

Standard Treatment Guidelines and Essential Medicines List



Overview of EML Review Process and Application of HTA Processes

Affordable Medicines Directorate
National Health Insurance Branch
National Department of Health, South Africa

Session 1: STGs and EML Webinar Series
25 June 2024

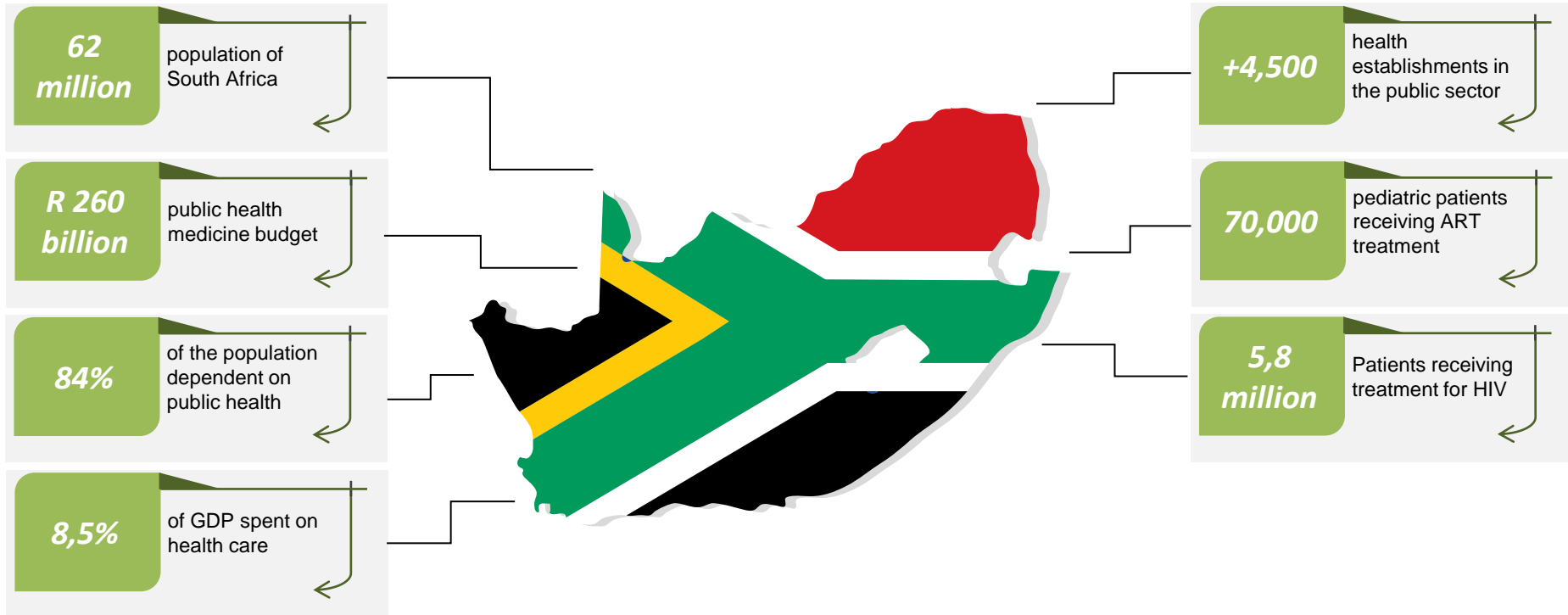


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Context of the South African Healthcare System

