

Gauteng Provincial Pharmacy and Therapeutics Committee

Biennial Report

1 April 2012- 31 March 2014



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ABBREVIATIONS AND ACRONYMS

ADR	adverse drug reaction
ATC	Anatomical Therapeutic Chemical [classification]
CL	Circular Letter
CV	curriculum vitae
EML	essential medicines list
PPTC	Provincial Pharmaceutical and Therapeutics Committee
PTC	Pharmaceutical and Therapeutics Committee
RMU	rational medicines use
STG	standard treatment guideline
TORs	terms of reference

DEFINITIONS

ABC analysis: Classification of inventory items into three categories (A,B, and C) according to the value of their annual usage, which is useful for analysing medicine consumption and utilisation, comparing actual versus planned purchases, justifying procurement budgets, guiding procurement patterns, and setting priorities for stock management.

Adverse drug reaction:A response in human or animal to a medicine which is harmful and unintended. This might occur at any dosage and can also result from lack of efficacy, off-label use, overdose, misuse, or abuse of a medicine.

ATC classification: Anatomical Therapeutic Chemical (ATC) classification system¹, in which the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties. Medicines are classified in groups at five different levels.

Conflict of interest: A state that exists when an individual's secondary interests, (e.g. personal, financial) interfere with or influence judgements regarding the individual's primary interests (e.g. patient welfare, education, research integrity).

Essential medicines:Medicines that satisfy the priority health care needs of the population; essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.²

Evidence-based medicine:A process of independent and objective decision making based on consideration of objective data with integration of best research evidence (external) with clinical expertise (internal) and patient values.

Formulary:A list of medicines that are approved for use in the health care system by authorised prescribers and dispensers.

Medicine use evaluation:A performance improvement method that focuses on evaluating and improving medication use processes with the goal of optimal patient outcomes.³

Rational medicine use: A system that requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.⁴

Terms of reference: Terms that describe the purpose and structure of a committee. They are essential because they provide a documented basis for making future decisions as well as developing a common understanding of the objective among members and stakeholders.

¹http://www.whocc.no/atc/structure_and_principles/ (accessed 13/02/2014)

²http://www.who.int/medicines/services/essmedicines_def/en/ (accessed 13/02/2014)

³<http://www.ashp.org/DocLibrary/BestPractices/FormGdlMedUseEval.aspx> (accessed 13/02/2014)

⁴http://www.who.int/medicines/areas/rational_use/en/ (accessed 11/03/2014)

FOREWORD

To effectively fulfil its mandate of promoting access to safe, quality, and cost-effective medicines in Gauteng Province, the Provincial PTC cannot work as an isolated entity. The Provincial PTC needs to actively engage with and among other institutional PTCs, healthcare providers, the Medical Supplies Depot, health programmes, communities, and the National Department of Health. Building trust between the Provincial PTC and its counterparts is essential for effective implementation of the Provincial PTC's decisions. To trust, one first needs to understand. The Provincial PTC believes that communication and transparency are the first steps towards establishing a fruitful collaboration with relevant stakeholders.

It is my pleasure to introduce the first *Gauteng Provincial Pharmaceutical and Therapeutics Committee Biennial Report*. This 2012–14 biennial report is intended to present information related to the structure and functioning of the Gauteng Provincial PTC, the activities carried out during the period, the achievements realised, and the challenges encountered.

My thanks go to the members and secretariat of the Gauteng Provincial PTC for their commitment to quality care in our province.

We also acknowledge support provided by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, funded through the US Agency for International Development (USAID) under the terms of cooperative agreement number AID-OAA-A-11-00021.



Mrs. Nocawe Thipa
Chairperson of the Gauteng Provincial PTC

Date: 15 July 2014

INTRODUCTION

In South Africa, the provision of pharmaceutical services is guided by the National Drug Policy (NDP), which was adopted in 1996. The health goal of the NDP is “to ensure the availability and accessibility of essential medicines to all citizens.” Within a resource-constrained environment, irrational medicine use has the potential to compromise available health care resources, hence posing a serious threat to the functioning of the health system. The development and use of national essential medicines lists (EMLs) as well as the establishment of pharmaceutical and therapeutics committees (PTCs) have been identified as key interventions to promote rational medicine use (RMU). In South Africa, the National Essential Medicines List Committee is responsible for the development of the country’s standard treatment guidelines (STGs) and EML for the three levels of care—primary health care and the secondary and tertiary hospital levels.

The NDP requires the establishment and strengthening of multidisciplinary committees, the PTCs, to ensure rational, efficient, and cost-effective supply and use of medicines.

