Australian Government
Department of Health
Therapeutic Goods Administration

Assessed listed medicines pathway for complementary medicines

From 19 March 2018 complementary medicines sponsors have the option to enter their medicine in the Australian Register of Therapeutic Goods (ARTG) via a new pathway for listing – the ***assessed listed medicines pathway*** *– AUST L(A)*

A three-tiered risk-based framework for the regulation of complementary medicines

Introduction of the assessed listed medicines pathway will establish a three-tiered risk-based regulatory framework for complementary medicines:

- **Lower risk** medicines are listed in the ARTG after self-certification by sponsors that all legislative requirements are met.
- **Intermediate risk** medicines are listed in the ARTG after the self-certification of quality and safety of the product and undergo pre-market assessment for efficacy evidence (assessed listed medicines).
- **Higher risk** medicines are registered in the ARTG after successful full pre-market assessment of quality, safety and efficacy.

The new assessed listed medicines pathway will allow sponsors to use indications that fall outside the permitted indications list (**intermediate** level indications), but in all other respects the medicine meets the eligibility criteria for listed medicines (permitted ingredients, GMP and compliance with applicable standards).

Intermediate indications are generally more definitive and may relate to more serious health conditions. Incorrect use of these medicines may lead to a delay in seeking medical treatment and adverse consequences for the consumer.

Intermediate level indications can be used following successful pre-market assessment of efficacy evidence

Intermediate level indications may include references to:

- Prevention or alleviation of non-serious forms of a disease, ailment, defect or injury.
- **Restricted representations** (i.e. a serious form of a disease).

Assessed listed medicines are the same as listed medicines in all respects - except for the indications they are able to use.
Assessed listed medicines will be included in the ARTG following successful pre-market assessment of efficacy evidence by the TGA.

Evidence provided must meet minimum data requirements

Assessment of efficacy data will include a detailed evaluation of evidence to support intermediate level indications and any permitted indications to determine if the data supplied adequately supports those indications. The evidence dossier requirements, which will introduce different methods in establishing efficacy for intermediate indications, and supporting guidelines will be made available before the assessed listed medicines pathway is implemented.

Evidence to support low level indications will align to the evidence requirements for listed medicines.

Eligibility and regulatory requirements for assessed listed medicines

Ingredients	Must draw exclusively from the permitted ingredients list. Ingredients must not be included in a schedule to the Poisons Standard.
Indications	Intermediate level indications that exceed the permitted indications list but are not high level indications. May also include lower level indications.
Product & Manufacturing quality	Must comply with applicable standards. Must not be required to be sterile. Must be manufactured under GMP.
Level of pre-market assessment and evidence requirements	Approval by a delegate of the Secretary. Assessment of the efficacy of the finished product and label prior to approval. No evaluation of quality or safety prior to approval, this is self-certified by the sponsor. Evidence submitted by sponsor to support all associated indications and claims is assessed pre-market by the TGA.

Not all complementary medicines are suitable for the assessed listed medicines pathway

The intended purpose of assessed listed medicines pathway is not to assess complementary medicines that only make low level indications (indications that are, or meet the criteria to be included on the permitted indications list). Only products supported by **quality scientific evidence** for efficacy will be accepted for assessment through the assessed listed medicines pathway.

supported by quality scientific evidence will be accepted for pre-market assessment

Assessed listed medicines will have the option to use a label claimer

Complementary medicines that have undergone TGA pre-market assessment (this includes registered complementary medicines) will have the option to use a claimer on labels that their product has been assessed for efficacy by the TGA. The specifics of the claimer are **currently being finalised**.

For more resources and further information go to

www.tga.gov.au/complementary-medicines-reforms

Complementary.Medicine.Reforms@health.gov.au