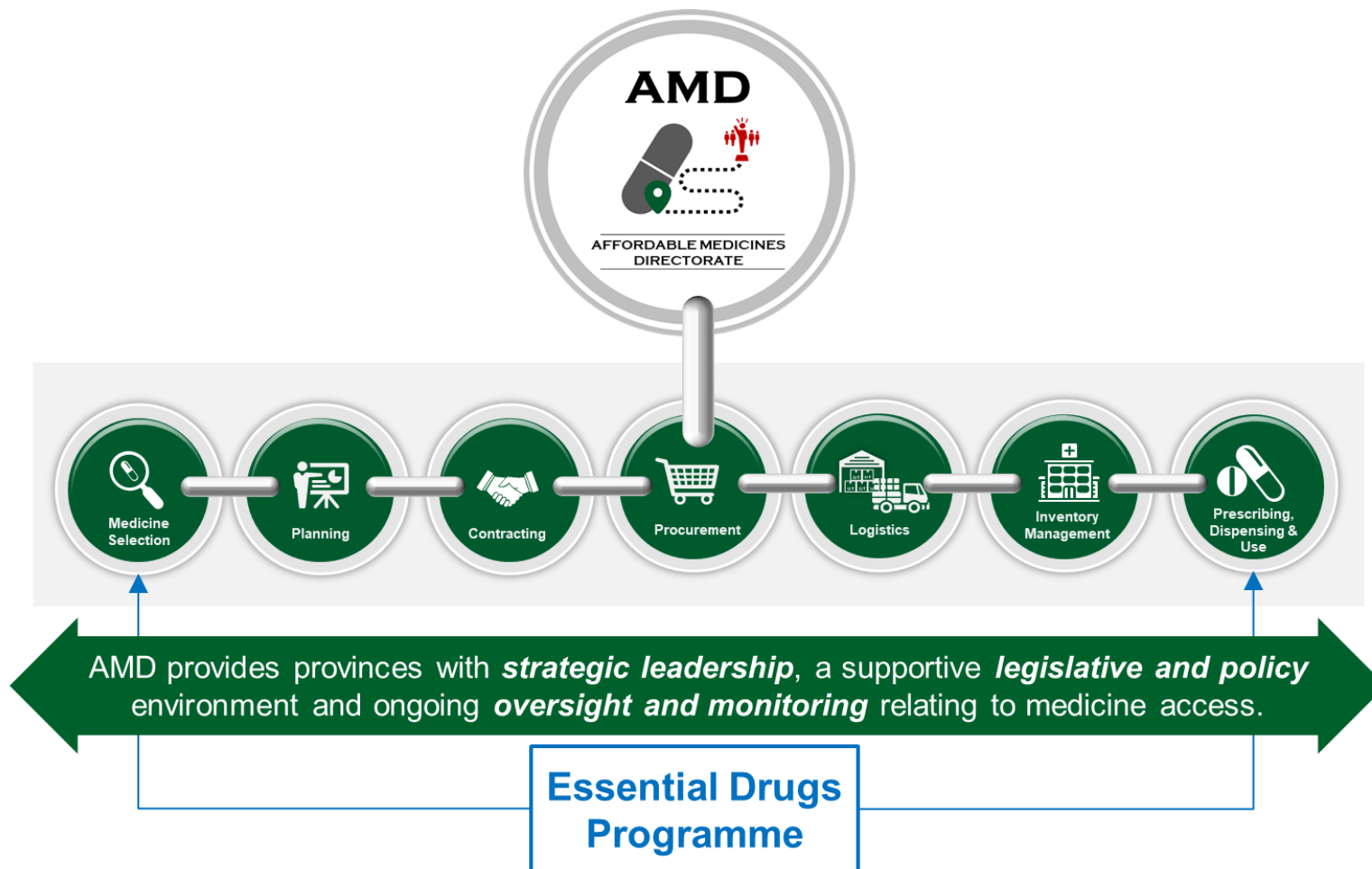


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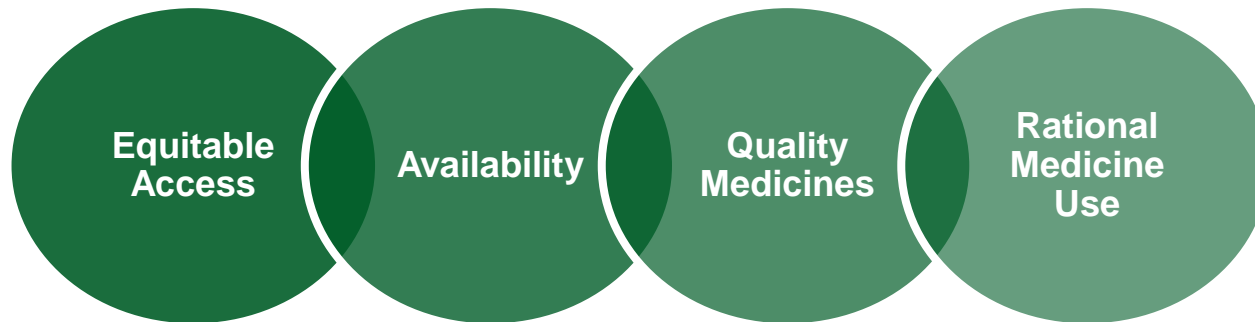


Essential Drugs Programme



EDP aims to ensure that:

*“affordable, good quality essential **medicines** are available at all times in adequate amounts, in appropriate dosage forms, to all citizens”*



- EDP oversees development and implementation of the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) of SA through the National Essential Medicines List Committee (NEMLC) and supporting Expert Review Committees (ERCs)
 - **EML:** Developed to satisfy the priority health care needs of the population
 - **STGs:** Provide guidance on how to use medicines which appear on the EML