The PTCs are responsible for supporting the implementation of the EML and STGs within their constituencies. Among other functions, PTCs develop a formulary list that provides prescribers and dispensers with information on the medicines authorised for use within the sphere of the health care system within which they are practising. PTCs conduct regular assessments to identify potential medicine use problems and design interventions to correct them. Because PTCs are custodians for quality therapeutic care, a sound decision making process and good governance among PTCs are of paramount importance to avoid undue influence.

The Gauteng Provincial PTC aims to promote equitable access to quality, safe, and cost-effective medicines for people in Gauteng Province and preserve healthcare resources through RMU and strong governance systems. Now, two years after its revitalisation, the Gauteng Provincial PTC takes a look back at its achievements and challenges.

REVITALISATION OF THE GAUTENG PROVINCIAL PTC: A LONG BUT SUCCESSFUL JOURNEY

The process of revitalisation of the Gauteng Provincial PTC was started in 2011 under the leadership of the Gauteng Health Head of Department, Dr N. Xundu.

The first step entailed the development of new terms of reference (ToRs) for the Gauteng Provincial PTC, with the establishment of four sub-committees, mirroring the structure of the National Essential Medicines List Committee. The four sub-committees (Figure 1) are:

- Formulary sub-committee
- Procurement sub-committee
- Safety and Quality sub-committee
- Rational Medicine Utilisation sub-committee

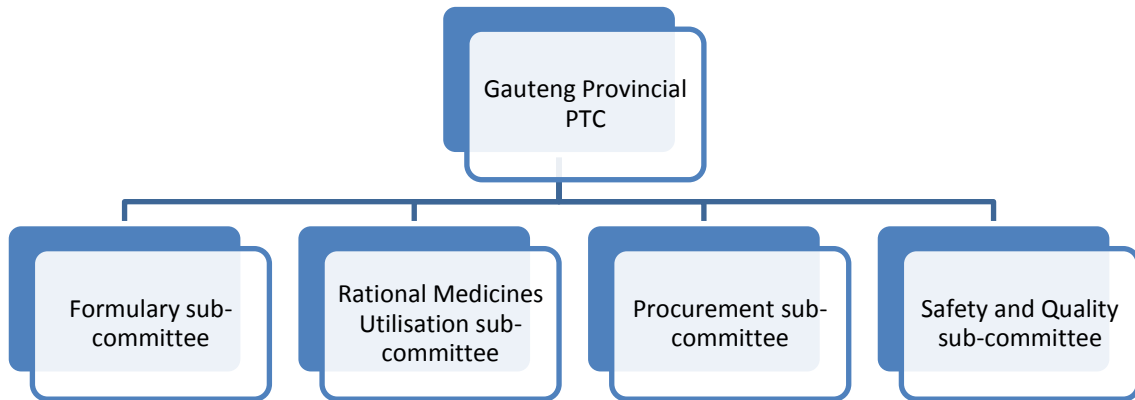


Figure 1. Four sub-committees of the Gauteng Provincial PTC

The National Essential Medicines List Committee's Confidentiality Policy and Declaration of Interest Policy were adapted for the use of the Provincial PTC.

A stringent selection process followed, ensuring that all expertise needed in the Provincial PTC, as listed in the membership requirements section of the ToRs, were represented and that the selection was fair and transparent.

The total number of members selected per area of expertise was determined by the ToRs and served as a basis for the selection process.

The process (Figure 2), started after the draft ToRs were approved by the Head of Department, was as follows:

