



National Prescribing Service Limited

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How are medicines approved for use in Australia?

In the latest issue of *Australian Prescriber*, Dr John McEwen, Principal Medical Adviser to the Therapeutic Goods Administration (TGA) explains how medicines are regulated and how they are made available to consumers in Australia.

What is the TGA?

The Therapeutic Goods Administration (TGA) is the government agency that regulates medical devices and medicines in Australia. It is responsible for making sure that prescription, over-the-counter and complementary medicines are safe, effective and of a high quality.

How do I know my medicines are safe?

Medicines that meet Australian standards are included on the Australian Register of Therapeutic Goods (ARTG). Medicines have to be either listed or registered to be sold in Australia. Your medicines will be labelled with either 'AUST R' (registered) or 'AUST L' (listed) if they have been approved by the TGA.

What is a registered medicine?

Registered medicines have 'AUST R' printed on their label. These include prescription medicines, vaccines and almost all over-the-counter medicines, like paracetamol and aspirin. A small number of complementary medicines are also registered when there is enough evidence to show they help prevent or treat a disease.

The company that makes the medicine gives the TGA information about how it is made and supplies results of clinical trials that show it is safe and effective. If the medicine meets strict standards, it is registered for use in Australia.

What is a listed medicine?

Listed medicines have 'AUST-L' printed on their label. These products are almost all complementary medicines, including vitamins, herbal medicines, mineral supplements and traditional medicines.

Listed medicines are not registered because it is thought they are less likely to have adverse effects. Listed medicines must meet certain manufacturing standards and must not contain ingredients that are illegal in Australia.

For the complete article visit the *Australian Prescriber* web site www.australianprescriber.com. *Australian Prescriber* is an independent review providing critical commentary on drugs and therapeutics for health professionals. It is published by National Prescribing Service (NPS), an independent, non-profit organisation funded by the Commonwealth Department of Health and Ageing. NPS works to improve the health of all Australians through Quality Use of Medicines.

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