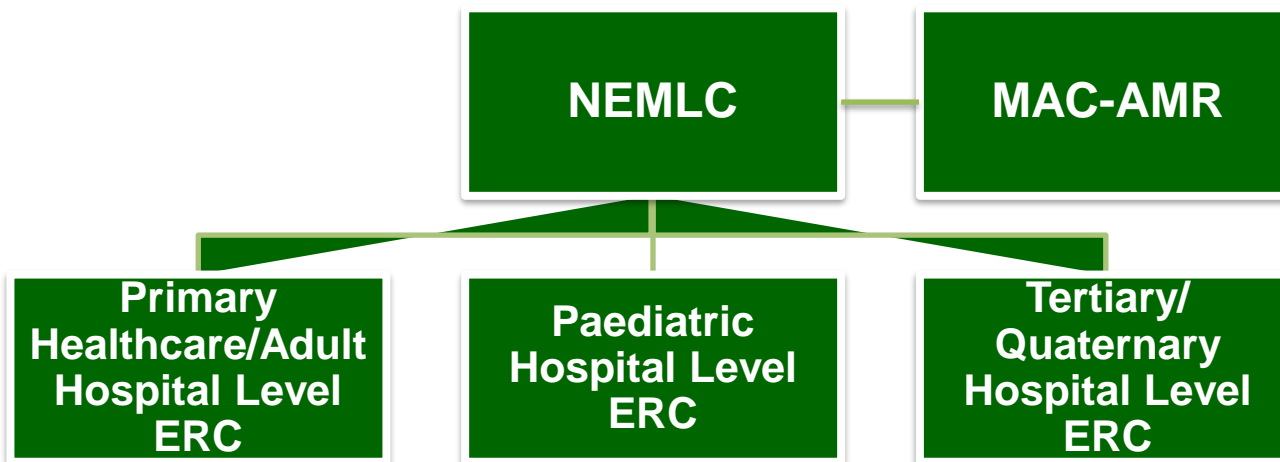


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Expert Committees



NEMLC

The **National Essential Medicines List Committee (NEMLC)** is a non-statutory advisory Committee to the Minister of Health responsible for the development of the national Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) for primary, secondary, and tertiary/quaternary care levels

ERCs

NEMLC is supported by **Expert Review Committees (ERCs)** who conduct the technical work required for the review of the STGs and EML

MAC-AMR

Ministerial Advisory Committee on Antimicrobial Resistance (MAC-AMR) – oversight of the coordination and inter-sectoral efforts on AMR using the One Health approach inclusive of human, animal and environmental health relating to antimicrobials, promoting advocacy, awareness, and education initiatives as well as monitoring and evaluating the implementation of the Strategy.



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Committees – Governance and Composition



NEMLC Composition

Expertise in evidence-based medicine, health economics, methodologists, clinical experts, representatives from Programmes, Medical Schemes, Academia and others.



ERC Composition

Expertise in evidence-based medicine, methodologists, health economics, clinical experts and clinicians from various levels of care.



Governance Processes

Terms of References, Policies – Conflict of Interest, Confidentiality, Appeals



Updated STGs and EML



Primary Healthcare Level: 2020 edition
(under review, to be completed in 2024, PDF to be published early 2025)

Adult Hospital Level: 2019 edition
(under review, to be completed in 2024, PDF to be published early 2025)



Paediatric Hospital Level: 2023 edition

Tertiary and Quaternary EML: May 2024

Chapters are accompanied by technical documents e.g., medicine reviews, costing analyses, NEMLC reports, summary slides (for PHC STGs and EML)



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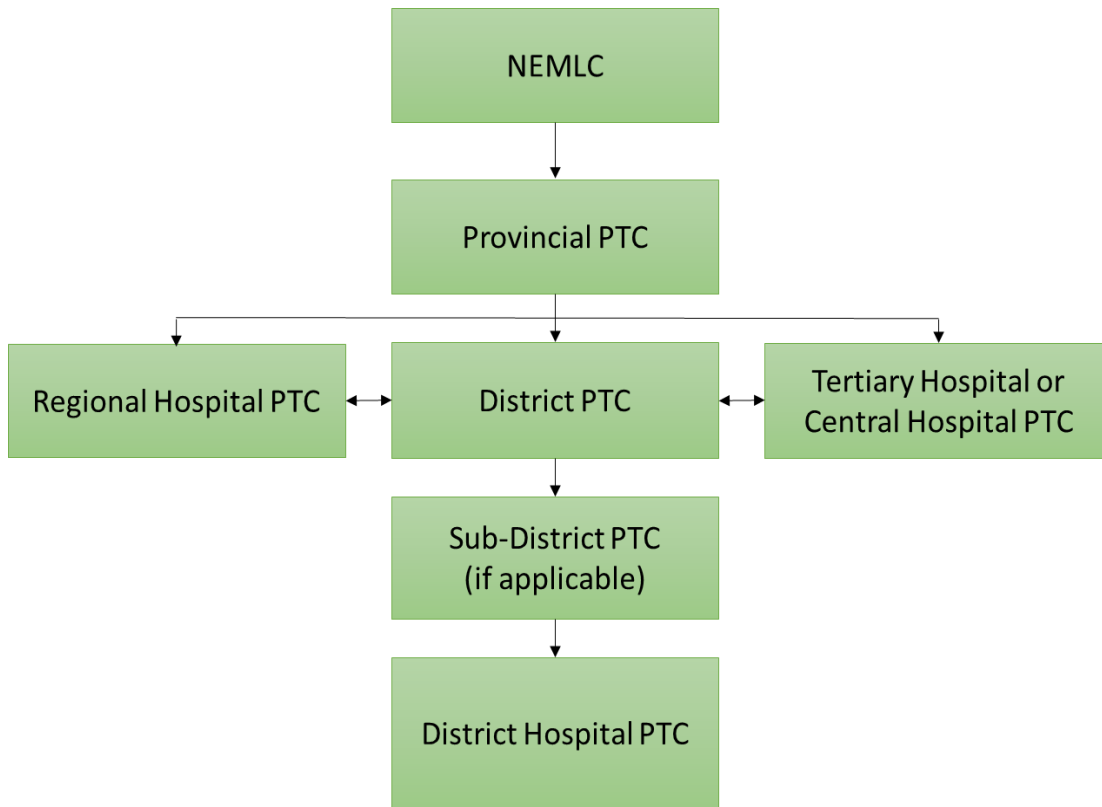
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Pharmaceutical & Therapeutics Committees (PTCs)



