Australian Government
Department of Health
Therapeutic Goods Administration

The three-tiered risk-based framework for complementary medicines

On 19 March 2018 a new pathway to enter a complementary medicine in the Australian Register of Therapeutic Goods (ARTG) will be introduced – the assessed listed medicines pathway. Australia will then have three types of complementary medicines available to consumers: listed medicines, assessed listed medicines and registered complementary medicines. These are categorised on the ingredients they contain, and therapeutic indications (claimed health benefits) they use.

Listed and assessed listed medicines may only use ingredients which are included in the Therapeutic Goods (Permissible Ingredients) Determination. Registered complementary medicines may use any complementary medicine ingredient, provided it is not in Schedules 4, 8 or 9 of the Poisons Standard.

The table below assists sponsors in determining the appropriate risk category of the medicine based on based on the claimed therapeutic indications.

Three-tiered risk-based hierarchy of indications

Lower risk	Intermediate risk	Higher risk
A low level indication may refer to: • health enhancement • health maintenance • prevention of dietary deficiency • a disease, ailment, defect or injury other than a serious form of those diseases. A low level indication **must not**: • refer to, or imply, the prevention, alleviation, or cure of any form of a disease, ailment, defect or injury • contain a prohibited representation • contain a restricted representation • have been specified in any non-permitted indications list.	Intermediate level indications may refer to: • refer to the prevention, cure or alleviation of a non-serious form of a disease, ailment, defect or injury • restricted representations (i.e. a serious form of a disease). An intermediate level indication **must not**: • refer to the prevention, cure or alleviation of a restricted representation (i.e a serious form of a disease) • contain a prohibited representation.	High level indications may refer to: • prevention, alleviation or cure of a serious form of a disease, ailment, defect or injury (i.e. restricted representations). A high level indication **must not**: • contain a prohibited representation.

Listed medicines may only use lower risk indications drawn exclusively from the list of permitted indications. Provided they only use permitted indications and ingredients permitted for use in listed medicines, they can be listed in the ARTG without undergoing pre-market assessment by the TGA.

Assessed listed medicines must have at least one intermediate risk indication, and may also include lower risk indications. Due to the slightly higher risk of assessed listed medicines, evidence of efficacy for all indications require successful pre-market assessment by the TGA before listing in the ARTG.

Registered complementary medicines may carry higher risk, intermediate risk and low risk indications. All aspects of registered complementary medicines undergo pre-market assessment.

The table below summarises the key aspects and regulatory requirements for each pathway to enter a complementary medicine in the ARTG.

Regulatory requirements for complementary medicines pathways

	Listed medicines AUST L	Assessed listed medicines AUST L(A)	Registered medicines AUST R
Ingredients	Must draw exclusively from the permitted ingredients list. Ingredients must not be included in a schedule to the Poisons Standard	Must draw exclusively from the permitted ingredients list. Ingredients must not be included in a schedule to the Poisons Standard	An ingredient from the permitted ingredients list and/or an ingredient in a schedule to the Poisons Standard, other than Schedule, 4, 8 or 9
Indications	Low level indications drawn exclusively from the permitted indications list	Intermediate level indications that exceed the permitted indications list but are not high level indications, and low level indications	High level indications which are not suitable for the listed or assessed listed medicines pathway, and intermediate and low level indications
Application	Self-certification that all legislative requirements are met	Self-certification of quality and safety with pre-market assessment of efficacy	Full pre-market assessment
Evidence	Evidence held by the sponsor	Efficacy evidence must be assessed pre-market by the TGA	Safety, quality and efficacy must be assessed pre-market by the TGA
Manufacturing Quality	Manufactured under GMP	Manufactured under GMP	Manufactured under GMP
Presentation	Presentation cannot state that the product has been assessed by the TGA	Sponsor able to use a 'claimer' on the label and other promotional material to indicate that efficacy of the product has been independently assessed	Sponsor able to use a 'claimer' on the label and other promotional material to indicate safety, quality and efficacy of the product has been independently assessed
Post-market compliance	Products may be selected for random or targeted review to confirm applicant certifications are correct. May include review of evidence to support claims	Products may be selected for random or targeted review to confirm applicant certifications are correct Efficacy evidence would not be routinely reassessed post-market	Products may be selected for post-market review; e.g. if there are safety concerns