health

Department:
Health
REPUBLIC OF SOUTH AFRICA

National Guideline for the Development, Management and Use of Formularies

1. ABBREVIATIONS

AMD	Affordable Medicines Directorate
CHC	Community Health Centre
EDP	Essential Drugs Programme
EML	Essential Medicines List
ERC	Expert Review Committee
HOPS	Head of Pharmaceutical Services
INN	International Non-proprietary Name
IT	Information Technology
MHPL	Master Health Product List
MMDS	Medicine Master Data System
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee
PDoH	Provincial Department of Health
PHC	Primary Health Care
PMPU	Provincial Medicine Procurement Unit
PPTC	Provincial Pharmaceutical and Therapeutics Committee
PTC	Pharmaceutical and Therapeutics Committee
RMU	Rational Medicine Use
STG	Standard Treatment Guideline
TQEML	Tertiary/Quaternary Essential Medicines List

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2. DEFINITIONS

Dosage Form: The pharmaceutical form in which the active ingredients and excipients, and physical formulation of a medicine is presented.

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.[1] The EML status of a medicine is independent of its pack size but is dependent on its dosage form and indication.

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 the Affordable Medicines Directorate (AMD). The national EML is deemed to satisfy the priority health care needs of the population.

Essential Drugs Programme (EDP): The unit established in terms of the National Drug Policy (1996) within the Affordable Medicines Directorate, which aims to ensure that affordable, good quality essential medicines are available at all times in adequate amounts, in appropriate dosage forms, to all citizens[2] by implementation of the Standard Treatment Guidelines (STGs) and EML.

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[3].

[1] World Health Organization. Essential Medicines and Health Products. (http://www.who.int/medicines/services/essmedicines_def/en/ - accessed 05/02/2017)
[2] Minister of Health. National Drug Policy for South Africa. Pretoria, 1996.
[3] South African National Department of Health. National Health Act, 2003 (Act No, 61 of 2003)

International Non-proprietary Name (INN): The unique name which is globally recognised and facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients[4] designated by WHO and thus standardised globally.

Level of Care: The minimum 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 clinics and community health centres (CHCs);
- Secondary level – district hospitals and regional hospitals;
- Tertiary/Quaternary level – tertiary hospitals 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 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.

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 EML and Standard Treatment Guidelines (STGs). The STGs and EML guide clinical practice at all public sector health establishments and inform procurement of medicines in the public sector.

[4]World Health Organisation. International Non-proprietary names, 2016. http://www.who.inc/medicines/services/inn/en/

Pack Size: Number of dosage forms, doses or metric quantity contained in a unit pack e.g. 100 tablets.

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.

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.

Product: The branded version of a medicine or medical device prepared by a manufacturer and which has a brand/ proprietary/ trade name, and in the case of a medicine has a dosage form, strength and pack size.

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 of time, and at the lowest cost to them and their community.[5]

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 and are organised per level of care.

Strength: Amount of active pharmaceutical ingredient contained in one dosage unit of a product.

Therapeutic Class: A group of medicines which have active ingredients with comparable therapeutic effects. 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

[5] World Health Organisation. 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).

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[6].

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.

[6]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.

3. PURPOSE OF THE GUIDELINE

The purpose of this guideline is to define 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 guidance in the development, management and use of such formularies at all levels of care. It aims to emphasize 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.

NOTE: Due to the dynamic nature of the Medicine Master Data System (MMDS) development, some detail within this guideline may be amended and will be finalised after finalisation of development of the MMDS.

4. SCOPE OF THE GUIDELINE

This guideline contains the high level principles and business rules to inform on the development, management and use of formularies in the public health sector, and in private sector health establishments that provide health care services on behalf of the public sector.

The guideline does not include detailed processes, procedures and tools for decision making and activities relating to:

- The development and management of the STGs and EML, or formularies;
- Granting of authorisation by means of licences to procure, prescribe, or dispense medicines;
- Authorisation for access to medicines which do not appear on a formulary;
- Procurement and supply of medicines in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and
- Rational medicine use.

5. OBJECTIVE OF THE GUIDELINE

The objective of this guideline is to facilitate the development, management and use of a formulary in the public sector by:

- Defining the concept of a formulary and providing guidance for the minimum content thereof;
- Providing standardised terminology for development, management and use of formularies;
- Describing the principles of a standardized hierarchy of formulary development from the EML for all levels of care;
- Providing a high-level outline of the method of development, management and use of formularies; and
- Allocating the expected roles and responsibilities of various stakeholder groups for the development, management and use of formularies.