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 rational selection and use of medicines at all levels of care**



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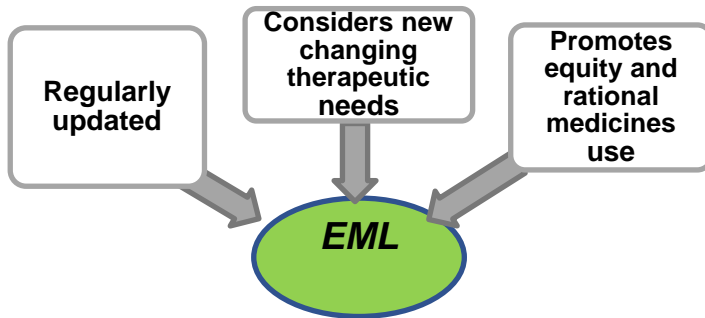
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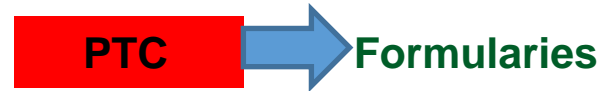
EML Versus Formularies



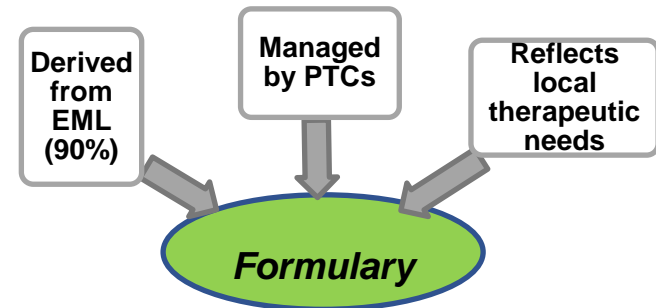
- Satisfies the priority health care needs of the South African population



EML Status	EML Sub-Category
EML	Approved
	Special Access
Non-EML	Not approved
	For review
	Not yet reviewed
	Under review
	Other e.g. galenicals/ insulin needles



- Satisfies the priority health care needs of the population served by the health establishment/s



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

PTCs may approve the use of medicines for 'Individual Patient Use' where a medicine is needed but is not covered on the EML



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Evolution of Decision Making



GOBSAT

NDoH template for medicine reviews was developed in collaboration with Cochrane SA

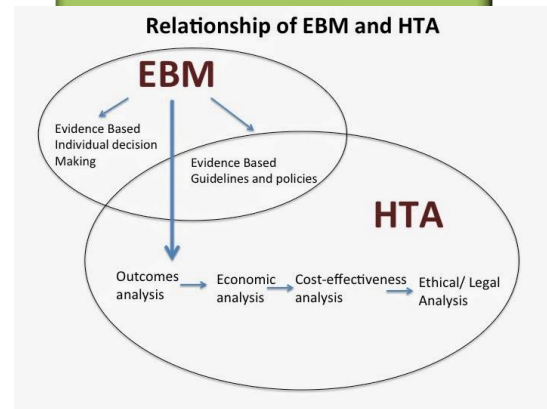
Good Old Boys Sat Around a Table

EBM

Rigorous process of transparent, multi-layered, evidence-based decision making

HTA

Evidence to Decision (EtD) framework



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Selection Criteria



Need: Public Health Relevance

- Priority health diseases and conditions - burden of illness and injury
- Local epidemiology



Quality, Safety & Efficacy & Effectiveness

- Product registered in terms of the Medicines Act
- Evidence of efficacy, safety and effectiveness.



Cost & Affordability

- Affordability of medicine, compared to current standard of care
- Within budgets-of providers of health care services.



