

# The role of the Therapeutic Goods Administration and the Medicine and Medical Devices Safety Authority in evaluating complementary and alternative medicines in Australia and New Zealand

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## Abstract

Currently, the regulation of complementary and alternative medicines and related health claims in Australia and New Zealand is managed in a number of ways. Complementary medicines, including herbal, minerals, nutritional/dietary supplements, aromatherapy oils and homeopathic medicines are regulated under therapeutic goods/products legislation. The Therapeutic Goods Administration (TGA), a division of the Commonwealth Department of Health and Ageing is responsible for administering the provisions of the legislation in Australia. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) administers the provision of legislation in New Zealand. In December 2003 the Australian and New Zealand governments signed a Treaty to establish a single, bi-national agency to regulate therapeutic products, including medical devices prescription, over-the-counter and complementary medicines. A single agency will replace the Australian TGA and the New Zealand Medsafe. The role of the new agency will be to safeguard public health through regulation of the quality, safety and efficacy or performance of therapeutic products in both Australia and New Zealand. The major activities of the new joint Australia New Zealand therapeutic products agency are in product licensing, specifying labelling standards and setting the advertising scheme, together with determining the risk classes of medicines and creating an expanded list of ingredients permitted in Class I medicines. A new, expanded definition of complementary medicines is proposed and this definition is currently under consultation. Related Australian and New Zealand legislation is being developed to implement the joint scheme. Once this legislation is passed, the Treaty will come into force and the new joint regulatory scheme will begin. The agency is expected to commence operation no later than 1 July 2006 and will result in a single agency to regulate complementary and alternative medicines.

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## 1. Introduction

A range of complementary and alternative medicine practices are being increasingly used by the Australian and New Zealand public (MacLennan et al., 2002; Robson, 2003). An industry survey indicated that 77% of Australians use complementary medicines,

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supplied by a growing US\$ 1 billion industry comprising small, medium and large companies (Bensoussan et al., 2004; <http://www.medsafe.govt.nz/hot/fact.htm>). A good example is for Crohn's disease (CD), which mainly affects people in affluent developed countries, with approximately 500,000 sufferers in the US and a similar number in Europe. A recent New Zealand survey showed that a large percentage of CD patients utilise complementary or alternative therapies, with 72% finding dietary adjustment to be useful ([www.nutri-genomics.org.nz](http://www.nutri-genomics.org.nz)). Complementary medicines, including herbal, mineral and nutritional/dietary supplements, aromatherapy oils and homeopathic medicines are regulated under therapeutic goods/products legislation. These products are readily available from supermarkets, health food shops, pharmacies, by mail order or direct selling and supplied by various types of practitioners. The *Therapeutic Goods Act 1989* (Commonwealth of Australia, 2001a,b) came into effect in 1991. The Therapeutic Goods Administration (TGA) (<http://www.tga.gov.au/>), a division of the Commonwealth Department of Health and Ageing (<http://www.health.gov.au/>), is responsible for administering the provisions of the Act in Australia. On the other side of the Tasman Sea, Medsafe (<http://www.medsafe.govt.nz/>) is New Zealand's Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health (Acts and Regulations; Medicine Management; <http://www.moh.govt.nz/>), and is the authority responsible for the regulation of therapeutic products in New Zealand. This includes medicines, related products, herbal medicines, medical devices, controlled drugs used as medicines, etc., through the Medicines Act 1981 and regulations 1984, and parts of the Misuse of Drugs Act 1975 and Regulations 1977. The overall objective of these Acts is to ensure the quality, safety and efficacy of therapeutic goods, including medicines and medical devices, available to the Australian and New Zealand public.

