Australian Government
Department of Health
Therapeutic Goods Administration

Australian regulatory guidelines for complementary medicines (ARGCM)

13 December 2013

The Australian regulatory guidelines for complementary medicines (ARGCM) provide information for manufacturers, sponsors, healthcare professionals and the general public on the regulation of complementary medicines in Australia.

If you want to supply a complementary medicine in Australia, you may choose to employ a regulatory affairs consultant (for a list of consultants, refer to the Complementary Healthcare Council (http://www.chc.org.au/) the Australian Self Medication Industry (http://www.asmi.com.au/) and the Association of Therapeutic Goods Consultants (http://www.atgc.com.au/)).

Contents

Abbreviations

Refer to the TGA acronyms & glossary (/about/glossary.htm) for terms, definitions & acronyms used in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

Version history

Version	Description of change	Author	Effective date
V5.0	ARGCM V5 is a revision and restructure of ARGCM V4.2. Changes to the original document include formatting, corrections and clarification of information. While the revised document does not introduce any new procedures or procedural changes, the ARGCM V4.2 contained outdated information which has been amended to reflect current regulatory practice.	Office of Complementary Medicines	November 2013

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance) when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au (/index.htm)>.

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