The International Journal of Healing and Caring On-Line

Volume 6, No. 1

January, 2006

RECENT DEVELOPMENTS IN COMPLEMENTARY MEDICINES REGULATION IN AUSTRALIA

John Hall, PhD

Abstract

This paper provides a brief overview of how complementary medicines are regulated in Australia and of important new developments occurring in the regulatory environment.

Following wide-ranging reforms in governmental regulation in the area of complementary medicines in the late 1990s, which were premised on the emerging recognition of roles they can play in healthcare, progress toward greater acceptance and use of these medicines has continued at an increasing pace.[1] Not only has this meant greater numbers of consumers and healthcare practitioners embracing complementary medicines but it has also posed significant challenges for the regulatory framework which operates for medicines in Australia.

The regulatory framework for complementary medicines in Australia

In Australia, medicines are regulated federally by the Therapeutic Goods Administration (TGA), which is a statutory body included within the Australian Government's health portfolio.

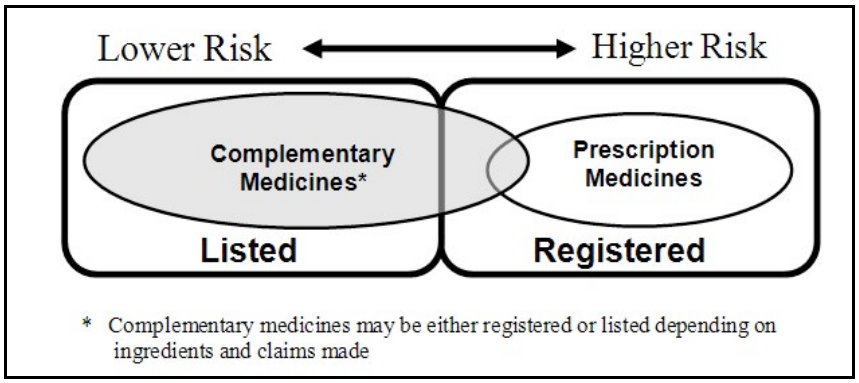
The TGA is responsible for administering the provisions of the Therapeutic Goods Act of 1989. The overall objective of the act is to ensure the quality, safety, efficacy and timely availability of therapeutic goods, including medicines, supplied in or exported from Australia. The TGA regulates many of the 'finished' medicine products presented for commercial sale and then prescribed by some healthcare therapists but has no responsibility for how such therapists are regulated or the interventions they use, these tending to be more matters of State jurisdictions.

Included among the types of medicines regulated by the TGA are complementary medicines which include herbal medicines, vitamin, mineral and nutritional supplements, traditional medicines such as Ayurvedic medicines and traditional Chinese medicines (TCM), homoeopathic medicines and aromatherapy oils.

The TGA maintains the Australian Register of Therapeutic Goods (ARTG), a database that includes details of all therapeutic goods that are imported into, supplied in, or exported from Australia. It is a legal requirement that, unless specifically exempt or excluded, all therapeutic goods be included in the ARTG prior to their supply. Therapeutic goods cannot be included in the ARTG unless an application is lodged by a 'sponsor' who is the person or company responsible for the product.

Based on risk, Australia has a two-tiered approach to regulation of medicines [2] (see Figure 1). Risk is determined by factors such as the ingredients in a medicine, the dosage form, indications and claims, the significance of side effects and the effects of prolonged or inappropriate use of the medicine.

Figure 1. The two-tiered risk-based approach to the regulation of medicines, showing the relationship between Listed and Registered medicines



Registered medicines

Medicines that are assessed to be of higher risk are individually evaluated for safety, quality and efficacy before they can be released onto the market.
If, following evaluation, they are approved by the TGA for use, they are included in the ARTG as Registered goods. Registered medicines include both prescription complementary medicines and non-prescription complementary medicines.

Listed medicines

A different process is applied to low–risk medicines, which includes most complementary medicines. Low–risk medicines are included in the ARTG as 'Listed' medicines and most complementary medicines fall into this category. These medicines are not individually evaluated before they are released onto the market, but are checked to ensure they comply with certain legislative requirements. The process by which these medicines gain entry to the ARTG is via a rapid automated system described below. (See Electronic Listing Facility).

