DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

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NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST FOR PRIMARY HEALTHCARE AND ADULT HOSPITAL LEVEL OF CARE

The ministerially appointed National Essential Medicines List (EML) Committee has reviewed the following sections of the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) for Primary Healthcare (PHC) and Adult Hospital Levels of care:

Level of care	Chapter
Adult Hospital Level	Ch9: Systemic and healthcare-associated infections
Adult Hospital Level	Ch20: Emergencies and injuries

Please note that there is a supporting NEMLC report for the chapter, which provides the rationale and evidence for any changes to the medicine recommendations in each chapter. Please review the proposed drafts together with the respective NEMLC report; and medicine reviews/costing analyses, as appropriate.

The Primary Health Level STGs and EML are aimed for use by doctors and nurse prescribers providing care at primary healthcare facilities; whilst the Adult Hospital Level STGs and EML are aimed for use by doctors providing care at district and regional level hospitals to provide access to pharmaceuticals to manage common conditions at the respective levels of care.

Kindly circulate the request for comment to relevant healthcare professionals at your institutions. Constructive comment regarding the identification of major errors, particularly involving diagnosis and treatment, will be appreciated. Please include a short motivation to substantiate any comment made.

Where an alternative medicine is recommended, this should be supported by appropriate evidence. Attached is the guideline for the Motivation of a New Medicine on the National Essential Medicines List.

It would be appreciated if comments can be received by **30 November 2022.**

Comments may be submitted via e-mail to:
Dr Janine Jugathpal
E-mail: Janine.Jugathpal@health.gov.za

Your co-operation in this regard is appreciated.

Kind regards

ASSOC PROF. AG PARRISH
CO-CHAIR: NATIONAL ESSENTIAL MEDICINES
LIST COMMITTEE (NEMLC)
DATE: 20th October 2022

DR R DE WAAL
CO-CHAIR: NATIONAL ESSENTIAL MEDICINES
LIST COMMITTEE (NEMLC)
DATE: 20th October 2022

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 the generic name.

» 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 a 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_4, VL etc.
- Risk benefit: this should 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	a	c	a + c
Control group	b	d	b + d

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

Reference - Aust Prescr 2008;31:12–16

» 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[1] 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 takes into account 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:

High quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality	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
Very low quality	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 that can be included:
      o 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.
      o 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.
      o 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.

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[1] 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

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

DEPARTMENT OF HEALTH
Republic of South Africa

Section 1: Medication details			
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

Section 2: Evidence and motivation

2.1 Estimated benefit - key outcome(s)	
1. *Outcome*	
Effect size	
Risk difference (95% CI)	
NNT	
2. *Outcome*	
Effect size	
Risk difference (95% CI)	
NNT	

2.2: Motivating information *(Determine the certainty of evidence ideally using the GRADE approach)*

High quality	Moderate quality	Low quality	Very low quality

A. New product

Author	Title	Journal ref

B. Product currently listed on the EML, new indication

Author	Title	Journal ref

2.3: Cost-considerations

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

2.4: Additional motivating comments.

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