# Generic Medicines - Facts and Fallacies

**GENERIC MEDICINES = QUALITY + AFFORDABILITY**

**Generic medicines have been available in Australia for 40 years, and widely supplied through the Pharmaceutical Benefits Scheme for over 20 years, delivering the same health benefits as the original brands at a lower cost to government and the community**.

Through monitoring generic medicine use over this time, their role as safe & effective treatment options has been confirmed.


## Facts

The following statements about generic medicines are TRUE

**A generic medicine is simply another brand, which contains the same active ingredient as the original brand, and which is accepted to work in the same way.**

Therefore generic medicine is the same quality as the original brand, and meets the TGA standards of safety and performance equivalence to the original brand.

**A generic medicine is subject to much greater government scrutiny compared to other "generic" or home brand consumer products that you buy at the supermarket.**

All medicines sold in Australia, whether a generic medicine or original brand, must meet the same tough quality standards set by a government agency called the Therapeutic Goods Administration (TGA). The role of the TGA is to evaluate and verify that all prescription medicines provide an appropriate safety and performance profile.

**Generic medicines, and their sites of manufacture, are thoroughly evaluated and approved by the government before they can be sold. The safety and performance of generic medicines is then continually monitored for as long as they are sold.**

The manufacturer of generic medicines must meet strict production and quality assurance standards set by TGA.

The performance of a generic medicine is then continually monitored once it becomes available to consumers. Any significant change to the accepted safety and performance profile of the medicine must be notified to TGA, doctors, pharmacists and consumers.

**Generic medicines always contain the same amount and type of active ingredient as the original brand, but sometimes they can contain different fillers and colours. Regardless of the ingredients used, all must meet the same strict standards of quality and safety.**

Fillers and colours are only changed to take advantage of newer or safer ingredients or to ensure the generic medicine delivers the active ingredient in a manner equivalent to the brand medicine.

The list of TGA approved fillers and colours that can be used to manufacture any medicine is relatively small, so similar ingredients are generally used in both the generic medicines and original brands.

**Given that the same active ingredient and same types of fillers are used in generic medicines compared to the original brand, how can a generic medicine be less expensive?**

Usually, original brand companies have been selling the active ingredient in a generic medicine for many years before the law permits a generic medicine to be made. This means that a great deal is already known and understood about the safety and performance of the active ingredient. This also means that the generic medicine's manufacturer can make the medicine at lower cost.

Generally a generic medicine manufacturer also spends less on advertising and promoting the medicine than the original brand company. The associated savings are often large and are passed along to you in the form of lower prices.

The Pharmacy Guild of Australia

GBMA Generic and Biosimilar Medicines Association

# Fallacies

The following statements about generic medicines are FALSE

**Here are some common misconceptions relating to the quality, safety or performance of generic medicines, and the reasons why they are incorrect.**

### ☒ A generic medicine is less expensive because it contains less active ingredient, cheaper fillers or meets lower standards

Generic medicines must by law contain the same active ingredient, use fillers and colours that are approved by the TGA for medicine manufacture, and deliver the same amount of active ingredient to the body in the same way as the original brand

### ☒ The government allows a generic medicine to contain up to 25% less active ingredient than the original brand

If a generic medicine contained, or delivered 25% less medicine than the original brand it would fail the strict TGA standards applied to all medicines in Australia and would be prohibited from sale.

### ☒ Because a generic medicine can be a different shape or colour compared to the original brand, it may produce more side effects or allergy.

The appearance of a medicine does not determine how well it works or the side effects it may produce. The safety and performance profile is entirely determined by the active ingredient and fillers used.

### ☒ A generic medicine may not work as well as the original brand because it is not required to undergo as much testing or human trials before it is sold.

All quality studies applied to the original brand must also be performed on the generic medicine. Some human trials testing safety and performance do not have to be repeated because we already know the outcomes of these tests, and the TGA accepts that the same safety and performance outcomes will be shared by the generic medicine and original brand.

### ☒ It's easy to develop a generic medicine, as it is only a copy of the original brand.

A generic medicine must contain the same amount of active ingredient, and be "bioequivalent" to the original brand. Meeting these requirements requires rigorous scientific testing and is harder than it seems. Should the generic medicine fail to meet the standards it will not be approved for sale in Australia.

'Bioequivalence' means that the generic medicine delivers the active ingredient into the body at the same rate and extent as the original brand, as determined in a trial. Even a small change in delivery (less than 10%) can cause the generic medicine to fail this test.

## REFERENCES


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To request more Facts and Fallacies resources, please contact:


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