## 2. Regulation of complementary medicines under the joint regulatory scheme

The Australian and New Zealand Governments have agreed to harmonise the regulatory arrangements for therapeutic products between both countries. They signed a Treaty in Wellington in December 2003 to establish a single, bi-national agency to regulate therapeutic products, including medical devices and prescription medicines, and over-the-counter, complementary and alternative medicines. The single agency that will replace the Australian TGA and the New Zealand Medsafe will

be accountable to both Australian and New Zealand Governments and will have a fully functional office in both countries (<http://www.jtaproject.com>). Under the joint Australia New Zealand therapeutic products agency (the joint agency), products represented as being for therapeutic use are to be regulated as therapeutic products. This includes complementary medicines such as herbal substances, homoeopathic and related medicines, as well as vitamin and mineral supplements, other nutritional supplements, traditional medicines and aromatherapy oils.

The new regulatory activities would draw on the best features of New Zealand, Australian and international approaches. Extensive public consultation occurred in December 2004 followed by release of a discussion document prepared by New Zealand and Australian officials to facilitate informed debate about the details of the scheme. Three consultation papers are now available for stakeholder comment (<http://www.jtaproject.com>). The papers propose new regulatory definitions for complementary medicines and homoeopathic medicines, and the appropriate level of regulation of homoeopathic medicines and related medicines and herbal substances under the joint agency. The papers focus on the development of an appropriate regulatory system for these medicines, which meets the needs of consumers, industry, health professionals and regulators, while protecting and enhancing public health and safety in Australia and New Zealand (<http://www.jtaproject.com>). Interested parties are invited to send their comments on the matters addressed in the consultation papers.

Article 1 of the Treaty defines 'therapeutic product' for the purposes of the joint scheme. This definition includes prescription medicines, over-the-counter medicines, complementary medicines, human blood and blood components, medical devices, and other products meeting the definition of therapeutic products. The related Australian and New Zealand legislation is currently being developed to implement the joint scheme. Once this legislation is passed, the Treaty will come into force and the new joint regulatory scheme will begin. The New Zealand and Australian Governments have announced a firm operational date for the new trans-Tasman therapeutic products agency of no later than 1 July 2006, although it could start earlier.

## 3. The current regulatory framework for therapeutic goods in Australia

Australia is a federation of states with a Commonwealth (Federal) Government and six State and two Territory governments. While the Therapeutic Goods Act

(Therapeutic Goods Administration, 2001) provides a substantially uniform national system of controls over therapeutic goods, other Commonwealth and separate State and Territory legislation may apply to certain therapeutic goods. In fulfilling its responsibilities under this Act, the TGA is required by the Australian Government to recover its operating costs through fees and charges.

The Australian Register of Therapeutic Goods (ARTG) is a database maintained by the TGA. It 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 must be included in the ARTG prior to their supply. Some aromatherapy oils and homoeopathic medicines are exempt from the requirement to be included on the ARTG database. The TGA, in consultation with the key Australian complementary medicines industry bodies the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia, have developed the Australian Regulatory Guidelines for Complementary Medicines (ARGCM, 2004; <http://www.tga.gov.au/docs/html/argcm.htm>). The ARGCM details TGA regulatory processes and indicates the minimum requirements to support the quality, safety and efficacy of Registered and Listed complementary medicines. In addition, eight adjunct guidelines have been developed to supplement the ARGCM to provide specific advice on:

- Guidance on the use of the term ‘quantified by input’<sup>1</sup> for complementary medicines.
- Questions and answers on stability testing of Listed complementary medicines.
- Questions and answers for the identification of herbal materials and extracts.
- Guidelines for levels and kinds of evidence to support indications and claims for non-registerable medicines, including complementary medicines, and other listable medicines.
- Colouring permitted in medicines for oral use.
- Guidance on product changes in the Electronic Listing Facility (ELF 3).
- Guide to interpretation of the Australian Code of Good Manufacturing Practice for Medicinal Products (16 August 2002) applicable to the manufacture of complementary medicines.

<sup>1</sup> The term ‘quantified by input’ refers to the practice of justifying some situations where the assay of an active ingredients in every batch of finished product is not necessary.

