*b + d*

Measure	**Equation**
Absolute risk	[b/(b+d)] – [a/(a+c)]
Number needed to treat	1 ÷ [b/(b+d)] - [a/(a+c)]
Relative risk	[a/(a+c)] ÷ [b/(b+d)]
Odd ratio	$\frac{[a/(a+c)] \div [c/(a+c)]}{[b/(b+d)] \div [d/(b+d)]} = (a/c) \div (b/d)$

Motivating information (Level of evidence based on the SORT system)

Level I	Good quality evidence	• Systematic review of RCTs with consistent findings • High quality individual RCT
Level II	Limited quality patient orientated evidence	• Systematic review of lower quality studies or studies with inconsistent findings • Low quality clinical trial • Cohort studies • Case – control studies
Level III	Other	• Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series

Newer product: for most newer products, level I evidence such as high quality systematic reviews or peer-reviewed high quality randomised controlled trials should be identified and referenced in the space provided

Comparison product(s): many of these products were developed prior to the wide use of randomised controlled trials. However, there may be level I evidence where the product was used as the control arm for a newer product. If no level I evidence can be identified, then level II data from poorer quality controlled trials or high quality observational studies should be referenced in the space provided on the motivation form.

Cost considerations

- Where a published reference supporting the review of cost is available comments should be made regarding its applicability to the South African public sector environment.
- Possible unpublished information that can be included:
  - Cost per daily dose for course of therapy – for long term or chronic therapy such as hypertension the usual daily dose should be calculated (one single dose multiplied by the number of times dosed per day for the patient) then converted into the number of dosing units e.g. tablets. This is then used to calculate the cost per day.
  - Cost minimisation is used where there is evidence showing equivalent outcomes between the alternatives being compared; (e.g. generic equivalents) and aims to identify the least costly treatment by identifying all the relevant costs associated with the treatment.

- Cost-effectiveness analysis is used to compare treatment alternatives that differ in the degree of success in terms of the therapeutic or clinical outcome. By calculating a summary measurement of efficiency (a cost-effectiveness ratio), alternatives with different costs, efficacy rates, and safety rates can be fairly compared. If any of these calculations have been performed tick the relevant block on the motivation form and send all calculations as an attachment. If possible, the calculation spread sheet should be supplied electronically.

Annexure C

Individual Patient Application Scenarios and Applicable Sections for Completion

Section to Complete	1. Patient and Medicine Details	2. Current medical details and Medical History	3. Clinical Summary	4. Motivation with Evidence	5. Cost Effectiveness and Clinical Efficacy	6. Application and Approval Details
EML medicine to be available at lower level of care	Yes	Yes	Yes	Yes e.g. evidence of appropriate prescriber available, diagnosis	No	Yes
Non-EML Medicine	Yes	Yes	Yes	Yes e.g. diagnosis	Yes	Yes
PTC pre-approved Individual Patient Access	Yes	No	No	Yes e.g. evidence that patient meets defined criteria	No	Yes
Special Access (EML – subject to restrictions)	Yes	No	No	Yes – evidence that patient meets defined criteria	No	Yes
Down-referral	As above – a detailed referral letter and prescription from referring health establishment is required to contain the above information.					