6. POLICY AND LEGISLATIVE PROVISIONS

This document is informed by the following policy and legislative provisions, which have been arranged in chronological order to display progression in thinking over time:

National Drug Policy for South Africa (1996)

Section 7.5 of the National Drug Policy on Hospital Therapeutic Committees states that:

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

These therapeutic committees will consist of at least a senior pharmacist, a senior nurse, a senior financial officer and senior clinicians or their nominated representatives in their absence. Their terms of reference will include responsibility for:

- *the accurate estimation, prompt procurement and optimal storage and supply of drugs and medical supplies*
- *the compilation and preparation of a hospital formulary*
- *cost-effective drug use*

- *proper staff establishments to carry out these functions*[7]

Pharmacy Act, 1974 (Act 53 of 1974)

The rules relating to good pharmacy practice published in terms of Section 35A of the Pharmacy Act, 1974 (Act 53 of 1974) specify the minimum standards for the selection of pharmaceuticals by institutional pharmacies. In terms of Rule 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.

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

Section 10 of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees 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.*

[7] The National Drug Policy for South Africa (apps.who.int/medicinedocs/documents/s17744en/s17744en.pdf – accessed 19.03.2018)

Section 12 of the policy 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.*

7. DEFINITION OF A FORMULARY

A formulary was defined in the *National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa*, approved in January 2015, as a list of medicines that is approved for use in the healthcare system by authorised prescribers and dispensers.[8] This definition has been developed further, with the revised definition referring to *'A continually updated list of medicines and related information, 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.'*

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

8. PURPOSE OF A FORMULARY

The purpose of a formulary is thus to:

- Identify medicines required to satisfy the needs of the population served by a particular health establishment or group of health establishments;
- Guide management of medicines at all levels of care in accordance with the principles of good governance;
- Inform transparent decision-making in the development and management of medicine-related budgets at all levels of care;
- Promote rational medicine use throughout the health care system.

A formulary thus provides the list of medicines that may be procured within a province (thus replacing the code list or catalogue referred to previously), or in the case of a health establishment/s, the list of medicines that may be procured by or stocked at a specific health establishment/s (thus constituting a replenishment list or entitlement list).

9. BENEFITS OF A FORMULARY

The formulary provides multiple benefits according to its use, including:

- **For prescribing and dispensing:** The formulary indicates what is available for prescribing at each level of care, to facilitate standardised provision of care to patients and guide rational medicine use through transparency to enable efficient monitoring and evaluation.
- **For procurement:** The formulary guides effective use of budget, efficient demand and supply planning and improved inventory management and control.

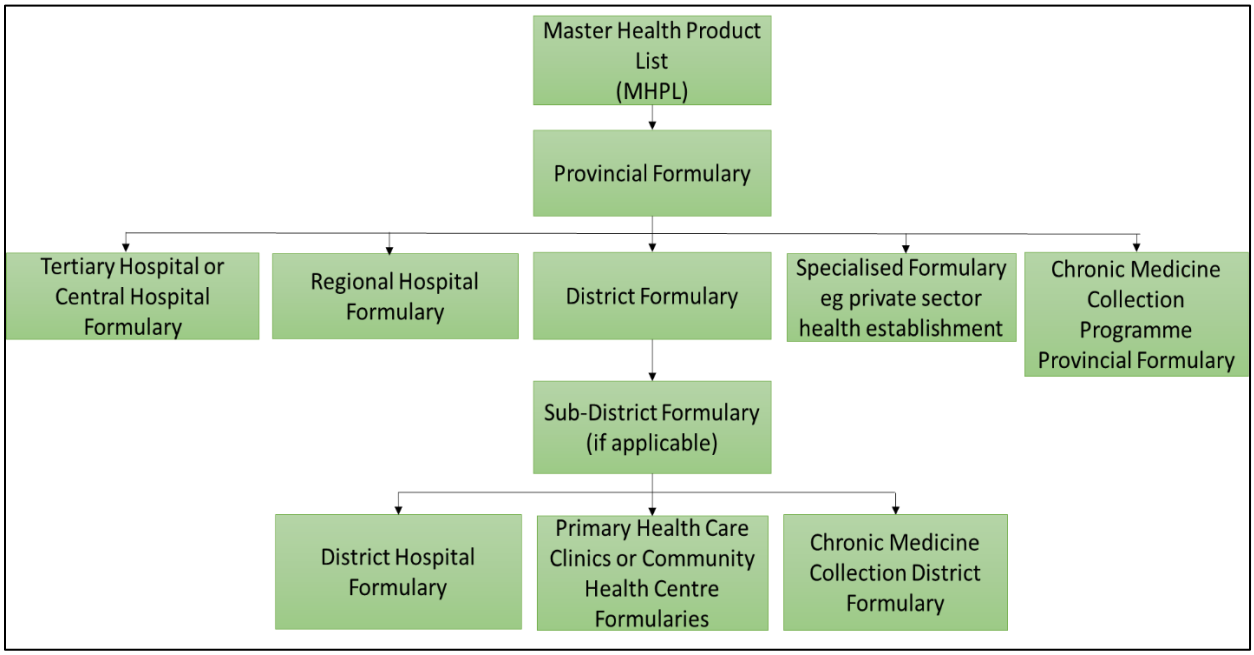
The formulary may also be used for medicines benefit programmes or reimbursements to support universal health care under National Health Insurance.