- Supplementary requirements for therapeutic goods for minimising the risk of transmitting Transmissible Spongiform Encephalopathies (TSEs).

There is a number of expert committees which provide advice to the TGA, including the Complementary Medicines Evaluation Committee (CMEC). The evaluation or assessment undertaken varies depending on the therapeutic product and its indications and claims. The Australian Adverse Drug Reactions Advisory Committee (ADRAC) provides advice on all areas of drug safety to the TGA including prescription medicines, vaccines, over-the-counter medicines and complementary medicines (Boyd, 2002).

### 3.1. Complementary medicine regulation

Australia has a unique regulatory system for complementary medicines and other therapeutic goods, the latest developments of which were based on a regulatory reform package introduced into legislation in 1999. Complementary medicine substances are defined in section 52F of the Therapeutic Goods Act 1989 (Commonwealth of Australia, 1989). Essentially, if the substance is a designated active ingredient that has an established identity and tradition of use, it is a complementary substance. A number of new substances (for example, activated charcoal, bovine colostrum powder, lutein, etc.) approved for inclusion in Listed medicines are now included in the latest consolidation of Schedule 4 of the Therapeutic Goods Regulations 1990. Indications and claims can be based on evidence of traditional use of a substance or product, and/or on scientific evidence. Indications/claims and evidence are categorised as being ‘general’, ‘medium’ or ‘high’ level.

#### 3.1.1. Indications/claims based on evidence of traditional use

To make an indication or claim based on evidence of traditional use, sponsors must first assess the level of the evidence and hold one of the following sources of evidence:

- TGA-approved Pharmacopoeia;
- TGA-approved Monograph;
- three independent written histories of use in the classical or traditional medical literature;
- availability through any country’s government public dispensaries for the indication claimed.

If one of the above sources of evidence is held, a general level evidence is held. If two of the above sources of evidence are held, medium level evidence is held. High

level indications and claims are not permitted based on evidence of traditional use.

If general level evidence is held, general level indications and claims can be made relating to:

- health maintenance, including nutritional support;
- vitamin or mineral supplementation;
- relief of symptoms (not related to a named disease, disorder or condition).

The following kinds of indications and claims are permitted for medium level evidence:

- health enhancement;
- reduction of risk of a disease/disorder/condition;
- reduction in frequency of a discrete event;
- aiding/assisting in the management of a named symptom/disease/disorder/condition;
- relief of symptoms of a named disease/disorder/condition.

### 3.1.2. Indications/claims based on scientific evidence

General level evidence includes:

- descriptive studies, case series or reports of relevant expert committees;
- texts, such as TGA-approved Pharmacopoeias or Monographs;
- other evidence-based reference texts.

The following kinds of evidence constitute medium level evidence:

- evidence obtained from well-designed controlled trials without randomisation;
- evidence obtained from well-designed analytical studies preferably from more than one centre or research group, including epidemiological cohort and case-control studies;
- evidence obtained from multiple time series with or without intervention, including within country and between country population studies.

The level of indications/claims for general and medium evidence are the same as required for evidence of traditional use.

High level evidence relates to diseases or disorders and includes:

- treatment, cure or management of any disease/disorder/condition;
- prevention of any disease, disorder or condition;

- treatment of a specific named vitamin or mineral deficiency diseases.

High level indications/claims require scientific evidence obtained from:

- a systematic review of all relevant randomised, controlled trials. The trials must be without significant variations in the directions and degrees of results; or
- at least one properly designed, randomised controlled (preferably multi-centre) double blind trial. It is preferable to have data from at least two trials independent of each other, but in some cases, one large well-conducted trial may suffice.

It is only possible to make high level indications/claims for registerable medicines. Listable medicines cannot carry high level indications and claims. Listed medicines are considered to be of lower risk than Registered medicines. Most, but not all, complementary medicines are Listed rather than Registered in the ARTG. Listed or Registered goods can be identified by the inclusion on the product label of a unique number preceded by either AUST L or AUST R, respectively.

