

Complementary (Traditional and Herbal) Medicines: An Australian Regulatory Perspective

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The article on *Traditional Medicine* by Dr Balasubramaniam (2010), notes that few countries have policies for such medicines. In addition, different countries have defined herbal products as foods, supplements or medicines with varying degrees of regulation.

Australia is a multi-cultural society with an indigenous and immigrant population encompassing many cultural, ethnic, linguistic and religious traditions. Around one in four Australians have been born overseas. This raises the question of how to ensure a diverse population has access to their own traditions of medicines while at the same time protecting them from the dangers of unregulated products and claims.

This problem has become more acute because increasingly these medicines are produced, marketed and sold to the public as a profit making venture in isolation from the tradition in which they originated.

Problems that have been identified include the adulteration of herbal products with dangerous western medicines such as sildenafil (Viagra), claims for efficacy that are out of all proportion to the evidence available and failure to inform consumers of potential adverse effects, including interactions with conventional medicines. There is also a problem with practitioners. Until recently, Australian doctors and pharmacists received little or no training in complementary medicines while the education of naturopaths, homoeopaths, herbalists and other complementary practitioners is so varied (and there is so much division in their ranks) that few have achieved national registration status.

Current Regulation of Complementary Medicines in Australia

Australia has defined (and regulated) indigenous medicines, traditional Chinese medicines, Ayurvedic medicines, homoeopathic medicines and other medicinal products containing herbs, vitamins, and minerals as Complementary Medicines and incorporated them into Australian Medicines Policy.

The legislative basis for regulation is the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* administered by Therapeutic Goods Administration (TGA). All therapeutic goods that are imported into, supplied in, or exported from Australia must be included on the Australian Register of Therapeutic Goods (ARTG) prior to supply. The aim is to ensure the quality, safety and efficacy of therapeutic goods. A two-tiered regulatory system is based on risk assessment (TGA, 2006).

Most complementary medicines are regulated as “Listed” (low risk) products by the TGA. They are identified by an AUST L number on the product label. Product efficacy is not evaluated. Sponsors self-enter details of their product on the Australian Register of Therapeutic Goods (ARTG) using a web-based electronic listing facility. The only routine checks made are that the ingredients are on TGA's “relatively low-risk” list. Listed medicines are restricted to indication and claims relating to health maintenance, health enhancement or non-serious, self-limiting conditions. Sponsors must certify that they hold evidence supporting the claims made about their product (evidence of “traditional use” is acceptable) but their product information and promotional material is rarely reviewed. The listing system provides rapid market entry at minimal cost.

By contrast, conventional medicines (“Registered” products) are thoroughly evaluated by the TGA for safety, quality and efficacy before they are allowed onto the market. They are identified by an AUST R number on the product label. Generic versions of clinically proven products must demonstrate therapeutic equivalence. Sponsors of both innovator and generic products must negotiate approved product information with the TGA and also provide consistent consumer

medicines information and promotion. Registration fees are substantial and the time taken for evaluation can be protracted.

The production of both Listed and Registered medicines is required to be in accord with good manufacturing practice and both are subjected to post-marketing surveillance, prioritised according to risk. The latter includes monitoring reported adverse reactions and random and targeted audits and testing of product ingredients.

The promotion of medicines in Australia is subject to a complex system of co-regulation underpinned by the *Therapeutic Goods Act 1989* and the *Competition and Consumer Act 2010* (previously the *Trade Practices Act 1974*). The Therapeutic Goods Advertising Code provides the standard for all advertising directed to consumers. In addition, there are relevant industry codes of practice. There are substantial differences in the timeliness, transparency and the sanctions applied by the different systems to complaints about the promotion of complementary compared to conventional medicines.

While the Australian regulation of complementary medicines is far more rigorous than that of many other countries a number of problems (and policy suggestions) have emerged (Harvey et al., 2008; Harvey, 2009).

Current controversies and problems

Product claims, names and warnings

Research on complementary medicines used for weight loss showed that some sponsors self-entered indications and/or claims on the ARTG that could not be substantiated (Harvey et al., 2008). These were then used in promotional material. Other sponsors made conservative claims on the ARTG but then made very different claims in promotional campaigns. In addition, product names such as “Fat Magnet”, “Weight Loss Accelerate” and “Slim-Me” appear equally misleading and deceptive.

