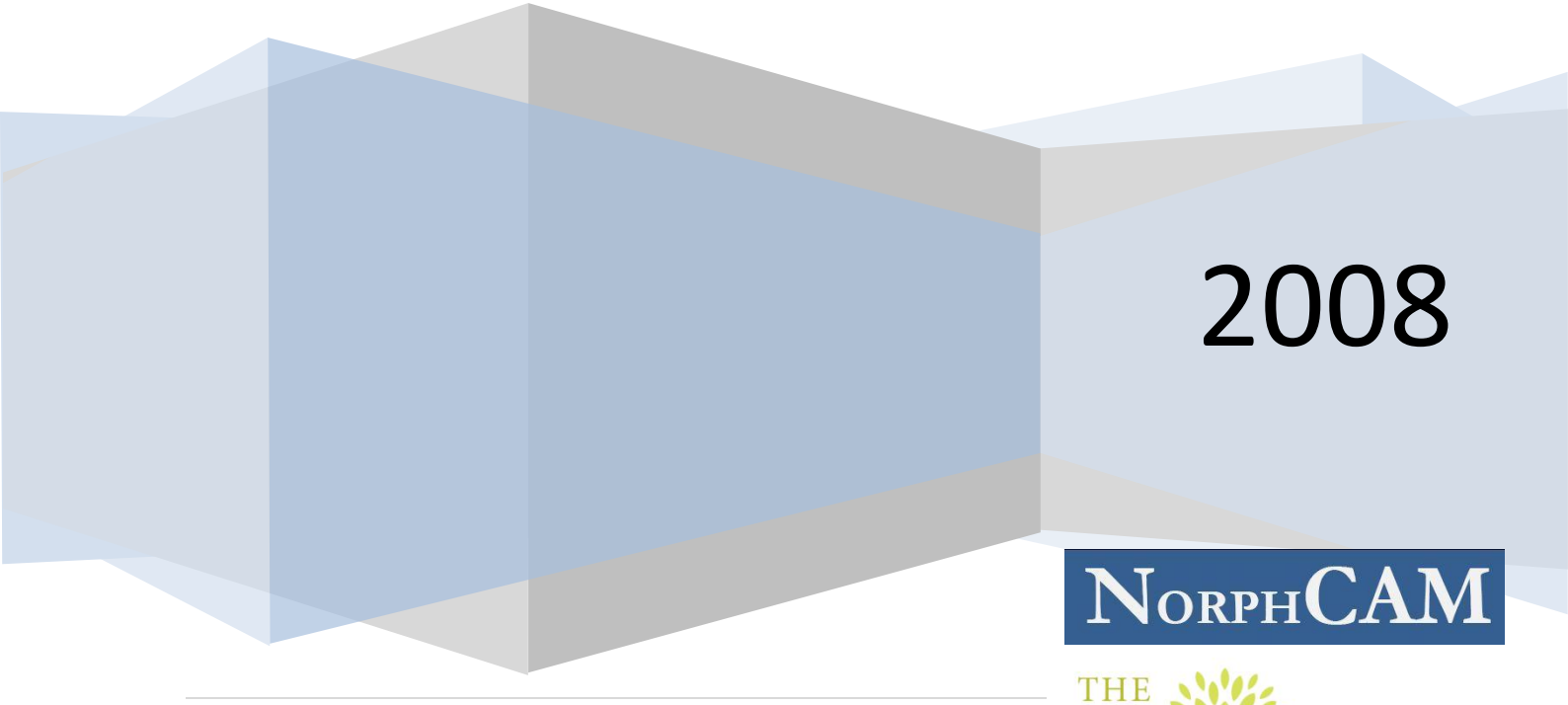
Regulation of complementary medicines

A brief report on the regulation and potential role of complementary medicines in Australia

Jon Wardle



2008

NorphCAM

THE NATUROPATHY FOUNDATION

This invited report was submitted to the Federal Parliamentary Secretary for Health and Aging in August 2008.

"*This report discusses statutory regulation, which shall be hereafter referred to as regulation in this document. Any non-statutory forms of regulation shall be addressed by either their individual forms of regulation, unregulated, or a similar term*"

Published by:

The Naturopathy Foundation
PO Box 87
Fortitude Valley Q 4006

NORPHCAM - The Network of Researchers in the Public Health of Complementary and Alternative Medicine
School of Population Health
University of Queensland
Herston Q 4000

ISBN: 978-0-646-52265-4

This document may be freely downloaded at:
http://www.norphcam.org/cmregreport/cmregreport.pdf

Address correspondence to the author:
Jon Wardle
School of Population Health
University of Queensland
Herston Q 4006
j.wardle@sph.uq.edu.au

Contents

Executive Summary

Introduction

CAM use is undoubtedly increasing amongst Australians; however the evolution of CAM regulation has failed to keep up with this surge in demand. CAM products represent an industry estimated to be worth between $1.5 and 3 billion annually. CAM practitioners provide up to a half of all health consults and may be the primary care providers for a third of their users.

However, current regulatory models for CAM are insufficient. It is recommended that the Department of Health and Aging regulates both CAM products and practitioners for a number of reasons, these are based on the criteria for regulation of a profession of the Australian Health Minister's Advisory Committee:

Criteria 1: It is a matter appropriate for the Health Minister

CAM practitioners and products are by any definition health practitioners and products.

Criteria 2: The risks of CAM warrant regulation

The risks of CAM are sufficient to warrant regulation and are comparable to those of regulated professions. These risks are economic, direct and indirect in nature.

- Economic risks include: The extreme variability of CAM products and lack of standardisation and surveillance in the marketplace. This makes consumers unable to distinguish between effective and ineffective CAM products; an unregulated environment means that consumers are at risk from unscrupulous marketing practices from companies and health practitioners that seek to gain profit from their patients and; practitioners not trained in CAM may be unable to identify effective treatments, thereby prescribing ineffectively.
- Direct risks include: Adverse events caused directly from CAM products and practices; Potential for pharmacological interactions between CAM and conventional treatment; inappropriate responses to adverse events in CAM and; risks to public health and safety caused by unregulated rogue practitioners unable to be barred from practice due to lack of barriers of entry.
- Indirect risks include: poor training of some CAM practitioners leading to risks from scope of practice such as misdiagnosis, lack of referral and being unaware of the limitations of their practice and; false consultations from unqualified persons under the impression that they are a CAM practitioner.

Criteria 3: Existing measures do not adequately address public health and safety issues

Current self-regulatory models fail for a number of reasons:

- They are fragmented and confusing, making it unclear how to identify a quality practitioner or product and register valid complaints or adverse reactions;
- Lack of barriers to practice mean that there are no minimum training standards. Despite some CAM practitioners training for 4-5 years in degree courses they are currently treated no differently from other untrained practitioners or laypersons. Because of this CAM provision is often undertaken by other health professionals such as pharmacists and doctors who are often untrained in CAM, uninterested or whose expertise lies elsewhere;
- Lack of regulation means that those who are often most qualified to use some therapeutic CAM tools are often denied access to these CAM tools (for example, scheduled herbs). Instead practitioners with little or no training in these tools are allowed access;
- Lack of regulation means that CAM practitioners are not appropriately held accountable for their actions, even in matters of gross negligence.

Criteria 4: It is possible for regulation to occur in CAM

There are examples of regulation both nationally (Victoria with Chinese Medicine, all states and territories with chiropractic and osteopathic) and internationally demonstrating that the process is possible.

Criteria 5: It is practical to regulate CAM

Support for regulation of CAM exists at most levels within the profession thereby reducing practical difficulties caused by strong opposition.

Criteria 6: The benefits of CAM regulation outweigh the negatives

There are numerous benefits to regulation and only a few negatives – which are easily overcome through judicious application of a regulatory framework. These benefits are of a number of natures:

- Health benefits may occur from the addition of more treatment options. CAM has demonstrated ability in treating acknowledged medical 'effectiveness gaps' including chronic disease and preventative healthcare. Regulation may encourage further integration of CAM and conventional treatment to improve health outcomes.
- Direct economic benefits from reductions in direct health care costs as more treatment options with demonstrated cost-effectiveness are made available
- Indirect economic benefits may be made by addressing effectiveness gaps in healthcare that have evidence of increasing productivity and reducing time lost to injury in the workplace. Higher standards of CAM may energise the development of a competitive CAM sector that can compete internationally on the export market.
- Regulation may encourage the inclusion of CAM practitioners in research, addressing issues of evidence, efficacy and encouraging clinically relevant research.
- Regulation may improve dissemination of information to the public, allowing them to make more informed treatment choices.

Conclusions and recommendations

Whilst CAM undeniably presents a number of risks that warrant regulation, it also offers a variety of opportunities to health provision in Australia. For this reason it is recommended that a detailed, objective and thorough investigation into regulation of CAM practitioners and products is commenced at the earliest convenience. Detailed recommendations are made throughout the report. It is recommended that any attempt at regulation adhere to the following principles.

- CAM products and practice have an underlying risk that requires apposite regulation be enacted. However, these risks should be placed in appropriate context and CAM should be afforded the same objectivity as other health professions in the development of any regulatory framework.
- Appropriate deterrents and penalties should be enforced for those who shirk their responsibilities and requirements under a regulatory model.
- Clearer methods of distinguishing high- and low standard CAM practitioners, products and information should be enacted. Mechanisms should be put in place that rewards those that adhere to higher standards and ensure that those of lower standards are not unfairly given equal standing.
- It is highly recommended that CAM is increasingly treated as a therapeutic modality in its own right as opposed to continuously being given 'special case' status. For this reason it is strongly suggested that CAM be subjected to the same regulatory, evaluation and legislative requirements as other professions and therapeutic tools.
- However, as an industry in its infancy efforts should be made to build capacity in CAM, particularly in the areas of academia and research. Ultimately CAM should compete with other health modalities for research and facility funding on its merits alone.
- An appropriate regulatory framework cannot focus on CAM products alone. CAM practitioners are an integral part of the industry and most of the factors which define CAM are intrinsically linked to principles of practice rather than any particular products used
- CAM practitioners should be acknowledged as health providers and regulated accordingly to safeguard public health and safety. This can be achieved by ensuring minimum standards of education and appropriate levels of accountability. As those most qualified to make clinical decisions relating to CAM, CAM practitioners should form an active part of any CAM-related legislative, institutional, research or practical decision making.

Other health practitioners should not be prevented from practising CAM but should abide by the same minimum standards required of CAM practitioners. Other health professionals, whilst very much respected for their own areas of expertise, do not have an inherent expertise in CAM. For this reason adequately qualified and registered CAM practitioners should be considered the default CAM providers in Australia under a regulatory model.

Introduction

The most recent survey of complementary medicine (CAM) use suggests a sharp rise in use[1]. The most commonly sought products are nutritional supplements, western herbs and aromatherapy oils which in the last twelve months have been used by 45.8%, 16.3% and 16.1% of the Australian population respectively. In the last twelve months 21.1% of Australians have visited a naturopathic practitioner (incorporating herbalists and clinical nutritionists); 14.6% have visited a chiropractor or osteopath and 13.4% have visited a Chinese medical practitioner (incorporating acupuncturists, Chinese herbalist, Chinese massage therapists, Chinese exercise therapists and Chinese dietetics practitioner). Currently the provision of these services and products in Australia is either self- minimally- or unregulated. Recent attention has focused on the need for regulation of complementary medicines (CAM).

The need for regulation will be assessed by the criteria agreed to by the Australian Health Ministers' Advisory Council (AHMAC) *Criteria for Assessing the Need for Statutory Regulation of Unregulated health Occupations*[2]. Whilst strictly speaking this is more a model for CAM practice rather than products it is done for two major reasons: 1) It is an established criterion by which judgements regarding regulation of health issues can and has been made and; 2) Whilst much of the current medical, government and research focus on CAM relates to product only the reality is that CAM practice – though often overlooked – constitutes most of the general public's experiences with and perceptions of CAM and accounts for up to 51% of total health consultations in Australia[3] and it is estimated that approximately one third of patients rely on CAM practitioners as primary care professionals[4, 5]. The AHMAC criteria are:

- Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation/industry in question, or does the occupation/industry more appropriately fall within the domain of another ministry?
- Do the activities of the occupation/industry pose a significant risk of harm to the health and safety of the public?
- Do existing regulatory or other mechanisms fail to address health and safety issues?
- Is regulation possible to implement for the occupation/industry in question?
- Is regulation practical to implement for the occupation/industry in question?

As chiropractic and osteopathy are already regulated in every Australian jurisdiction; Chinese medicine has a prototype draft of regulation in Victoria; and naturopathy and the treatment tools it uses are by far the most common CAM modality in Australia this report will focus on this modality. However, its findings still extend to the broad scope of professional CAM practise.

1. Is it appropriate for Health ministers to exercise responsibility for regulating the occupation or industry in question, or does the occupation more appropriately fall within the domain of another ministry?

Complementary therapists are health practitioners, and are often engaged in a primary care role. Therefore they fall into the Health minister's responsibility for regulation according to AHMAC criteria.

There is widespread use of complementary therapists in Australia. A study of healthcare users in Southwest Australia found that consultations with complementary therapists accounted for 51% of all health consultations[3].

Complementary therapists are also governed by a number of Acts within the health portfolio: including the *Therapeutic Goods Act;* food standards legislation and hygiene standards under public health legislation[6]. Consumer complaints about complementary therapists are handled by the same body that handles complaints of other health professionals.

Moreover, of particular significance to the current political situation, the Labor party has written into the health section (Chapter 10) of its National Platform and Constitution a section on complementary medicines stating that it *"will review the current regulatory regime to ensure that it is both robust and effective"* and that it *"will work to establish appropriate registration and accreditation for practitioners and their products"*[7].

Criteria 1 conclusion

CAM practitioners and products are by any definition health practitioners and products. It is therefore clearly appropriate for Health ministers to exercise responsibility for regulating complementary medicine.

2. Do the activities of the occupation or industry pose a significant risk of harm to the health and safety of the public?

There are three major forms in which the injudicious use of CAM can cause public harm: Economic, direct health and indirect health [8]. Economic harm may result from the marketing and sale of ineffective or poor quality CAM to the general public either directly or via unqualified or inappropriate practitioner dispensing; Direct harm to health may result from the direct side effects of CAM use – for example herb-drug interactions or puncturing a lung with an acupuncture needle; and Indirect harm to health may result from the delay of medical treatment due to misdiagnosis or misinformation about unrealistic treatment of a condition.

2.1 Economic Risk

Economic risks may occur for a variety of reasons: 1) lack of standardisation of CAM products may affect efficacy, safety or reliability of these products thereby possibly denying the consumer value for money or the implied benefit; 2) unscrupulous practitioners may take advantage of consumers in an unregulated environment and; 3) lack of minimum training and education standards may result in the consumer receiving an ineffective treatment regardless of product quality or efficacy.

2.1.1 Extreme variability of product quality

Consumers are currently put at economic risk due to extreme variability in product quality. While many CAMs have demonstrated therapeutic benefit current the *Therapeutic Goods Administration* listing protocols consumers may be purchasing ineffective and poor quality products whilst under the impression they are purchasing a legitimate product. Whilst good evidence exists suggesting St John's Wort can be of use in depressive symptoms a study of the most common brands few had their stated active ingredient content[9]. A Canadian study of 54 international commercially available St John's Wort products found that the active *hypericin* and *hyperforin* contents were extremely variable and most products overestimated content by a factor of two[10]. Only 2 of the 54 products had levels within 10% of that stated on their label.

2.1.1.1 Lack of standardisation

Standardisation is much more of an issue in CAM than efficacy. According to a survey of 3000 South Australians, approximately half assumed that CAMs were independently tested by a government agency – 74.8% for quality and safety, 21.8% to validate health claims and 17.9%

efficacy of the product[11]. This overestimation of government monitoring may gift CAM a legitimacy it may not otherwise have earned and imply efficacy and safety claims on these products regardless of quality.

Most people assume that CAM products are of equal quality, or at the very least tested for efficacy by a government body. However, many CAMs are a natural product and like any natural product may possess a number of varying qualities – the same equivalent dry weight of grapes can yield fresh grapes, sultanas, grape juice, wines (with incredible differences in complexities of character) and sherry depending on a number of growing, manufacturing and processing factors yet we expect all products made from raw herb to be therapeutically equivalent regardless of these factors. Factors which may affect variability in natural supplements can include climate, growing conditions, time of harvesting and postharvest factors such as storage conditions (light, temperature and humidity) and processing (extraction and drying processes)[12]. Further examples of these are discussed in Table 2 on page 7.

Even in cases when efficacy may be in doubt lack of standardisation in the industry may cause false negatives in interpretation of the results. A British researchers conducting a systematic review of glucosamine confirmed the previous findings that there was little clinical evidence supporting its efficacy[13]. However, when they analysed the data further they found that one particular brand of glucosamine was not used in any of the negative reviews or trials and that 100% of the trials using this form had positive results. This raises questions as to whether inadequate regulation and standardisation in the industry is hampering the development of a suitable evidence base.

2.1.1.2 Differing forms of the same CAM

Even in a country with purported adequate regulatory regimes lack of standardisation can be a major issue. The Australian Consumer's Association took 26 glucosamine supplements available in Australian supermarkets, health food store and pharmacies and tested them for their glucosamine content. 3 of the 26 did not contain enough glucosamine to exhibit effect according to clinical guidelines (1500mg/day) and 2 were more than 7.25% outside the range stated on their label (outside the range of current government regulations)[14]. The findings also showed a good deal of variety in the forms of glucosamine used: *Glucosamine hydrochloride*; *glucosamine sulphate*; and *glucosamine sulphate potassium chloride* – which contain 75% glucosamine sulphate. It is difficult from labelling alone to know just how much of this is converted into active *glucosamine*. This also muddies the waters on research and efficacy. Most research suggests *glucosamine sulphate* is the more effective form yet more than half the products tested were *glucosamine hydrochloride*.

Other issues of safety may also arise. Most glucosamine is sourced from crustaceans with only 2 of the 26 products using vegetable sources. Although some very small clinical trials have expressed safety of glucosamine supplementation in individuals with crustacean allergies[15, 16] there have been documented cases of glucosamine supplementation causing hypersensitivity reactions in these individuals [17, 18]. The variability observed in glucosamine content, form and manufacturing process amongst supplements was one reason given for this apparently

paradoxical result[16]. Considering the fact that Australians think that CAM is overwhelmingly "safe" and "has no side effects" improved regulatory frameworks may be required to ensure public safety. The World Health Organisation has suggested that regulation of CAM products is the most appropriate method of ensuring quality and efficacy of these products [19].

2.1.1.3 Substitution or adulteration of product

In an unregulated environment it is not uncommon for CAM to substitute the active ingredient with cheaper alternatives. The substitution of *Panax ginseng* with the cheaper alternatives such as *Panax pseudo-ginseng*, *Panax quinquefolium* or *Eleutherococcus senticosus* is not uncommon and may potentially result in greater toxicity than normal [20-22]. A study of 50 brands of ginseng product failed to find any ginseng in 6 of these products whilst one product contained large amounts of ephedrine - leading a Swedish athlete to be inadvertently accused of doping [23]. In 2007 an urgent recall of a herbal libido tonic was initiated by the *therapeutic Goods Administration* after it was found that it was adulterated with *sildenafil or* Viagra[24].