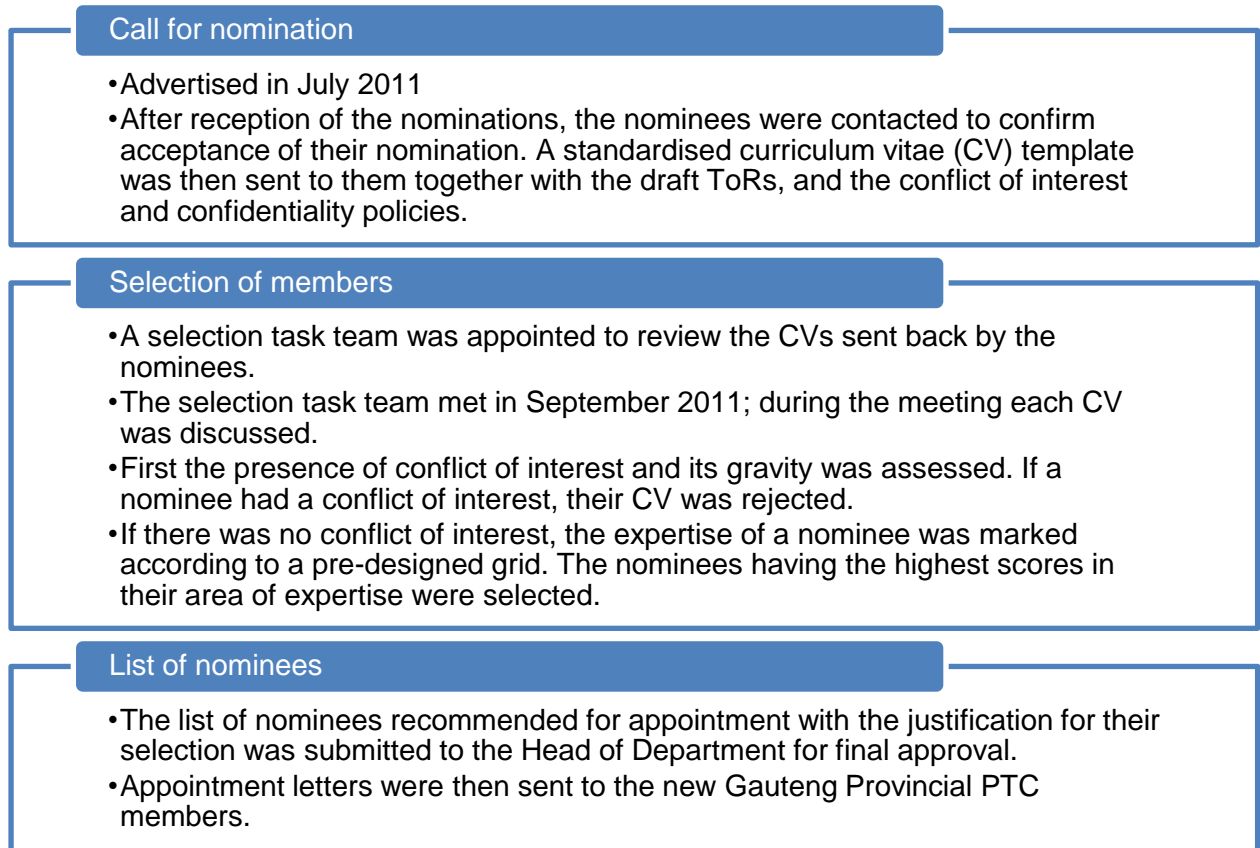


Figure 2. Process for the selection of the Gauteng Provincial PTC members

The newly appointed Gauteng Provincial PTC met for the first time on 15 March 2012; during the meeting, comments and amendments to the ToRs were made. The final version of the Gauteng Provincial PTC ToRswas adopted by the members during the second meeting of the Gauteng Provincial PTC, on 4 July 2012.

The ToRs of the Gauteng Provincial PTC cover the following:

- Purpose of the Gauteng Provincial PTC
- Accountability
- Authority to act
- Principles that govern functioning of the Gauteng Provincial PTC
- Objectives of the Gauteng Provincial PTC
- Functions of the Gauteng Provincial PTC
- Monitoring and reporting
- Membership requirements
- Appointment period, resignation, termination, and leave of absence
- Establishment of sub-committees and task teams
- Role and function of the chairperson
- Role and function of the secretariat
- Standing items on the Gauteng Provincial PTC agenda
- Urgent matters
- Attendance
- Voting and quorum
- Decision implementation
- Communication strategy
- Amendments

STRUCTURE OF THE GAUTENG PROVINCIAL PTC

The ToRs makes provision for 25 members with full voting rights. There are four categories of members (Figure 3), only two of which have full voting rights.

Ex-Officio Members (5)

These are members obliged to serve on the PTC by virtue of their position within the Department of Health. Ex-officio members have full voting rights.

Selected Members(20)

These members are selected to ensure representation of the expertise needed for the PTC to function optimally, as listed in the membership requirements section of the ToRs. They are appointed for a period of three years renewable and have full voting rights.

Each selected member was assigned to one of the four sub-committees during the Gauteng Provincial PTC meeting held on 15 March 2012. Each Gauteng Provincial PTC member must be actively involved in his/her sub-committee activities.

In case of one member resigning, the CVs previously received for the specific area of expertise will be reviewed. If no suitable candidate is found, there will be another call for nominations for the specific area of expertise.

Secretariat (9)

District Pharmacists from the five districts and drug controllers from the four academic hospitals compose the secretariat. There is one principal secretariat coordinator who oversees the secretariat activities. By virtue of their position, these pharmacists are obliged to serve on the secretariat of the PTC; they have no voting rights.

Co-Opted Members

Following the allocation of Gauteng Provincial PTC members to one of the four sub-committees, new members were co-opted based on their expertise. The co-opted members have no voting rights and as such are not counted in the quorum. They serve to enrich discussions with the expert knowledge relevant to the sub-committees.

