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Ref: 2020/12/10/EDP/01

NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST FOR PRIMARY HEALTHCARE (2020 EDITION) AND ADULT HOSPITAL LEVEL OF CARE (2019 EDITION)

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	Section/ STG
Primary Healthcare	Ch 10: Infections	Section 10.19.1: Coronavirus disease-19 (COVID-19)
Adult Hospital Level	Ch 6: Obstetrics	Section 6.7: Coronavirus disease-19 (COVID-19) in pregnancy
Adult Hospital Level	Ch 9: Infections	Section 9.4.2: Coronavirus disease-19 (COVID-19)

(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 **15 February 2021.**

Comments may be submitted via e-mail or by post to:
Trudy Leong
E-mail: trudy.leong@health.gov.za

Essential Drugs Programme
Private Bag X828
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Your co-operation in this regard is appreciated.

Kind regards

ASSOC PROF. AG PARRISH
CHAIRMAN: NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC)
DATE: 11 DECEMBER 2020

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	$\frac{1}{[b/(b+d)] - [a/(a+c)]}$
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)

» Motivating information (**Level of evidence based on the SORT system**)
  – The National Essential Drug List Committee has endorsed the adoption of the SORT system for categorising levels of evidence. This system[1] contains only three levels:

Level I	Good quality evidence	Systematic review of RCTs with consistent findings High quality individual RCT
Level II	Limited quality patient orientated evidence	Systematic review of lower quality studies or studies with inconsistent findings Low quality clinical trial Cohort studies Case-control studies
Level III	Other	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series

A: Newer product: for most newer products, level I evidence such as high quality systematic reviews or peer-reviewed high quality randomised controlled trials should be identified and referenced in the space provided.
B: Older products: many of these products were developed prior to the wide use of randomised controlled trials. However, there may be level I evidence where the product was used as the control arm for a newer product. If no level 1 evidence can be identified, then level II data from poorer quality controlled trials or high quality observational studies should be referenced in the space provided.

» 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.

[1] Ebell MH, Siwek J, Weiss BD, et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician. 2004;69:550-6.

DEPARTMENT OF HEALTH
Republic of South Africa

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

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			
Effect measure			
Risk difference (95% CI)			
NNT			
2.2: Motivating information (Level of evidence based on the SORT system)			
A. Newer product: High quality systematic reviews or peer-reviewed high quality randomised controlled trials (Level I)			
Author	Title		Journal ref
B. Older product with weaker evidence base: Poorer quality controlled trials or high quality observational studies (Level II)			
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:**