
Complementary Medicine: Handle with Care

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Some forms of complementary medicine are efficacious but many have unproven or no health benefits. Claims that cannot be substantiated by scientific research are common, and all have some degree of risk.

In Australia, complementary medicines are defined (and regulated) by the Therapeutic Goods Administration (TGA) as medicinal products containing vitamins, minerals, herbs, homeopathic medicines, traditional Chinese medicines, Ayurvedic (Indian) medicines and Australian indigenous medicines. Complementary therapies include massage, meditation, yoga and tai chi, aromatherapy, reflexology, iridology and reiki. Alternative medical systems developed in western cultures include chiropractic, naturopathy and homeopathy while traditional Chinese medicine and Ayurveda are examples of systems developed in non-western cultures.

Registration of health practitioners ensures a minimal level of education and training, standards of professional behaviour and complaint mechanisms. Chiropractors are registered in all Australian states and territories. Chinese traditional medicine practitioners are registered in Victoria but not in other states. Naturopaths, homeopaths and other complementary practitioners have not achieved registration status, in part because of division in their ranks but also because of their varied training.

My own research relates to complementary medicines as defined by the TGA. My background is that of a conventionally trained medical graduate who specialised in medical microbiology and infectious disease. I have moved from public hospital practice to academic public health where my main interest is medicinal drug policy, especially how to achieve

equitable access and cost-effective use of necessary medicines.

Experiences with some pharmacy colleagues in the group AusPharm Consumer Health Watch (formed in 2006 and now disbanded) stimulated my interest in complementary medicine. Another group was formed, this time with the aim of reviewing the regulation of complementary medicine using “weight loss” products as an example. We adopted the safer strategy of publishing our report in the *Medical Journal of Australia* (MJA).

We found that the use of complementary medicines by Australians was substantial and growing. More than \$2 billion is spent nationally, with up to two-thirds of the Australian adult population using at least one product annually. The average out-of-pocket cost to individual consumers is similar to that for conventional pharmaceuticals.

Despite this widespread use, the regulation of these products is considerably weaker than conventional medicines. Most complementary medicines are regulated as “listed” products by the TGA. This means that they should only contain ingredients from a list the TGA regards as “relatively safe”; they should be produced in accord with good manufacturing standards; and the sponsors (those who have submitted a marketing application to the TGA) should only make “low level” promotional claims for which they have scientific evidence.

Sponsors self-assess whether their medicines are “listable” using a web-based computer system

provided by the TGA. The system checks that the ingredients entered are consistent with those allowed, asks the sponsor to certify that they hold evidence to support the indications (and claims made), and then issues a certificate of listing after receipt of the appropriate fee.

The TGA conducts occasional audits of these products but they are not routinely evaluated to determine if there is scientific evidence that substantiates the sponsor's claims. By contrast, all conventional medicines ("registered" products) are thoroughly evaluated for safety, quality and efficacy before they are allowed onto the market. In theory, consumers can distinguish "listed" from "registered" products by the type of number on the pack, but in practice most people have no idea what an AUST L or AUST R number means.

Our study of "weight loss" complementary medicines showed that more than 1000 of these products

had entered the market within the last 10 years. The promotional claims made were often far in excess of the limited scientific evidence available. Complaint procedures were overloaded and the "sanctions" available did not deter repeat offenders. The end result was a proliferation of heavily promoted products of dubious efficacy with promotional

claims that could not be substantiated.

Weight loss products are clearly a lucrative market. A recent survey of 1000 Australian women aged between 18 and 35 by *Famous* magazine showed that 56% had used slimming tablets. Most women surveyed believed that slimmer women were more successful with the opposite sex (79%) and in their careers (64%).

Our MJA paper concluded with recommendations for regulatory reform. These included proposals that the label of complementary medicines include a statement such as, "this medicine has not been evaluated by Australian health authorities for efficacy", that the advertising complaint system should be strengthened and, in the longer term, complementary medicines should be assessed for efficacy and delisted if evidence is lacking.

A vigorous debate ensued. A professor of complementary medicine from Southern Cross University believed that our recommendation to assess complementary medicines for efficacy was "ill-conceived and totalitarian in nature" and "would lead to the deci-

mation of the complementary medicine sector".

Others felt that our paper did not do justice to the Office of Complementary Medicine within the TGA. I accept that the current TGA listing process provides some protection to the public by ensuring that complementary medicines only contain relatively low-risk ingredients manufactured in accordance with the Code of Good Manufacturing Practice.

Herbal products comprise a complex mix of ingredients. Just as all red wine is not Grange Hermitage, 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, in vastly different formulations and with varied evidence of efficacy from clinical trials.

