

## Technical Alert

### Administrative update for the Evidence Guidelines for Listed Medicines (Phase 1)

### Upcoming 2019 TGA consultation of clarity of Evidence Guidelines (Phase 2)

#### Administrative update to the Evidence Guidelines for Listed Medicines released (Phase 1)

The TGA has released an updated version of the *Evidence Guidelines: Guidelines on the evidence required to support indications for listed complementary medicines*, Version 3.0 January 2019, which is replacing Version 2.1 July 2014.

The new version reflects changes to the regulatory framework in 2018, particularly the introduction of permitted indications in March 2018, as well as the availability of the new pre-assessed pathway for listed medicines, “Listed Assessed medicines” (note that Listed Assessed medicines still retain their own separate Evidence guidelines).

Key changes include:

- Removal of general introductory information at the start of the document that is available in other guidance material, notably the ARGCM (Australian Regulatory Guidelines for Complementary Medicines).
- Changes to the examples used, to be consistent with permitted indications.
- Other formatting and typographical changes including updated hyperlinks.

#### Resources:

The updated January 2019 Evidence Guidelines is available on the TGA website [here](#) and by [PDF](#).

The former July 2014 Evidence Guidelines is available on the TGA website [here](#) and by [PDF](#).

#### Upcoming 2019 TGA consultation of clarity of Evidence Guidelines (Phase 2)

In 2019, the TGA will be reviewing and updating the Evidence Guidelines for improved clarity. CMA are preparing a submission for the TGA to consider when updating the guidelines.

As an outcome of the review, the TGA is interested in how the following can be achieved for sponsors:

- An increased understanding of the evidence requirements for listed medicines.
- A greater understanding of how to ensure that indications align with evidence for the medicine.
- How to hold and present better quality evidence packages to support medicine indications.

CMA welcomes all member views and experiences regarding evidence challenges for listed medicine sponsors, the kinds of issues that have been arising, and how the best balance can be achieved.

Concerns can be directed to [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au)

**ENDS**