New complementary medicine substances

New substances intended to be included in Listed complementary medicines must have a hard-copy application to the TGA. They are assessed for safety and quality by the Office of Complementary Medicines and then considered by an independent expert body, the Complementary Medicines Evaluation Committee (CMEC), which advises the TGA on suitability for inclusion in Listed medicines.

The Electronic Listing Facility (ELF)

This is an online computer-based Listed medicines market-entry system, which allows sponsors to directly interact with an electronic database to put new products on the Australian market. The latest version of the 'ELF' which replaced earlier paper-based and semi-automated electronic applications is a 'smart' system that reviews the ingredients of a new listable medicine and the medicine's Good Manufacturing Practice (GMP) status to determine eligibility for listing, prior to the listing of the medicine. It also provides users with the ability to view and update current ARTG medicines information and it electronically validates the information submitted by the sponsor or their agent to ensure that certain essential legislative requirements are met. For example, if any advisory statements or dose limits apply in relation to the proposed ingredients then the ELF system reminds sponsors of this.

In terms of the claims or indications allowed to be made for these products, sponsors may either select from a list of pre-set or 'coded' indications on the ELF system or they can make up their own 'free-text' indications. However sponsors also must certify to the TGA that they hold information or

evidence to support any claim or indication made in relation to the Listed medicine.
Currently there are about 19,000 Listed complementary medicines on the ARTG, with the vast majority of these being entered via electronic ELF-based applications.

Further detailed information on the ELF system is available on the TGA website.[3]

Post-market monitoring for complementary medicines

The risk-based approach taken by the TGA to the assessment of low–risk medicines allows for timely market access, but with a level of pre-market evaluation that delivers an assurance of safe, quality products. An important feature of this risk–management approach to regulation is that the early market access for Listed medicines is supported by a range of appropriate post-market regulatory activities.

A post-market monitoring system for complementary medicines has been developed by the TGA over recent years:

- to provide a high level of assurance of the safety of complementary medicines through a risk-based program of post-market monitoring and surveillance;
- to provide a high level of consumer confidence in the efficacy, safety and quality of complementary medicines; and
- to ensure a high level of industry compliance with regulatory standards and guidelines for complementary medicines.

A Post Market Unit within the Office of Complementary Medicines, in conjunction with other areas of the TGA, carries out a range of measures in order to meet these objectives including:

- targeted and random desk based audits of Listed products;
- monitoring of suspected adverse reactions;
- targeted and random laboratory testing of products and ingredients
- targeted and random surveillance in the market place;
- an effective, responsive and timely recalls procedure;
- audit of good manufacturing practice (GMP);
- surveillance with respect to investigation of illegal activities; and
- an effective co-regulatory approach to control advertising.

These measures have greatly assisted in providing timely identification and appropriate regulatory responses to problems with the formulation, manufacture, labeling and advertising of complementary medicines.

Review of Complementary Medicines

A major recall of more than 1,600 medicine products, mainly complementary medicines, took place in Australia in April 2003. This followed serious concerns by the TGA about the quality, and therefore safety, of medicines made by the particular manufacturer. A panel of experts, called the Expert Committee on Complementary Medicines in the Health System, was established to undertake a high level review of complementary medicines in the Australian Health System by examining and providing advice on:

- the regulatory controls covering appropriate standards of quality, safety and efficacy;
- consumer information;
- education and training of healthcare practitioners;
- interactions between complementary and prescribed medicines;
- restrictions on advertising; and
- activities to promote an innovative, responsible, and viable complementary medicines industry.

The Expert Committee made forty-nine recommendations relating to aspects of the complementary medicines industry and the practice of complementary medicine.[4] The topics covered by the recommendations included:

- *quality standards for ingredients*
- *levels of evidence of efficacy*
- *labeling information for recall purposes*
- *nationally consistent therapeutic goods legislation*
- *reporting of adverse reactions*
- *regulation of practitioners; and*
- *identification and funding of research needs in complementary medicine.*

After extensive consultation in Australia and New Zealand, the Government responded to each of the recommendations and accepted a package of initiatives aimed at further developing consumer awareness of and confidence in complementary medicines as well as enhancing Australia's reputation as a supplier of quality and safe medicines.[5] TGA has been given the responsibility for implementing the recommendations of the Expert Committee that are accepted by the Government. A detailed implementation plan, including time frames and consultative arrangements will be released in the near future.