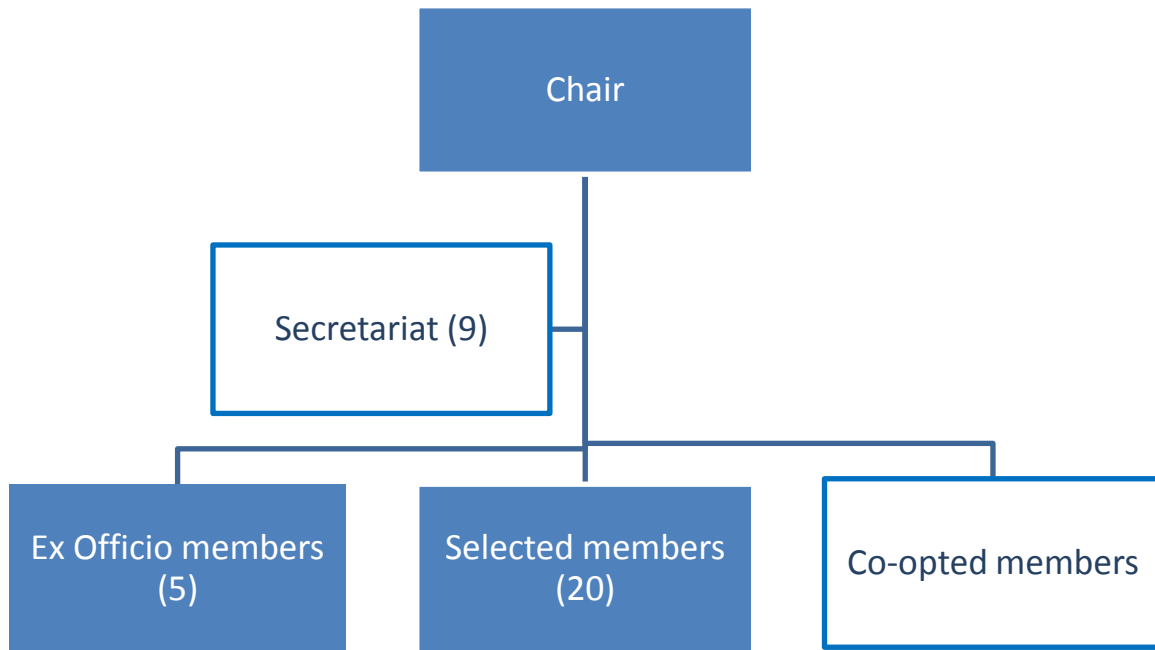


Figure 3. Structure of the Gauteng Provincial PTC

FUNCTIONING OF THE GAUTENG PROVINCIAL PTC

The Gauteng Provincial PTC holds quarterly meetings. A quorum of 64% of members is needed for the meeting to take place. Should the quorum not be reached, the meeting would be postponed.

During these meetings (generally run for five hours), each standing item on the agenda is discussed. Each sub-committee presents the work done during the quarter as well as their recommendations for discussion and resolution by the Gauteng Provincial PTC. A majority of 80% is required for adoption of a resolution.

All the discussions and decisions are properly recorded and documented. The minutes are reviewed by a panel of members for accuracy, clarity, and true reflection of the meeting; the minutes are then sent to all the members for review prior to the next meeting, where they will be adopted. The minutes of the meetings are available upon request to the chairperson.

District and institutional PTCs have an opportunity to submit items for discussion and recommendation to the secretariat of the Gauteng Provincial PTC following the communication strategy established by the ToRs.

The two-way communication (Figure 4) ensures that the resolutions made by the Gauteng Provincial PTC are circulated to all districts and institutions for implementation.

STANDING ITEMS ON THE PPTC AGENDA

1. Declaration of conflict of interest
2. Minutes
3. Matters arising
4. Feedback on NEMLC meeting
5. Feedback on national tenders
6. Stock-outs
7. Safety, quality assurance, and ADR reports
8. Rational medicine use
9. ABC analysis / VEN analysis
10. Pharmaceutical expenditure versus budget
11. Expenditure on non-EML
12. Local (institutional) PTC reports
13. Formulary
14. Named patient report
15. Drug supply management report