2.1.2 Inherent weaknesses of good manufacturing practice guidelines

Currently CAM products are required to comply with *Good manufacturing practice (GMP)* standards. This code defines a number of procedures and observances including as listed in the table below.

Good Manufacturing Practice Guidelines
Validation of equipment and process
Documented standard operating procedures covering every aspect of manufacture
Documented cleaning and calibration logs for equipment
Control of the manufacturing environment, air and water
Quarantining and unique identification and testing of raw materials, labels and packaging
Discrete batch identification
Comprehensive batch record documentation
Reconciliation of raw materials, product, packaging and labels
Quarantining and testing of finished products
Documented release for sale procedures
Testing of stability of finished product
Documentation of customer complaints and recall procedures

Table 1: Good manufacturing practice requirements

However, whilst these measures do proffer a guarantee (though small) of safety in CAM they do little to address issues of standardisation or efficacy of CAM products. In practice CAM manufacturing under pharmaceutical GMP may be more complex as many of them are derived from biologic agents and: may be incorrectly identified; may vary in chemical content and hence efficacy; carries with it a history (and therefore may be contaminated with unwanted

substances); the processing of biological agents may enhance or impair their safety and efficacy and; stability may be difficult to define or measure[25].

Adhering to GMP principles CAM may be afforded a degree of legitimacy in the eyes public. However, there is little that CAM manufacturers have to do to earn this legitimacy. The regulatory system should encourage evidence and efficacious CAM products and appropriate sanctions and enforcements should downgrade the claims made on products which don't satisfactorily meet this evidence base. Whilst GMP principles do offer a degree of standardisation in some values of product *quality*, it should be remembered, and made clear, that this does not extend to *therapeutic efficacy* of the product.

2.1.2.1 Lack of minimum standards of therapeutic efficacy

The lack of enforced regulation in this area puts consumers at risk by denying them the ability to choose between CAM with and without demonstrated efficacy. The biological complexity of many CAM products has important implications in healthcare provision and for this reason current regulatory frameworks are insufficient.

The generic concept of synthetic pharmaceuticals – such as the interchangeability of paracetamol containing products - is invalid for CAM[26]. Due to the biological complexity of most CAM classification of particular products (for example *glucosamine* or *St John's Wort*) is insufficient. Meta-analyses and systematic reviews of CAM may be easily misinterpreted as the products made from the same 'substances' may be very different (see Table 2) – and any conclusions drawn can only be applied to the particular products that have been trialled. Whilst traditional use may be a valid form of evidence used in evaluation[27], it should only be used in promotion or claims targeted at those with sufficient knowledge of CAM – such as adequately trained CAM practitioners – to make critical judgements based on this advice.

CAM products should be subject to similar requirements as conventional medicines. Perhaps it is time to stop treating CAM as a product class entirely different to other forms of treatment and instead treat it as a medicine or therapeutic agent on their own individual merits. At the moment the complex arrangement of regulatory frameworks subject CAM to either unnecessarily harsh or unnecessarily lax requirements. A move towards adherence to the Code of Conduct of Medicines Australia will help to establish adequate standards in this area.

As part of the evaluation process for TGA listing CAM products should be subjected to another battery of specific tests of therapeutic efficacy and equivalency and possible contamination. Not requiring sponsors to have evidence to support claims of their specific products encourages low quality[28]. The British Herbal Pharmacopeia provides a useful guide to British and European standards to this regard[29]. However, it should be noted that these complexities demonstrate the need for the involvement of professionals with intimate clinical and theoretical knowledge of CAM treatments in any regulatory process.

Factor affecting quality	Example
Substitution	▪ It is estimated that deliberate substitution of Namibian Devil's Claw (*Harpogophytum procumbens*) with cheaper Angolan *Harpogophytum zeyheri* – a safe yet therapeutically far less effective substitute – may account for 50% of total imports of this herb[30, 31]. ▪ Not all substitution may be intentional. In Canada Siberian Ginseng (*Eleutherococcus senticosus*) was initially classed as toxic after being accidently substituted in some products due to a combination of misinterpretation of its traditional name *Wu-Jia-Pi* and poor quality control by product manufacturers[32].
Ecology (Growing Area)	▪ The essential oil of Basil (*Ocimum basilicum*) may exhibit different chemotypes depending on area grown. Basil essential oil grown in Madagascar, Comoros, Seychelles and areas of Thailand exhibits higher levels of *methyl chavicol* – a known skin irritant and carcinogenic agent[33]. ▪ Thyme (*Thymus vulgaris*) may exhibit any one of six major chemotypes with differing chemical constituents – all with very different therapeutic applications – depending on area grown and growth stage at which it is harvested[34, 35]. ▪ *Tribulus terrestris*, a herb often used in treatment of male infertility and menopause, demonstrates significantly different chemical profiles depending on geographic location the material is sourced from. Research suggests that many markers of quality – including levels of the active steroidal saponin *protodioscin* – occur in herbal product sourced from Eastern Europe and Western Asia, but not that sourced from India, China or Australia[36].
Part Used	▪ Evidence suggests that root parts are more effective and less allergenic as aerial (leaf) parts of *Echinacea spp*[37] yet most commercial preparations sold in Australia continue to use the cheaper aerial parts or a combination of parts which leads to wide variations in markers of active compounds[38]. ▪ Only standardised Ginkgo leaf tip extract from a limited amount of suppliers is used clinically in Europe as imported crude leaf has been found to contain high quantities of therapeutically inactive leaf and stem material[39].
Variant used	▪ Glucosamine is sold in Australia in one of three major forms: *glucosamine sulphate*, *glucosamine sulphate potassium* and *glucosamine hydrochloride*[14]. Only *glucosamine sulphate* at doses of at least 1500mg daily has demonstrated efficacy in trials[40]. More than half the supplements available in Australia are of the cheaper, ineffective *glucosamine hydrochloride* variety[14].
Manufacturing process	▪ Inactive ingredients used in manufacturing process may render active constituents inabsorbable and therefore ineffective. An investigation of commercially available Coenzyme Q10 supplements in New Zealand found marked differences in bioavailability despite similar labelled doses due to variation in excipients used[41]. ▪ The proportion and type of solvents used in the extraction of herbs will determine amount of therapeutic agent extracted[42].
Contamination	▪ Some imported Ayurvedic and Chinese Medicines in Australia have been shown to have dangerous levels of heavy metal concentrations[43]. It is currently left to the discretion of the manufacturer to test for these according to GMP. ▪ CAM products may be contaminated with pharmaceutical drugs. An Australian herbal libido tonic was the subject of an urgent withdrawal in 2007 after it was found to contain sildenafil[24].

Table 2: Potential factors affecting quality of CAM products

2.1.3 Potential for conflict of interest

The federal government has already asked the Australian Competition and Consumer Commission to investigate the complementary medicines when it was uncovered that some doctors were taking advantage of the rise in CAM use by selling products for their patients[44]. It was reported that some GPs were earning $90 000 per annum by enlisting their patients in multi-level marketing schemes for CAM products[45] and CAM manufacturers continue to aggressively pursue health professionals of all persuasions and often market their products as ideal ways to supplement clinic income[46, 47]. One manufacturer was audacious enough to suggest that one of the benefits of attendance of its educational seminar targeted at medical and CAM practitioners was that it would teach attendees how to ensure "an ongoing flow of supplement sales, creating an income stream that requires little or none of your time to generate"[48].

It is estimated that 78% of naturopaths sell pre-prepared products directly to patients[49]. This demonstrates a clear potential for conflict of interest. Adequate codes of conduct – and equally adequate penalties for breaching that code of conduct – need to be implemented to ensure that unscrupulous practitioners are not able to take advantage of their patients. Unlike the pharmaceutical industry, the CAM industry is comprised of a significant direct-to-consumer segment which accounts for approximately 25% of total sales[50]. This segment may escape the scrutiny that products sold through more regulated mechanisms may have go through, unnecessarily exposing these consumers to risk. The current self-regulatory regime insufficiently protects CAM consumers from these economic risks.

As it stands there is no sound health reason as to why health professionals should be encouraged to sell pre-prepared manufactured and marketed products directly to their patients. The most common reason cited is that the products may be otherwise difficult to procure however it is envisaged that an appropriate regulatory environment will encourage innovative solutions to this problem[6]. Ideally complete removal from practitioner consultation and retail sales would be desirable though there may be some special dispensations – the dispensing of individual liquid herbal formulations by herbalists for example. It is thought that an appropriate regulatory framework could encourage the establishment of measures which ameliorate this conflict of interest – for example central apothecaries or dispensaries staffed by a person with adequate CAM training where practitioners can send patients to fill prescriptions (a *"natural pharmacy"* per se) by establishing minimum standards in the industry and enforceable codes of conduct.

2.1.3.1 Extemporaneous medicines

However, some complementary medicine practitioners may use extemporaneous treatments (those that they have manufactured or mixed themselves) such as liquid herbal formulations in practice. Removing these from traditional complementary medicine practice also carries the risk of reliance on manufactured or pre-packaged products – reducing therapeutic options for patients and potentially increasing the influence of commercial interests. Such extemporaneous

supply requires adequate levels of training, minimum standards of practice and the oversight of an appropriate regulatory body to ensure public safety from economic harm.

2.1.4 Injudicious use of an otherwise effective CAM

Lack of barrier to entry to CAM practise, poor levels of CAM training of conventional health practitioners, propensity towards self prescription and lack of easy access to sources of reputable CAM information may also pose economic risk through inappropriate use of otherwise effective remedies. For example, a non-CAM practitioner or consumer may choose to use *Echinacea* for immediate relief of cold and flu symptoms, whereas traditional practice would suggest that they should use *Andrographis* instead as *Echinacea* has a lead-in period of approximately 7-10 days[51]. In this case it may injudicious and ineffective clinical decision making rather than the lack of efficacy of CAM products that may render the treatment ineffective. These issues are discussed in more detail in other sections of this report that refer to education and training (section 3). Issues relating to lack of barriers to practice are discussed further in this section.

2.2 Direct Risk

Direct risks are those which relate directly to use of the CAM product or practice. Direct risks can take the form of those relating to product – such as adverse reaction and potential interactions – and those relating to practice – such as gross negligence and incompetence in practice:

2.3 Products

2.3.1 Adverse Reactions

Medical Practitioners estimate that they see one CAM adverse event per 125 consultations, or an average of 1 per week [6]. Australian naturopath workforce data suggests that naturopathic practitioners will experience one adverse event every eleven months or 1 per 423 consultations[52]. In the ten years to 2007 on average of 395 adverse reactions to CAM were reported to ADRAC, with possible links to deaths in 62 cases[53](see Figure 4). It is estimated that adverse reactions to CAM medications account for approximately 3% of total adverse reaction reports in Australia[54]. There appears to be significant under-reporting to government agencies of adverse events for a variety of reasons[6] including: non-disclosure of CAM use; lack of awareness

of avenues for reporting; fear of having therapeutic tools taken away and inappropriate avenues for reporting – such as the *Therapeutics Goods Administration Adverse Drug Reaction Reporting System* database being limited in its usefulness and applicability for CAM when compared to pharmaceutical medications.

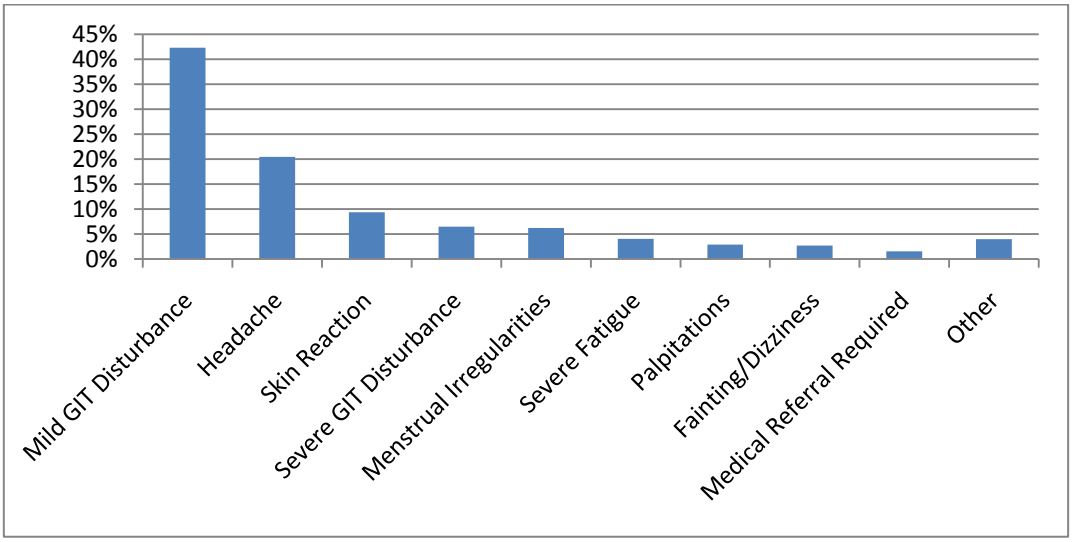


Figure 1: Proportion of adverse reactions of CAM products in Australia *Source: ADRAC*

Lack of regulatory frameworks makes it difficult to determine where to report these adverse reactions. Experience suggests that implementing regulatory models for CAM does increase reporting of CAM adverse reactions. Unpublished studies from Queensland have found the proportion adverse incidents attributable to CAM to be as high as 13.4% when clear mechanisms for public reporting are known[55].The World Health Organisation received reports of 9854 adverse reactions to CAM products in 2002 alone compared to less than 4000 during the entire period 1990-99 after engaging stricter frameworks on reporting[56]. Australian examples of the effects of regulation on reporting and complaints mechanisms are discussed further in Section 3.

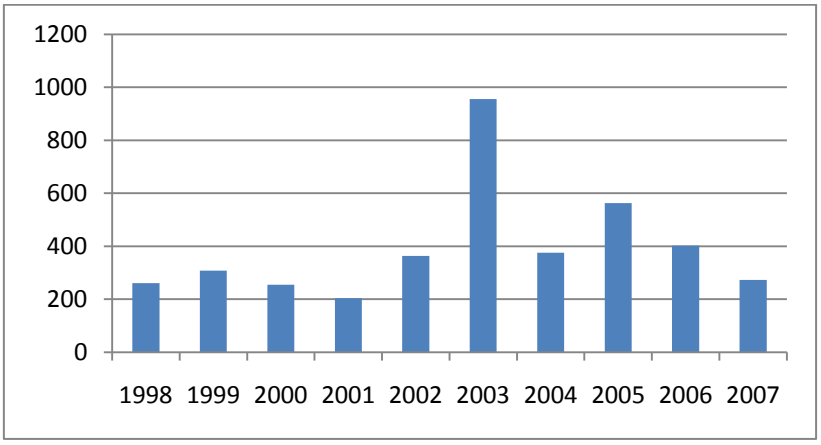


Figure 2: Number of adverse reactions associated with CAM[+] *Source: ADRAC*

Perhaps it will not be until regulation is enacted may expel the myth that CAM products are inherently safe as few adverse reactions are reported. Whilst it is true that between 1968-1998 only 149 reports involving adverse reactions to CAM were reported to the *Adverse Drug Reactions Advisory Committee* through the *Therapeutic Goods Administration* it is often forgotten that *ADRAC* only began receiving reports on CAM in 1998[6]. Current mechanisms are woefully inadequate and may severely underestimate the real situation. These issues are discussed further in Section 3.

2.3.2 Misinformed reactions to adverse events

Although obvious risks are apparent from CAM consumption these do have to be taken in context. Whilst the level of risk is certainly enough to warrant regulation and minimum standards of practice they still represent a generally safe and beneficial therapeutic option in most cases. Conventional medicines, whilst providing tremendous benefit, are responsible for over 80 000 hospitalisations at an estimated annual cost of $350million[57] whilst 16.6% of Australian hospital admissions result in adverse events[58]. For these reasons, it is important to extend the same courtesy as is extended to evaluation of safety of pharmaceutical medications and maintain objectivity when evaluating CAM safety. This is important for a number of reasons:

The media may be unnecessarily alarmist in its misrepresentation of CAM adverse reactions. In the prestigious medical journal *Annals of Internal Medicine* a case study – "*Coma from the health food store: interaction between kava and alprazolam"* – was published which upon closer report was actually a case of lethargy whilst the patient was also concurrently taking cimitidine, which has known interactions with alprazolam[59]. Many of these misunderstandings occur either through lack of understanding of CAM or lack of consultation with CAM experts.

Lack of understanding of CAM medicines may result in similar alarmist reactions being made on a legislative level. Therefore it is imperative that as part of a regulatory framework those with specific CAM experience and expertise are incorporated into decision making. An example of possible misunderstanding is the prominent case concerning Kava regulation, which has been banned from sale in several Australian and international jurisdictions due to questionable safety data[60]. In Australia it was thrust into the limelight by the following case:

In 2002 a 56 year old Melbourne woman died from complications of a liver transplant required due to deterioration of the liver caused by ingestion of a herbal formula purportedly containing a solvent extraction of Kava (*Piper methysticum*), Passionflower (*Passiflora incarnate*) and Skullcap (*Scutellaria lateriflora*). Subsequent investigation of the product found that one of the listed ingredients – *Scutellaria lateriflora* – was absent and that an unidentifiable ingredient was in its place though Kava was still deemed to be the causative agent [61]. However, systematic reviews have found that aqueous extracts of Kava are relatively safe and they have been used traditionally by people of the South Pacific for thousands of years without issue[62] which suggests that the adulterated substance or the solvent extraction may be the primary cause for liver failure.

Whilst concerns such as these need to be considered, CAM should be subjected to the same objective risk-benefit evaluation as conventional medicines. Alarmist reactions such as that demonstrated in the aforementioned Kava incident – often brought through lack of understanding – demonstrate the need to incorporate individuals with intimate knowledge of CAM to develop appropriate regulatory mechanisms. Otherwise potentially valuable therapeutic tools – Kava has demonstrated definitive positive results in the treatment of anxiety[63] – may be unnecessarily restricted considering the significant but relatively small number (compared to similar conventional treatments) of adverse events that have been attributed to its use[60]. This may also pose a risk to public health and safety, namely through denial of effective treatment.

2.3.3 Risk of interactions with conventional medications

Many CAM have significant pharmacological activity and therefore have potential interact with other medications in the same way that drug/drug interactions can occur[64]. These can be either negative or beneficial. Negative interactions may include decreasing plasma drug concentrations – which may be of particular concern in dugs with narrow therapeutic ranges such as digoxin, chemotherapeutics or anti-retroviral treatments – or enhancing therapeutic effect – for example taking anti-coagulant CAM in conjunction with warfarin may induce haemorrhaging[65]. Beneficial interactions may include utilising CAMs that enhance therapeutic effect to increase therapeutic options for patients and using CAM to ameliorate side effects of pharmaceutical medications[64]. Regardless of whether the interaction is negative or beneficial it is clear that unmonitored use poses a major health and safety risk.

