



Listed medicines

The role of Australia's medicines regulator

Different types of medicines are regulated in different ways by the Therapeutic Goods Administration (TGA), depending on what they contain and how they are to be used. The level of regulatory scrutiny increases with the level of risk the medicine can pose to consumers. This approach allows resources to be targeted effectively.

Prescription medicines and most over-the-counter medicines are higher risk, which means they are classified by the TGA as registered medicines. These medicines go through thorough data evaluation by the TGA before they can be supplied in Australia, and registered medicine labels are marked with an AUST R number.

The TGA classifies low risk medicines as listed medicines. You will see an AUST L number on the label of a listed medicine. Generally, AUST L medicines can be selected off the shelf at supermarkets, health food shops, pharmacies and other retailers. Listed medicines may include vitamin and mineral supplements, traditional Chinese medicines and herbal medicines. Unlike registered medicines, which include all prescription medicines and many over-the-counter medicines, such as pain killers and antihistamine tablets, the TGA does not assess each listed medicine to determine whether or not it will work in the way the supplier claims it will.

Supply of listed medicines in Australia

A listed medicine can only be marketed in Australia if:

- it contains nothing but pre-approved low-risk ingredients. These pre-approved ingredients have been evaluated by the TGA for quality and safety—but not for evidence that they will work.
- the manufacturing site (if in Australia) is inspected and licensed by the TGA, or if manufactured in a facility overseas, the site has been assessed by the TGA and determined as meeting appropriate standards. This means there are systems in place to control the quality of the final medicine.
- it does not make claims or imply that it will be useful in the treatment or prevention of serious illnesses that would require the involvement of a health professional.

Sponsors of listed medicines must hold evidence that:

- supports the health benefits or claims they are making about their product
- the medicine has been manufactured by a facility that has been authorised by the TGA
- the medicine only contains pre-approved low-risk ingredients.



Listed medicines—what the TGA looks at and does not look at

Many listed medicines, for example, multivitamins, have multiple ingredients that go into the final medicine. Before an ingredient can be used in a listed medicine, TGA scientists review the ingredient's safety. The TGA does not assess whether there is any evidence to show that the ingredient in the listed medicine is effective in the way claimed by the sponsor of the medicine.

In undertaking a review to establish the **quality** of an ingredient for use in listed medicines, the TGA will look at, among other things:

- composition of the ingredient (what the ingredient is and its purity)
- stability of the ingredient (how long the ingredient remains stable at a particular temperature without deteriorating significantly—this is used to determine shelf life and recommended storage temperature)

To ensure an ingredient is **safe** for use in listed medicines the review includes looking at:

- history of use
- biological activity (how the ingredient interacts with systems in the body)
- the likelihood of the ingredient being harmful based on available published evidence
- any reported adverse reactions.

Therapeutic goods must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied in Australia. Prior to listing on the ARTG the TGA does not evaluate:

- the final product (in contrast to the ingredients)
- the label
- the therapeutic claims made for the medicine or the evidence the sponsor may have to show the product will do what they say it will do.

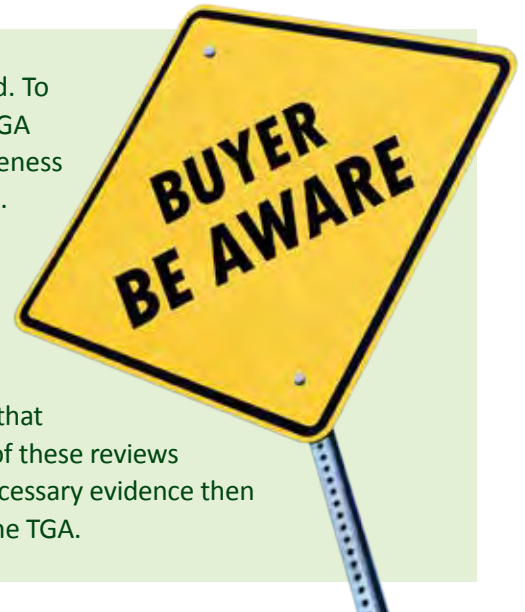
This evaluation does occur for registered medicines.

However, when listing the medicine the applicant must make a statutory declaration stating that the information submitted is true, the final product contains only permitted ingredients, the label complies with all regulatory requirements and the company has the necessary evidence to support the claims being made, including the therapeutic claims.



Consumers want access to a variety of medicines that they can afford. To reduce costs that would otherwise be passed onto consumers, the TGA does not require listed medicines to be evaluated for clinical effectiveness prior to marketing—but does require suppliers to hold that evidence.

However, no-one wants to risk their health or waste money when buying medicines and the Australian Government has taken this into account in relation to the regulation of listed medicines. This is why the TGA undertakes a number of targeted reviews of therapeutic claims made by particular listed medicines and assesses the evidence that companies are required to hold to support these claims. If as a result of these reviews it is found that the company listing the medicine does not have the necessary evidence then the approval to supply the medicine (the listing) can be cancelled by the TGA.



Regulation of listed medicines once they are in the marketplace

The TGA conducts both targeted and random surveillance of products in the marketplace. This can include laboratory testing, desk-based compliance reviews of sponsors' evidence and inspections of manufacturing facilities.

During these checks, problems that may be identified are:

- inappropriate claims being made for the medicines (and/or the sponsors not having evidence to substantiate claims)
- incorrect ingredients being used
- inappropriate or inaccurate labels
- manufacturing or quality issues.

The TGA then requires the supplier to remedy the situation or face cancellation of the product's listing, which means that the product would no longer be able to be legally sold in Australia.



Use of listed medicines

Make sure that you:

- always read a medicine label carefully and look closely at the claims (noting that the TGA has not independently verified these claims)
- follow the instructions for use
- consult a health professional about your health issues
- tell your health professional about all the medicines you are taking and any other therapies you are undertaking
- talk to your doctor or pharmacist about any other medicines that you may be taking before starting a new listed medicine. Some listed medicines may interact with other medicines or other supplements and may have side effects of their own
- be aware that there are risks associated with taking all medicines and try to find information on the benefits of the medicines as well as the risks—the [NPS Medicinewise](http://www.nps.gov.au/medicines/complementary-medicines) site can help you find information
- [report to the TGA](http://www.tga.gov.au/safety/problem.htm#medicine) any adverse event that you consider might be related to a medicine.



Links

NPS Medicinewise <<http://www.nps.org.au/medicines/complementary-medicines>>

Report a problem to the TGA <<http://www.tga.gov.au/safety/problem.htm#medicine>>