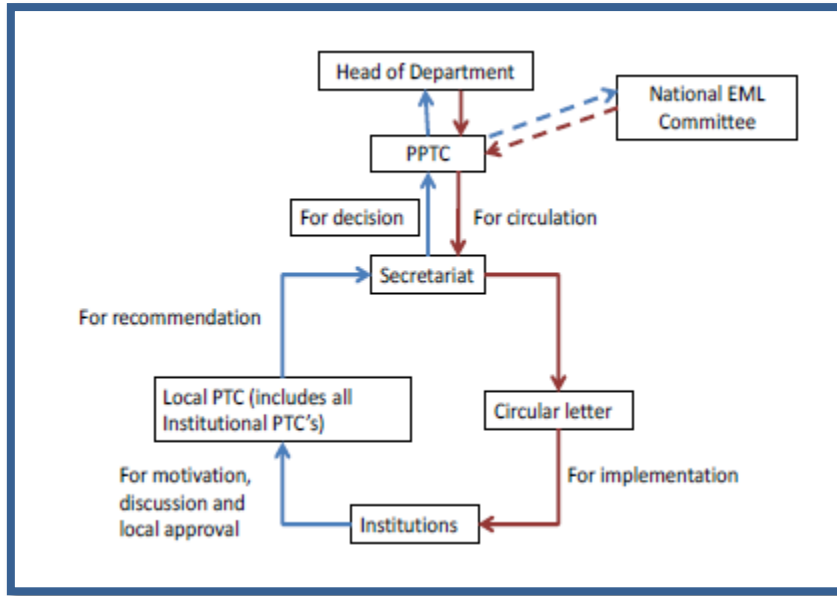


Figure 4. Gauteng Provincial PTC communication strategy

SO MUCH HAS BEEN DONE: INTERVENTIONS AND ACHIEVEMENTS

As the Gauteng Provincial PTC strives to promote access to quality health care in the province, the principles of equity, transparency, and evidence-based medicine are at the core of each intervention developed and resolution taken. The Gauteng Provincial PTC, as the custodian of governance principles in the province in all matters related to pharmaceuticals and therapeutics, has established strong governance systems to guard against conflict of interest or breach of confidentiality and ensure transparency and accountability.

Achievements

Guidelines for Implementation of PTCs in Gauteng(Circular Letter [CL] 02 of 2014)

Institutional and district PTCs play an essential role in promoting RMU in healthcare facilities. However, the functions and role of local PTCs will differ according to the level of care provided at the facility.

To support local PTCs in improving their functionality and strengthening governance across the province, the Gauteng Provincial PTC has developed *Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province* (Figure 5). These guidelines address the functions and role of local PTCs per level of care, governance structures and processes, accountability and responsibilities, and the communication strategy in the province between PTCs.

The guidelines provide the necessary tools for the local PTCs to fulfil their role effectively and efficiently.

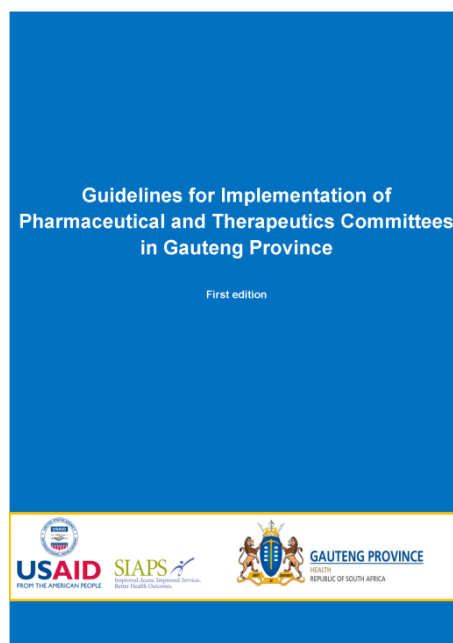


Figure 5. Guidelines for implementation of PTCs in Gauteng

Formulary Maintenance: Standardised Process for Application to Access Non-EML Items

The principle of equity among all South Africans for use of medications governs the functioning of the Gauteng Provincial PTC. In respect to this principle, the Gauteng Provincial PTC has developed a procedure for local institutions to request access to new medications, typically non-EML and non-Gauteng Medicine Formulary items. The process for application to access non-EML items (Figure 6) can be found in the *Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province*.

The process followed by local institutions to request access to new medications is designed to ensure respect of the equity principle at all times by providing all local institutions with access to the same level of expertise during the selection process.

The stratified process reinforces the governance principle and assists in avoiding influence of pharmaceutical companies in the final decision making.

