HOW TO USE THESE GUIDELINES

Principles

The National Drug Policy[1] provides for an Essential Drugs Programme (EDP) - a key component of promoting rational medicines use. Medicines are included or removed from the Essential Medicines List (EML) following an evidence-based review of safety and effectiveness and considering cost and other relevant practice factors. The review process is dynamic, and starts with prioritisation of chapters, medicines, or disease areas. The EML, STGs, and the reviews informing them are then updated and published on an ongoing basis. Each new review or update involves seeking input and comments from external stakeholders. Stakeholders are also given opportunity to input prior to final publication. All reasonable steps are taken to align the Standard Treatment Guidelines (STGs) with Department of Health guidelines available at the time of review. Some recommendations might not be aligned with the indications or doses included in South African Health Products Regulatory Authority (SAHPRA) approved professional information but are guided by the best available scientific evidence.

The perspective adopted in the Primary Healthcare (PHC) STGs is that of a competent authorised prescriber practising in a public sector facility. The STGs serve as a standard for practice but do not replace sound clinical judgment. It is important to remember that the treatments recommended are guidelines only, based on the assumption that prescribers can manage patients with the relevant conditions. This includes rational prescribing in the elderly and palliative care, as the use of some medicines, especially as people get older or more ill, can cause more harm than good. Optimizing medication use through targeted de-prescribing is vital in managing chronic conditions, avoiding adverse effects, improving outcomes, reducing pill burden, and maintaining or improving quality of life.

The PHC EML and STGs allow for managing patients with relatively common conditions at the primary level of care. They also guide the referral of patients with more complex or uncommon conditions to facilities with the skills and resources to provide further investigation and management. As such, they are a progression to the Adult and Paediatric hospital-level EMLs and STGs.

The PHC STGs and EML should be used by healthcare workers providing care at clinics, community health centres, mobile clinics, outreach programmes, and gateway or out-patient clinics at hospitals.
Pharmaceutical and Therapeutics Committees (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 the rational selection and use of medicines at all levels of

[1] National Drugs Policy, 1996. https://www.gov.za/documents/national-drugs-policy

care.[2]

Provincial PTCs are authorised to reasonably adapt the STGs/EML according to local circumstances and available expertise, and to facilitate and control access to medicines listed on the Adult and Paediatric hospital level EMLs at specific PHC facilities, where appropriate prescribers may be present.

Provincial PTCs are also responsible for facilitating access to medicines at PHC level for specific patients through down-referral from higher levels of care. This flexible approach aims to promote better utilisation of resources while providing access to healthcare that is more convenient for patients.

Given that the STGs and EMLs for the various levels of care are reviewed at different times, there may be periods when they are not perfectly aligned. Likewise, updated STGs and EMLs will not always be synchronised with public sector pharmaceutical tenders, and Provincial and local PTCs should facilitate the phase in/out of the relevant essential medicines.

Local formularies

A formulary is a continually updated list of medicines and related information on the diagnosis, prophylaxis, or treatment of disease and the promotion of health to satisfy the needs of the majority of the population served by a particular health establishment/s.[3]

All EML medicines should be available at the relevant level of care based on the package of services provided at a particular health establishment/s. PTCs should develop formularies aligned to treatment guidelines and protocols subjected to robust evidence-based interrogation and consideration of cost implications.

The EML has been developed to the generic or International Non-Propriety Name (INN) level. Each province, through the provincial PTC, is expected to review the EML and prevailing tenders and compile a formulary which:

» lists formulations and pack sizes that will facilitate care in alignment with the STGs and EML;
» selects the preferred member of a therapeutic class based on cost; and
» implement formulary restrictions that are consistent with the local environment.