Interactions between preparations can be classified scientifically into two main types – *pharmacokinetic* and *pharmacodynamic* interactions[66]. A pharmacokinetic interaction occurs when one agent alters the absorption, distribution or elimination of another; for example in conventional medicine the macrolide antibiotic *erythromycin* alters the elimination of drugs such as statins that are metabolised by the cytochrome p450 enzyme system[66]. The herb St John's Wort exhibits the same pharmacokinetic interactive capacity[64]. A pharmacodynamic interaction occurs when one agent augments or diminishes the effect of the other without altering pharmacokinetics. In conventional medicine the additive central nervous system with hypnotics and tricyclics antidepressants is an example[66], whereas the additive effects of St John's Wort on serotonin levels – potentially leading to serotonin syndrome – when used in conjunction with pharmaceutical anti-depressants offers an example in CAM[64].

More than half of CAM users do not disclose this use to their medical practitioner[11]. Also, 34% of patients who had recently seen a naturopath were taking concomitant pharmaceutical medication[6]. Australian data also suggests that 50% of CAM users used conventional medications on the same day as their CAM treatments[11]. This obviously leads to a potentially very high incidence of polypharmacy amongst CAM users placing CAM users at risk of interaction.

As CAM can exhibit both pharmacological forms of interaction their use should be judiciously monitored by an appropriate health professional. As the majority of their patients feel

uncomfortable discussing CAM with them medical practitioners may not be the best choice to perform this role. An appropriate regulatory regime could encourage qualified CAM practitioners – as the only health professionals suitably qualified with sufficient CAM knowledge – to perform this role in an integrative environment. As CAM also has the potential to have both negative and beneficial interactions it a qualified CAM practitioner may be able to assist with developing quality use of medicines in patients. However, unmonitored and often unknown use, as exists currently, is unnecessarily putting the public at risk. The CAM interactions of the ten most commonly prescribed pharmaceutical medications are listed below:

Pharmaceutical drug	Use	Common names of CAMs with demonstrated ability to *specifically* affect medication
1. Atorvastatin	Lipid modifying agent	St Mary's Thistle, Fish Oils, Chromium, Garlic, Myrrh, Policosanol, Oats, Niacin
2. Simvastatin	Lipid modifying agent	Peppermint Oil, St John's Wort, Chromium, Garlic, Myrrh, Policosanol, Oats, Niacin
3. Paracetamol	Fever/Anti-inflammatory	Zinc, Folate
4. Omeprazole	Gastric acid disorders	Folate, Iron, B12
5. Esomeprazole	Gastric acid disorders	Folate, Iron, B12
6. Atenolol	Beta Blocker	Astragalus, Devil's Claw, Hawthorn, Magnesium, Myrrh, Fish Oils, Garlic, Evening Primrose Oil, Guarana, Hawthorn, Liquorice, Oats, Olive Leaf
7. Perndopril	ACE Inhibitor	Iron, Fish Oils, Garlic, Evening Primrose Oil, Guarana, Hawthorn, Liquorice, Oats, Olive Leaf, Calcium, Magnesium, Zinc
8. Irbesartan	ACE Inhibitor	Iron, Fish Oils, Garlic, Evening Primrose Oil, Guarana, Hawthorn, Liquorice, Oats, Olive Leaf, Calcium, Magnesium, Zinc
9. Ramipril	ACE Inhibitor	Iron, Fish Oils, Garlic, Evening Primrose Oil, Guarana, Hawthorn, Liquorice, Oats, Olive Leaf, Calcium, Magnesium, Zinc
10. Irbesartan with hydrochlorothiazide	ACE Inhibitor	Dandelion Leaf, Nettle, Thiamine, Iron, Fish Oils, Garlic, Evening Primrose Oil, Guarana, Hawthorn, Liquorice, Oats, Olive Leaf, Calcium, Magnesium, Zinc

Table 3: Top ten pharmaceuticals by number of Australian prescriptions listed with CAM with demonstrated interaction [67-75]

Even commonly used medications may have interactions that the public and conventional health practitioners may have little knowledge of. The top twelve CAM treatments sold in Australia and the pharmaceutical drugs they interact with are listed below:

CAM	Known Pharmaceutical interactions
Echinacea	▪ Theoretical concerns exist with decreasing the effects of immunosuppressants
Ginkgo	▪ Causes bleeding when used with warfarin ▪ Causes raised blood pressure when used with a thiazide diuretic ▪ May induce coma when used with trazodone ▪ Increases action of digoxin and aspirin
St John's Wort	▪ Lowers blood concentrations of cyclosporine, amitriptyline, digoxin, indinavir, warfarin, phenrocoumon, midazolam, simvastatin, nefazodone, methadone, sertraline, paroxetine and theophylline ▪ Causes delirium when used with loperamide ▪ Causes intermenstrual bleeding when used with oral contraceptives ▪ Causes mild serotonin syndrome when used with loperamide or selective serotonin reuptake inhibitors
Fish Oils	▪ Increases the effects of warfarin
Evening Primrose Oil	▪ Increases risk of seizures when used with phenothizines
Garlic	▪ Lowers blood concentrations of warfarin, saquinavir and ritonavir ▪ Changes the pharmacokinetics of paracetamol ▪ Causes hypoglycaemia when used with chlorpropamide
Valerian	▪ Potentiates barbiturates, benzodiazepines and nervous system depressants
Saw Palmetto	▪ Theoretical concerns exist with current treatments for benign prostatic hypertrophy (alpha blockers and 5-alpha reductase inhibitors) due to additive effects
Korean Ginseng	▪ Lowers blood concentrations of alcohol and warfarin ▪ Induces mania when used with phenelzine ▪ May cause bleeding when used with warfarin
Glucosamine	▪ Causes bleeding when used with warfarin ▪ Theoretical concerns exist when used with blood sugar medications
Peppermint Oil	▪ Increases absorption of 5-fluorouracil
Tea Tree Oil	▪ Increases absorption of 5-fluorouracil ▪ Lowers blood concentrations of pentobarbital and amphetamines

Table 4: Top twelve CAMs sold in Australia and their known negative pharmaceutical interactions [68-75]

As can also occur with conventional pharmaceutical medications rare, often idiosyncratic reactions can also occur. The majority of these are due to allergy. Ordinarily these cases are impossible to predict, however, clinical knowledge of these tools is invaluable to reduce potential risk. Some allergenic therapeutic tools are well-known to competently trained CAM practitioners – for example it is well-known that Chamomile *(Matricaria recutita*) is a member of the daisy or *Asteraceae* family and will therefore induce an allergic reaction in people with allergies to this family[51]. However, documented cases of anaphylactic reactions due to injudicious use in Australia have been observed[76].

2.3.4 Lack of standards for labelling

Herbal medicines in particular lend themselves to confusion: Herbal remedies may share common names – for example Brahmi can mean either *Bacopa monnieri* or *Centella asiatica*; Herbal remedies may share similar names – for example the generic ginseng label could refer to any one of *Panax ginseng* (Korean 'Ginseng'), *Panax notoginseng* (Tienchi), *Panax quinquefolium* (American), *panax pseudo-ginseng* (Japanese), *Eleutherococcos senticosus* (Siberian), *Withania somnifera* (Indian), *Gynostemma pentaphyllum* (Southern), *Pseudostellaria heterophylla* (Prince), *Pfaffia paniculata* (Brazilian), *Lepidium meyenii* (Peruvian) or *Oplopanax horridus* (Alaskan); Transliteration of Chinese herbal formulas may be difficult – for example *Panax ginseng* is known by its common name Korean Ginseng but is often labelled by its Chinese name *Ran-Shen* or its Latinised pharmaceutical name *Radix ginseng*. This confusion could be ameliorated by standardisation of labelling and manufacturing requirements. Latin binomial names are recommended as this leads to less chance of duplication or confusion[77].

Whilst lack of labelling has been demonstrated to reinforce perceptions of complementary medicines being benign, natural and safe; increased labelling requirements – although positively viewed by the population – may not necessarily result in a more informed consumer. A Canadian study investigating the effects of new labelling regulations demonstrated that rather than answering consumer's questions and concerns relating to efficacy and safety increased labelling merely generated more questions on complementary therapies for health care practitioners [78]. Increased regulations regarding provision of information on complementary medicine should extend beyond labelling to include health workers to ensure they have received appropriate levels of complementary medicine training to appropriately respond to the expected increase in questions.

2.3.5 Uninformed self prescription

The ease of access to CAM products and the lack of consultation in procuring these may place the public at undue risk from these products. Although considered generally safe when used incorrectly or in inappropriate situations CAM products have the potential to cause great harm. Whilst this may be only economic in nature (for example taking the wrong remedy due to incorrect assumptions based on self-diagnosis) physical harm may also result:

Self-prescription may exacerbate or initiate health problems when not properly monitored. For example, a woman was able to self-prescribe a nutritional supplement known to cause peripheral neuropathy for 10 years from the same health food store due to recommendation by an unqualified health food store staff member[79]. This was the only health consultation the woman had had in this time. When taken off the supplement the woman's symptoms resolved.

In 2006 a 75 year old Brisbane man procured 200 grams of sodium selenite (purity 96% selenium) powder and tablet supplements from two pharmacies without instructions after

researching prostate treatment on the internet. Four hours after ingesting 10g (10 000 times the recommended daily dose) he died of cardiac arrest in hospital [80].

A gate keeping position, not unlike that of a community pharmacist, is required in these situations to ensure that consumers are able to exercise choice without being unnecessarily exposed to risk or misinformation. However, those charged with this gate keeping role need to have adequate levels of training specific to the dispensing of CAM. Regulation of minimum CAM education requirements could help to underpin this role.

2.4 Direct risk of CAM Practice

Direct risk of CAM practice include the undocumented and in many cases unknown CAM use of the general public; and those related to poor standards of practice. The major determinant of risk in CAM practice is poor levels of CAM-specific training[19, 81]. However, the lack of minimum training standards required to practice CAM (though posing a very real risk to public health and safety) will be covered in section 3. Instead this section will focus on the other risks apparent from removing barriers of entry to CAM practice – predominantly on the activity of rogue elements within the practitioner sector.

2.4.1 Risks of undocumented CAM use

Whilst it has long been known that most CAM users do not disclose their CAM use to their medical practitioner[11] many people are unaware of how deep this lack of documentation may go. A study of 511 patients at St Vincent's Hospital in Sydney found that more than a third of CAM users continued to take CAM during their hospital stay and half of these medicines were not noted on their charts[82]. Of these 11 patients and twenty CAMs were noted in which there was a strong risk of interaction with their current medical treatment. A study of 234 cancer patients in the Wentworth Area Health Service of New South Wales found that whilst 17% of their patients were using ingestible CAMs during cancer treatment 52.5% had disclosed this use to clinical staff[83].

Until a regulatory framework is set in place, practitioners of complementary medicines cannot be distinguished from laypersons.

2.4.1.1 Lack of regulation of practitioners

Regulation protects the public in a variety of ways: Registering adequately trained practitioners and restricting others from representing themselves as registered practitioners; Responding to

physical and mental impairment in members of the profession; Disciplining practitioners who behave unprofessionally; and ensuring the clinical competence of registrants. However the self-regulatory model has failed to achieve the majority of these – which will be discussed in further detail in Section 3.

2.4.2 Public safety from rogue practitioners

The current self-regulatory models and safeguards offer the public no protection against rogue elements or dangerous practitioners. As there are no barriers to entry to practise as a complementary therapist in most Australian jurisdictions anyone, irrespective of past history or suitability to practise as a health professional, is entitled to practise as a complementary therapist. Even in within the current model of self-regulation a workforce survey found that it was far too easy for practitioners to gain credibility by joining, or in some cases creating, dubious professional associations [52]. A statutory regulatory framework is required to protect the public against unethical and unqualified practitioners – examples of whom are listed below:

A Newcastle naturopath was charged with manslaughter of an infant in 1999 after convincing the infant's parents to refuse surgery and rely on naturopathic treatment for a congenital heart condition. The infant died of cortical aortic stenosis – a condition that can only be corrected with surgery – at 18 days after the naturopath claimed to have treated the condition with herbal drops and an electromagnetic device[84].

A Lismore naturopath was charged with several counts relating to repeated use of medical titles and medical practices under the *Fair trading Act 1987* and *Business Names Act 1962* for false advertising, claiming to be a medical doctor when his only qualification was in Swedish massage and claiming to be able to diagnose and treat conditions such as cancer[85]. Although successfully prosecuted in 2002 and fined $33 000 he was able to change his name and continue practising in Sydney where he was narrowly acquitted of the manslaughter of a 37 year old man. Whilst acquitted of manslaughter the coroner contended he was grossly negligent in convincing his patient to cease conventional medical care during treatment[86]. A strong regulatory framework that is nationally consistent would ensure unsuitable practitioners do not fall through regulatory cracks by changing jurisdictions[87].

Another Newcastle naturopath was one of the primary reasons for the New South Wales government's enacting of legislation that enables the Health Care Complaints Commission to investigate and prosecute complementary therapists. Despite faking his qualifications – including a doctorate of philosophy – and breaching several codes of conduct he remained a member of his professional association, the Australian Traditional Medicine Society, for fear of legal action against it and is still allowed to practise, albeit without making certain claims or treating certain conditions[88]. Before advertising himself as a naturopath the individual in question had numerous convictions for fraud and armed robbery and questions concerning his suitability as a health professional had previously arisen[89]. An adequate regulatory environment these may have precluded him from practising in the first place, thereby upholding public safety.

Legislation as it stands affords no protection to patients even when practitioners are charged with heinous and unethical crimes. Even when charged with 11 counts of rape and 16 counts of indecent exposure a Melbourne naturopath was allowed to continue practising as there was no legislation or regulatory body to suspend him until the case was heard by a court[90]. The naturopath – eventually found guilty of 22 counts of sexual assault, 11 counts of rape and one count each of sexually penetrating a child under 16 and committing an indecent act with a child under 16[91] – admitted that he was still freely practising naturopathy and massage while his case was being heard.

Complementary therapists have been elevated by the public to a position of trust[92] and it is time for a adequate regulatory framework that recognises the potential harm form abuse of this trust by rogue elements within the sector.

2.5 Indirect risks

Indirect risks arise predominantly from acts of omission in practice – most often when practitioners have inadequate skills or are unaware of the limits of their practice. These may include failure to detect significant underlying pathologies; misdiagnosis; failure to refer or failure to disclose (for example adverse events).

2.5.1 Indirect risks from scope of practice

Medical practitioners are most concerned with the indirect risks of inappropriate CAM practise. Most medical practitioners as concerned by possible adverse events of CAM – a potential for harm which is shared by most conventional medical interventions – but rather the possibility of delayed or missed diagnoses or treatment due to CAM use [93]. However, research suggests that CAM practitioners are not necessarily interested in gaining diagnostic powers and believe that this is an area best left for conventional medical practitioners[94]. Most CAM practitioners want to form closer ties with conventional medical practitioners though often feel as though they are unable to do so due to lack of support from the conventional medical community[94]. This feeling may be warranted, as it has been suggested that most medical pracititioners would prefer to refer to another medical practitioner for CAM even if they had less training than a CAM practitioner [95-97].

One of the major areas of concern amongst the medical community is that users of CAM may delay or avoid conventional treatment of documented benefit[98]. Guaranteeing minimum standards of health science training in CAM practitioners would allow these practitioners to competently assess situations in which appropriate referrals are required. An appropriate regulatory framework would also hold CAM practitioners accountable for their actions and advice in these situations and ensure that public health and safety is upheld[99].

Another failure of the current model of self-regulation is the lack of transparent accountability that it places on CAM practitioners[100]. The director's of Melbourne's Royal Children Hospital's Neurology and Haematology and Oncology departments called for regulation of CAM practitioners after a Melbourne child given a 60% chance of survival died after his parent's ceased chemotherapy and focused on unconventional therapies based solely on their naturopath's advice[101]. This had followed incidents whereby an epileptic infant under the age of one and a child with an aggressive brain tumour at the same hospital were also denied medical treatment on the advice of their family naturopath. A regulatory framework is required to ensure CAM therapists are held accountable in issues of gross negligence.

2.5.2 False consultations

Another risk identified in focus groups conducted for the Victorian Department of Human Services report on regulation of naturopathy was the phenomenon of "false consultations" whereby consumers believe they are getting professional advice from a "naturopath" at a health food store[6]. Issues of qualification and training will be further discussed in Section 3, however, health food stores (and pharmacies who employ "vitamin consultants" and equivalent staff) offer particular risk due to their accessibility to consumers. Consumers may be unduly put at risk due to statements made by unqualified persons in these environments who may falsely appear qualified by virtue of their position.

A Canadian study of health food store operators found that all health food stores suggested that CAMs purchased from their store would "work better than the patients current medication"[102]. A telephone study of health food stores in Arizona found that whilst 82% claimed that CAM was suitable for migraine or nausea in pregnancy 5% of recommendations made were directly contraindicated and no dosage instructions were given [103].

Source of training	Proportion of health food store employees
Books	35%
Supplier	15%
Formal training	9%
In-store training	6%
Undisclosed	35%

Table 5: Training of Canadian Health Food Store Employees [104]

Another Canadian study suggested that 68% of health food store staff did not ask about current medications and 6% suggested their products would cure the cancer [104]. It was also found that misinformation on CAM was often deliberately given in health food stores to secure sales [105]. The same safeguards are required in health food stores, pharmacies or other areas in which CAM is directly accessible to the public as is now seen with pharmaceutical medications.

Placing health decisions in unqualified hands can often lead to deleterious consequences, especially when these people are placed in a position of authority by the consumer. When asked if St John's Wort could be used in conjunction with antidepressants – in particular *selective serotonin reuptake inhibitors* or *monoamine oxidase inhibitors* – 75% of health food store employees said they could and 42% suggested they cease their medication and use the CAM product instead[9]. To think that this situation is not relevant to Australia would be remiss as the same low standards of qualification for these roles exist here as well. The major difference is where in the Canadian and American studies pharmacies were demonstrated to provide more qualified information, in Australia they performed as bad as, or worse than, health food stores[106]. This may be due, in large part, to the fact that CAM is often seen in pharmacy as presenting commercial opportunities rather than health ones[107, 108].

Criteria 2 conclusion

CAM practitioners and products pose very real economic, direct and indirect risks sufficient to warrant regulation and comparable to other regulated health professions. It is also important to place this in context of the expanding scope of CAM practice in Australia. Minimisation of these risks can be achieved through appropriate regulatory frameworks

3 Do existing regulatory or other mechanisms fail to address health and safety issues?

Current regulatory and legislative mechanisms fail to address health and safety issues due to a number of reasons:

3.1 Fragmented regulatory framework

CAM is currently framed by a myriad of legislation and regulations at state and federal levels. This amounts to a complex and confusing array of regulatory mechanisms. These measures represent disparate and at times contradictory responses to various legislative or policy imperatives from time to time. No coherent regulatory or legislative framework currently exists to address the public health and safety issues of CAM products and practice.