10. FORMULARY DEVELOPMENT AND MANAGEMENT

10.1 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



The national Essential Medicine List (EML) is determined by the National Essential Medicines List Committee (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, which 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.

The Master Health Product List (MHPL) which forms part of the AMD Medicine Master Data System (MMDS) includes medicines which have been approved for inclusion on the EML, as well as those that are classified as Non-EML. This latter classification includes medicines which have been reviewed by NEMLC but not approved, medicines which are under review and medicines which have not been reviewed. Medicines which appear on the EML may be subject to restrictions imposed by NEMLC including for example, who may prescribe the medicine (e.g. doctor initiated), the level of care at which the medicine may be prescribed, a requirement for informed consent to be provided and/or the diagnosis and clinical history of an individual patient.

EML Statuses and sub-categories are provided below in Table 1:

Table 1: Categorisation of EML Status on the Master Health Product List (MHPL)

EML Status	EML Sub-Category
EML	Approved Special Access
Non-EML	Not approved For review Not yet reviewed Under review Other

Every province must have a formulary, developed and managed through a mandated Provincial Pharmaceutical and Therapeutics Committee (PPTC) based primarily on the EML, and derived from the MHPL. The PTC should develop a formulary aligned to treatment guidelines and protocols subjected to robust evidence-based interrogation and consideration of cost implications.

Non-EML medicines with the sub-category of “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. Review indicators such as price may be allocated to any medicine reviewed and not approved by NEMLC which, if evidence is presented to indicate a change in the review indicator, will stimulate further review of the medicine.

All regional, tertiary and central hospitals must have a formulary, developed and managed through a mandated PTC and based on the formulary of the province in which they are situated. A cost analysis should also be undertaken to determine the impact on the budget of the relevant health establishment/s.

All districts and sub-districts (where applicable) must have a formulary developed and managed through a mandated PTC and based on the formulary of the province in which they are situated. Where sub-districts are in place and have a sub-district formulary, this must be based on the formulary of the district in which they are situated.

All primary health care clinics, CHCs and district hospitals must have a formulary, developed and managed through a mandated PTC and based on the formulary of the district or sub-district (if applicable) in which they are situated.

Formularies may not be unique to a particular health establishment and may be applicable to a group of health establishments - for example, the same formulary may be applicable to a group of primary health care clinics, CHCs or district hospitals.

A formulary for the supply of medicine via a chronic medicine collection programme, such as the Centralised Chronic Medicine Dispensing and Distribution (CCMDD) programme, must be developed and maintained by the relevant PPTC in the case of a province wide medicine collection programme, or district PTC where the medicine collection programme is applicable only to a particular district.

Where private sector health establishments provide health care services on behalf of the public sector, medicines must be available and used in accordance with a formulary approved by the relevant PPTC.

10.2 Changes to a Formulary

Any additions, deletions or changes (such as change to strength, dosage form or pack size) to medicines on the national EML only take place through the NEMLC review process. When a medicine is removed from the EML following a decision in this regard by NEMLC, the status of the medicine on the MHPL will change from “EML” to “Non-EML (Not approved)”. The decision on whether to retain such medicine on the provincial formulary is then taken by the relevant PPTC.

Changes to the national EML and formularies at higher levels of care should trigger an analysis of possible changes required to formularies at the levels below. This approach requires frequent multi-directional communication between PTCs at all levels of care, with formularies being electronic in nature and designed to enable ease of revision and circulation.

