Section 21 Considerations for Inclusion in the Standard Treatment Guidelines, Essential Medicines List and Therapeutic Interchange Database

Guidance Document

Background

The South African Health Products Regulatory Authority (SAHPRA) is mandated to regulate the safety, efficacy and quality of all medicines in South Africa. Section 21 of the Medicines and Related Substances Act (Act No. 101 of 1965, as amended) states that:
(1) The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or in-vitro diagnostic (IVD) which is not registered.
(2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine[1].

The SAHPRA Guideline for Section 21 Access to Unregistered Medicines states that authorisation may be granted by SAHPRA *on an exceptional basis, where conventional therapies have been ruled out, have failed or are unavailable,* and emphasizes that *registered medicines should always be considered and/or used before considering the use of an unregistered medicine*[2].

Principles for Topic Prioritisation

Only medicines registered with SAHPRA should usually be considered for review by the National Essential Medicines List Committee (NEMLC) for inclusion in the Standard Treatment Guidelines (STGs), Essential Medicines List (EML) and Therapeutic Interchange Database, except under exceptional circumstances as detailed in this document. Any perceived intentional attempt to circumvent the SAHPRA registration process will not be considered an exceptional circumstance. The SAHPRA registration status of medicines can be confirmed at: SAHPRA Registered Health Products.

Medicines not registered with SAHPRA may be **considered for review** for inclusion in the STGs, EML and Therapeutic Interchange Database under the following circumstances:

- If **no other alternative medicine for the prevention, diagnosis or treatment** (which may include strength and dosage form) is registered and/or available in South Africa for an existing disorder within the STGs e.g. artesunate for severe malaria (prior to registration) and high strength atropine for organophosphate poisoning;
- If the medicine is included in the **current standard of care** for a particular disorder within the STGs but is no longer registered in South Africa e.g. glyceryl trinitrate;
- In a **public health emergency** such as an outbreak or pandemic, an unregistered medicine may be considered if it is essential for disease prevention or management and no registered alternative is available e.g. tecovirimat;

[1] Government of South Africa. *Medicines and Related Substances Act No. 101 of 1965, as amended*. Pretoria: South Africa.
[2] South African Health Products Regulatory Authority, 2025. *Guideline for Section 21 Access to Unregistered Medicines*. Pretoria: South Africa.

- If a new medicine is **anticipated by SAHPRA to be registered soon** (transparency of the SAHPRA registration pipeline required) e.g. dolutegravir and lenacapavir.

The rationale for reviewing the unregistered medicine and the recommended mechanism for its implementation, including registration status, must be clearly stated to guide implementation.

Principles of Implementation within the STGs and EML – Following Review

Once reviewed, one of the criteria for approval of the medicine to be included in the STGs, EML and Therapeutic Interchange Database is **registration status**. NEMLC may approve a medicine on the STGs, EML and Therapeutic Interchange Database that is not registered but approved via Section 21 on a case-by-case basis. Considerations include, but are not limited to:

- Immediate unmet clinical need and urgent safety issues e.g. artesunate IV for severe malaria prior to registration (refer to Appendix 1);
- Long-term availability, affordability, and sustainability of supply; and
- Transparent regulatory timelines for registration, if available.

Section 21 applications must be submitted to SAHPRA in accordance with the SAHPRA Guideline for Section 21 Access to Unregistered Medicines[3].

[3] South African Health Products Regulatory Authority, 2025. *Guideline for Section 21 Access to Unregistered Medicines*. Pretoria: South Africa.

Appendix 1

Example of Implementation of a Historical Section 21 Medicine Prior to Registration - Artesunate IV for Severe Malaria

Adult Hospital Level Standard Treatment Guidelines and Essential Medicines List 2015

MEDICINE TREATMENT

Intravenous therapy:

The preferred agent is parenteral artesunate:

- Artesunate IV, 2.4 mg/kg at 0, 12 and 24 hours; then daily until patient is able to tolerate oral therapy.
  - Administer at least 3 IV doses before switching to oral artemether/lumefantrine.

If parenteral artesunate is not available:

- Quinine, IV (1 mL = 300 mg quinine salt).
  - Loading dose: 20 mg/kg in dextrose 5% administered over 4 hours.
  - Maintenance dose: 8 hours after start of the loading dose, give 10 mg/kg in dextrose 5% over 4 hours repeated every 8 hours until there is clinical improvement and the patient can take oral therapy.
  - Monitor for hypoglycaemia and dysrhythmias at least 4 hourly.
  - If there is significant renal failure increase dose interval to 12 hourly after 48 hours.