3.2 Failure of self-regulation

The current model of self-regulation has produced variable standards of training and a multiplicity of professional and industry associations which have led to a number of problems, including:

- Educational standards of CAM practitioners varies widely, with courses being available at certificate, diploma, advanced diploma or bachelor's degree level and offered by both tertiary and vocational sectors. Courses not accredited by monitoring bodies such as the *Office of Higher Education* or similar body can still be formally recognised by an association.
- Lack of regulation, understanding and enforcement by the *Therapeutic Goods Administration* on the factors that contribute to the efficacy and safety of CAM has led to an unregulated free-for-all whereby consumers are unable to distinguish quality therapeutic products from ineffective or poorly produced products.
- Other health professionals (for example general practitioners) are unaware of how to identify CAM practitioners or products for appropriate referral.
- Currently, accrediting associations may have strong links with particular segments of the industry – for example manufacturing or education providers – and may therefore exhibit conflict of interest.

The confusing situation that has arisen out of attempts at self-regulation has made it difficult for the public and other healthcare professionals to identify CAM practitioners who have been adequately prepared for safe and competent practice or CAM products that have been adequately scrutinised for public use. Current arrangements with the *Therapeutic Goods*

Administration and the *Australian Taxation Office* have not provided effective self-regulation[109]. However, due to this institutional recognition, the public is often under the belief that government institutions play a major role in setting minimum standards in the provision of CAM products and practice[11]. However, this is not the case as these institutions often leave accreditation of practice to professional associations.

The *Australian Taxation Office*, for example, recognises a CAM practitioner for the purposes of *Good and Services Tax* exemption only as someone who is a member of a "recognised professional association with uniform national entry requirements" – of which there are more than 20 of variable quality and with various entry standards – and the *Australian Taxation Office* makes it very clear that it is not responsible for setting minimum practice standards in these professions for recognition[110]. The only provision placed upon professional associations is that their entry requirements be the same across all states and territories rather than any measure of competence to practice.

3.3 Poor complaints mechanisms

There are currently multiple channels for complaints management of CAM products and practitioners – including statutory authorities, professional associations and health complaints commissioners – but these mechanisms vary in quality and ease of access. This confusing situation which has arisen out of self-regulation would benefit from a single complaints mechanism that would result from the implementation of an appropriate regulatory framework.

Some of the complaints mechanisms are also managed by organisations with clear conflicts of interest, for example; the Complementary Healthcare Council, an industry lobby group, is responsible for handling complaints about advertising CAM products in areas not specified by other legislation; professional associations are responsible for handling the complaints of many of its members – whilst this may not in itself facilitate conflict of interest the ambiguity, lack of transparency and variable quality of the processes used by associations may ultimately lead to perception or possibility of conflict of interest.

Leaving complaint management to these groups may also result in problems not related to conflict of interest. Members or office bearers charged with these responsibilities may not necessarily be trained in the processes of fair and judicious process in these matters. The processes may not be transparent to the public; have limited avenues of appeal; and lack the power to impose sanctions or penalties on those who have breached specified codes and standards. For these reasons current complaint mechanisms remain fundamentally flawed.

The two major areas of complaints, which both have unique requirements, are complaints relating to CAM products and complaints relating to CAM practitioners:

3.3.1 Complaints relating to products

Currently complaints against CAM products must go through one of three bodies (see Table 6, below). Of particular concern is the fact that Point-of-Sale and 'educational' advertising – those most likely to influence consumers – is essentially self-regulated by industry organisations rather than monitored by a statutory authority. It is thought complaints and adverse reactions to CAM are often underreported[111] and the lack of a centralised body may cause unwarranted confusion in this process. Whilst the current structures may remain for complaints against CAM products, the development of a central regulatory framework (for example a Naturopathic or other CAM Registration Board that could have the inbuilt capacity and obligation to handle and pass on complaints about herbal medicines to relevant authorities) that could receive and pass on viable complaints could encourage those with valid concerns to come forward by offering a clear and unbiased mechanism to do so.

Complaint	Regulation
About product quality or claims made on the pack or pack insert	Therapeutic Goods Administration's Office of Complementary Medicines
About promotional claims made in specified media (television, radio, internet, newspapers, magazines, outdoor signs and cinema)	Complaints Resolution Panel assesses concerns against the Therapeutic Goods Advertising Code
About other advertising, such as pharmacy window displays, brochures, leaflets and catalogues	Complaints Resolution Committee of the Complementary Healthcare Council of Australia or Australian Self-Medication Industry's Complaints Panel

Table 6: Bodies handling complaints about listed products and registered over-the-counter products [106]

3.3.2 Complaints relating to practitioners

Although there have generally been few complaints regarding professional practice this may be due to a lack of public awareness or appropriate avenues of complaint or the inadequate nature of complaints mechanisms currently put in place by the associations – some of which demonstrate a lack of clear process – rather than any lack of legitimate concerns. The number of complaints levied in states and territories that received complaints against CAM practitioners is listed below:

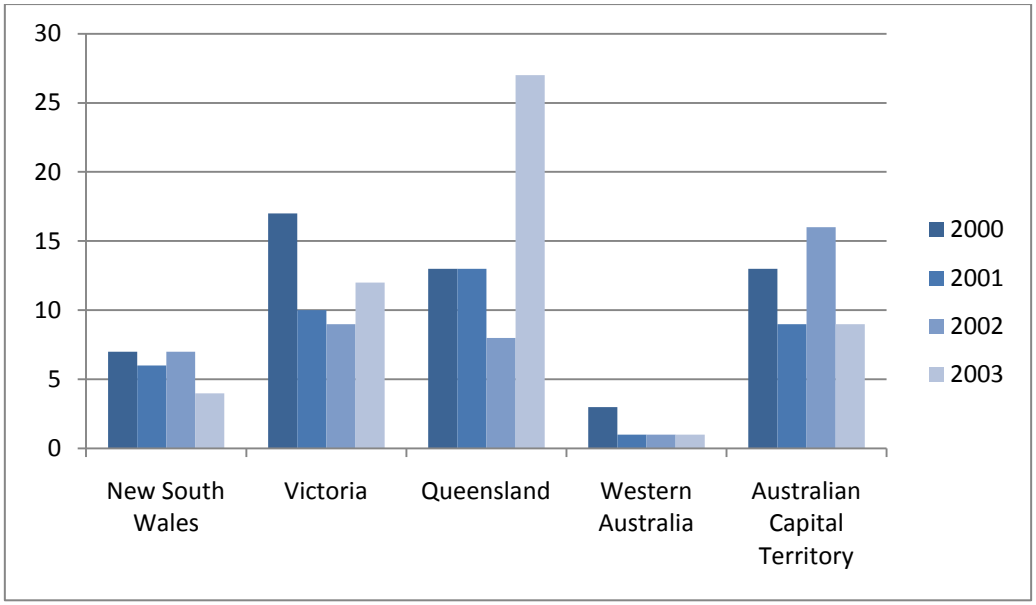


Figure 3: Number of complaints levied against complementary therapists registered by State Health Care Complaints Commissioners *Source:* [6]

However, a regulatory mechanism may ensure more effective complaints mechanisms by improving public awareness, providing easier access and providing an appropriate mechanism for receiving and handling complaints and imposing disciplinary actions. Although these numbers seem small enough to not warrant specific regulation the current confusing nature of avenues for complaints against CAM practitioners may be stopping people from bringing forward legitimate complaints. After registration of Chinese medical practitioners in Victoria and the Chinese Medical Registration Board began receiving and handling complaints in 2002 the number and nature of these complaints against these practitioners significantly increased as seen in the graph below:

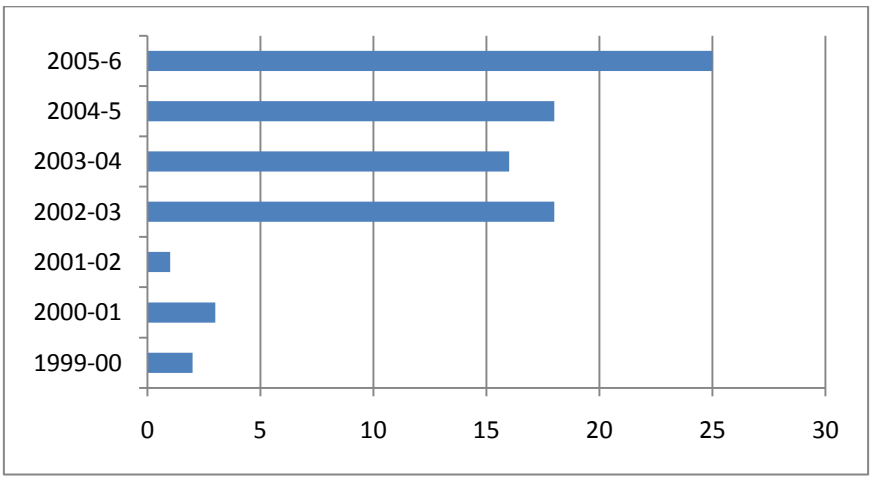


Figure 4: Complaints registered against Chinese medical practitioners in Victoria 1999-2004 *Source: CMRB*

The types of complaints levied against these practitioners include: Misleading advertising; Breaches of conditions and undertakings (for example not maintaining insurance or conditions on registration); Consumer issues, including treatment and financial matters; Practice issues, including unlawful use of endangered species or infection control issues; Professional ethics issues (such as giving a false impression of being qualified or registered and character matters); and Occupational health and safety concerns. The range of issues by numbers of complaints is listed below:

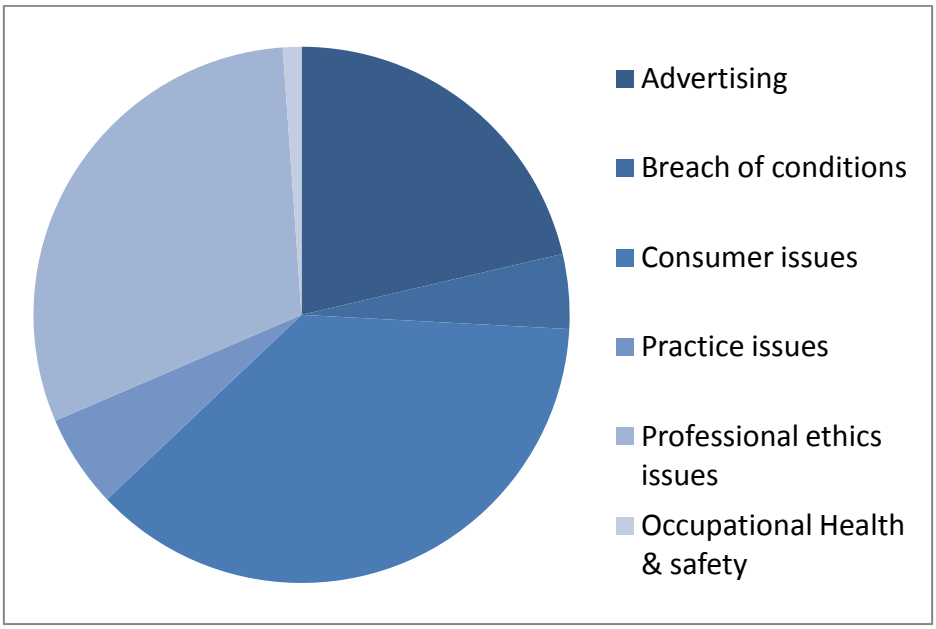


Figure 5: Types of complaints levied against Chinese Medical Practitioners via the Chinese Medical Registration Board (CMRB) *Source: CMRB*

3.3.3 Adverse events reporting

A workforce survey of naturopathic practitioners found that only 33.4% regularly reported adverse events when they occurred and only 27.1% were aware of the Australian procedures for reporting adverse reactions[112]. The confusing and fragmented nature of current self-regulatory structures in has meant that those that do report do so to a multitude of mechanisms, predominantly manufacturers or suppliers, as shown in Figure 8 on the following page:

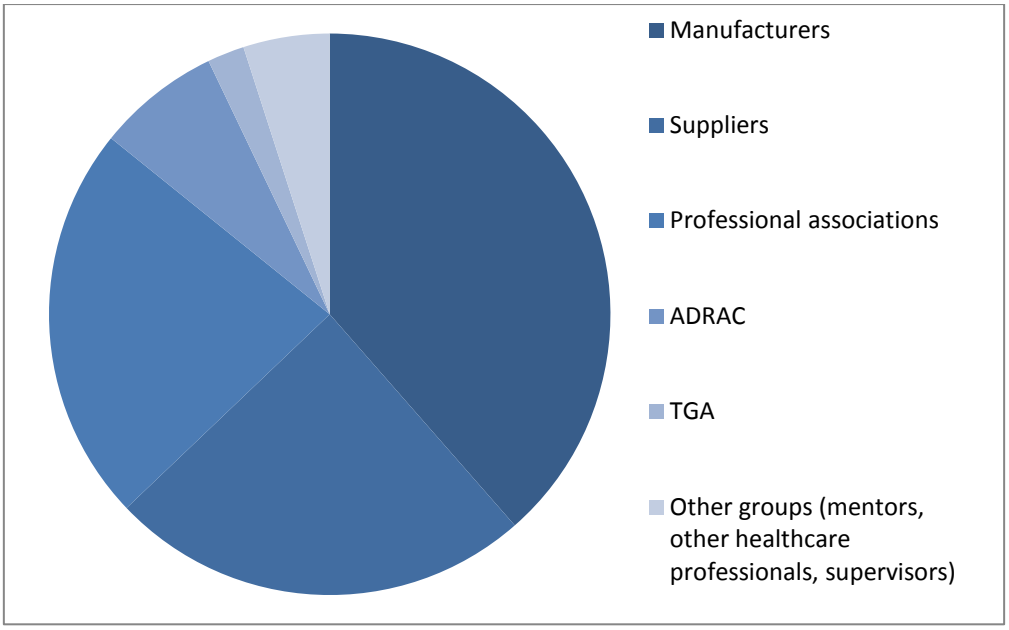


Figure 6: Naturopaths methods of reporting adverse events *Source:* [112]

Issues of poor adverse reaction reporting may not be limited to CAM practitioners – a study of older Australians found that 19% of them had adverse drug reactions that were routinely missed in clinical care[113]. However, adequate regulation may help to ameliorate some of these issues in respect to CAM practitioners by encouraging minimum standards of training in these matters. Currently 87.5% of tertiary level naturopathy courses – and 100% of the courses at Bachelor level – provide training in adverse reaction reporting as part of their clinical curricula[6]. Regulation can ensure this becomes standard practice amongst CAM practitioner training. Other issues relating to levels of training will be discussed further in the next section.

3.4 Minimum standards of practice

Existing regulatory mechanisms fail to adequately protect the health and safety of the public. Currently the regulatory structure relies primarily on non-specific regulation that makes it difficult for consumers to identify well trained practitioners and to obtain a remedy in the case of misadventure[100]. In fact, existing half-hearted and self-regulatory mechanisms may actually be risking public safety by increasing the legitimacy of CAM in public opinion due to assumptions on levels of government monitoring[11].

As mentioned in Section 2, as there are no barriers to entry to the CAM professions, expelled, disgraced or disbarred members and deregistered persons cannot be prevented from practising CAM. Whilst barred practitioners may be banned from making certain claims or treating specific conditions they may still practise within these caveats, or even under different labels – for example as a natural therapist as opposed to a naturopath[114]. Regulation, and the protection of title and registration of practitioners that would be expected to go with it, would afford a

mechanism by which the general public can identify practitioners who meet minimum standards.

3.4.1 Education standards of CAM practitioners

The degree of risk in their practice (as described in Section 2) and the need for better integration of CAM into mainstream care require education levels of at least a Bachelor's degree. This would also assist in the fostering of a scholarly community of CAM practitioners and eventually lead to a critical mass of academics able to make an impact on implementing CAM research that has real clinical relevance. The Bachelor degrees currently offered in Australia, whilst quite comprehensive, vary considerably in their clinical hours, health sciences content and research output (see below). Differences in structure (for example private versus public institutions) may pose other problems of variability, for example the private colleges whose focus on casual staff may mean that they are unable to conduct non-teaching academic which may potentially undermine the development of scholarship and research in the industry. Courses should be subject to external accreditation to ensure they reach minimum benchmarks in these areas. These independent standards would be embedded within an effective system of regulation.

The average Australian Bachelors degree in Naturopathy consists of 2586 contact hours with an average of 992 hours of clinical experience and 746 hours of sciences training [6]. Most bachelor levels courses also offer entire units devoted to CAM-drug interactions. However, practitioners are still allowed to practice with no qualifications or training and course are still being offered at the certificate and diploma level.

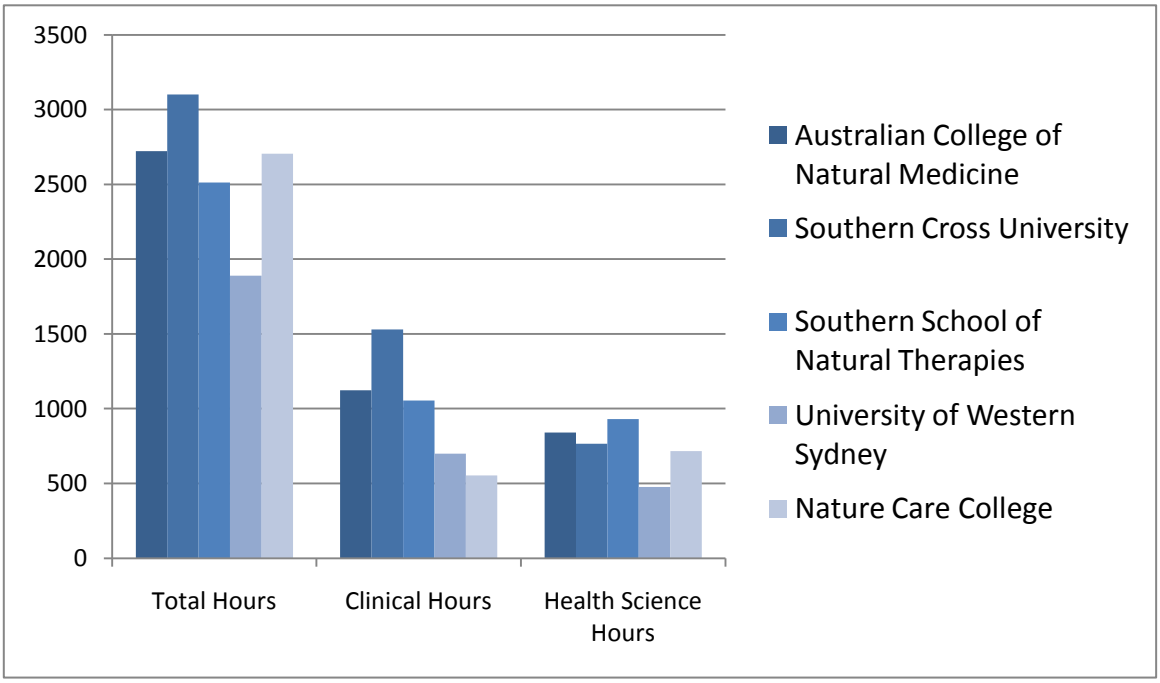


Figure 7: Composition and content of Australian Bachelor degrees in Naturopathy *Source: [6], UWS, NCC*

However, professional associations expressed concerns that commercialisation of education has driven down the quality of education[6]. Also of concern is that some of the professional associations are controlled by boards consisting of the private educational institutions themselves – leading to a clear conflict of interest[6]. Lack of regulation has allowed a greater number of providers and increasing competition – sometimes at the expense of quality. An appropriate regulatory model would ensure minimum standards of education without placing barriers to entry to the marketplace.