Implications for Practice

- Pragmatic considerations
- Feasibility (e.g. adherence)
- Acceptability
- Monitoring & evaluation

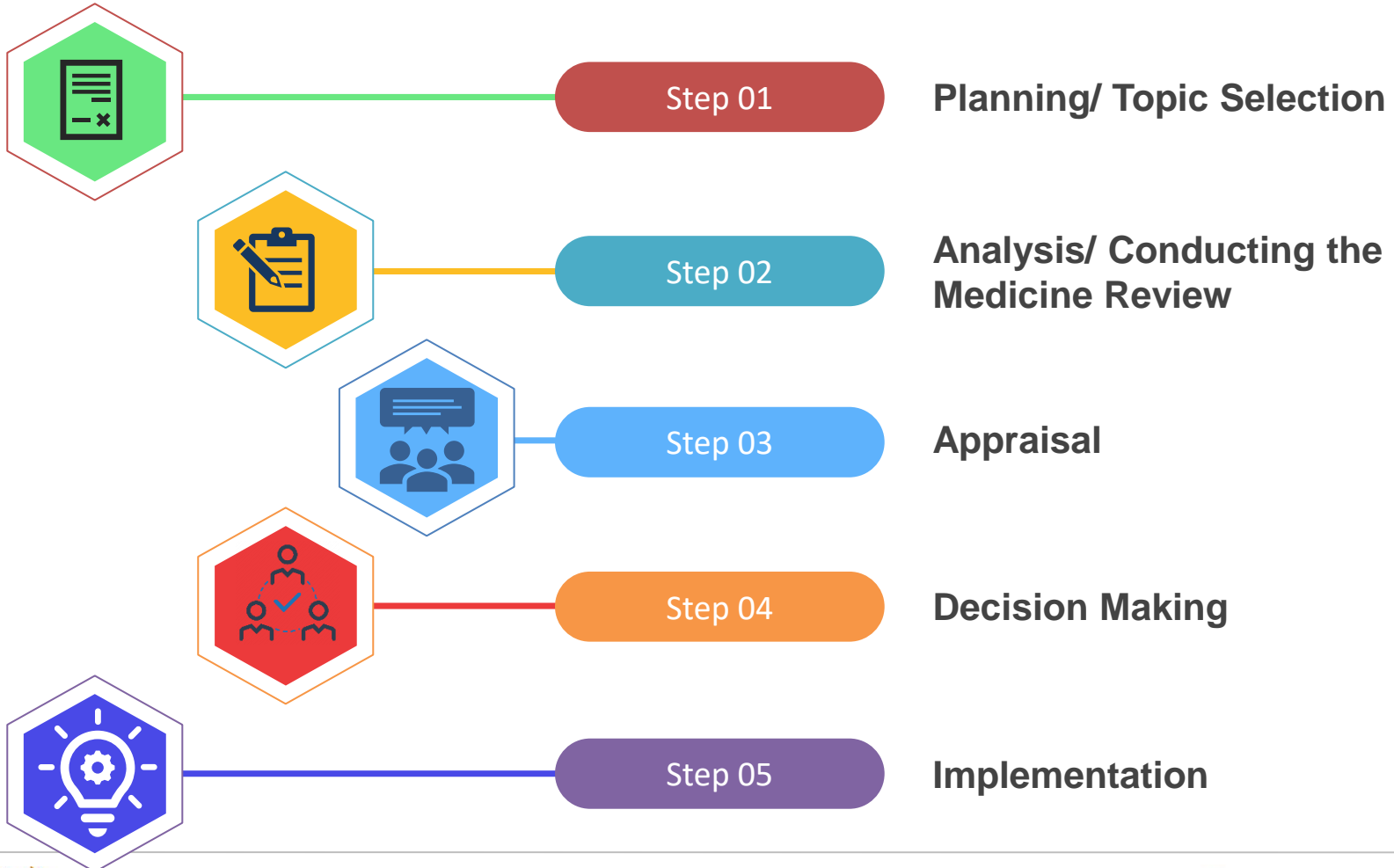


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Medicine Selection Process





Step 01: Planning/Topic Selection

Topic identification

Identification of potential topics informed by:

Pharmaceutical and Therapeutics Committee (PTC)

- based on local usage and needs

Affordable Medicines Directorate

- based on ABC Analysis of utilisation data

Any stakeholder

- newly registered medicines (accompanied by medicine motivation form)

Expert Review Committees

- review of medicines highlighted by chapter review of STGs

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- high priority medicines

Notifications of new prices or clinical information

Topic prioritisation and selection

Conducted by

NEMLC

+

relevant

Expert Review Committee

Supported by:

EDP

Topic referred for appraisal to Expert Review Committee

Expert Review Committee formulate project plan for Medicine Review



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Step 02: Analysis/ Conducting the Medicine Review