Any changes made to the EML or a formulary that will have an impact on supply chain processes must be communicated and flagged electronically (as applicable) to relevant stakeholders, including but not limited to, the Contracting and Contract Management Units at AMD, Heads of

Pharmaceutical Services, Provincial Medicine Procurement Units (PMPUs), Programmes and PTCs at other levels of care immediately after approval thereof by NEMLC or the relevant PTC. Contractual commitments should be taken into account before implementation of changes to the EML or a formulary. All electronic systems need to have processes in place to deal with these updates.

10.3 Considerations for additions, deletions and amendments to the formulary

The following factors are taken into account using evidence-based processes when decisions are made as to whether a medicine should be included in a formulary:

- Local epidemiology;
- Effectiveness, safety, cost effectiveness and affordability, as per the manual used in the medicine review process;
- The package of services to be provided at the relevant level of care;
- Implications for clinical practice;
- Therapeutic class membership; and
- Contractual commitments.

Medicines considered for inclusion in a formulary should undergo, effectiveness, safety, cost-effectiveness and affordability evaluation using a structured, evidence-based approach.

A PPTC may add a non-EML medicine to the provincial formulary and must inform the AMD of the inclusion of any non-EML medicine on a formulary via email (SAEDP@health.gov.za). If not already included on the MHPL, the PPTC must provide the minimum data elements relating to such non-EML item for inclusion in the MHPL, as provided in Section 11. Only 10% of formulary items should have a non-EML status.

Medicines may only be added to a formulary if present on the formulary of the level above – as depicted in the diagram provided in Figure 1. If a PTC lower in the hierarchy requires a non-EML medicine to be added to its formulary, when not present on the formulary of the level above, a motivation in this regard must be approved by the PTC of the level above. For example, if a district PTC requires a non-EML medicine to be added to its formulary, it must motivate to the PPTC for inclusion of the non-EML medicine on the provincial formulary if not already included.

10.4 Formulary review period

Formularies should be reviewed by the relevant PTC on at least a quarterly basis.

11. CONTENT OF A FORMULARY

The STGs, EML and MHPL are interdependent and should be developed in a systematic and harmonised way. The minimum data fields of the medicines included in these documents should be consistent and are designated at national level. VEN status is also determined at a national level.

The following are the minimum data fields necessary in a formulary:

- National Stock Number
- International Non-proprietary Name (INN)
- EML Status and Sub-Category (as per Table 1)
- Review Indicator
- Individual Patient Use
- Dosage Form
- Strength
- Pack Size
- Level of Care
- Prescriber Level
- VEN Status
- Therapeutic Class

Prescriber privileges included in a formulary will be maintained by the relevant PTC.

Formularies for all levels of care are based primarily on the MHPL. Medicines in a formulary may be grouped into therapeutic classes per indication/disorder as designated by NEMLC. The formulary will contain the medicine master data needed to guide procurement, inventory management, prescribing and dispensing. A formulary must contain the minimum fields which together create a unique line item. The formulary may be augmented by additional data fields according to needs of electronic health systems.

12. ACCESS TO MEDICINES NOT GENERALLY AVAILABLE ON THE FORMULARY OF A HEALTH ESTABLISHMENT

Although the use of formularies is an accepted approach to optimising use of resources and promoting the rational use of medicine, a mechanism is needed to enable access to medicines (either EML or non-EML) for patients who cannot be managed effectively with medicines generally available on the formulary of the health establishment where the patient is receiving health care services.

Below is some guidance to PTCs on what medicines may be approved for 'Individual Patient Use':

- Not on the formulary of the health establishment where the patient is receiving health care services;
- When a patient is referred from a health establishment and requires medicines which are not on the formulary of the receiving health establishment;
- On the formulary of the health establishment but require more control for various reasons e.g. cost or possible irrational medicine use and is designated for individual patient use only;
- Has not responded to or has failed treatment with an essential medicine, which has been prescribed at an appropriate dose, administered for an adequate length of time and despite appropriate adherence to such treatment;
- Is not able to tolerate the available treatment, for example, the patient has experienced a serious adverse drug reaction or allergic reaction to such treatment, which reaction has been documented, and where no alternative for such treatment is available; or
- Has a rare disease (low incidence) for which no medicines are available.

12.1 Applications for 'Individual Patient Use'

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

All authorisations should be for a course of therapy, with the period for authorisation being determined to suit the relevant condition or medicine required. A motivation for continued use of the medicine (including progress reports, where applicable) should be submitted to the relevant PTC if continuation of such therapy is needed.