Standards of CAM practitioner education in Australian are viewed as amongst the best in the world[115]. However current regulatory frameworks render this achievement worthless. The current self-regulatory model has resulted in no barrier to practise and a multitude of professional associations of with entry requirements – and therefore members – of varying quality and competence. This has resulted in a highly trained workforce left on the fringes of healthcare provision and placed on the same level as those with little or no training at all. An adequate and appropriate regulatory framework would identify these practitioners thereby allowing access to the public to a previously untapped, highly qualified healthcare profession whilst maintaining public health and safety.

3.4.2 Poor knowledge of conventional practitioners

Conventional health practitioners may not be the most appropriate individuals to deliver complementary medicines. Conventional healthcare practitioners generally have poor training or knowledge of CAM when compared to CAM practitioners[6, 22]. The training and knowledge of pharmacists and medical practitioners are detailed below as these health professionals – along with CAM practitioners – are viewed as the most trusted sources of CAM information amongst the general Australian public[116].

A study of Melbourne hospitals found that 81% of hospital doctors and pharmacists did not feel confident in their knowledge of CAM to be able to identify if CAM could adversely affect patient care[117]. Although 67.5% felt that CAM could dangerous and patient use should be monitored only 28% had asked about patient use of CAM. The most commonly cited reasons for not asking were forgetting (44%); thinking it not relevant (38%) or feeling as though they had insufficient knowledge to ask (34%). As 46% of patients use CAM in the two weeks immediately prior to hospitalisation and 54% of these CAM users plan to continue CAM use during hospitalisation, of which 64% had not discussed this use with their medical practitioner or nurse – often because they were not asked – it may be prudent to establish a framework by which those qualified to make judgements on CAM are utilised to detect and supervise this use[118]. Given the very real risk exposed to patients a regulated environment could allow the inclusion of qualified CAM experts or practitioners into conventional medical environments to fulfil this role.

Relying on conventional health providers may not be sufficient in respect to CAM. A knowledge test of the 11 most common CAMs was given to 200 surgeons, physicians and anaesthetists at

four Melbourne hospitals. Although Ginkgo, glucosamine and ginger have been associated with excessive post-operative bleeding and glucosamine, garlic and ginger may potentiate the effects of warfarin the medical practitioners scored an average of 18% on the tests[119]. Similar results have been seen in other studies[120]. Although few doctors had received education in CAM and admitted little knowledge of CAM the majority expressed negative attitudes towards it[121]. This may result in an overzealous reaction by medical practitioners which may cause patients to unnecessarily cease CAM use during hospitalisation when it may actually be beneficial for them[118].

CAM Practitioners are already beginning to be recognised as legitimate healthcare providers by these groups and it is thought that a regulatory framework would foster integration between these professions[122]. This integration could assure public health and safety is protected by ensuring adequately trained, competent CAM professionals are identified. The World Health Organisation has identified poor training of practitioners in CAM, whether they be CAM or conventional in their focus, as a major determinant of risk in CAM practice[19, 81].

3.4.3 Conventional medical practitioner CAM education and training

In general, medical practitioners receive far less training and have less knowledge of CAM when compared to CAM therapists – less than half the medical practitioner community feel sufficiently knowledgeable about complementary medicine [123-126]. Most GPs who practise CAM have less than one month of formal training and 36% who practise CAM have no training whatsoever [96, 127]. Some studies go as far to suggest that many medical practitioners may actually rely on their patients for information on complementary medicines as opposed to more authoritative sources[128, 129]. This supports a need to ensure that GPs have access to adequately trained and qualified CAM practitioners, as would be supplied under a regulatory framework, to ensure they can utilise this option without being burdened by further training requirements they are either uninclined or unable to commit to.

Another study of Australian General Practitioner's training in CAM showed that less than one-fifth of GPs had any training in CAM, and most of this was either self-taught or by attending and introductory workshop [93]. Less than a quarter of the surveyed GPs expressed an interest in completing further education and 15% expressed a desire to learn more, but felt overstretched and ceded that they probably wouldn't act on this desire. Those that do express interest in further study would prefer it in the form of short courses or workshops rather than more formal study thereby further questioning their appropriateness as potential CAM professionals [93].

This lack of specific training may be exposing the public to potential risk. A study of adverse events relating to acupuncture found that medical practitioners and qualified acupuncturists had 1 adverse event for every 1009 and 368 patients, respectively [130]. This was thought to be attributable to the differences in average length of complementary medicine training amongst these practitioners, which were eight months and 43.9 months respectively.

Another factor that may limit the role of conventional medical practitioners as the preferred sources of CAM information and practise is consumer hesitance to place them in this role. Whilst it is well known that CAM users may not disclose CAM use to their medical practitioner – 57% of Australian CAM users do not disclose this use to their medical practitioner[11] – the National Health and Wellbeing Survey found that 20% of patients would not disclose their CAM use even if they were asked by their medical practitioner[131]. Patients may not disclose CAM use to their medical practitioners for fear of disapproval, criticism or lack of understanding and are generally more open to discussing these issues with a qualified CAM practitioner[132], suggesting that these practitioners may be the preferred vehicle for CAM information and delivery in an institutional setting.

3.4.3.1 Conventional medical practitioner attitudes to CAM

It has also been demonstrated that even an increasing evidence or knowledge base for CAM may be unlikely to increase CAM use by medical practitioners. Literature from the US suggests that most doctors have limited knowledge of CAM and that this is primarily determined by their beliefs about the legitimacy of these therapies[133]. There is also evidence that many conventional medical practitioners are unaware of the evidence base that does actually exist for CAM[117, 120, 134]. For these reasons conventional medical practitioners may simply not have the CAM knowledge suitable for delivery of CAM in a clinical setting[135].

There are other issues with conventional medical practitioner provision of CAM services: Whilst community attitudes to CAM have changed considerably during this timeframe, medical practitioner attituteds to CAM have not changed considerably in the last twenty years[136]; whilst requests for CAM referrals have increased, the amount of medical practitioners practising CAM has actually decreased in the last decade[96] and medical practitioners may simply not have the time to appropriately train in and practise CAM[137]. For these reasons as well it may be more prudent to focus CAM provision in a regulatory model on well-qualified CAM practitioners as opposed to delivery mechanisms through often untrained and uninterested conventional medical practitioners.

3.4.4 Pharmacists CAM education and training

Whilst Australian pharmacists generally have positive attitudes towards CAM[138] most pharmacists both in Australia and internationally have little knowledge of CAM[139-145]. Fewer than 15% of Australian pharmacists express confidence in their knowledge of CAM[146] and 27% of pharmacists sold CAM from a pharmacy with no access to CAM information[138]. In fact, pharmacists were no more likely to identify potential adverse effects of common CAM products as non-pharmacy trained pharmacy staff[147]. As with medical practitioners an overwhelming amount of training in CAM is informal either being self taught or from manufacturers with 20.4% of pharmacists having no CAM training, informal or otherwise [146]. Even when formal CAM

training was included in the undergraduate curriculum this appeared to have little if any effect on increasing CAM knowledge in pharmacists[148]. A list of CAM training sources used by Australian pharmacists is listed below:

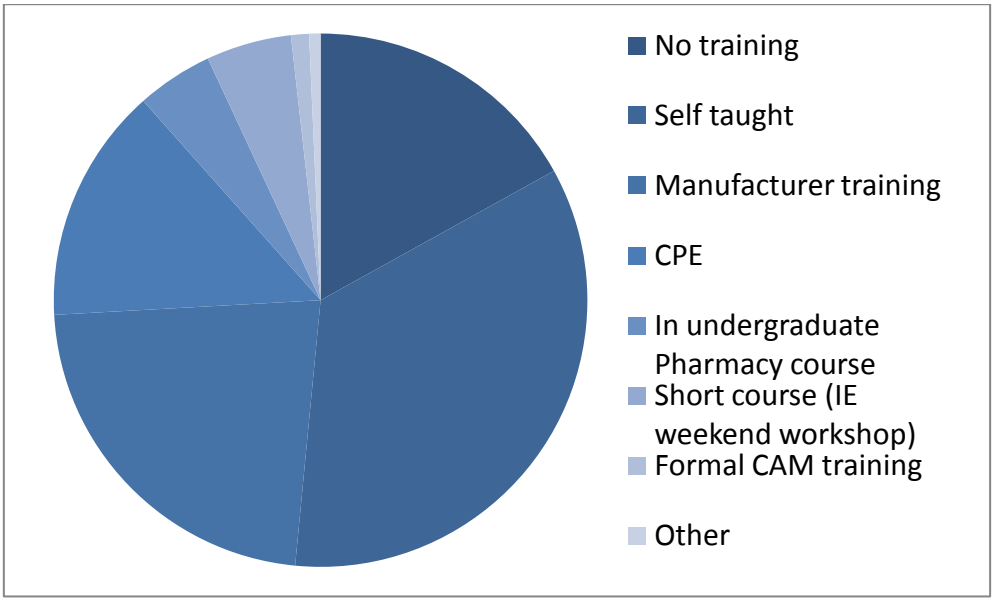


Figure 8: Major sources of CAM training for Australian pharmacists *Source: adapted from*[146]

The medical literature is peppered with studies suggesting that literature is peppered with research articles and editorials indicating that medical and conventional health practitioners in most Western countries do not have formal education about CM and are not aware of the evidence of its efficacy or safety, have limited personal experience of its effects and do not routinely ask patients about use thereby missing out on receiving patient feedback. One of the reasons complementary therapists believe medical practitioners are not aware of CAM efficacy is that their lack of communication with CAM practitioners combined with lack of communication on CAM with their patients means that they are rarely exposed to any positive feedback from CAM, instead only being informed of adverse events when things do go awry [94].

3.5 Issues of litigation

It is argued that a doctor's common law obligation to provide information requires that they have a duty of care to provide information about CAM therapies were that information would be material to that particular patient [149-151]. In New South Wales these recommendations have even been incorporated into the *Civil Liberties Act 2002*. However, current regulatory frameworks hamper this obligation by either: a) exposing the practitioner to medical negligence charges in areas where they are forced to offer information which they are not qualified to give – in which case they are not providing adequate standards of care; or b) leaving them open to medical

negligence charges by referring to a CAM practitioner whereby treatment consequences of this referral are still the responsibility of the medical practitioner[152, 153] – as is demonstrated in the example below:

> Current regulatory frameworks do not adequately protect medical practitioners making referrals to CAM practitioners. In McGroder v Maguire contested at the New South Wales Supreme Court a GP was found guilty of medical negligence when he referred a patient to a CAM practitioner for neck and back pain. After treatment the plaintiff's condition worsened markedly. However, the GP was deemed responsible despite the CAM practitioner's treatment constituting a "new intervening act" [154]. Regulation of CAM practitioners could alleviate concerns of referrals from conventional medical practitioners by placing accountability upon the CAM practitioner.

An adequate regulatory framework for CAM practitioners can ensure that these issues are appropriately addressed by placing the legal responsibility of consequences practise on the persons administering the treatment in the case of CAM referral[99]. It also removes the obligation of the medical practitioner to provide potentially unqualified, incompetent or insufficient CAM information or treatment to their patients by providing clear pathways with which to provide appropriate referrals to registered CAM professionals in the event in which they are not confident in their own knowledge of the subject.

3.6 Lack of access to tools of the trade

> The fact that injudicious use of CAM poses a public health risk is undeniable; however the evidence for their potential therapeutic benefit is also strong. Often complementary therapists are the only practitioners qualified and with adequate training to use these substances. A regulatory mechanism would allow for the identification of qualified, registered professionals trained. Current mechanisms may exist to allow for appropriate access to potentially dangerous therapeutic tools to qualified complementary therapists whilst limiting supply to those without appropriate qualifications.

3.6.1 Restricted CAM therapeutics

Several complementary medicines are currently have limited access via the Standard for the Uniform Scheduling of Drugs and Poisons. Whilst this denies access to practitioners without adequate qualifications it also denies access by competent complementary therapists to valuable tools of the trade. 69.6% of naturopaths identified lack of access to herbs they would find valuable in clinical practice as detrimental to their practice and 82.3% believed that the use of scheduled substances should be allowed by qualified practitioners[6]. This may also affect consumers, who may be denied appropriate treatment due to restrictions on access to certain therapeutic agents.

Lack of knowledge of CAM may exacerbate perceived risk in many instances. Potentially valuable therapeutic benefits may be denied to competent practitioners by virtue of their potential for risk. Whilst the *Therapeutic Goods Administration* recently placed warnings on products containing Black Cohosh due to risk of hepatotoxicity[155]there is a possibility that these risks may be exaggerated due to the unknown nature of CAM. A Nebraskan woman sued an American herbal supplement manufacturer alleging use of a supplement containing Black Cohosh caused her autoimmune hepatitis and subsequent liver transplantation[156]. The judge ruled against the plaintiff when it was uncovered that she had for many years taking several pharmaceutical medications specifically indicated in causing liver damage. Whilst ultimately an objective decision was made by the judge, the media controversy it created may have informed more subjective opinions in other circles.

CAM practitioners are worried that assumptions that CAM is the underlying cause for idiopathic complaints may be justified. In the 1970s the death of a young man from liver failure caused the herb Comfrey to be scheduled. the cause of death was unknown though it was assumed Comfrey was indicated as he had been taking a product containing it shortly before his death[6]. Around the same time two Canadians were poisoned after consuming Comfrey tea that had been adulterated with *Atropa belladonna* – a herb with known toxic properties[157].When a Melbourne woman died of liver failure after taking a combination herbal supplement Kava was immediately implicated even though one of the herbs in the formulation was found to be substituted with an unknown substance [61].

3.6.2 Inappropriate access mechanisms for restricted CAM therapeutics

The current system, whereby only registered practitioners are allowed to access many of these tools is untenable as it allows access to those with insufficient knowledge whilst barring those with adequate knowledge of these substances. Most conventional medical practitioners have little knowledge, or little interest in increasing, their knowledge of complementary therapies [158-160] yet are often the only ones granted access to these restricted complementary medicines. Many unsafe medications – such as paracetamol – are often freely available to the public or at the very least available for prescription by appropriately qualified health professionals. Regulation would also reduce the potentially anti-competitive nature of such laws by granting complementary medicines the same level of restriction conventional medications.

The risk of a remedy producing an adverse reaction depends not only on the remedy and its dosage but also on consumer related parameters such as age, genetics, concomitant disease and concurrent use of other drugs [161]. For these reasons it is entirely appropriate that these remedies and tools are available for supply only to those with appropriate levels of clinical knowledge specifically pertaining to CAM. Often, the only people with sufficient training in CAM or who are qualified to exercise such clinical judgements are the CAM therapists themselves. Other non-CAM health professionals wishing to use CAM should also have set minimum levels of CAM training before being allowed to use these products.

The Commonwealth commissioned Expert Committee on Complementary Medicine suggested that complementary therapists with appropriate levels of professional education should have access to some restricted substances, and that an appropriate Schedule under the Standard for the Uniform Scheduling of Drugs and Poisons (such as the *Schedule 1* provision in Victoria) should be implemented in a nationally consistent manner [162]. Existing mechanisms provide this framework and can assist practical application of these suggestions.

3.6.3 Scheduling arrangements for CAM with sufficient risk

The Victorian *Chinese Medicine Registration Act 2000* offers a precedent. The act provides a mechanism that will authorise any practitioner regulated under that act to obtain, possess, use , sell or supply any *Schedule 1* poison in accordance with the lawful practice of their profession and amended Section 13 of the *Drugs, Poisons and Controlled Substances Act 1981 (Victoria)* to grant registered Chinese medicine practitioners prescribing rights to these substances. The Therapeutic Goods Administration and Council of Australian Governments have also considered extending Schedule 1 to include a number of complementary medicines that may warrant limited access but may also provide therapeutic benefit[163].

Complementary medicines labelled "for practitioner dispensing only" already share labelling requirements with prescription medications from Schedules 4 and 8 of the Standard for the Uniform Scheduling of Drugs and Poisons under provision of Therapeutics Goods Order 69[164] – specifically the restriction of supply to specific health practitioners and the lack of requirement to include a statement of purpose on the label. This existing framework could be expanded to extend to labelling requirements for CAM products supplied safely only by a qualified healthcare professional (such as a registered CAM practitioner) as Schedule 1 medications as proposed by the Victorian government[165].

Criteria 3 conclusion

Current regulatory frameworks for CAM are either entirely absent or woefully inadequate. Consumers and health professionals are unable to identify competent and qualified CAM practitioners or differentiate good quality or effective CAM products from those of poor standing, quality or therapeutic efficacy. These are exacerbated by an unclear mechanism through which legitimate concerns about these products and services can be voiced. This places the general public at undue risk. An appropriately regulated environment would ameliorate these issues.

4 Is regulation possible to implement for the occupation or industry in question?

Many complementary therapies are defined professions, with defined modalities and established educational provision for which regulation is possible to implement. Those modalities with increased inherent risk and increased educational requirements – such as naturopathy and acupuncture – are the ones that lend themselves most to regulation.

