



Motivation of medicines for inclusion on the Essential Medicines List

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

- PTCs may motivate for addition, deletion or amendment of a medicine (or appeal a selection decision) on EML
- The approved application form along with evidence (Appendix 18) can be used





Appendix 18:
National Essential Medicine List
Indicate the Level of Care Medication Review Process
Component:

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.

Motivation

Define request:

PICO question

- **P (patient/population):** define group
- **I (intervention):** medication being requested
- **C (comparator):** current standard of care
- **O (outcome):** key outcomes from therapy



Forms research question

Search



- **Outline search strategy** (document to allow to be reproduced)

Considerations

Other important information to consider

- Number of patients expected to require therapy
- Practical issues related to new/old therapy
- Add on or alternative
- Who would prescribe it
- Would PTC monitor on a patient basis
- Monitoring of effect if implemented
- If new therapy added, would previous one be removed/limited
- Cost/affordability considerations

Evaluation Process by National (Essential Drugs Programme)

Allocation to Expert Review Committee (ERC)

Tertiary – receive motivations at any point

Primary Healthcare and Hospital Level (Adult and Paediatric) – Stakeholder comment requests

ERC reviews (efficacy, safety, cost) and takes recommendations to NEMLC

NEMLC makes ultimate recommendation

Implementation (tenders, monitoring, etc.)

Therapeutic Interchange

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Therapeutic Class

A group of medicines which have:

- Active ingredients with **comparable therapeutic effects**,
- May /may not belong to the same pharmacological class,
- May differ in chemistry or pharmacokinetic properties,
- May possess different mechanisms of action,
- May result in different adverse reactions,
- May 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**.

Therapeutic Interchange Policy



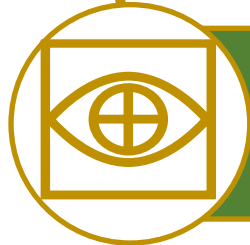
- Enables the prescribing of an alternative medicine instead of a medicine that was originally prescribed, **provided that both medicines are from the same therapeutic class.**
- These therapeutic classes have been **designated by NEMLC** with the criteria that none of the members of the class offer 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.

Therapeutic Interchange Policy – PTC responsibility

PTCs Responsibility:



Timeously facilitate communication of policies around designation of medicines into therapeutic classes from NDoH to relevant stakeholders



Implement and oversee processes to facilitate the switch from one member of the therapeutic class to another - minimise confusion or risks for patients



Put processes in place for the monitoring and reporting of adverse events and medication errors and ensure that these processes are followed

Thank you