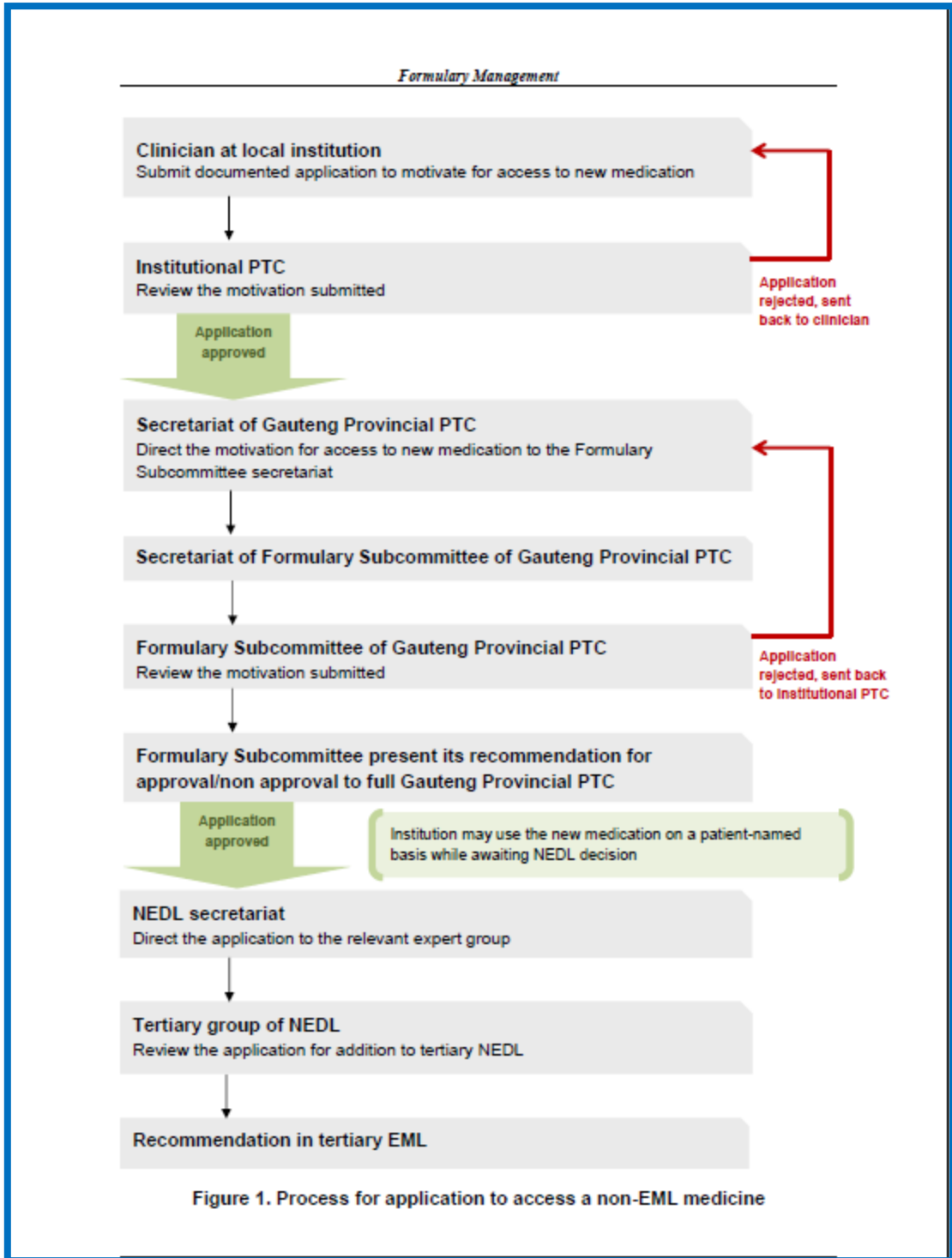


Figure 6. Process for application to access a non-EML medicine

Formulary Decisions (CL01 of 2014)

Following analysis of expenditure per medicine and per therapeutic class, the Gauteng Provincial PTC reviewed the available evidence and reached the conclusion on appropriate interventions that could result in significant reduction in expenditure without compromising safety and efficacy. For instance, it is estimated that switching patients from nifedipine to amlodipine and from perindopril to enalapril would result in savings of up to R30million to the province. The decisions ranged from restricting medicines to a higher level of care to requesting pre-approval by the institutional PTC for removal from the provincial formulary.