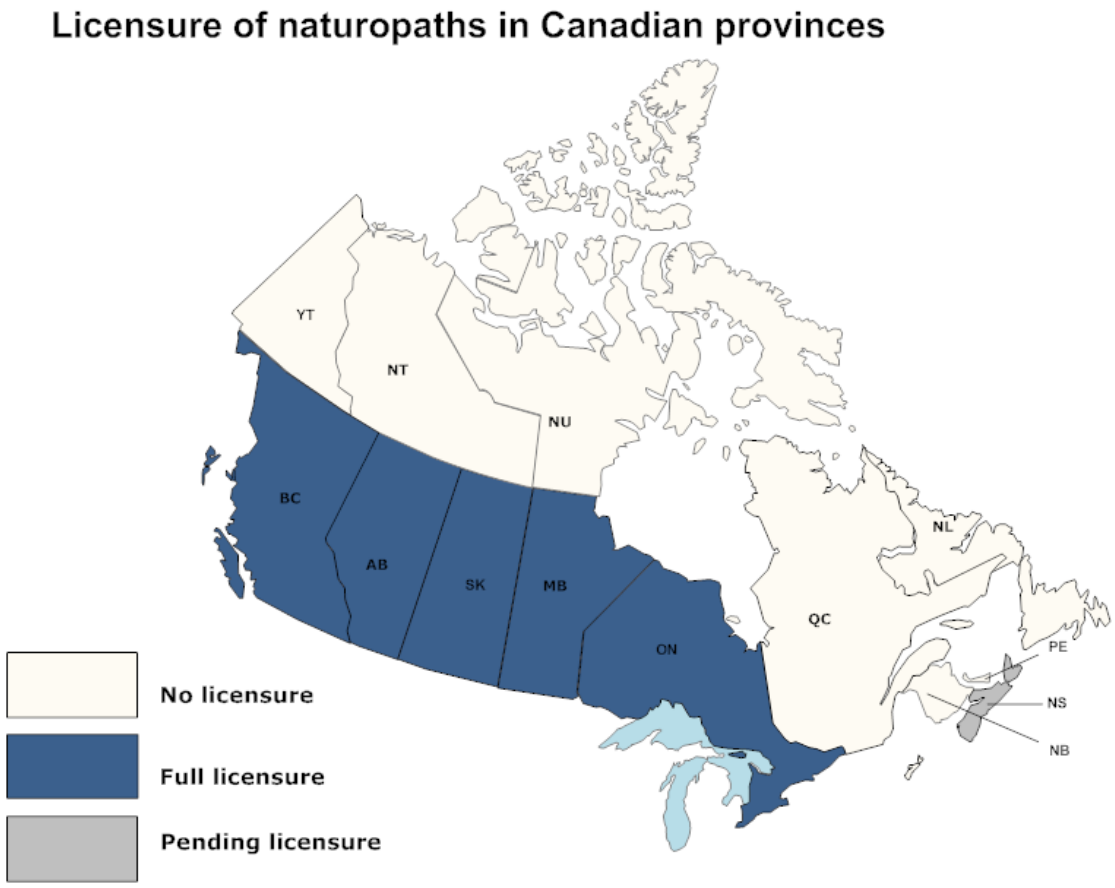
4.1 Australian precedents

Several precedents have been set for regulation of complementary therapists. Herbal and Traditional Chinese Medicine has already been defined and regulated by an Australian government under the *Chinese Medicine Registration Act 2000* in Victoria. The Victorian government also commissioned a report, *The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine* which recommended that these professions be immediately regulated in a statutory framework with protection of title only[6]. The Victorian government initially confirmed that it would move to regulate these practitioners[166] though have since had to rescind or delay this move after agreeing to the arrangements for a Health Profession's National Registration and Accreditation Scheme at the Council of Australian Governments meeting in 2007[167]. However, these moves demonstrate that regulation of CAM professions is possible and should be enacted in accordance to their need to improve health outcomes rather than delayed due to political expediency.

4.2 International precedents

A number of international jurisdictions have made moves towards statutory regulation of CAM products and practitioners. Those most relevant to the Australian context (in terms of sharing similar legal, social and practical obstacles) include the Canada, Ireland, New Zealand, the United Kingdom, and the United States[6]. North American jurisdictions that currently have statutory regulation for naturopathic physicians are shown in Figure 11 on the following page.

The World Health Organisation has acknowledged the valuable role CAM has to play in healthcare provision – in both the forms seen in developing and developed nations – and has noted a number of challenges that require immediate action, including: a lack of official recognition for CAM providers and their roles; inadequate or non-existent regulation; lack of access to CAM (for example for financial reasons); inequitable distribution of benefits from CAM and; inadequate allocation of resources for development, capacity building and research in CAM[19]. These challenges will be discussed in more detail throughout this report though it is clear that an appropriate regulatory framework will make progress on these issues.



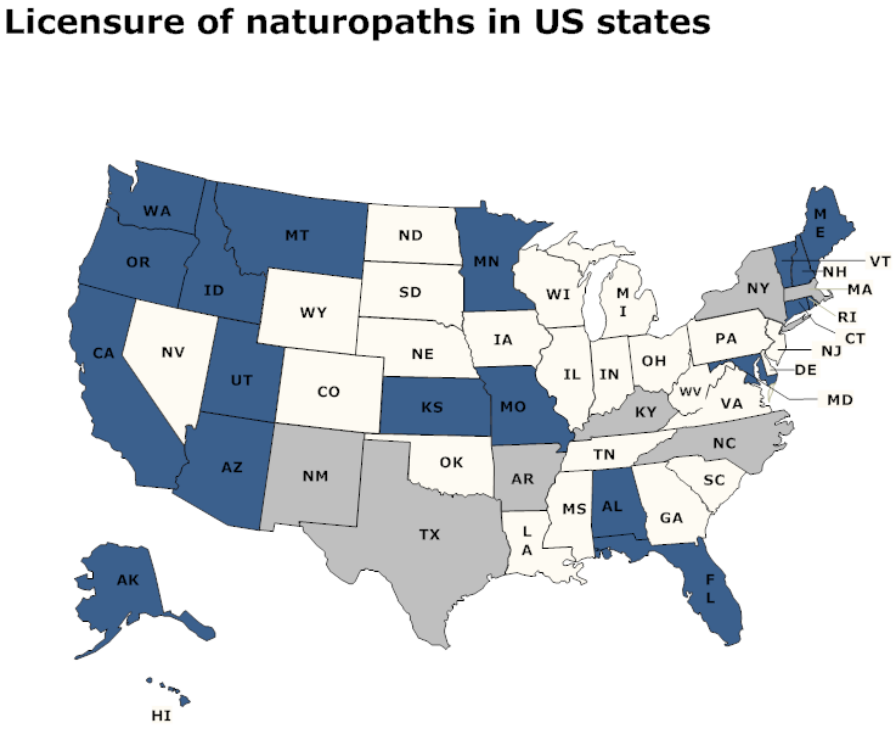


Figure 9: North American jurisdictions licensing naturopaths *Source: AANP, CAND*

Regulation of CAM professionals in the UK has been recommended by the House of Lords and moves are underway in the instances of homoeopathy and herbal medicine[168]. In 2001 the Irish Health Minister announced plans to implement a robust system of registration and regulation of CAM to afford protection to the public when accessing these services[169]. In 2002 the *United States of America White House Commission on Complementary and Alternative Medicine Policy Final Report* recommended that public accountability for CAM practitioners was required and urged all states to investigate regulatory infrastructures for CAM practitioners and products[170].

Internationally regulation of complementary therapists is a trend that is increasing rather than decreasing. The number of US states and territories that license naturopathic physicians – requiring that they graduate from an accredited four-year program and sit a comprehensive entry examination – has increased from 7 to 19 in the period 1992 to 2008. Minnesota is the most recent state to grant licensure and legislation is being considered in seven states (Arkansas, Kentucky, Massachusetts, New Mexico, New York, North Carolina and Texas). The Canadian provinces of Alberta, British Columbia, Manitoba, Ontario and Saskatchewan also license naturopathic practitioners.

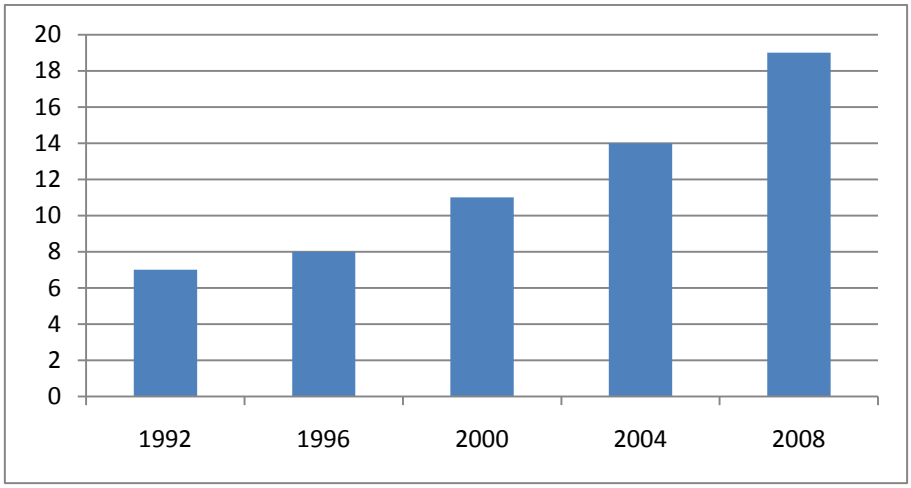


Figure 10: Number of US states and territories licensing naturopaths *Source: AANP*

4.3 Definition of occupational boundaries

Definition of occupational boundaries may prove troublesome as there are estimated to be anywhere between 20 and 200 specific CAM modalities. However, moves such as protection of title do not require boundary definition whilst allowing the general public to easily identify qualified, competent practitioners.

Criteria 4 conclusion

Whilst there are complexities related to regulation of CAM and CAM products international and Australian experience suggests that it is possible. Evidence also suggests that it is a trend that is increasing rather than decreasing and more and more jurisdictions are establishing regulatory frameworks for CAM.

5 Is regulation practical to implement for the occupation or industry in question?

Notwithstanding previously implemented examples mentioned in Section 4, current high levels of support for regulation support the practicality of implementation of regulation of CAM.

5.1 Support for regulation

5.1.1 General support for regulation

The Australian Medical Association has deemed the regulation of CAM practitioners in Australia "essential" [171] and the current medical literature has actively suggested that lack of regulation is a major hurdle to integration of CAM practitioners or products into conventional healthcare delivery[93]. A survey conducted by the Victorian Department of Human Services found that 77% of general practitioners support government regulation of CAM therapists[6]. Studies have suggested that conventional medical and health practitioners may be more open to utilisation of CAM products and services in healthcare delivery if adequate regulatory regimes were set in place [93, 172, 173]. In one of the few studies done on public perceptions of regulation of CAM practitioners a Scottish study found that 61% thought that this was essential and 29% thought this was desirable [174]. This is mirrored by Australian data from an online survey conducted by the Australian Naturopathic Practitioners Association which found that 91% of the general public supported a model of government regulation whilst only 5% supported the current self-regulatory model and only 4% supported no registration, as can be observed in the figure below.

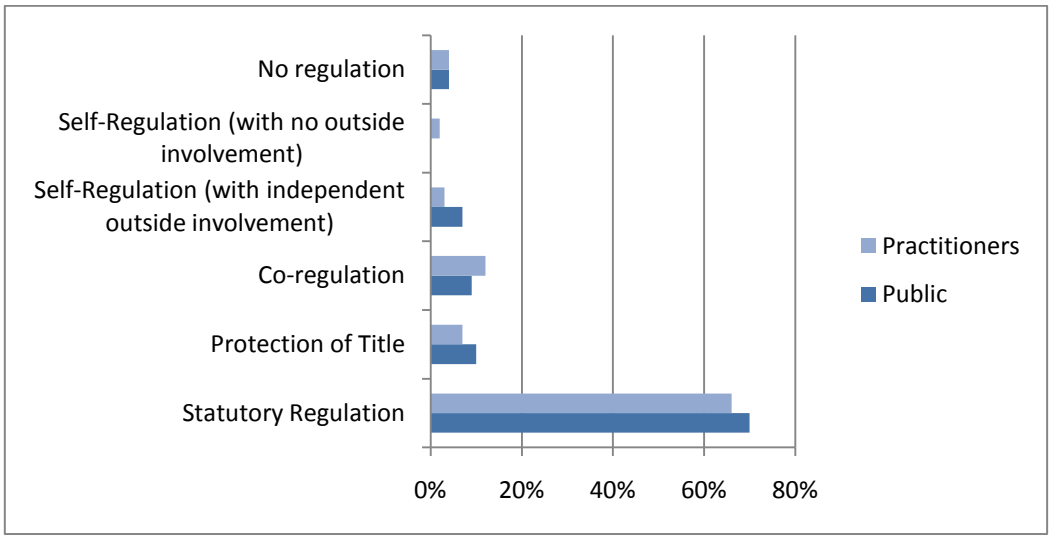


Figure 11: Support for various regulatory models by members of the Australian Naturopathic Practitioners Association and the general public *Source: ANPA*

5.1.2 Industry support for regulation

Whilst it is envisaged that commercial interests may not support regulation overwhelming industry support for registration exists within the community of practitioners, professional associations and education providers. The only professional association that does not support some form of statutory regulatory model is the Australian Traditional Medicine Society (ATMS)[175-181]; however a survey of ATMS members suggests that this goes against the views of its members - 72% of whom support statutory regulation[22]. 64% of professional associations governing naturopathy actually felt negatively towards self-regulation [6]. Current attitudes of various components of the industry can be seen in the following graph:

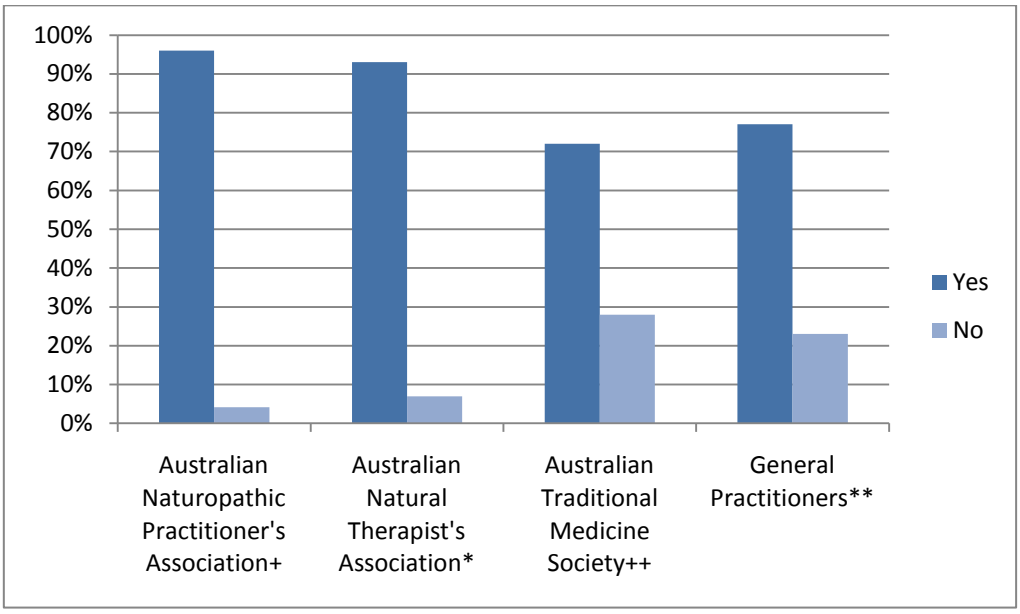


Figure 12: Support for government regulation of CAM practitioners by members of various groups *Source: +ANPA *ANTA ++[52] **[6]*

Whilst the issue has not been studied in great depth other studies have uncovered strong support for regulation. An exploratory study of rural naturopaths practising in the Darling Downs region found unanimous support for the implementation of regulation for naturopaths[94]; qualitative research conducted in the Victorian Department of Human Services investigation into regulation of naturopaths found the majority of practitioners supported regulation[6] and a workforce survey found that naturopaths believe regulation will improve the standards and quality of practice and education, improved research outcomes and enhance integration[52].

An online survey of members and the general public conducted by the Australian Naturopathic Practitioners Association[182] found that both practitioners and the public overwhelmingly supported government regulation over other forms.

However, concerns have been expressed that if done incorrectly regulation could "medicalise" complementary medicine [183]. Naturopaths are unwilling to give up their role as primary care practitioners and envisage a role of collaboration with, as opposed to subordination to, medical practitioners [94].

A number of approaches can help to alleviate these legitimate concerns regarding regulation: 1) registration boards that consist of a majority of practitioners who are well qualified in the non-medical traditions of complementary medicines and 2) increased research into the holistic frameworks applied in complementary medicine[6].

Current perceptions that professional associations are hostile to regulation may be unfounded (At present ATMS is the only professional association opposed to any form of regulation). Statutory regulation will not render the professional associations irrelevant any more than the establishment of state medical boards have limited the role of medical associations such as the *Australian Medical Association* or *Australian General Practice Network*. The professional CAM associations would still have important roles to play in: continuing to represent CAM practitioners; supporting them through allegations of misconduct; providing advice on education and practical matters; and advising government on the future needs of the professions[6].

Criteria 5 conclusion

Whilst regulation is not without its practical difficulties international and Australian experience can be drawn upon to combat these difficulties during implementation. Strong support from a majority of stakeholder groups ameliorates many of the practical difficulties involved in setting up a regulatory framework.

6 Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

6.1 Potential benefits of regulation

6.1.1 New therapeutic options for patients

CAM may be particularly suited at closing 'effectiveness gaps' in current healthcare provision[184]. This means that rather than competing with existing health provision, a regulated CAM industry may be able to target areas that hitherto have seen little success with conventional treatment.

The range of possible benefits that CAM may offer in areas of emerging health priority may be broader than we think. Recent research unveiled at the recent International Congress of Complementary Medicine hosted in Sydney suggested that: St John's Wort may be more effective than nicotine replacement therapy in encouraging smoking cessation[185]; Ginkgo may be beneficial in reducing dementia[186]; Acupuncture may improve stroke rehabilitation[187]; and as will be discussed in further detail CAM already has demonstrated effectiveness in the myriad of cardiovascular disorders that are increasing as the major component of Australia's total disease burden[188-190]. These findings may offer significant new options for patients in these areas of increasing need.

The incorporation of CAM into healthcare delivery – with their focus on holism, prevention and proactive health interventions – may help to finally give meaning to the World Health Organisation definition of health of "not simply the absence of disease but a positive state of mental, physical and social well-being"[191].

6.1.2 Filling healthcare effectiveness gaps

Effectiveness gaps are areas of healthcare which do not generally see success with conventional models of treatment for a variety of reasons: lack of effective treatments; adverse effects of available treatments; unacceptability of patients to treatments; difficulty in defining a compliant; poor patient compliance; treatment interactions or prohibitive costs[184]. Most conventional practitioner referral to CAM comes from an effort to fill these effectiveness gaps[120]. The major effectiveness gaps in current healthcare according to GPs are shown in the following figure:

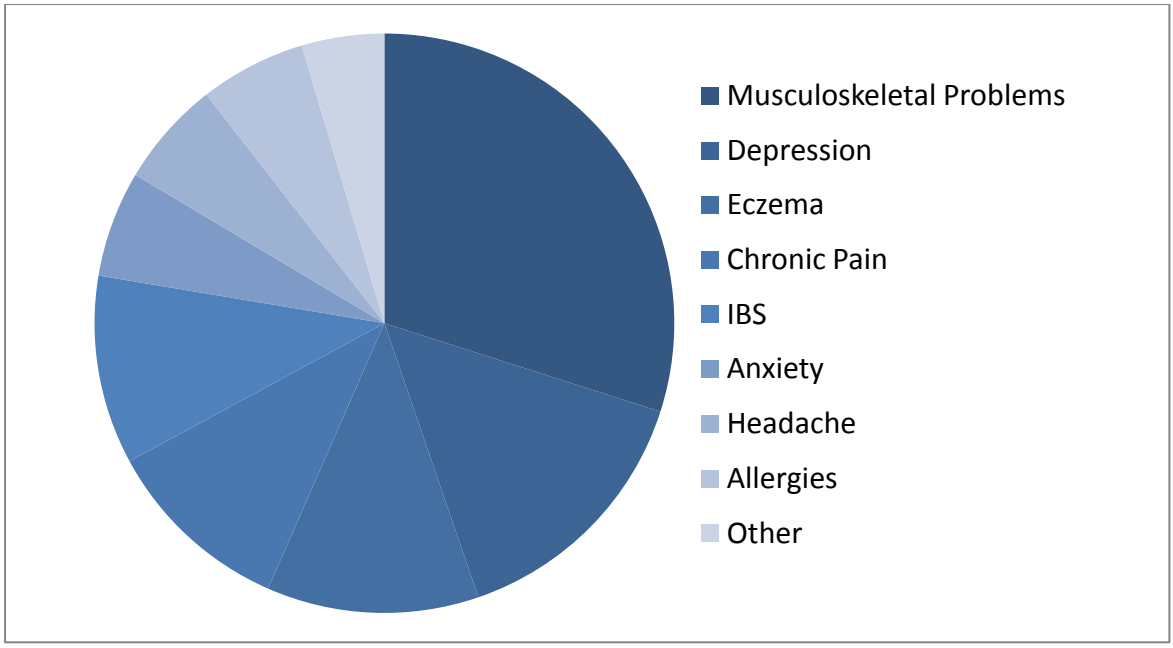


Figure 13: Effectiveness gaps according to general practitioners *Source:*[184]

CAM may offer an opportunity in these areas traditionally ineffectively treated by conventional models of care. A good well-researched example of this is low back pain, a health issue estimated in Australia in 2003 to have direct costs (costs of actual treatment) of $1.02bn and indirect costs of $8.15bn – a total economic burden of $9.17bn annually [192]. Various studies have demonstrated the effectiveness of CAM in reducing health costs and improving health outcomes in this condition:

Another trial utilising naturopathic treatment for lower back pain in Canada Post employees reduced absenteeism attributable to this condition by 9.4 days per employee and saved the corporation $18 per day lost to injury [193]. Estimated savings of direct medical cost of $207 and indirect societal costs of US$1212 per participant were also observed. Quality of life and symptom scores were also improved when compared to current conventional methods of treatment [194].