Medicine Review lead and support reviewer selected by Expert Review Committee

Conduct Medicine Review (analysis)

*Use Medicine Review template
Include a systematic search of the appropriate clinical evidence, as well as an assessment of the relevant financial and economic considerations*



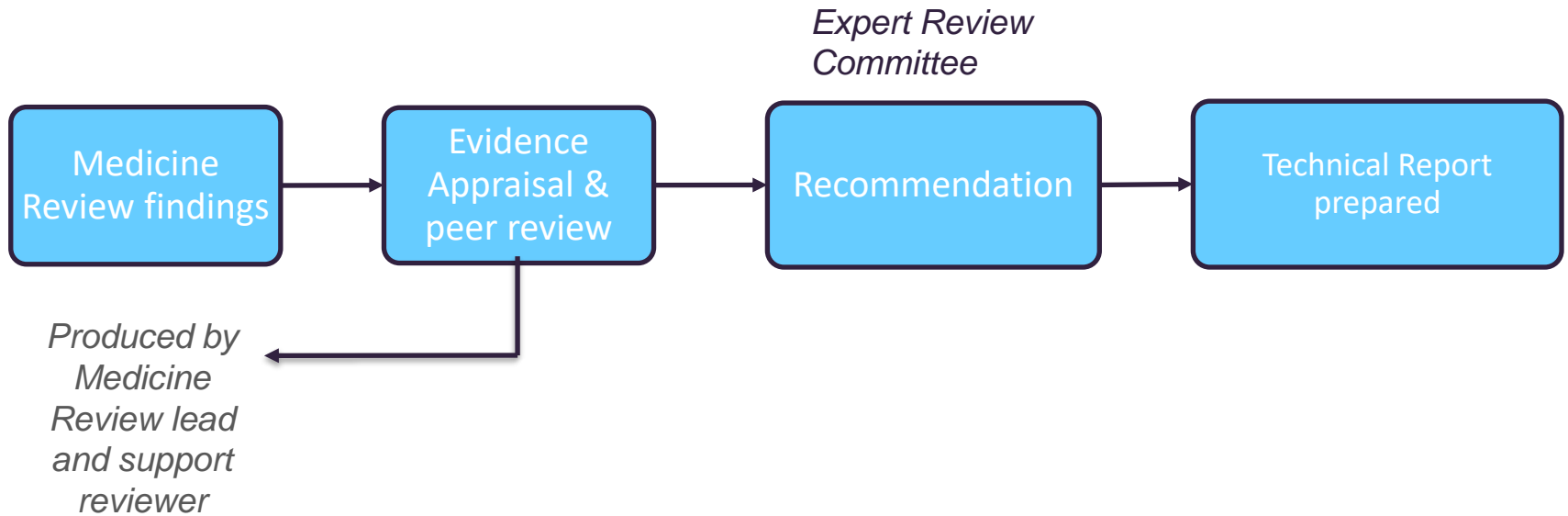
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Step 03: Appraisal



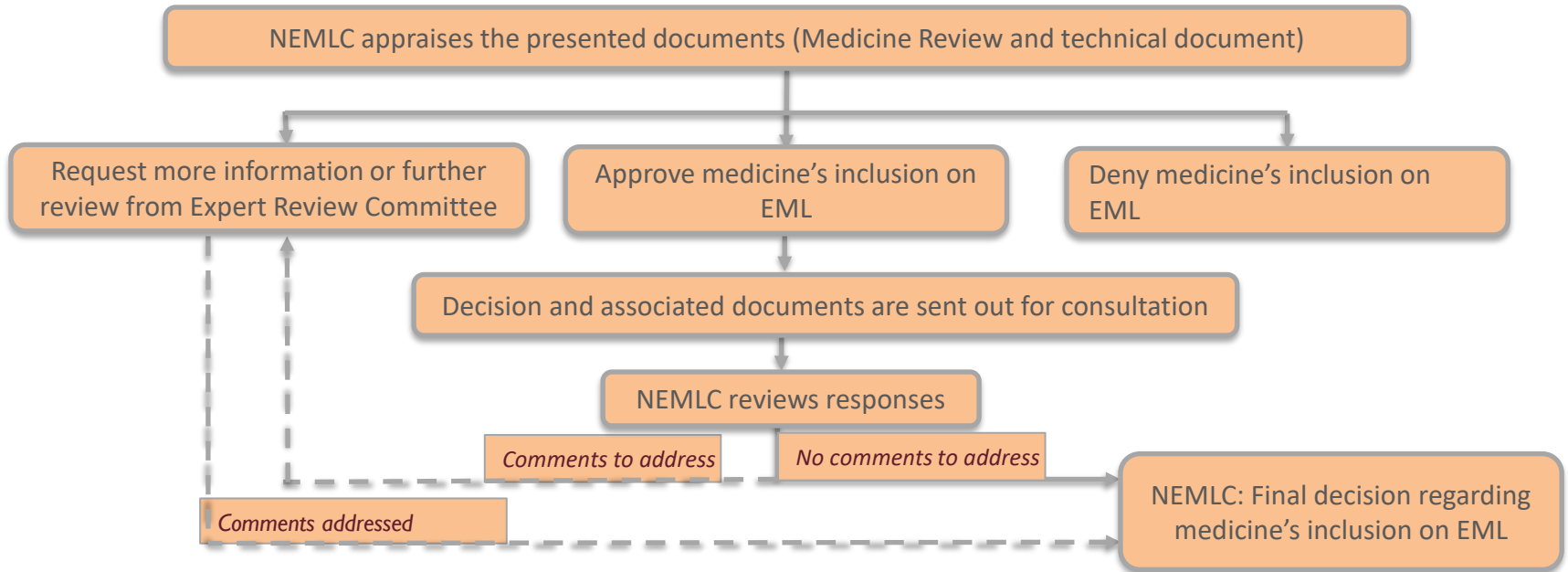
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Step 04: Decision Making