The problem of unsubstantiated claims is not limited to weight loss products. Some recent examples submitted to the Complaint Resolution Panel (CRP) include, “All adults should take vitamins to prevent chronic disease”, “Homeopathic immunisation is a safe and effective way to protect you and your family against childhood and other epidemic diseases” and, “there are no reports in the literature of an interaction between glucosamine and warfarin”. None of these statements are in accord with the scientific literature and the last one also contradicts warnings by the Australian Adverse Drug Reaction Advisory Committee.

Currently, the only way to correct such inaccuracies is by submitting complaints. However, the CRP is under-resourced, overloaded and lacks effective sanctions. It even lacks resources to follow-up its own determinations which make them easily ignored. It can take multiple complaints before non-compliance with a CRP determination is passed to the TGA. That organisation, citing “commercial-in-confidence” considerations, currently tells complainants nothing and publicises nothing. However, in response to publicity about this lack of transparency a government spokesperson has indicated that this policy will change (Cannane (Lateline), 2010).

In 2007, the TGA was asked to review the efficacy of all ingredients used in weight loss products in the hope that up-stream evaluation would reduce the need for down-stream complaints. What ultimately eventuated was a “Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss” which, because of industry opposition, was never finalised (TGA, 2009a). More recently, in response to ongoing concern and a number of government enquiries, the TGA has produced a new, “Consultation document on levels and kinds of evidence to support indications and claims for listed medicines” (TGA, 2012). It remains to be seen whether this draft will be finalised and, if so, whether effective sanctions will be introduced for sponsors who ignore it.

Research by the Australian National Prescribing System (NPS) showed a major disconnect between consumers perception of complementary medicines as “natural” and “risk-free” and the reality that they contain pharmacologically active substances capable of producing drug-drug

interactions and adverse effects (NPS, 2008). My own analysis of advertisements for complementary medicines suggests that this perception is created and/or maintained by extensive promotion that emphasises the word “natural” and the use of associated imagery and colour.

Warnings about serious drug side-effects and drug-drug interactions are currently communicated to health professionals by *Australian Prescriber*, a free, independent drug bulletin, published by the NPS. In addition, the TGA may require sponsors to add key warnings to the medicine label for consumers. The following is a recent example, “Warning: In very rare cases, Black cohosh has been associated with liver failure”. However, there are now numerous Australian Internet sites from which consumers can purchase complementary medicines without having the opportunity to read a product label; there is no requirement that important safety information should be communicated on these web sites and there is variable implementation of such warnings.

Similarly, the perception that complementary medicines are part of a “holistic” approach to “maintaining good health” ignores the reality that many of these products are devised and marketed (in isolation) to take advantage of consumer anxieties and concerns. For example, while there is good evidence that some formulations of Hawthorn extract can be an effective treatment for heart failure its common promotion for “Heart health” would appear to be the complementary medicine version of “disease-mongering”.

Product efficacy

Traditional use has revealed many useful herbal products such as *Artemisia annua* for the treatment of malaria and St John’s wort for the management of mild to moderate depression. But traditional therapies have also proved to be harmful; the bloodletting that was performed for centuries by the medical profession is a classic example. When clinical trials were conducted, bloodletting was shown to kill patients, not cure them. Scientific study is required.

Herbal products are comprised of a complex mix of ingredients; just as all red wine is not of Bordeaux quality, different products containing the same herb are not necessarily chemically or therapeutically equivalent. Variability can be caused by the use of different species or sub-

species, growth conditions, methods of cultivation, the time of year and stage of growth cycle harvested, extraction methods, and formulation and storage of the finished product. Even glucosamine (used for arthritis) is available as several salts: glucosamine sulphate, glucosamine hydrochloride, and also as N-acetyl glucosamine, in vastly different formulations and with varied evidence of efficacy from clinical trials (Vlad et al., 2007).

The TGA does not require clinical trial data to support the efficacy of listed products, nor evidence of therapeutic equivalence with proven products. As a result, there is no certainty that all formulations of complementary medicines on the Australian market are efficacious.