It has been suggested that CAM may be particularly useful in the treatment of complex and chronic conditions that are becoming an increasing part of Australia's burden of disease[195]. The National Expert Panel on Community Health Promotion has suggested that CAM should play an integral part in fighting the burden of chronic disease[196]. It has also been suggested that CAM practitioners be employed to apply this as their treatments – based on principles and practice rather than products – focus on preventative and proactive models of health rather than existing reductionist frameworks favoured by conventional medicine and may achieve better results in these settings[127, 197].

6.1.3 Improving quality use, efficacy and safety assurance

There is a misconception that all pharmaceutical products must be registered with the *Therapeutic Goods Administration* but this is not the case. A new product utilising a pharmaceutical agent – paracetamol for example – would not have to undergo a full safety or efficacy evaluation but rather it would be based upon existing available information in pharmacopoeias and other sources[198]. As the most pressing issue in CAM quality is not efficacy so much as standardisation similar CAM products should be able to use existing information where appropriate. In saying this, however, the burden of proof should be placed upon CAM manufacturers to show that their product is of the same quality as that for which the evidence is being compared.

6.1.3.1 Quality use and efficacy of conventional medicines

Whilst most attention is focused on the negative interactions of CAM it is actually also possible for some CAM treatments to positively interact with current treatment. Some conventional medications for hypercholesterolemia (statins) are more effective[199-201] and side effects reduced[202] when combined with fish oils – considering Australia spends $1.14 billion annually[203] on this class of medicines substantial economic benefits could also be made to mirror those gained in health. Other beneficial interactions are known: The efficacy of imipramine in bipolar disorder is improved with supplemental L-tryptophan and nicotinamide of ; Kava and Valerian may be useful in treating benzodiazepine withdrawal[204, 205]; CAM supplementation can reduce post-surgical complications and care costs[206]; Glutamine may attenuate gastrointestinal damage caused by non-steroidal anti-inflammatory drugs (NSAIDs)[207]; curcumin, resveratrol, St Mary's Thistle and licorice may protect against liver damage from medication[208]; cinnamon may act synergistically with insulin treatment in diabetes[209]. A number of beneficial reactions that have the potential to reduce dosage requirements or attenuate side effects have also been theorised[210].

6.1.3.2 Safety

Whilst this report has documented the fact that CAM poses enough risk when used incorrectly, in relative terms it is generally considered safer than many conventional medical treatments[210]. Cost savings can occur not only in terms of treatment cost but also in reduction of inherent risk. For example, findings that the use of non-steroidal anti-inflammatory drugs – one of the most commonly prescribed medication classes in Australia – can increase the risk of a heart attack by 24 and 55%[211] and often require concomitant medication to reduce gastrointestinal complications[212] is of considerable financial and epidemiological consequence to the delivery of healthcare in Australia. The safer alternatives and the means to attenuate side effects provided by CAM offer many opportunities in this area.

Between 1981 and 2002 the number of people admitted to hospital due to adverse events from pharmaceutical medications increased fivefold[213], whilst it is estimated that up to 60% of hospital admissions in patients over 70 years of age may be associated with adverse events of prescribed medications. The cost savings of using relatively safer treatments is quite large – even notwithstanding the potential litigation and compensatory costs of use of these treatments.

Incorporating CAM in a regulatory framework in conjunction with conventional medical care or health practices may have further benefits. Whilst it is undeniable that CAM-drug interactions do exist, it is also possible that several interactions may be manipulated to give therapeutic benefit[214]. Many CAM interactions are caused by additive effects – that is they perform the same action as the pharmaceutical agents and effectively 'double the dose' – The Smallwood Report designated 8 CAM medications that had evidence of clinical and cost-effectiveness over pharmaceutical agents in a variety of conditions. [215].

It also suggested that impressive evidence, although not yet conclusive, existed for the utilisation of other CAMs as alternative therapeutic agents in some instances – for example Kava in the treatment of anxiety disorders, Curcumin as an alternative to NSAIDs, herbal combination medicines in Irritable Bowel Syndrome, Black Cohosh in the amelioration of menopausal symptoms, Chaste Tree in the treatment of menstrual disorders, acupuncture in migraine and many others[215].

If issues of safety, standardisation and qualifications of prescribers in CAM can be ameliorated – as they would in an appropriately regulated framework – CAM may have much to offer in terms of increasing choice, safety and cost-savings of healthcare delivery.

6.1.1 Potential economic benefits

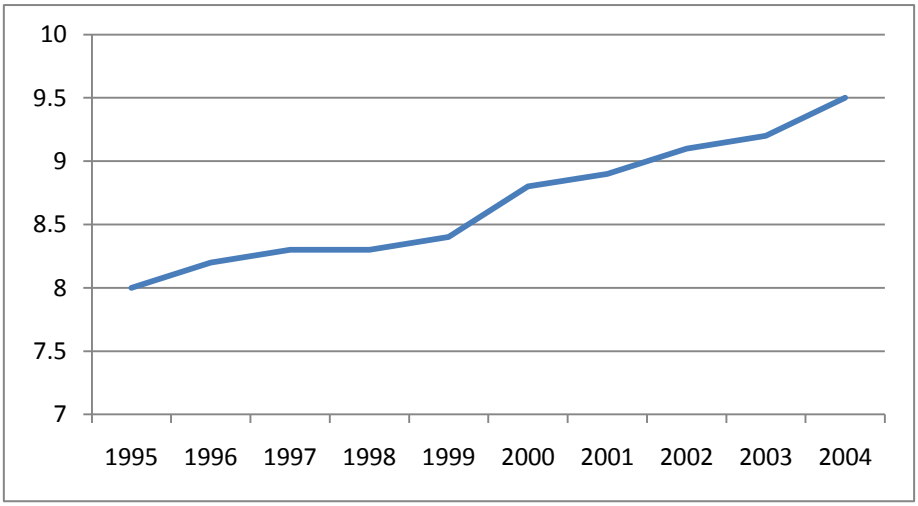


Figure 14: Health costs in Australia as a proportion of GDP *Source: OECD*

As can be observed in the preceding chart, Australia spends $86.9 billion, or 9.5% of its GDP, on healthcare provision annually[216]. Expenditure on health, both in gross and relative (to GDP)

terms has been increasing significantly: a trend which shows no signs of abating as our population ages. CAM may offer several opportunities to substantially reduce direct healthcare costs. CAM may also offer indirect health cost and non-health benefits to the Australian economy. These are discussed in further detail in the following section.

6.1.1.1 Direct healthcare costs

Although the area of economic evaluation of CAM is hampered by a lack of data, most current studies suggest that compared to conventional patients, CAM patients generally had lower costs, even when out-of-pocket payments were considered [217]. CAM users were also significantly less likely to require hospitalisation during the course of their lifetimes[218].

In 2005 the Prince of Wales Foundation released the results of a report it in which it had commissioned economist Christopher Smallwood to investigate the role of CAM in British healthcare[215]. The major focus of the report centred on the economic benefits of CAM inclusion. It found:

- That the most effective CAM therapies corresponded to recognised effectiveness gaps in NHS treatment – in particular chronic and complex conditions; anxiety, stress and depression; and palliative care – and therefore had the potential to make an important contribution if allowed to integrate with conventional healthcare delivery.
- Where costed primary case studies of CAM integration into conventional healthcare delivery existed (in Newcastle-Upon-Tyne, Glastonbury and the London NHS trusts of Westminster and Haringey) significant resource savings were experienced. General Practitioner consultations had reduced by a third and prescription medication costs reduced by 50% over the three examples.
- Significant direct savings could be made through incorporation of CAM into healthcare delivery. The report identified a number of herbal therapeutic agents that exhibited both clinical efficacy and were more cost-effective than current treatment (see Table 7). The report estimated that suitable delivery of CAM in appropriate situations could realise savings per prescription of £10.54 in patients currently using anti-depressants and £10.02 in patients currently using non-steroidal anti-inflammatory agents. The report acknowledged that direct cost-comparisons were difficult as CAM often varied in potency, quality and number of varieties available and therefore recommended tighter regulation of these products. A number of other CAMs have been suggested as possibly useful though lack of data, rather than lack of evidence of efficacy, means that at this time no definitive judgement could be made.
- The report suggested significant indirect savings could also be made – partly due in part to the “whole practice” nature of CAM provision. The data from costed case studies suggested patients returned to work sooner and had less sick days after CAM provision had been made available.
- That there was a social case for extending CAM modalities into institutional healthcare delivery, as the psychosocial and chronic ailments in which they were of most use were

particularly prevalent in deprived areas who would otherwise have little access to their therapeutic benefits.

- The report warned against allowing untrained practitioners, or those who are predominantly trained in other modalities, practise CAM in these settings as cost-effective use of CAM required competent CAM practitioners who would make competent clinical judgements in this area.

Herbal therapeutic	Conditions
Phytodolor [219, 220]	Musculoskeletal problems (including rheumatoid arthritis)
Echinacea [37, 221, 222]	Viral infections and common cold
St John's Wort [223-226]	Mild-moderate depression
Ginkgo biloba [227-229]	Alzheimer's disease; Intermittent claudication; dementia
Devil's Claw [230, 231]	Musculoskeletal problems (including arthritis)
Hawthorn [232-234]	Heart problems (including congestive heart failure)
Horsechestnut [235, 236]	Circulatory problems (including chronic venous insufficiency)
Saw Palmetto [237-240]	Benignly Prostatic Enlargement

Table 7: Herbal therapeutic agents displaying both clinical and cost efficacy [215]

The report warned against the current self-regulatory environment and specifically indicated that statutory regulatory bodies be set up for CAM as soon as possible so that doctors could begin referring to statutorily registered practitioners to realise these benefits.

A number of other studies have also suggested that utilising CAM in healthcare delivery may be responsible for health and economic gains. A two-year study of 141 Anthroposophist (a form of naturopathic medicine) medical practices in Germany found that despite an increase in consultation times initially the patients exhibited long term stable reduction of chronic disease (a 46% reduction in disease scores and a 43% reduction in symptom scores); a 14% increase in health related quality-of-life scores and reductions in health costs of 4.2% or €152 annually per patient[241].

A pilot homoeopathy service in a GP practice run by the Coventry Primary Care Trust resulted in reductions of primary symptoms scores, reducing the mean 6-month general practice consultation rate by 1.18 consultations per patient and resulted in 57 patients reducing or stopping their medication saving the NHS £2807.30 per patient per year in medication costs alone[242].

A Canadian evaluation suggested that direct savings to the Ontario government from incorporating chiropractic care into the treatment of neuromusculoskeletal conditions would range between CDN$199.5 million-CDN$769 million and indirect savings of between CDN$795.2 million-CDN$3034 million[243]. When the Ontario government changed and the new government delisted chiropractic care from provincial healthcare delivery a Deloitte & Touche analysis

estimated this move would increase hospital expenditure by CDN$112-225 million annually, approximately 1% of total provincial hospital expenditure[244].

In 2005 the health insurance trust of the Vermont Automobile Dealers Association expanded its coverage to include naturopathic care to its 1182 members and realised direct cost savings of US$315 817 (US$267.22 per person) and indirect cost savings of US$1 143 657 (US$967.56 per person) in the first year – predominantly due to a 36% reduction in hypertension; a 17% reduction in hypercholesterolemia; and a 15% reduction in obesity[245]. Considering the Pharmaceutical Benefits Scheme currently spends $1.18 billion annually on anti-hypertensive medications and $1.22 billion annually on cholesterol lowering medications the potential savings may be quite substantial.

Systematic reviews have generally shown that musculoskeletal problems and migraines are treated more effectively and often more cost-effectively with CAM modalities such as acupuncture and chiropractic than they are with conventional medical care [217, 246, 247].

6.1.1.2 Indirect economic benefits

Many of the benefits of implementing CAM into healthcare derive more from its indirect or non-specific benefits rather than immediately and specifically quantifiable results. For example, whilst few trials are able to definitively prove that CAM works in very specific situations, most derive very obvious and significant benefits in more complete or holistic measures such as Quality of Life score[248]. These results – if measured with appropriate utilities – may be more readily transferable to societal economic evaluation than more limited clinical data, as Quality Adjusted Life Years (QALYs) are the standard measure of cost effectiveness in drug evaluation for institutions such as the Pharmaceutical Benefits Advisory Committee[248, 249].

These indirect savings were often thought to offset some of the additional expense in introducing seemingly more expensive options of CAM delivery into healthcare. Although costing £4 million more than conventional care to implement, introduction of chiropractic care as an option for treatment of low back pain of mechanical origin in the UK was estimated to introduce indirect savings of £2.9 million in social security costs and £13 million from fewer days off work in addition to improved direct outcomes on pain intensity on range of movement[250].

6.1.1.3 Productivity

A Canadian manufacturer was able to reduce employee absenteeism from 9.6 to 2.4 days per employee and reduce medical drug costs (both CAM and conventional) by 69% by incorporating CAM practitioners (in this instance registered naturopaths and chiropractors) into its employee health program[251].

6.1.1.4 Non-health economic opportunities

Regulation and the minimum standards, quality assurance and standardisation practices that go with it may present a number of non-health related economic opportunities. Regulation could resolve many of the variability issues that currently affect CAM quality. It is estimated that approximately half the raw materials used in therapeutic products could be grown locally[252] whilst currently 90% is sourced from overseas suppliers of varying quality[50]. Regulation could encourage growth of a pharmaceutical quality industry that would be in an ideal position to take advantage of global growth in CAM consumption whilst also catering to concerns of quality and variability.

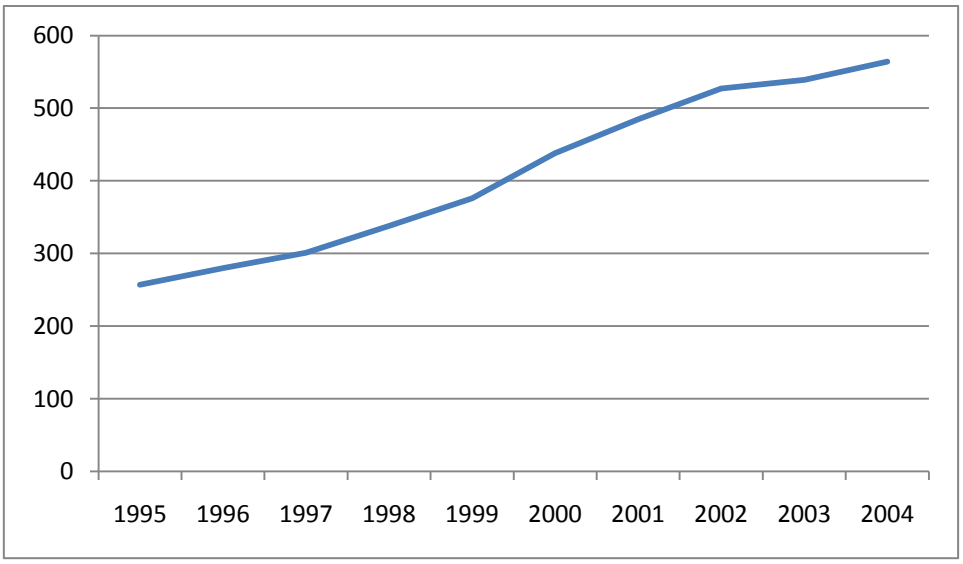


Figure 15: Per capita PBS spending on pharmaceuticals in Australia (AUD$)

6.1.2 Encouraging consumer choice

One of the arguments against regulation of CAM is that it actively goes against current policies encouraging competition and choice[253]. However, the opposite may indeed be true. In 1995 the Commonwealth and all State and Territory governments signed *the Competition Principles Agreement*. This agreement states that legislation should not restrict competition unless it can be demonstrated that: a) The benefits of restriction to the community as a whole outweigh the costs; and that b) The objectives of the legislation can only be achieved by restricting competition[254].

Regulation of CAM benefits the community in matters of public safety, risk reduction, health provision, access and choice and ensures quality and efficacy of CAM treatments chosen by the

community which can only be provided through adequate regulatory frameworks. Current arrangements may actually be anti-competitive in nature, as public health provision by and large excludes unregulated professionals, thereby removing CAM equal opportunities in healthcare provision.

It is suggested that current government policy that excludes complementary therapists may be increasing medical costs by reducing competition. As long ago as 1982 Nieuwenhuysen and Williams-Wynn suggested that moves such as the creation of supportive government policy such as implementing statutory regulation of CAM practitioners could reduce medical costs by increasing competition in healthcare delivery and re-orienting healthcare delivery to a more preventable model, encouraging other practitioners to follow suit [255].

6.1.2.1 Increased competition

A regulated environment, and the transparency that results from it, may also be beneficial to the consumer via encouragement of increased competition or at the very least more competitive practices. Currently 70-80% of contract manufacturing is dominated by three companies – Cardinal, Lipa and Sphere; and just two companies (Blackmores and Symbion) account for 42% of total retail sales[50]. Any industry dominated by a small number of major players runs the potential risk of developing monopolistic practises in the absence of an appropriate regulatory regime.

6.1.3 Improved professional standards

The registration process of Chinese medical practitioners in Victoria consisted of 1400 applications. Of these more than 150 (10.7%) were refused – primarily on the grounds of inadequate qualifications or lack of evidence of competence. Conditions of registration were imposed on 20 (1.4%) of cases. The board has also successfully prosecuted 9 people who were using protective title whilst unregistered[256]. The Chinese Medicine registration Board has set minimum standards in regards to matters such as assessment of qualifications, education and competence; English proficiency; first-aid arrangements; continuing education and professional indemnity insurance and ensures these standards are consistently met by members and initiates disciplinary action when these it deems conduct or fitness to practice is in doubt.

