

HISTORICALLY ACCEPTED USE OF ESSENTIAL MEDICINES

The evidence of efficacy for many older medicines is often limited, however, they have been considered to be the “standard of care” and have been used successfully in a particular setting for many years, without harm. Moreover any further critical review is unlikely to provide any additional information. As a result there are instances where certain medicines may be retained on the EML on the strength of their historically accepted use.

For the sake of transparency, the below criteria have been defined for the inclusion of such medicines on the EML on the basis of historically accepted safe use.

Historically accepted use may be justified on the following criteria:

1. The medicine is included in the WHO Model Essential Medicines List, either as a core or complementary item, for the indication requested.
2. The medicine is currently registered by SAHPRA for the indication.
3. There is evidence of long-established (prior to 1996*) safe and effective use of the medicine for the recognised indication in the public health sector.
4. There are no new safety or efficacy concerns.
5. The budget impact is not expected to be sufficiently large that a *de novo* review is justified.
6. Equitable access across the country is essential, and is limited only by the availability of adequately trained staff and availability of equipment.

All criteria should be met, and described in the Historically Accepted Use motivation template. If one or more of the criteria cannot be met, the designation can still be considered by the Committee, on motivation, with rationale for continued recommendation clearly documented.

Periodic monitoring and evaluation for new safety and efficacy data of agents listed on the historically accepted use list.

NEMLC ratified criteria: 21 February 2019

* The Essential Drugs Programme (EDP) of South Africa was established in terms of the National Drug Policy (NDP) which was implemented in 1996.