The following decisions were adopted by the Gauteng Provincial PTC over the period:

Antihypertensive medicines

- **Rationale for the decision:** Contract prices
- Amlodipine to replace nifedipine XL for the treatment of hypertension; nifedipine XL will only be available on motivation per patient at regional and tertiary hospitals
- Enalapril to replace perindopril for the treatment of hypertension; perindopril will only be available on motivation per patient at regional, tertiary, and central hospitals

Oral antidiabetics

- **Rationale for the decision:** Not recommended in the latest edition of the EML
- Acarbose and glipizide to be removed from the Gauteng formulary

Proton-pump inhibitor

- **Rationale for the decision:** EML recommendation
- Parenteral pantoprazole to be used as an emergency medicine at hospital level for the treatment of gastric bleeding only where omeprazole cannot be used or is ineffective

Vitamins

- **Rationale for the decision:** Not recommended in the latest edition of the EML
- Parenteral vitamin C to be removed from the Gauteng formulary
- Parenteral vitamins B₁ and B₁₂ to be removed from the Gauteng Primary Health Care formulary

Parenteral iron

- **Rationale for the decision:** Not recommended in the latest edition of the EML
- Parenteral iron to be removed from the Gauteng Primary Health Care formulary
- Parenteral iron to be restricted to tertiary level except for lower-level hospitals with dialysis unit

Parenteral paracetamol

- **Rationale for the decision:** Not recommended in the latest edition of the EML or by the Gauteng Provincial PTC
- If approved by the institutional PTC, parenteral paracetamol should be restricted to one ampoule per patient for control of post-op pain

Diclofenac

- Parenteral and oral diclofenac to be removed from the Gauteng formulary
- Only the non-steroid anti-inflammatory medicines listed in the formulary should be used

Chloramphenicol

- **Rationale for the decision:** Not recommended in the latest edition of the EML
- Parenteral chloramphenicol to be removed from Gauteng formulary

Glutamine

- Glutamine-containing products not to be procured in the province
- Only non-glutamine-containing preparation to be used in Gauteng Province

Rational Medicine Use Decisions (CL01 of 2014)

To promote RMU in the province, the Gauteng Provincial PTC conducts regular assessments to identify potential inappropriate use of medicine. ABC analyses are performed on a quarterly basis; to get a more comprehensive picture, analyses are done alternatively per item and per ATC class (Anatomic Therapeutic and Chemical). When potential inappropriate use has been identified, the need for intervention or for further investigation is discussed among Gauteng Provincial PTC members.

The interventions are designed to support the safe and cost-effective use of medicines at district and hospital levels by strengthening the compliance with the National STGs.

The following interventions were designed and implemented by the Gauteng Provincial PTC over the period:

Use of surfactant for the treatment of hyaline membrane disease

- **Rationale for assessment of usage:** Difference in contract prices
- **Intervention:** Analysis of the cost per milligram of surfactant; cost of poractant per milligram higher compared to beractant
- **Recommendation:** Institutions should preferably purchase the most cost-effective beractant 4 ml and 8 ml instead of poractant 1.5 ml and 3 ml

Rational usage of intravenous phenytoin

- **Rationale for assessment of usage:** High usage of intravenous phenytoin raised safety concerns because of the need for careful cardiac monitoring
- **Intervention:** Analysis of quantities of intravenous phenytoin issued to individual facilities followed by communication to facilities on their own usage and EML recommendations on usage of intravenous phenytoin
- **Recommendation:** Remove intravenous phenytoin from Gauteng Primary Health Care formulary because it is not recommended in the latest edition of the EML for the primary health care level
- **Recommendation:** Hospitals to reinforce and promote safe use of intravenous phenytoin as per hospital-level EML

Rational usage of insulin pen sets

- **Rationale for assessment of usage:** High usage of insulin pen sets has large cost implications
- **Intervention:** Analysis of quantities of insulin, pen sets, and vials issued to individual facilities followed by communication to facilities on their own usage and EML recommendations on usage of pen sets (children and visually impaired patients)
- **Recommendation:** Hospitals and district services to reinforce the recommendation of the EML regarding usage of insulin pen sets (pre-filled syringes)

Rational usage of antibiotics


- **Rationale for assessment of usage:** Inappropriate and unnecessary use of antibiotics leads to antimicrobial resistance
- **Intervention:** Analysis of quantities of antibiotics issued to individual facilities followed by communication to facilities on their own usage
- **Recommendation:** All institutional PTCs to establish an antimicrobial stewardship sub-committee to promote rational use of antimicrobials per recommendation of the EML

Cost-effective use of lamotrigine and sodium valproate

- **Rationale for assessment of usage:** Sodium valproate is more expensive than lamotrigine in the management of epilepsy in adult patients
- **Intervention:** Analysis of quantities of lamotrigine and sodium valproate (oral) issued to individual facilities followed by communication to facilities on their own usage
- **Recommendation:** All institutional PTCs to investigate the use of sodium valproate versus lamotrigine in the management of epilepsy in adult patients and implement cost-effective measure as needed

Reporting Requirements from the Institutional PTCs (CL01 of 2014)

The template developed by the Gauteng Provincial PTC aimed to assist the local PTCs in reporting on key activities pertaining to hospital and district PTC functions. The template (Figure 7) is available in the *Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province*.