Once approval has been granted such medicines must be included in the formulary of the health establishment and designated for 'individual patient use' only; in which case such inclusion needs to be communicated to EDP via email on SAEDP@health.gov.za.

13. ACCESS TO MEDICINES DESIGNATED AS 'EML – SPECIAL ACCESS'

Certain EML medicines may be designated by NEMLC as suitable for use in individual patients who meet pre-defined criteria and are receiving health care services at any level of care. EML medicines on the Tertiary/Quaternary EML (TQEML) that are approved subject to restrictions are classified as Special Access.

For Special Access medicines on the TQEML, an application may be submitted to the health establishment's PTC for use if a patient meets the criteria defined by NEMLC.

An application for use of a Special Access medicine may only be initiated at the tertiary/quaternary level of care by an appropriate specialist or under the supervision of an appropriate specialist at a lower level of care.

Applications for use of Special Access medicines must be submitted to the applicable PTC on an approved application form by the relevant treating clinician. Evidence must be submitted that the patient meets the predefined criteria determined by NEMLC.

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.

14. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

A description of the main stakeholders and their roles and responsibilities are outlined below in Table 2:

Table 2: Stakeholders with Roles and Responsibilities

Stakeholder Level	Stakeholder	Roles and Responsibilities
NDoH	**Contracting Unit**	Plan, forecast and estimate usage of medicines based on formularies and epidemiology of the population served.
NDoH	**Contract Management Unit**	Monitor and evaluate availability of medicines based on the formularies of health establishments. Prioritise contracting based on inclusion of medicines on provincial formularies.
NDoH	**Essential Drugs Programme (EDP)**	Coordinate the process of developing and reviewing the STGs and EML; Coordinate implementation of the STGs and EML; Monitor non-EML use at provincial, district and health establishment level; Prioritise medicines for review by NEMLC; Communicate changes to the EML to relevant stakeholders; Conduct/coordinate rational medicine use activities.
NDoH	**Expert Review Committees (ERCs)**	Provide recommendations to NEMLC regarding addition or deletion of medicines and amendments to the STGs/EML based on medicine reviews conducted.

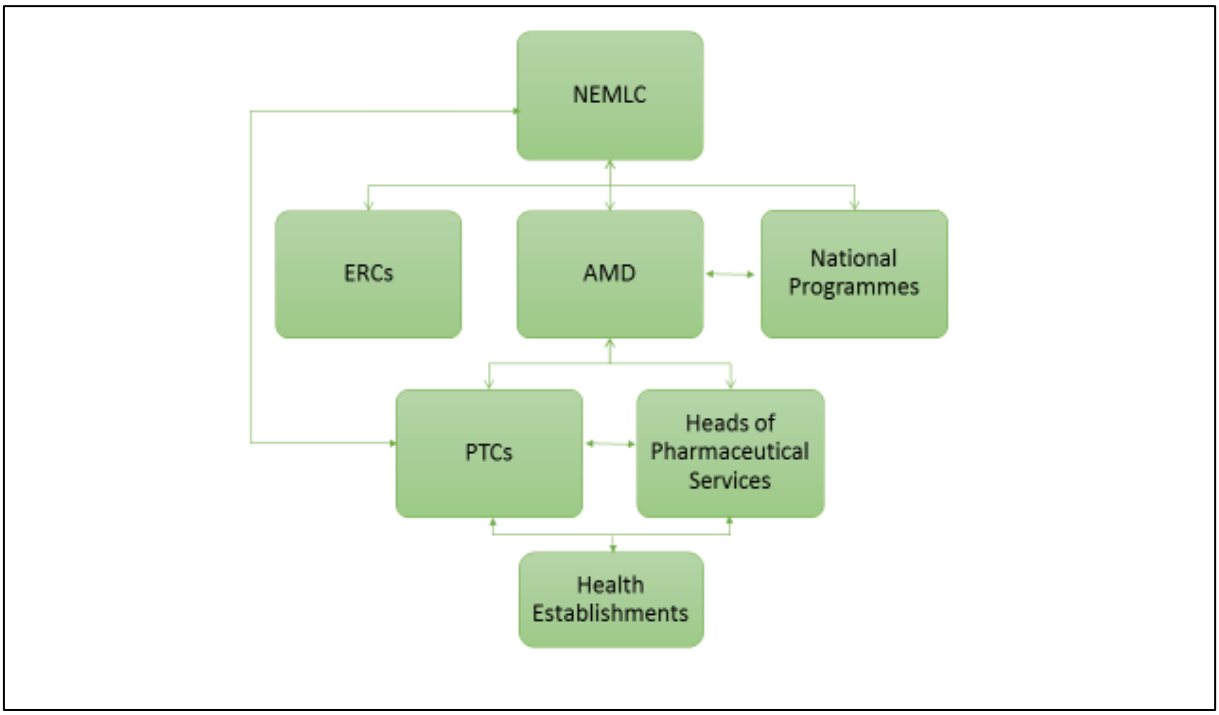
Stakeholder Level	Stakeholder	Roles and Responsibilities
NDoH	**National Essential Medicines List Committee (NEMLC)**	Develop and review the STGs and EML, making decisions based on recommendations from the ERCs.
NDoH	**National Programmes**	Liaise with the EDP to align programmatic guidelines with the STGs and EML; Assist with review of the STGs and EML in alignment with programmatic needs including through representation on NEMLC.
PDoH	**PMPU**	Undertake data analytics based on formularies to inform planning, monitoring and continuous improvement; Ensure access to data for all appropriate provincial stakeholders; Vet requisitions to ensure that items ordered are in accordance with the appropriate formulary approved by the relevant PTC.
PDoH	**Heads of Pharmaceutical Services (HOPS)**	Provide oversight of formulary development, management and use at provincial level; Ensure that formularies based on the provincial formulary are in place for all health establishments in the province.
PDoH and Health Establishments	**Chronic Medicine Collection Programme providers and Private Sector Health Establishment managers**	Procure, prescribe and/or dispense medicines in accordance with the applicable formulary and per service/s provided.
PDoH and Health Establishments	**Pharmaceutical and Therapeutics Committees (PTCs)**	**Development and Management of Formularies:** Develop formularies based on national and local mandates; Manage formularies taking into consideration changes to the STGs and EML and local context;