Adulterated and substandard products

The TGA has detected dangerous adulteration of some complementary medicines such as Herbal Health International products, Excite for women and Ultimates for men, found to contain an analogue of sildenafil (Viagra) (TGA, 2007). These products have been taken off the market.

Other types of adulteration do not concern safety but rather truth in labelling and product integrity. For example, products containing Ginkgo biloba in the United States of America have been shown to be frequently adulterated or “spiked” with less expensive sources of flavonol glycosides, such as rutin (from buckwheat), that can trick routine testing to make a product with little or no real ginkgo appear to be real thing. When the TGA investigated similar products in Australia 6 of 20 randomly sampled products had results consistent with adulteration (TGA, 2009b). The TGA now requires sponsors to test for such adulteration. Substandard products containing low levels of active ingredients (e.g. Echinacea) have also been found in Australia by Choice emphasising the need for targeted audits of GMP and testing of product ingredients (Choice n.d., 2004).

Harm

While complementary medicines are regarded as “relatively low-risk” products they are not without adverse effects and interactions with conventional drugs. For example, Echinacea can cause allergic reactions, Black cohosh has been associated with rare cases of liver failure requiring liver transplantation and St John’s wort interacts with a wide range of conventional

drugs including oral contraceptives (Braun & Cohen, 2007). In addition, when a number of “relatively low risk” ingredients are combined unexpected adverse effects may result. Recognition of such problems can be difficult because many patients do not tell their doctors that they are taking complementary medicines and doctors often do not ask. As a result, adverse effects of complementary medicines are almost certainly under-recognised. In addition, ineffective complementary medicines have a significant adverse effect on consumer’s hip pockets (or purses) and, more importantly, they can delay or prevent the use of more evidence-based therapy.

Independent information

Unlike conventional medicines, complementary medicines lack TGA approved product information and consumer medicines information. NPS research also showed that GPs and pharmacists believed they did not have enough access to evidence-based information about CM. As a result they were not confident in discussing these medicines with their patients. Many GPs and pharmacists were unaware of the side effects of some commonly used complementary medicines and their potential interactions with conventional medicines. More than 80 per cent of GPs and community pharmacists felt that CM needed more scientific testing (TGA, 2009a).

The NPS has identified and recommended several independent sources of good information about complementary medicines but these require subscription and are not commonly used. In addition, generic information about an ingredient does not necessarily apply to specific Australian formulations. The ARTG does provide public summaries of product information but this is compiled by the sponsor, rarely reviewed by the TGA and often contains information that lacks an evidence base. The Canadian Natural Health Products Ingredients Database is more helpful as it contains referenced information on indications and risks (Health Canada n.d., 2010).

Research

Dr Balasubramaniam’s article on *Traditional Medicine* emphasised the importance of research to investigate the safety and efficacy of herbal medicines. However, from an industry perspective, difficulties in protecting the intellectual property (IP) of complementary medicines significantly inhibit investment in research. Once an ingredient or herbal extract is characterised it can be

used by any sponsor and the claims made are not usually restricted by regulators to specific formulations that have shown clinical efficacy.

In 2007-08, in recognition of the need to strengthen the evidence supporting complementary medicines, the Australian government announced more than \$7 million in research grants. Funding of \$1.74 million was awarded to establish three National Institute of Complementary Medicine (NICM) Collaborative Centres and a further \$5.3 million for 13 projects funded by the National Health and Medical Research Council (NHMRC) (Lucas, 2008). The American National Center for Complementary and Alternative Medicine (NCCAM) has also invested substantial research funds into this area which is improving the evidence base (NCCAM, n.d.)

Conclusions

The Australian regulatory system for complementary medicines is regarded as world best practice. In addition, most health professionals and consumers accept that evidence-based complementary medicines have a place in health care. Despite this, dubious products with unethical claims have proliferated and it is difficult for individual consumers or health practitioners to distinguish efficacious products from those of uncertain quality and efficacy. There is also no agreed standard for educating health professionals about complementary medicines. Pressure is being brought to bear by health professionals and consumer organisations to improve the regulatory and educational systems but, not surprisingly, others wish to preserve the status-quo. These problems are not unique to Australia.

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