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REPORTING TEMPLATE FOR PTC MEETINGS

Name of PTC:	
Date of meeting:*	
List of attendees:	
Apologies:	
1. Resolutions:	
2. Actions implemented (findings, corrective interventions developed, and results):	
3. Unresolved matters that need input or discussion at GPPTC level:	
4. List of items outside EML procured for previous period:	
5. Red flags in facility pharmacy (e.g., human resource implications, stock availability):	
6. ADR reporting and product quality issues:	
7. Cost drivers (top 10) or ABC analysis:	
8. Report of expired medicines:	
9. Interventions undertaken to support the rational medicines use:	

*Please include a copy of the PTC meeting minutes with this report. Please submit this report to the regional PTC secretariat for submission to the GPPTC.

Figure 7. Reporting template for PTC meetings

Baseline data was requested but received from only 60% of the PTCs. The information collected highlighted the strengths and weaknesses in PTC functionality. Through regular monitoring of PTCs activities, the Gauteng Provincial PTC will undertake the appropriate intervention(s) to strengthen the PTCs' functionality in the province.

Standard for Procurement and Use of Non-Pharmaceuticals (CL24 of 2012)

One of the Gauteng Provincial PTC's purposes is to develop and maintain medicine procurement systems that are compliant with relevant policy and statutory requirements and optimise cost efficiencies.

The expenditure versus allocated budget for pharmaceutical and non-pharmaceutical items was presented and reviewed on a quarterly basis. With no EML or formulary for the non-pharmaceutical items, the Gauteng Provincial PTC identified the need to develop a procurement system to optimise cost efficiency.

Ongoing Activities

Pharmacovigilance

The Gauteng Provincial PTC aimed to enhance the pharmacovigilance system in the province. To promote reporting of adverse drug reactions (ADRs) and product quality problems, the document *Guidelines for Reporting Adverse Drug Reactions and Quality Product Problems* was developed. Over the period, the ADR reports received were reviewed by the Gauteng Provincial PTC and compiled in a provincial ADR database for further analysis.

New training material was developed as a pilot project at Helen Joseph Hospital to improve the quality of reporting and streamline the process for reporting. The Gauteng Provincial PTC is awaiting the assessment of the intervention on the quality and frequency of reporting.

Budget monitoring

The provincial pharmaceutical expenditure against allocated budget and the percentage of expenditure on non-EML items out of overall pharmaceutical expenditure are monitored on a quarterly basis.

Formulary maintenance

The maintenance of the Gauteng Provincial formulary is an ongoing activity aimed to ensure alignment with the EML and the national contracts. During the process, a number of additional areas have been flagged for further investigation. These include large volume parenteral and oral antibiotics.

Rational medicines use

The Gauteng Provincial PTC conducts regular assessments and then designs and implements interventions to address the inappropriate medicine use identified.

CHALLENGES

Implementation of Gauteng Provincial PTC's Interventions by Local PTCs

The Gauteng Provincial PTC establishes the standards in the province, conducts regular assessments, and designs interventions to investigate and/or correct identified problems. The PPTC plays an advisory role and has to rely on the district and hospital PTCs for the implementation of the interventions designed.

Although the Gauteng Provincial PTC has the authority to act, the level of responsiveness of the institutions and their willingness to collaborate with the Gauteng Provincial PTC is a challenge and slows down the implementation of the interventions.

Operational Issues

The Gauteng Provincial PTC has encountered operational challenges, such as securing a suitable venue, having a functioning budget for printing, catering, and transport for some members to attend the quarterly meetings.

During these quarterly meetings, each sub-committee presents its work and recommendations for the Gauteng Provincial PTC to take the final decision. The work is done by the members outside the meetings. The amount of work needed for the Gauteng Provincial PTC was not expected by some members, who chose as a result to resign.

CONCLUSION

This report has covered the structure and functioning of the Gauteng Provincial PTC to provide greater insight into its role and functions in an effort to ensure the quality of therapeutic care in the province.

The activities undertaken and the challenges encountered highlighted the need for greater commitment by all role players and stakeholders towards ensuring that the people of Gauteng have access to quality, safe, and cost-effective medicines.

Its innovative structure has allowed the Gauteng Provincial PTC to build a robust governance system and sound decision making process, pre-requisites for an effective and efficient use of existing resources. The positive aspect of the sub-committees translated, among other benefits, into the strong promotion of RMU in the province. Ultimately, the development of a guidance document for local PTCs ensured that the benefits gained at provincial level cascaded down to hospital and district levels PTCs for an integrative and comprehensive approach towards an optimum use of available resources.