



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



Reference: 2024/12/12/EDP/01

Enquiries:

DETAILS	STG LEVEL OF CARE	Contact
Jane Riddin	Paediatric Hospital Level	Jane Riddin
	Tertiary and Quaternary Level Essential Medicines List	E-mail: <a href="mailto:jane.riddin@health.gov.za">jane.riddin@health.gov.za</a> Tel: 012 395 8224
Maropeng Rapetsoa	Primary Healthcare Level	Maropeng Rapetsoa
	Adult Hospital Level	E-mail: <a href="mailto:maropeng.rapetsoa@health.gov.za">maropeng.rapetsoa@health.gov.za</a> Tel: 012 395 8465

## NOTICE OF REQUEST FOR COMMENT ON THE NATIONAL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE

The ministerially appointed National Essential Medicines List Committee (NEMLC) is responsible for developing and maintaining the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) for the public health sector for three levels of care, *i.e.* primary, secondary, and tertiary/quaternary care. The Primary Healthcare Level (PHC) STGs and EML are aimed for use by doctors and nurse prescribers providing care at PHC facilities; whilst the Adult and Paediatric Hospital Level STGs and EML are aimed for use by doctors providing care at district and regional level hospitals to provide access to essential medicines to manage common conditions at the respective levels of care. The Tertiary and Quaternary Hospital Level EML is aimed for use by prescribers at this specialist level of care.

The current Term of Office of the ministerially appointed NEMLC will end on the 7<sup>th</sup> of April 2025 and thus preparation for the next Committee's Term of Office and review cycle is underway. As part of the preparation, a prioritisation process will be undertaken to identify and select which topics will be prioritised for review during the next review phase.

This call for comment is to specifically help inform the topic prioritisation process and aid in identification of potential STG chapters and medicine review topics for review. This information will be utilised along with other criteria to inform selection of topics for review across all levels of care and for adults and paediatrics.

Stakeholders are therefore requested to provide input regarding the identification of potential topics for review (STG chapters and medicine amendments), where there are major errors, misalignment between levels of care and areas where significant review is required, will be appreciated. **Please note this is not a request for comprehensive comment on the actual STGs and EML.** If a topic is selected for review by NEMLC, there will be further opportunity for detailed comment and feedback before the review commences, as well as before final publication. All relevant stakeholders will be informed of the topics selected for review by the NEMLC.

# NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE

Please complete the forms below to substantiate any comment and topic suggestion made for the STGs (*Motivation Form for Request to Update Standard Treatment Guidelines* or *Motivation form for the inclusion of a new medication or new indication on the National Essential Medicines List*). **Please note that motivations received do not result in automatic qualification for review but will help inform the overall topic prioritisation process.**

The URL to the latest versions of STG chapters and associated technical documents is:

<https://www.health.gov.za/nhi-edp-stgs-eml/> or scan here:



Please note that updated STG chapters are now available separately for the PHC and Hospital Level STGs and EML (Adult and Paediatrics). Kindly circulate the request for comment to relevant healthcare professionals at your institutions. It would be appreciated if comments can be received by **07 February 2025**. Comments or queries related to this call for comment may be submitted *via* e-mail to:

Jane Riddin Tel: 012 395 8224 E-mail: jane.riddin@health.gov.za	Maropeng Rapetsoa Tel: 012 395 8465 E-mail: maropeng.rapetsoa@health.gov.za
---	---

Your support and input in this regard is encouraged and appreciated.

Kind regards



**ASSOC PROF. AG PARRISH  
CO-CHAIR: NATIONAL ESSENTIAL  
MEDICINES LIST COMMITTEE (NEMLC)  
DATE: 12 December 2024**



**DR R DE WAAL  
CO-CHAIR: NATIONAL ESSENTIAL  
MEDICINES LIST COMMITTEE (NEMLC)  
DATE: 12 December 2024**

**NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE**

**MOTIVATION FORM FOR REQUEST TO UPDATE STANDARD TREATMENT GUIDELINES**

*\*For new medicine motivations (new medicine or new indication), please go to pages 5 and 6.*

<b>Section 1: Motivator's Details</b>			
<b>Are you submitting as: A) An individual; B) Through a Pharmaceutical Therapeutic committee (PTC); or C) On behalf of an organisation? <i>Please mark 'x' in the applicable section</i></b>	<b>Individual</b>	<b>PTC</b>	<b>Organisation</b>
	<i>See Section 1A</i>	<i>See Section 1B</i>	<i>See Section 1C</i>
<b>Please fill in the relevant section and state N/A for the other sections and then move on to Section 2</b>			
<b>Section 1A. Individuals</b>			
<b>Name:</b>	<b>Date submitted:</b>		
<b>Email:</b>	<b>Phone number:</b>		
<b>Qualification:</b>	<b>Registration number:</b>		
<b>Name of your organisation/employer:</b>			
<b>Signature of motivator</b>			
<b>Section 1B. Through a PTC</b>			
<b>Name of motivator (individual submitting):</b>	<b>Date submitted:</b>		
<b>Email:</b>	<b>Phone number:</b>		
<b>PTC Details:</b>			
<b>Signature of motivator</b>			
<b>PTC Chair:</b>	<b>PTC Chair signature:</b>		
<b>Section 1C. Organisation</b>			
<b>Name of motivator (individual submitting):</b>	<b>Date submitted:</b>		
<b>Email:</b>	<b>Phone number:</b>		
<b>Name of your organisation/employer:</b>			
<b>Signature of motivator</b>			

**NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE**

<b>Section 2: Submission details</b>			
<i>This section allows for motivation for three STG topics, please fill in additional forms if additional motivations are required.</i>			
<b>Standard Treatment Guideline proposed for review?</b>  <i>Please mark relevant box with an 'X'</i> <i>Select more than one if applicable</i> <i>(disorder across levels of care)</i>	<b>Primary Healthcare Level</b>	<b>Paediatric Hospital Level</b>	<b>Adult Hospital Level</b>
<b>Specific chapter proposed for review</b>			
<b>Rationale for proposal</b>			
<b>Standard Treatment Guideline proposed for review?</b>  <i>Please mark relevant box with an 'X'</i> <i>Select more than one if applicable</i> <i>(disorder across levels of care)</i>	<b>Primary Healthcare Level</b>	<b>Paediatric Hospital Level</b>	<b>Adult Hospital Level</b>
<b>Specific chapter proposed for review</b>			
<b>Rationale for proposal</b>			
<b>Standard Treatment Guideline proposed for review?</b>  <i>Please mark relevant box with an 'X'</i> <i>Select more than one if applicable</i> <i>(disorder across levels of care)</i>	<b>Primary Healthcare Level</b>	<b>Paediatric Hospital Level</b>	<b>Adult Hospital Level</b>
<b>Specific chapter proposed for review</b>			
<b>Rationale for proposal</b>			
<b>Other suggestions</b>			
<b>If this topic is selected for review, are you as an individual, or on behalf of your organisation or PTC, interested in being a part of the review process?</b>			

# NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE

## GUIDELINES FOR THE MOTIVATION OF A NEW MEDICINE ON THE NATIONAL ESSENTIAL MEDICINES LIST

### Section 1: Medication details

- » Generic name  
A fundamental principle of the Essential Drug Programme is that of generic prescribing. Most clinical trials are conducted using generic names.
- » Proposed indication  
There will usually be many registered indications for the medication. However, this section should be limited to the main indication which is supported by the evidence provided in section 2.
- » Prevalence of the condition in South Africa  
This information is not always readily available. However, it is an important consideration in the review of proposed essential medicine.
- » Prescriber level  
Here the proposed prescriber level should be included. If more than one level is proposed each relevant box should be ticked.

### Section 2: Evidence and motivation

- » Estimated benefit
  - Effect measure: this is the clinical outcome that was reported in the clinical trial such as BP, FEV, CD<sub>4</sub>, 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 Need 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	<i>a</i>	<i>c</i>	<i>a + c</i>
Control group	<i>b</i>	<i>d</i>	<i>b + d</i>

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

Reference - Aust Prescr 2008; 31:12–16.

# NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE

- » Motivating information (GRADE approach to assess the quality of evidence)
  - The National Essential Medicine List Committee has endorsed the adoption of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach<sup>1</sup> for determining the certainty of evidence. Please provide information about the overall certainty of the evidence for each outcome according to that reported in the citations you use and ideally using the GRADE approach. The GRADE approach considers issues related to internal validity (risk of bias, inconsistency, imprecision, publication bias) but also to external validity, such as directness of results.
  - The GRADE approach – quality of evidence and definitions:

<b>High quality</b>	Further research is very unlikely to change our confidence in the estimate of effect
<b>Moderate quality</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
<b>Low quality</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
<b>Very low quality</b>	Any estimate of effect is very uncertain

- » 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 can be included:
    - Cost per daily dose or course of therapy – for long term or chronic therapy such as hypertension the usual daily dose should be calculated (Dose x number of times a day) and converted into the number of dosing units e.g. tablets. This is then used to calculate the cost per day. For medications used in a course of therapy such as antibiotics this is then multiplied by the number of days in the course of therapy.
    - Cost minimisation is used where there is evidence to support equivalence 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 along a level playing field.

Where any of these have been performed tick the relevant block and send as an attachment with all the calculations. If possible, the spread sheet should be supplied electronically.

### Section 3: Motivator’s Details

The receipt of all submission will be acknowledged. In addition, all decisions with supporting arguments will be communicated where appropriate. This section therefore forms a vital link between the motivator and the decision-making process.

<sup>1</sup> Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol. 2011;64(4):383-94

**NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE**



**health**

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



**Motivation form for the inclusion of a new medication on the National Essential Medicines List**

<b>Section 1: Medication details</b>			
Generic name (or International Non-proprietary Name):			
Proposed indication:			
Prevalence of condition (based on epidemiological data, if any):			
Prescriber level			
Primary Health Care 1	Medical Officer 2	Specialist 3	Designated Specialist 4
<b>Section 2: Evidence and motivation</b>			
<b>2.1 Estimated benefit - key outcome(s)</b>			
1. <u>Outcome</u>			
Effect size			
Risk difference (95% CI)			
NNT			
2. <u>Outcome</u>			
Effect size			
Risk difference (95% CI)			
NNT			
<b>2.2: Motivating information</b> ( <i>Determine the certainty of evidence ideally using the GRADE approach</i> )			
High quality	Moderate quality	Low quality	Very low quality
<b>A. New product</b>			
Author	Title	Journal ref	
<b>B. Product currently listed on the EML, new indication</b>			
Author	Title	Journal ref	
<b>2.3: Cost-considerations</b>			
Have you worked up the cost?	YES		NO
	Daily cost	Cost minimisation	Cost-effectiveness analysis
Other relevant cost information if available:			
Author	Title	Journal ref	
<b>2.4: Additional motivating comments</b>			

**NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LISTS FOR ALL LEVELS OF CARE TO GUIDE TOPIC PRIORITISATION FOR THE 2025 NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE REVIEW PHASE**

<b>Section 3: Motivator's Details</b>	
<b>Name:</b>	<b>Date submitted:</b>
<b>Qualification:</b>	<b>Registration number:</b>
<b>PTC motivation: Y/N</b>	<b>PTC Details:</b>
<b>PTC Chair:</b>	<b>PTC Chair signature:</b>