Stakeholder Level	Stakeholder	Roles and Responsibilities
		Constantly update formularies and manage additions, deletions and amendments; Communicate and implement formulary changes, including phase in and out of medicines on the formulary; Communicate with EDP and other PTCs to recommend possible changes to the STGs and EML. **Dissemination and Access of Formularies:** Provide comprehensive access to formularies through the use of innovative systems and technologies; Monitor operations for compliance with STGs and EMLs; Monitor and evaluate formulary use; Conduct rational medicine use activities; Liaise periodically with stakeholders to provide information on changes to STGs and EML, policy, guidelines and protocols.
Health Establishments	**Prescribers, Dispensers and Inventory Managers**	Use formularies as per relevant function for medicines selection, procurement, prescribing and dispensing.
Health Establishments	**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.

15. COMMUNICATION AND DISSEMINATION

Communication across the health system should ensure that the available expertise is used for clinical and formulary-related decision-making to the benefit of the majority of the population. Communication should follow a two-way path, as illustrated in Figure 2 below:

Figure 2: Communication of Formulary Decisions



Regular communication between the EDP Unit and National Programmes of the NDoH is key to ensure alignment of the STGs and EML with National Programme Guidelines, prior to implementation of relevant changes.

Decisions related to EML and formularies should be communicated timeously and effectively to internal and external stakeholders, and practical implications relating to phasing-in or phasing-out of medicines should be considered and communicated.

16. RESOURCES

The executive authority of each health establishment must ensure the availability of appropriate resources to support the optimal functioning of the PTC, as well as development, management, and use of formularies under their responsibility through the MHPL.

17. MONITORING AND EVALUATION

17.1. General Formulary Reporting

Regular monitoring and evaluation of the development, management and use of formularies must be undertaken. Reports on changes to formularies should be generated regularly from the MMDS.

17.2. Monitoring of Individual Patient Use and EML – Special Access

Individual patient and EML – Special Access use must be monitored as follows at the facility level:

- A register (database) must be maintained by the relevant PTC of all applications received, as well as approval granted and rejected per health establishment and district (as applicable);
- Each health establishment must keep a record of patients receiving these medicines, as well as the time period that the medicine has been approved per patient;
- Records must be considered when the formulary of the province, district or health establishment is reviewed, for addition to or removal of medicines from such formulary;
- The PPTC must maintain oversight of all non-EML medicines used in the province and submit an annual report to NEMLC to assist in generating a signal that such medicine be reviewed.