**Technical Alert**

# TGA Listed Assessed Pathway & Guidelines now available

The TGA have now released information about the Listed Assessed pathway for complementary medicines on the TGA website.

To be eligible for the pathway, medicines must only contain listable ingredients, and must contain *at least one* "intermediate level" indication, which:

- Make a reference to, or imply, the prevention, alleviation, or cure of a non-serious disease, ailment, defect or injury; or
- Refer to a restricted representation (i.e. a serious form of disease) – such as a health benefit or symptom relief, not prevention, alleviation or cure.

Medicines listed through the assessed listed medicines pathway will be included in the ARTG following self-certification by the applicant of the safety and quality of the product, and TGA assessment of the efficacy evidence supporting the proposed indications.

Medicines listed through the pathway will also be eligible to include a "positive claimer" of efficacy on the product label. The proposed design(s) of the positive claimer are expected to be released for public consultation in the next several weeks.

## TGA Weblinks

- TGA Overview of Listed Assessed Pathway
- A description of the three-tier framework for complementary medicines
- Decision Tree for pathways
- Frequently Asked Questions
- Webpage for Version 1.0 of Assessed Listed Medicine Evidence Guidelines
- PDF of Version 1.0 of Assessed Listed Medicine Evidence Guidelines

## Fees

Applications for the new listed assessed pathway may be submitted to the TGA, following a (free) pre-submission meeting. Applications for the new pathway incur the following charges:

Full de novo evaluation of efficacy ("LA3"); or, Evaluation of efficacy based on international evaluation reports[1] which meet the minimum data requirements ("LA2"):

- **$15,160** (1,760 application fee + 13,400 evaluation fee)

Evaluation of a clone of an existing product, where the only difference is the name and/or flavour, fragrance, printing ink or colour ("LA1"):

- **$2,070** (430 application fee + 1,640 evaluation fee).

[1] Note that a list of comparable overseas regulators is not yet available, the TGA's intention is for the list to be built over time. They are intending to publish guidance and application checklists for applicants based on the proposed framework soon.

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## Requirement to Transition

A listed medicine will need to transition to the assessed listed medicines pathway in the next 3 years if it has intermediate level indications that are not included in the list of permitted indications, and you intend to continue using these indications. Alternatively, if these indications fit the criteria to be a permitted indication, a sponsor can apply to have the indication added to the permitted indications list. CMA is also currently discussing the addition of some kinds of permitted indications with the TGA on behalf of members in certain situations. In other cases, the TGA application fee will continue to apply.

CMA has further information about both of the above, please contact CMA if you are unsure of the status of particular indication not included on the current permitted indication list and that is on your product, at technical@cmaustralia.org.au

**ENDS**

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