The ingredients or kind of ingredients permitted to be included in complementary medicines are shown in Table 1 (Commonwealth of Australia, 2001c; Briggs, 2002). If a new substance is proposed for use in a Listed complementary medicine, it must first be evaluated. Only when accepted as low risk will it be permitted for use in a Listed medicine. Only certain claims and indications may be made for Listed medicines, regardless of whether

Table 1

Designated or kind of ingredients permitted in complementary medicines

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A choline salt
A homeopathic preparation
A microorganism, whole or extracted, except a vaccine
A mineral including a mineral salt and a naturally occurring mineral
A mucopolysaccharide
A lipid, including an essential fatty acid or phospholipid
A substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
A sugar, polysaccharide or carbohydrate
A vitamin or provitamin
An amino acid
Non-human animal material (or a synthetically produced substitute for material of that kind), including dried material, bone and cartilage, fats and oils and other extracts or concentrates
Plant or herbal materials (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll

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they contain only low risk ingredients (see later). If a complementary medicine ingredient is not considered suitable for use as a Listed medicine, it may, following evaluation, be suitable for inclusion in Registered complementary medicines.

All indications/claims must be true, valid and not misleading, and should not lead to unsafe or inappropriate use of the products. Evidence must relate to the whole product or the same active constituent(s) with similar dosage regimen, dose form and route of administration to the product/ingredient for which a claim is being made. Sponsors must hold evidence in line with these guidelines before claiming an intended use or indication for a product.

### 3.2. *The current regulatory framework in New Zealand*

Medsafe is New Zealand's Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. These include medicines and related products defined as a product that is primarily a food, dentifrice or cosmetic but has a secondary therapeutic use, herbal medicines, medical devices and controlled drugs used as medicines. The mission of Medsafe is to enhance the health of New Zealanders by regulating therapeutic products to maximise safety and benefit. Medsafe operates out of four offices, with centralised administrative functions, product approval and standard setting based at their head office in Wellington. In carrying out its functions, Medsafe is accountable to the Ministry of Health, and through the Ministry to the Minister of Health. It is also accountable to the pharmaceutical industry for those activities, which are funded by fees collected from the industry. Medsafe is responsible for administering the Medicines Act 1981 and Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Regulations 1977. At the moment, Medsafe does not regulate dietary supplements. These are regulated by the Dietary Supplements Regulations 1985 under the Food Act, administered by the New Zealand Food Safety Authority (NZFSA; <http://www.nzfsa.govt.nz>). Medsafe does regulate those products that make therapeutic claims and therefore are medicines. For example, when a herbal capsule claims to help or cure a disease state (for example, psoriasis or heart disease) the product is a medicine and requires approval through the route administered by Medsafe.

The objective of the medicine legislation is to manage the risk of avoidable harm associated with the

use of medicines. The legislation is designed to ensure that:

- medicines meet acceptable standards of safety, quality and efficacy;
- personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements designed to ensure that products meet acceptable standards right up until they are delivered to the end-user;
- information about the selection and safe use of medicines is provided to health professionals and consumers.

Medsafe is responsible for applying a framework of controls designed to ensure that the therapeutic products available in New Zealand are those that can be expected to have greater benefits than risks if used appropriately. This is achieved through pre-marketing approval of products, and post-marketing surveillance. The interface between therapeutic-type and food-type dietary supplements is subject to consultation between the NZFSA and Medsafe.

#### 3.2.1. *Pre-marketing approval*

Pre-marketing approval must be obtained for new and changed medicines. New medicines cannot be marketed in New Zealand without the consent of the Minister of Health (or his/her delegate). Medicines to which changes have been made cannot be marketed without the consent of the Director-General of Health (or delegate). Data that satisfactorily established the quality, safety and efficacy of the product, for the purposes for which it is to be used, must be submitted for evaluation before consent can be granted. The pre-market approval system for medicines is managed by Medsafe.