Therapeutic classes are designated in the “Medicine treatment” sections of the STGs, which provide classes of medicines followed by an example of each class, such as ‘HMG-CoA reductase inhibitors (statins), e.g., simvastatin’. Therapeutic classes are designated where none of the class members offers any significant benefit over the other registered class members. It is

2 South African National Department of Health. 2019. National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa. Pretoria, South Africa.
3 South African National Department of Health. 2022. National Guideline for the Development, Management and Use of Formularies. Pretoria, South Africa.

anticipated that by listing a class rather than a specific medicine, there is increased competition and, hence, an improved chance of obtaining the lowest possible price in the tender process.

Where therapeutic classes are listed in the STGs, the local formulary should be consulted to identify the specific medicine approved for the facility. A therapeutic interchange database has been developed that lists medicines grouped into a therapeutic class for a specific condition, as outlined in the policy for classifying medicines into therapeutic classes for purposes of therapeutic interchange. The database and policy are available on the National Department of Health website:
https://knowledgehub.health.gov.za/elibrary/primary-healthcare-phc-standard-treatment-guidelines-stgs-and-essential-medicines-list-em &
https://www.health.gov.za/nhi-hpp-edp/

Navigating the guidelines

Each chapter covers a broad organ system, with cross-referral to other chapters where necessary. Within each chapter, conditions are usually listed alphabetically.

ICD10 codes

Diagnosis codes from the International Statistical Classification of Diseases and Related Health Problems (ICD-10) are included for each condition to facilitate the accurate recording of diagnoses. The primary ICD-10 code may be accompanied by a secondary code that is bracketed to differentiate a secondary manifestation from the primary aetiology. (For example, uncomplicated broncho-pneumonia with severe penicillin allergy would be coded as: J18.0+(Z88.0)). All the rules and guidelines for using ICD-10 must be applied as per the World Health Organization (WHO), the agreed South African Morbidity Coding Standards and Guidelines document, and the South African Master Industry Table (MIT).
Available at: https://www.health.gov.za/icd-10-master-industry-table/

Diagnosis

A brief description and diagnostic criteria for each condition are included to assist healthcare workers in making a diagnosis.

Medicine treatment

Medicines may be listed in a preferential order (e.g., the first medicine is the first-line option, the second medicine is the second-line option, etc.). The dosing regimens provide the recommended doses for usual circumstances. The actual dose prescribed should consider the patient's capacity to eliminate the medicine, interactions, and co-morbid states.

Paediatric dose calculation

Paediatric doses are usually provided as weight-band dosing tables according to age. Doses should be calculated by weight, described as mg/kg. If this is not possible, choose a dose from the weight-band tables. Only use the dose according to age as a last resort. In particular, do not use age bands if the child appears small for his/her age or is malnourished. Particular care should also be exercised when treating neonates, as the doses provided for children may not always be appropriate in this age group.

Different conditions may require different doses of medicine. 'Standard' paediatric weight-band medicines dosing tables are in an appendix. Where a specific condition is not listed in the appendix, refer to the STG in the main text of the guidelines for the dose specific to that condition.

Prescription writing

All prescriptions must:

- » be written legibly in ink OR typed, and printed OR entered electronically, where such systems exist by the authorised prescriber, and signed with the date on the prescription form (NOTE: only advanced electronic signatures are acceptable, and require access to specific software packages);
- » include the full name, identification number and address of the patient;
- » specify the age and, in the case of children, the weight of the patient;
- » have prescriber details, including contact details, i.e., name, qualification, registration and/or practice number, address and contact telephone number;
- » indicate the diagnosis on the prescription, where the patient has provided consent.