Of particular interest are recommendations for major review in the regulation of herbal and homoeopathic medicines and considerable work that has been done by the TGA already on these.

Extensive consultation has recently taken place with regard to proposed new regulatory definitions for complementary medicines and homoeopathic medicines, and identified issues relating to the regulation of herbal substances, and the future regulation of homoeopathic and related medicines.[6] Some of the issues being addressed in the process include standardization and labeling of herbal ingredients and the labeling of homoeopathic products for potency in ways most easily understood by consumers. The submissions were used to inform the development of future legislative arrangements which will be in place in time for the commencement of a new joint Australia/New Zealand regulatory scheme for medicines. (See Establishment of a Trans-Tasman Agency to Regulate Therapeutic Products below).

Australian Regulatory Guidelines for Complementary Medicines

The TGA, in consultation with the key Australian complementary medicines industry bodies, the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia, has developed the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).[7] The ARGCM reflects both the special nature of most complementary medicines and the current Australian requirements for their regulation.

The ARGCM:

- provides information to help sponsors of complementary medicines meet their obligations under therapeutic goods legislation;
- helps ensure that applications to the TGA relating to complementary medicines uniformly meet all essential regulatory requirements so that applications may be processed successfully within minimum time frames;
- enhances clarity and transparency of processes leading to the inclusion of complementary medicines in the ARTG; and
- strengthens the basis for regulatory decisions made by the TGA.

The ARGCM details TGA regulatory processes and indicates the minimum requirements to support the quality, safety and efficacy of Registered and Listed complementary medicines. To meet the needs of all stakeholders requiring guidance on the regulation of complementary medicines, the ARGCM is structured to provide different levels of detail ranging from broad overviews to, for example, specific technical guidance on the selection and quality of published studies by product manufacturers to support the safety of complementary medicine substances.

The ARGCM has five subsections:

Part I – Registration of complementary medicines

This document provides guidance on the regulatory process and the requirements for quality, safety, and efficacy for the Registration of complementary medicines.

Part II – Listed complementary medicines

This provides guidance on regulatory process and the requirements for quality, safety, and efficacy for Listed complementary medicines.

Part III – Evaluation of complementary medicine substances

This provides guidance on the evaluation of complementary medicine substances for use in Listed medicines including both active and non-active (excipient) ingredients.

Part IV – General guidance

This provides general guidance in relation to complementary medicine modalities such as homoeopathy, traditional herbal medicine and aromatherapy. This part also provides information on exempt medicines, combination complementary/pharmaceutical medicines and the food/medicine interface and contains a glossary of terms.

There is no focus on complementary medicine/ conventional medicine interactive effects. This is a developing field and we don't see this as within the ambit of the guidelines for manufacturers.

Part V–policy documents and guidelines

This provides details of TGA policy guidelines relevant to complementary medicines.

Adjunct guidelines

Additional guidance has also been developed to supplement the ARGCM to provide specific advice on a range of manufacturing and quality control issues peculiar to complementary medicines including guidance on how to assemble evidence to support claims made for complementary medicines. These additional guidelines are available on the TGA website.[8]

Establishment of a Trans Tasman Agency to Regulate Therapeutic Products

The Australian and New Zealand governments have agreed to integrate the regulatory arrangements for therapeutic products, thereby removing unnecessary barriers to trade for Australian and New Zealand therapeutic products industries and have signed a treaty to this effect. The joint agency, which will commence on 1 July 2006, will replace Australia's TGA and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The new agency will be accountable to both the Australian and New Zealand Governments. It will be recognized in law in both Australia and New Zealand and will assume responsibility for the regulatory functions currently undertaken by the TGA and Medsafe.

The details of the joint regulatory scheme to be administered by the agency are being developed and include extensive consultation with stakeholders in both Australia and New Zealand.[9]

The primary policy objective for the joint scheme is to manage the risks to public health and safety from avoidable harm associated with the use of therapeutic products in both Australia and New Zealand and, in summary, it will cover:

- regulation of the manufacture, supply, import, export and promotion of therapeutic products;
- setting of standards in relation to the quality, safety, and efficacy or performance of therapeutic products and their manufacture, supply, import, export and promotion;
- post-market monitoring of therapeutic products; and
- enforcement of the requirements of the joint scheme.

