



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/), (<http://www.chc.org.au/>) the [Australian Self Medication Industry](http://www.asmi.com.au/) (<http://www.asmi.com.au/>) and the [Association of Therapeutic Goods Consultants](http://www.atgc.com.au/) (<http://www.atgc.com.au/>)).

Contents

- [Introduction \(/industry/cm-argcm-intro.htm\)](/industry/cm-argcm-intro.htm)
- [Part A: General guidance on complementary medicine regulation in Australia \(/industry/cm-argcm-part-a.htm\)](/industry/cm-argcm-part-a.htm)
- [Part B: Listed complementary medicines \(/industry/cm-argcm-part-b.htm\)](/industry/cm-argcm-part-b.htm)
- [Part C: New complementary medicine substance evaluation \(/industry/cm-argcm-part-c.htm\)](/industry/cm-argcm-part-c.htm)
- [Part D: Registered complementary medicines \(/industry/cm-argcm-part-d.htm\)](/industry/cm-argcm-part-d.htm)
- [Additional guidance material \(/industry/cm-argcm-additional-guidance.htm\)](/industry/cm-argcm-additional-guidance.htm)

Abbreviations

Refer to the [TGA acronyms & glossary \(/about/glossary.htm\)](/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 While the revised document does not introduce any new procedures or procedural changes, the ARGCM V4.2 contained outdated information which has been amended to reflect current regulatory practice.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 \(/index.htm\)](http://www.tga.gov.au (/index.htm))>.

Copyright

© Commonwealth of Australia 2013

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au (<mailto:tga.copyright@tga.gov.au>)>

Content last updated: Saturday, 30 November 2013

Content last reviewed: Saturday, 30 November 2013

Web page last updated: Friday, 13 December 2013

URL: <http://www.tga.gov.au/industry/cm-argcm.htm>