In all prescriptions:

- » State the treatment regimen in full:
  - medicine name (preferably the generic name or INN), strength and formulation,
  - dose,
  - dose frequency,
  - route of administration,
  - duration of treatment,
  - e.g., amoxicillin 250 mg capsules, 8 hourly orally for 5 days.
- » Write the name of the full medicine/preparation using the generic name.
- » Avoid abbreviations to reduce the risk of misinterpretation. Avoid the Greek mu (μ): write mcg as an abbreviation for micrograms.
- » Avoid unnecessary decimal point use. If necessary, write a zero in front of the decimal point only, e.g., 2 mg, not 2.0 mg, or 0.5 mL, not .5 mL.
- » Avoid Greek and Roman frequency abbreviations that cause considerable confusion (qid, qod, tds, tid, etc). Instead, state the frequency in terms of hours (e.g., '8 hourly') or times per day in numerals (e.g., '3x/d').
- » In the case of "as required", a minimum dose interval should be specified,

e.g., ‘every 4 hours as required’.

- » Most monthly outpatient prescriptions for chronic medication are for 28 days; check that the patient can access a repeat before the 28 days are completed. Repeats may be issued for Schedule 0 to 5 medicines for up to 6 months.
- » Prescriptions for Schedule 6 medicines are not repeatable and are to be issued monthly; the quantity should be expressed in words.

After writing a prescription, check that each item's dose, dose units, route, frequency, and duration are stated. Consider whether the number of items is too great to be practical for the patient, and check that there are no redundant items or potentially important drug interactions. Check that the prescription is dated and that the patient’s name, identification number and diagnosis/diagnostic code are on the prescription form. Only then should you sign the prescription and provide another way for the pharmacy staff to identify the signature if there are problems (print your name, use a stamp, or use a prescriber number from your institution’s pharmacy).

Nurses granted authorisation provided in terms of Section 56(6) of the Nursing Act 33, 2005, may prescribe medicines in accordance with the PHC STGs and EML and their scope of practice and the relevant Regulations. The STGs generally provide for all listed medicines to be prescribed by authorised nurse prescribers except where designated as “doctor prescribed” only or “doctor initiated”. Additionally, in some instances, a listed medicine may only be initiated by a nurse with the prior approval of a medical practitioner. The “doctor initiated” category refers to an initial prescription prescribed by a doctor, which a nurse prescriber may repeat. However, the latter provision does not apply to Schedule 5 or 6 medicines. The PHC STGs have been updated to include “Doctor prescribed” for all Schedule 5 and 6 medicines as PHC nurses with section 56(6) permits are limited to prescribing medicines up to Schedule 4 (GN.R. 2418 of 1984).

NEMLC reports

To promote transparency of medicine selection decisions, NEMLC reports, summary slide decks, medicine reviews and costing reports are available on the National Department of Health website: https://knowledgehub.health.gov.za/elibrary/primary-healthcare-phc-standard-treatment-guidelines-stgs-and-essential-medicines-list-em & https://www.health.gov.za/nhi-hpp-edp/

Other initiatives

The PHC STGs and EML supports the Ideal Clinic Framework (https://www.idealclinic.org.za/) and the Centralised Chronic Medicines Dispensing and Distribution (CCMDD) programme (See Central Chronic Medicine Dispensing and Distribution (CCMDD)).

Medicines safety

Provincial and local PTCs should develop medicines safety systems to obtain information regarding medication errors, prevalence and severity of adverse medicine events, interactions, and medication quality. These systems should support the regulatory pharmacovigilance plan and provide pharmacoepidemiology data to inform future essential medicine decisions and local interventions to improve safety.

In accordance with the SAHPRA's guidance on reporting adverse drug reactions in South Africa, healthcare workers (with the support of PTCs) should report all relevant adverse reactions to the National Adverse Drug Event Monitoring Centre (NADEMC). The Adverse Drug Reaction form and guidance on its use may be found at the following link: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/

Feedback

Comments that aim to improve these treatment guidelines are appreciated The submission form and guidance for completing the form are included with these guidelines under Guidelines For The Motivation Of A New Medicine On The National Essential Medicines List. Motivations will be accepted from Provincial PTCs only.

These guidelines are also reviewed regularly. During the review process, comments are requested during a comment period and should be forwarded directly to the EML Secretariat. Queries may be submitted to the Essential Drugs Programme via electronic mail to SAEDP@health.gov.za.