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Step 05: Implementation

EML amended by
EDP

EDP notifies all
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(including PTCs) of
changes

PTCs update
respective
formularies

Local
implementation
activities

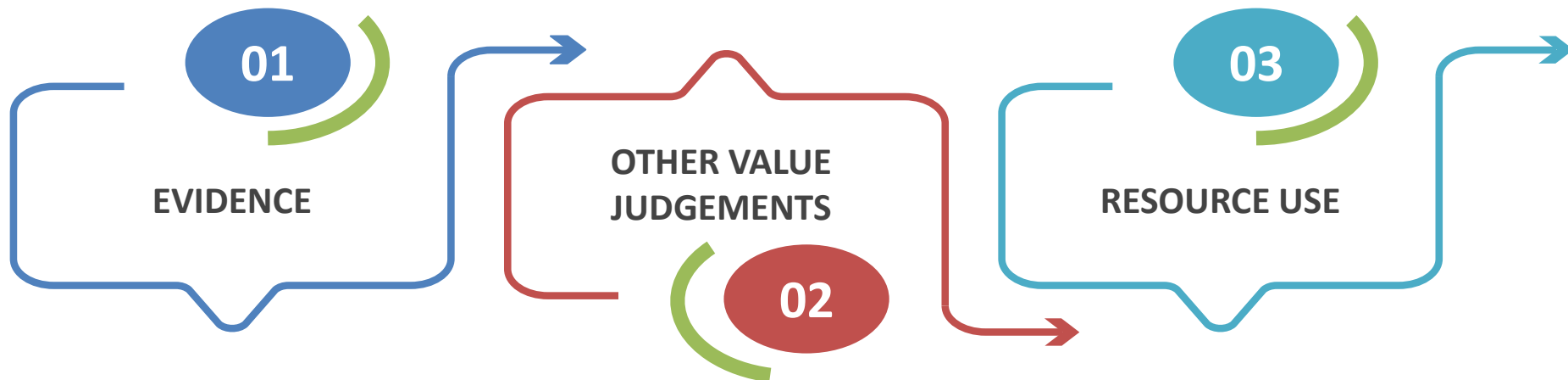


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Evidence to Decision Framework



What is the quality of the evidence?

- RCTs
- Systematic reviews and meta-analysis
- etc

What is the evidence of benefit?

- Impact on mortality and other health outcomes?
- Impact on hospital length of stay?

Do the benefits outweigh the harms?

- Risk of adverse events

Feasibility: can the recommendation be implemented?

- Registration status?
- Global supply?

Values, preferences and acceptability?

- Would the intervention be acceptable to patients and healthcare workers?

Equity and human rights?

- Impact on health inequity, access?

How large are the resource requirements?

Direct price of technology?

- Affordable?

Additional resources?

- Eg laboratory monitoring?

Note:

- The above-mentioned factors influence the direction and strength of the recommendation
- Recommendation (strong/ conditional) is agreed by consensus



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Motivation for Addition, Deletion or Amendment of Medicine on Provincial Formulary and EML



Motivation

- Provincial PTC 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

Call for Comment

- Opportunity for stakeholders to provide input during the “Call for Comment” process