#### 3.2.2. *Post-marketing surveillance*

Post-marketing surveillance monitors the safety of medicines and medical devices in use. Products shown to be unsafe are removed from use, and prescribers are advised about new safety information for products. Post-marketing surveillance is achieved through activities such as:

- monitoring adverse reactions to medicines used in New Zealand and monitoring the international literature and other information sources;
- testing marketed medicines against product quality standards;
- handling complaints and investigations;
- auditing of GMP.

### 3.2.3. Transition for complementary medicines

During the finite period of transition the aims are to reduce duplication and to allow both agencies to make more effective use of their resources while maintaining the high level of consumer and professional confidence in the safety of medicines in Australia and New Zealand. Transitional arrangements will be required to give suppliers and manufacturers of complementary medicines in Australia and New Zealand time to achieve compliance with regulatory requirements under the joint scheme. These arrangements will be based on the principles set out in the Treaty. Applications meeting the specified criteria will be identified and separated out during the evaluation process and assigned to a technical secretariat for evaluation of key elements. For new applications and those in progress the product details will be entered onto an interim register through the Complementary Medicines Transition (COMET) database (<http://www.medsafe.govt.nz/CompMedPage.htm>). The product will receive an interim product licence (PL) for New Zealand only that will be valid for the 3-year transition period. It will be necessary to apply for a joint agency PL during the transition period. For low risk medicines or related products which include mouthwashes, shampoos and toothpastes, applications will be submitted in the usual way. Until new legislation is passed, however, Medsafe will continue to evaluate medicines and dietary supplements sold under the old legislation.

## 4. Conclusion

The establishment in 2006 of a single, bi-national agency to regulate therapeutic products including complementary medicines in New Zealand and Australia has opened an unprecedented level of trans-Tasman cooperation and collaboration in medical therapeutics between the two countries. Very recently the Australian Government has backed the recommendations contained in a high level review by the Expert Committee on Complementary Medicines in the Health System aimed at enhancing the public's confidence in the Australian alternative medicines sector. The public in both countries will be the main beneficiaries of a new, world-class regulatory system in complementary and alternative medicine areas. Currently, an Interim Ministerial Council is operational and related Australian and New Zealand legislation is being developed to implement the joint scheme. The overarching principles to apply to the transitional arrangements are outlined in Article 21 of the Treaty, i.e. "on and after the commencement date, the manufacture, supply, import, export or promotion of a therapeutic product that was lawful in the territory of one party

immediately before the commencement date continues to be lawful in the territory of that party for a specified period by virtue of the deemed grant of a transitional approval under the scheme on the terms and conditions (if any) that applied in respect of the manufacture, supply, import, export or promotion of a therapeutic product before the commencement date". The major activities of the joint Australia New Zealand therapeutic products agency will be concerned with product licensing, labelling standards and advertising schemes, risk classes of medicines and the expanded list of ingredients permitted in Class I medicines. A new, expanded definition of complementary medicines is proposed and this definition is currently under consultation. The proposed definition includes more objective criteria for determining the eligibility of a medicinal product or ingredient to be regulated as a complementary medicine. Although most will be classified as Class I medicines it allows for inclusion into Class II medicines. Class I complementary medicines are low risk medicines. All other complementary medicines are higher risk Class II complementary medicines for which a product licence can only be granted following evaluation of the safety, quality and efficacy of the medicines. It is important to note that even if a medicinal product or ingredient is determined not to be a complementary medicine, it may still be eligible for regulation as a Class I medicine. The new proposed regulatory definition would allow for traditional methods of manufacture of complementary medicines, but also permit the use of more modern methods in their manufacture provided they meet the required standards. In conclusion although complementary and alternative medicines are currently regulated by different agencies in Australia and New Zealand, a new joint agency will regulate this type of products in the future.

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