However, because the TGA does not require clinical trial data of efficacy for "listed" products, nor evidence of therapeutic equivalence with proven products, we can have no confidence that Australian formulations of complementary medicines are efficacious. In contrast, "registered" conventional medicines must demonstrate efficacy (and safety) by well conducted clinical trials or, if they are generic copies of an innovator brand, they must demonstrate that they can produce similar blood and/or tissue levels of the active ingredient to the innovator brand.

Nigel Pollard and colleagues (*Medical Journal of Australia*, 2008) argued that the lack of evidence from well-conducted clinical trials does not necessarily mean that complementary medicines are clinically ineffective. I agree. 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 blood letting that was performed for centuries by the medical profession is a classic example. When clinical trials were eventually conducted, blood letting was shown to kill patients, not cure them.

Although complementary medicines are regarded as "relatively low-risk" products they are not without adverse effects and interactions with conventional drugs. For example, *Echinacea* (of dubious use to shorten cold symptoms) can cause allergic reactions; black cohosh (of some value in relieving symptoms associated with menopause) has been associated with liver failure, and St John's wort interacts with a wide

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range of conventional drugs including oral contraceptives. Recognition of such problems can be difficult because many patients don't tell their doctors that they are taking complementary medicines and doctors often don't 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 consumers' hip pockets (or purses) and, more importantly, they can delay or prevent the use of more evidence-based therapy.

There is a discrepancy between the number of people who believe in and use complementary medicine and the strength of evidence to support that use. To narrow this gap the Australian government has recently announced more than \$7 million of research grants to study the use of complementary medicine by consumers, to research mechanisms of action, and to perform clinical trials to determine efficacy and adverse effects.

However, Australian clinical trials can only evaluate a handful of the 16,000 listed products currently available in the market. *Choice* magazine has proposed a pragmatic solution to this problem: an independent evaluation of complementary medicines on an opt-in, cost-recovery basis. Products shown to be efficacious by well-conducted clinical trials, ethically promoted with appropriate consumer medicine information, would be awarded a Trade Mark of approval similar to the Australian National Heart Foundation's "red tick". *Choice* has set up a multi-disciplinary working party to explore the practicality of this proposal, but the concept is opposed by the two relevant industry associations: the Complementary Healthcare Council and the Australian Self-Medication Industry.

In conclusion, the current Australian regulatory system neither controls complementary medicine claims nor supports an evidence-based industry. This is unacceptable given that Australians spend an estimated \$2 billion on these medicines each year. It also represents a failure of Australian health policy.

The challenge for our Federal government is to overcome industry self-interest and the perception of regulatory "capture" and institute the reforms required. The challenge for the complementary medicine industry is to accept that its future must be based on evidence, not hype. And the challenge for both health professionals and consumers is to learn more about the benefits and risks of complementary medicines, to be open to new ideas but also sceptical enough to demand evidence of efficacy, and be open to discussing these matters with each other.

MAKING INFORMED DECISIONS

Complementary medicine is an inclusive term that incorporates complementary medicines, complementary therapies and alternative medical systems. The term *complementary medicine* now encompasses other names used historically such as alternative medicine, natural medicine and traditional medicine. The approaches used by complementary medicine are often regarded as outside the realm of conventional medicine.

Integrative medicine combines treatments from conventional and complementary medicine for which there is some high-quality evidence of safety and effectiveness. Ask a qualified registered health practitioner for advice in relation to complementary medicines, especially about:

- evidence of efficacy from well-conducted clinical trials that tested the specific therapy or product you are considering using for the condition you wish to treat (or prevent); and
- possible side-effects and potential interaction with your existing therapy.

Many clinical trials are underway and the evidence keeps changing. Always ask for the latest evidence.

The National Prescribing Service's Medicine Line provides excellent independent information about all medicines, including complementary medicines. Telephone 1300 888 762 for the cost of a local call.

Useful information may be in your local library or on the Internet. However, make sure the clinical trial evidence is critically reviewed and the source is recent.

Never buy medicines from overseas websites. More than 60% of drugs sold by overseas online pharmacies have been shown to be counterfeit or substandard. (Australian Internet pharmacies are regulated and reliable).

Take herbal medicines as a pill or capsules rather than powdered herbs or mixtures from herbalists. The former are more likely to have the correct dosage and less likely to be contaminated or adulterated.

Establish the cost of treatment, and shop around to compare prices.

Always tell your general practitioner and other health professionals what prescription, over-the-counter and complementary medicines you take, as they can interact.

Under no circumstances abandon a prescribed conventional medicine for a complementary medicine until you have discussed this decision at length with your general practitioner or medical specialist.