Appeal

- NEMLC Appeals Policy

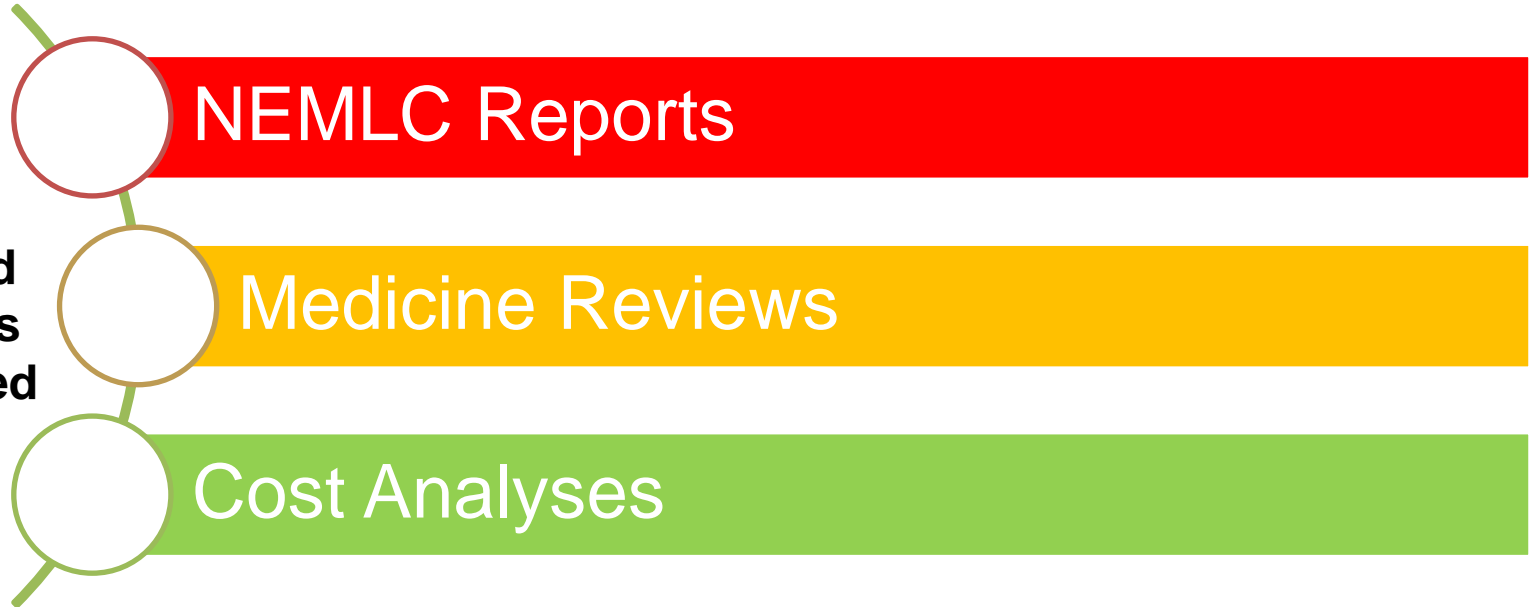


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Additional Documents To Note



NEMLC Bulletin:

- Released after each NEMLC meeting (usually quarterly).
- Summary of all decisions taken.



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Motivation for Addition, Deletion or Amendment of Medicine on Provincial Formulary and EML



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:



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Strengths and Challenges of current HTA system



STRENGTHS

- Evolution of decision making has strengthened
- Strong governance processes
 - Improved access to documents, transparency and stakeholder engagement
 - Improved alignment of selection of medicines with the procurement process

CHALLENGES

- Lack of skilled experts in HTA methodology, evidence-based medicine and pharmacoeconomics
- Complexity in decision making (refractory patients, rare diseases)
- No current mechanism to deal with industry submissions
- Patient/community education and involvement in decision-making processes not implemented
- Guideline alignment between different organisations in public/private sectors
 - Guideline implementation and alignment remains a challenge
- Assessment of clinical outcomes would provide an effective measure of the impact of the STGs and EML



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Access to STGs and EML



STGs and EML (Individual Chapters and PDF) and Related Technical Documents

- NHI Webpage: <https://www.health.gov.za/nhi-edp-stgs-eml>
- Knowledge Hub **eLibrary**: www.knowledgehub.health.gov.za/e-library
- EMGuidance Mobile & Desktop Application: <http://onelink.to/sy896k>
- NEMLC Bulletins – circulated after each NEMLC meeting
- Circulars
- All queries to be submitted to SAEDP@health.gov.za
(or email team directly)

Got Questions?
SAEDP@health.gov.za

Webinars

Knowledge Hub: <https://knowledgehub.health.gov.za/webinars>



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Meet Our EDP Team



Dr Janine Jugathpal
Deputy Director: EDP



Dr Jane Riddin
PPS Selection: Paediatric & TQ
Level



Ms Maropeng Rapetsoa
PPS Selection: PHC & AHL



Ms Olwethu Mambinja
PPS: RMU



Dr Ruth Lancaster
PPS: RMU & AMR



Ms Derusha Frank
Technical Assistant
CHAI



Ms Amanda Brewer
Technical Assistant
SCTA



Ms Kim MacQuilkan
Technical Assistant
SCTA



Dr Milli Reddy
Technical Assistant
SCTA



Ms Zahiera Adam
Technical Assistant
CHAI



Ms Nasreen Seedat
Technical Assistant
Right to Care

**Thank
you**



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