A new classification of medicines will accompany the new scheme and for the purposes of legislation, a two-class approach will be adopted with low risk medicines, now called Listed medicines, to be known as Class 1 Medicines and higher risk medicines, now called registered medicines, to be known as Class II medicines. Most complementary medicines will be included in low risk Class 1 medicines.

In terms of transition to the new agency, medicines of all kinds will be able to continue to be supplied legally on the market in Australia or New Zealand. Then, for the yet to be decided period of transition to final permanent arrangements, full product licenses (allowing supply in both countries) will be issued by the Agency when compliance with Agency standards is demonstrated.

In summary

The past decade has seen an increase in usage of complementary medicine products by consumers in Australia and in their integration into mainstream medical care. Approaches to the regulation of these medicines, commensurate with their (usually low) risk have needed to evolve in line with this trend. Australia now enjoys a regulatory environment where manufacturers are clear about their obligations to place safe medicines of high quality and with verifiable claims onto the market. This in turn has provided a greater degree of trust and confidence to consumers who choose to self-medicate with these products. A major review of this regulatory system, and of complementary medicine issues more generally, is currently underway with widespread input and interest from all stakeholders.

References

1. MacLennan AH, Wilson DH, Taylor AW, 2002. The escalating cost and prevalence of alternative medicine. Preventive Medicine 35: 166–173

2. The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods: www.tga.gov.au/about/tgariskmnt.pdf

3. The Electronic Listing System: http://www.tga.gov.au/cm/cm.htm#elf

4. Report of the Expert Committee on Complementary Medicines in the Health System: www.tga.gov.au/docs/html/cmreport1.htm

5. Govt response to the Expert Committee on Complementary Medicines in the Health System: www.tga.gov.au/cm/cmresponse.htm

6. Consultation papers relating to the proposed regulatory arrangements for complementary medicines in the joint Australian New Zealand therapeutic products agency: www.jtaproject.com/hot.htm#CMConsult

7. Australian Regulatory Guidelines for Complementary Medicines, www.tga.gov.au/docs/html/argcm.htm

8. Adjunct guidelines available on TGA website as follows:

- Quantified by Input: www.tga.gov.au/docs/html/argcmqbi.htm
- Questions & Answers on Stability Testing of Listed Complementary Medicines: www.tga.gov.au/cm/stabilityqa.htm
- Questions & Answers for the Identification of Herbal Materials and Extracts: www.tga.gov.au/cm/idherbal.htm
- Guidelines for Levels and Kinds of Evidence to Support Indications and Claims: www.tga.gov.au/docs/html/tgaccevi.htm
- Colourings Permitted in Medicines for Oral Use: www.tga.gov.au/meds/colourings.htm
- Guidance on Product Changes in ELF 3: www.tga.gov.au/cm/elf3productchanges.htm
- Guide to interpretation of the Australian Code of Good Manufacturing Practice for Medicinal Products (16 August 2002) applicable to the manufacture of complementary medicines: www.tga.gov.au/manuf/gmpcodau_cm.htm
- Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSEs): www.tga.gov.au/docs/html/tsesupp.htm

9. Trans Tasman joint agency: http://www.tga.gov.au/tta/index.htm

Acknowledgements

The contribution of the following TGA staff to the preparation of this paper is acknowledged: Dr Peter Bird, Dr David Briggs, Mr Pio Cesarin, Mr Shaun Flor, Mrs Vikki James, Ms Alisa Kovacs, Dr Gary Lacey and Mr Michael Wiseman.

John G Hall, PhD heads up the Pre-Market Assessment Section of the Office of Complementary Medicines in the Therapeutic Goods Administration (the TGA), the Australian medicines regulator. His team assesses the safety, quality and efficacy of new complementary medicine substances and products destined for the Australian market. Dr Hall holds a PhD in pharmacology from the Australian National University and undertook post-doctoral studies at the University of British Columbia, Canada, before joining the Health portfolio as a medicines toxicology evaluator in 1978. After being a founding staffer at the National Food Authority in 1991, he joined the Office of Complementary Medicines in 1999 when it was established as part of major government reforms which recognised the growing importance of complementary medicines in Australia.

Dr John Hall, PhD
Post: Therapeutic Goods Administration
P.O. Box 100, Woden, ACT, AUSTRALIA, 2902
Phone: 02 6232 8062 Fax: 02 6232 8577
Email: john.hall@health.gov.au