6.1.4 Addressing research and evidence issues

Investment in CAM research in Australia was $26.35 million over the five year period to 2005[50]. To put this in context this represents 0.35% of total NHMRC funding over the same period[257]. Although much fanfare was made recently over the governments contribution of $5 million for CAM research[258] through its special CAM NHMRC funding round this is clearly equally insufficient to close research gaps.

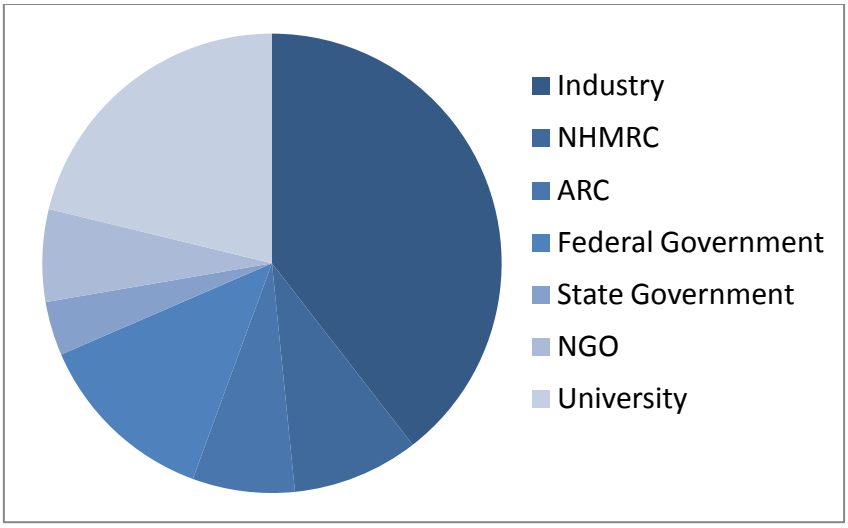


Figure 16: Research funding sources in Australia *Source:* [50]

However, this data may be misleading, as when individual projects are broken into types health and social research in CAM forms only a small proportion of total funding (see Figure 18, above). This presents a worrying trend whereby a vast majority of funding (63%) is spent on exploring commercial opportunities of CAM whilst less than a quarter of total CAM research funding (22% or $5.8 million over the four year period) was directly spent on health research[50].

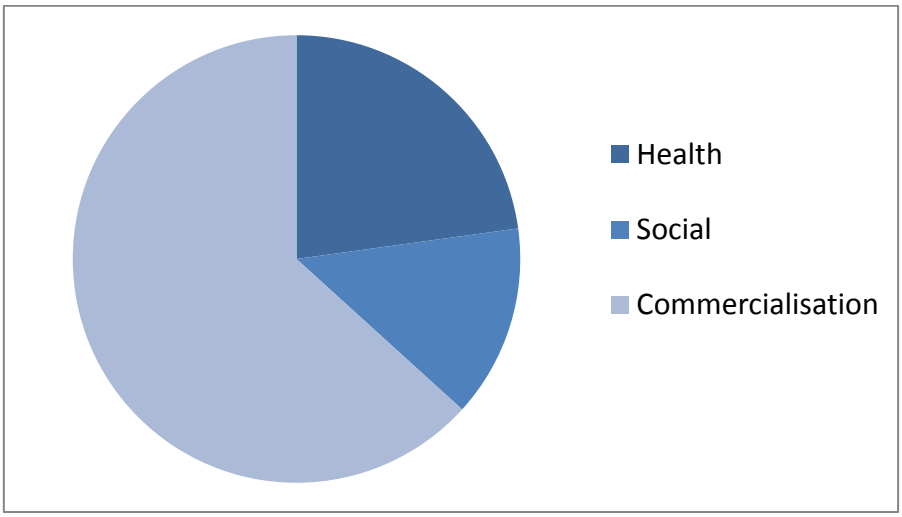


Figure 17: Types of CAM Research in Australia by funding proportion *Source:* [50]

It would be wrong to suggest that CAM should receive a free ride and suggest that CAM should be given preferential treatment in determining research agendas though initial support may be necessary to address some of the issues currently experienced in CAM research. Some of these are listed below. Ultimately the focus should be on developing capacity in CAM research so that it can effectively compete for research funding on its own merits.

6.1.4.1 Lack of CAM practitioners involved in CAM research

Whilst conventional and complementary medicines share various historical features, such as reference to vitalism, humoral balance and holism, an enormous gulf exists between the two[153]. This is accentuated by the absence of a common language between different CAMs because of their heterogeneity[259]. The only way to overcome this problem is to encourage CAM practitioners to undertake clinically relevant research in their particular modality. Regulation can assist this by opening opportunities in postgraduate education or research positions that may not exist for unregistered professionals.

Complementary medicine research is besieged with issues relating to inappropriate research practices. Much of the research is done by researchers with little training in complementary medicine which thereby produces research of little clinical consequence. Much of the research into the herb *Echinacea spp* is often conducted into areas in which trained herbalists would not consider. For example, whilst herbal texts suggest Echinacea spp has a 7 day lead in period before taking effect [51] most clinical research focuses on the immediate effects of the herb [37]. Whilst most herbalists shy from using aerial parts of the plant deeming the root to be more effective[51] most published research focuses on these traditionally unused parts. Many of these studies have shown negative results – a fate that would often be obvious to many CAM practitioners before research had even commenced. Through lack of consultation with those with intimate clinical, theoretical and practical knowledge of CAM much of the research to date has been of little to no clinical relevance[260]. This has essentially wasted what little time, money and resources that are spent on CAM research on research of little consequence to anybody.

Efforts need to be made to build capacity in the CAM research community. As mentioned in previous sections CAM practitioner courses are beginning to implement health science and research methodology course hours that are comparable to other health professions. However, little progress has been made in trying to close similar communication gaps by implementing CAM in conventional health courses. This may suggest that ultimately trained CAM professionals, as would be encouraged under an adequate regulatory environment[261], may be the most appropriate persons with sufficient combined clinical, theoretical and methodological expertise to perform CAM research that is clinically relevant.

However, Bachelor courses in naturopathy have only existed since the late 1990s[115] and most CAM professions are in a similar stage of professional infancy. This means that they may lack the academic critical mass required to perform on an equal footing with more established

professions. Whilst ultimately CAM should compete on its merits for research funding it is not entirely inappropriate and most likely extremely beneficial that initial support is given to develop academia and research scholarship in CAM. Regulation could assist this by: allowing access to graduates to scholarships and funding only open to registered health professionals; making active research involvement a criteria in the accreditation of CAM courses from both public and private education providers and ensuring minimum standards of practitioners which may foster integration and research in more indirect ways.

6.1.4.2 Methodological problems with CAM research

The House of Lords Committee suggested a number of methodological problems existed in CAM research [168]: Patients who most often referred for CAM exhibit multiple inter-related or complex complaints, making standardisation difficult; blinding may not be possible, particularly in non-pharmacological interventions; standardised treatments used in research may bear little relevance to clinical practice where individualised treatments are most often prescribed;

Placebo effect is also commonly touted as the real reasoning behind complementary medicines effects – however, lack of understanding of how they work does not preclude the possibility that they may work – nor do unknown mechanisms of action imply placebo at work. The placebo often used in acupuncture research (sham acupuncture) is often found to have higher placebo activity when tested against other placebos[262]. Whether this significant difference in fact makes sham acupuncture a placebo or render it a therapeutically active tool is debatable but regardless these findings suggest it may be an inappropriate placebo by which to measure the effectiveness of "real" acupuncture? Placebo should not be a dumping ground to disguise lack of understanding of mechanism of action of complementary therapies. No one would doubt the effectiveness of pharmaceutical interventions against placebo, though a cursory glance at any Pharmacology text will indicate that many commonly drugs also work via unknown mechanisms[66].

It is also incredibly difficult to find an appropriate placebo in a health system as individualised as most complementary therapies are. This difficulty in finding appropriate placebo is by no means limited to complementary medicine: other complex treatment therapies such as psychology[263, 264], surgical interventions and physiotherapy [265] also share the same concerns and suggest other study designs that don't rely solely on placebo be utilised in evidence based medicine.

An additional problem with many studies used by EBM is that they are often performed in settings completely different from clinical practice[266]. The gold standard of evidence based medicine is especially ill-suited to complementary medicine practice. Randomised controlled trials depend on homogeneity and reductionist treatment and do not accurately represent the heterogeneity of patients or whole practice therapies as practised by complementary medicine practitioners. Even Edzard Ernst, the major proponent of evidence based CAM, has admitted that he has been surprised to see the positive results seen in his many years of clinical CAM practice fail to translate into positive randomised controlled trials[267].Other epidemiological

studies or case studies may be more appropriate ways of determining efficacy of complementary medicine practice[268].

Perhaps it is not the inherent ineffectiveness of CAM, but rather the ineffective methods by which evidence of this effectiveness is being sought, that it is partly to blame for the dearth of data on CAM efficacy[269, 270]. Whilst it is undeniably true that there isn't a lot of evidence of efficacy for these products and practices it is often forgotten that there exists an equal paucity of proof for their ineffectiveness. One possible reason is that lack of CAM practitioner involvement in research may mean that there are few people interested in conducting good quality, clinically appropriate research. Regulation may offer some of the solutions to these problems by allowing access to people with high levels of practical and clinical expertise to research positions and scholarships.

6.1.4.3 Encouraging attempts at establishing evidence base

Notwithstanding the evidence debate is the obvious tradition of successful complementary medicine use *by complementary therapists.* For thousands of years these therapies have been used successfully – and sometimes unsuccessfully – in the treatment of disease. This empirical observation lead to the development of a body of knowledge before the advent of clinical trials and evidence based medicine. For this reason the World Health Organisation has encouraged the incorporation of this knowledge into research methodology and allowing it to be used as evidence for clinical

Some organisations have attempted to document and pool this knowledge – the British Herbal Medical Association's attempts to through publishing the *British Herbal Pharmacopeia* (expanded upon to some degrees in the *British Herbal Compendium*) is an example of this[29, 271, 272]. Detailed monographs on each herb containing available clinical evidence, pharmacological properties and traditional use was combined with the results of a survey was sent out to all practising herbalists to determine herbal treatments for specific conditions. Those with overwhelmingly consensus were listed as having "specific indication" (or *BHP specific* in practitioner parlance) and highly recommended for use. Whilst in itself this may not constitute satisfactory evidence it is given some validity – by organisations such as the Therapeutic Goods Administration for example – by the fact that it has documented the previously uncollated sum of knowledge gained from hundreds of years of clinical observation. At the very least it provides a framework by which future research questions should be decided to ensure the research has clinical relevance.

The success of complementary medicine has almost become its Achilles Heel in this age of evidence based-medicine. The fact that most of the trial and error in formulating effective treatments was done long before the advent of the scientific method protocols that are currently used has left it languishing behind conventional medicine – which had the advantage of being a product rather than a precursor of this new scientific revolution. Whilst this should not exclude complementary medicine from developing an evidence base – it demonstrates the importance of combining clinical knowledge from complementary therapists with modern

research methodology to ensure this knowledge is called upon to avoid wasting research resources on questions of little clinical significance.

6.1.4.4 Dogmatic adherence to and misinterpretation of evidence-based medicine principles

In fact the arguments against relying solely on "Evidence Based Medicine" principles do not stem solely from CAM. A study published in the New England Journal of Medicine found that relying solely on these principles alone for clinical decision making would lead to the adoption of an ineffective treatment in 32% of cases and lead to the rejection of an effective treatment in 33% of cases[273]. This is in addition to the fact that only 53-59% of current medical practice can be defined as "Evidence-Based"[274]. Of this, only 13% has definitive proof of effectiveness[275]. This is still no guarantee of effectiveness, as it is estimated that "off-label" prescriptions – prescriptions used for conditions in which they've not been studied –may account for one-fifth of total prescriptions in conventional medical practice[276].

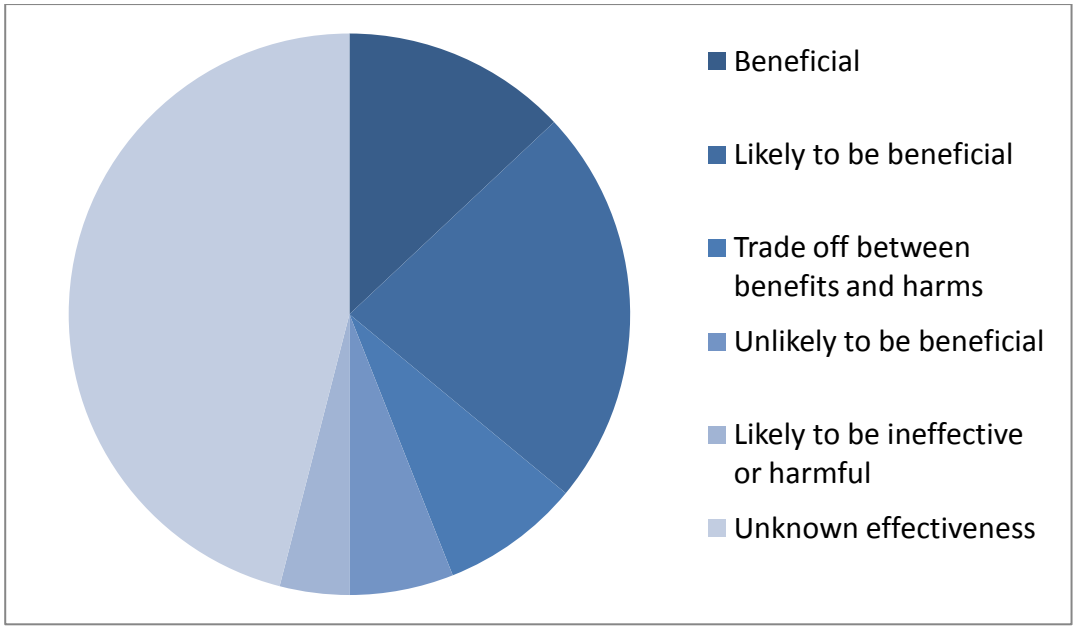


Figure 18: Known evidence of effectiveness of conventional medical treatments *Source:* [275]

Often it is the researchers alone that place unrealistic and impractical levels of importance on evidence based medicine principles. A survey of 1250 patients commissioned by *Australian Doctor* and Pfizer Australia found that patients generally don't trust research or evidence based medicine, believing that it is being driven by commercial interests in the pharmaceutical industry rather than to increase medical knowledge[277]. Medical practitioners despite positive attitudes to using evidence based medicine have derided its inflexible implementation as a

threat to clinical autonomy, a dangerous step towards a one-size-fits-all medicine and a removal from patient focused healthcare[278-282].

Evidence based medicine is only as good as the evidence that currently exists. This is why several other factors including clinical expertise is ideally a major component of evidence based practice and it is strongly suggested that research evidence informs clinical judgement, rather than controls it[283].

Blind adherence to evidence-based principles in conventional medicine would have radical ramifications: A recent meta-analysis suggested that the effectiveness of anti-depressants have been grossly overstated and many of them are only mildly, if at all, more effective than placebo[284]; a recent Cochrane review suggested that Non-Steroidal Anti-Inflammatory Drugs are no more effective than paracetamol for low back pain[285] yet they remain one of the most commonly prescribed drug classes in Australia; the British Medical Journal reports that quitting cigarette smoking on impulse is more effective than any treatment[286] yet it would be wholly irresponsible to discourage or halt planned quit attempts.

Whilst the "evidence based" movement is an important part of healthcare decision making heed should be taken to not fall into the trap of overemphasising its importance, dominance over other methods or adherence to dogmatic principles they may generate. Inflexible adherence to this principles may in fact risk being a hindrance to healthcare innovation[287]. Evidence based medicine is not a panacea for medical decision making. The results of randomised clinical trials apply to populations of patients, and the challenge is to translate the results to individuals. Individual patients require different thought processes because presentation and response vary. These factors should be taken into consideration when using evidence based arguments relative to CAM.

6.1.4.5 Where is the evidence?

Evidence based care relies on the conscientious, explicit and judicious of the *best available evidence* to make clinical decisions[288]. Often the issue in CAM is not evidence of inefficacy, but rather a dearth of any scientific evidence or research at all. However, lack of evidence is not the same as evidence of lack of effect and the confusion between the two is often used in criticism against CAM. Whilst this (lack of evidence) ultimately needs to be redressed, it may not be prudent to deny potentially efficacious therapeutic tools – especially when evidence *does* often exist for them, albeit in less scientifically rigorous forms.

The current model of "Evidence Based Medicine" may exhibit cultural bias towards CAM. In a study of the *British Medical Journal* articles a comparison of four studies with similar findings led the authors to develop very different conclusions – the studies on physiotherapy and antibiotics for urinary tract infections in children found their results inconclusive and concluded that "more research needs to be done"; the studies on homoeopathy and neuro-linguistic programming found their results similarly inconclusive though stated the "case for using these therapies is unproven"[289].

Whilst some critics of CAM research suggest that just because randomised controlled trials are ill suited to CAM does not preclude it from using other forms of evaluation such as epidemiological studies or modifications of current study design[290] these are not the studies on which evidence based medicine is founded. In fact, CAM research is often denounced for using these very methods[270]. The long-standing and established Bradford-Hill criteria for causality actually provide a number of ample opportunities to demonstrate efficacy of CAM, however many of these are not part of the "evidence based" movement either. The fact is that the current methods favoured by the "evidence based" movement are ill-suited to CAM research and the focus needs to placed towards more relevant methods of garnering evidence of efficacy or non-efficacy[269]. Involvement of CAM researchers is an integral part of this move as it would involve, for the first time, clinicians and researchers with intimate knowledge of the subject matter.

6.1.4.6 Inherent biases and misunderstandings in CAM research

A review of systematic reviews in CAM suggested that often the conclusions drawn from the same data can be very different based on subjective opinion on CAM and that researchers conducting these reviews were often negatively predisposed to CAM[291]. Finding people positively disposed to CAM to do research is equally subjective - however, including researchers who are as proficient in CAM methodology as they are in research methodology may ensure more informed discussion and analysis results from this research. As many as 38.7% of clinical trials may have some form of conflict of interest[292].

Lack of funding may be another source of disadvantage in CAM research[270]. Whilst pharmaceutical drugs offer the potential for reward and patentability there is no clear financial advantage in financing a CAM trial for a therapy that can be utilised by anyone. This may explain the paucity of sufficiently large or good quality CAM trials at the same time as exaggerating the efficacy of pharmaceutical or conventional interventions. Those funding these pharmaceutical trials may not release findings of negative studies. When unpublished studies of a number of anti-depressants were combined with published studies many of the drugs previously deemed significantly effective were found to actually be ineffective or only mildly better than placebo[284]. Whilst these barriers exist to CAM research commercial interests may outweigh scientific endeavour. Already a vast majority of CAM research funding has a commercial interest[50]. Encouraging more industry involvement may encourage biases such as publication bias. Adequate regulation can encourage other sources of funding to step forward but government sources also need to make a firm commitment to CAM research to ensure that clinically relevant and applicable research that benefits the community, rather than the industry, can be performed.

Research funding should be made more available to clinical practitioners of CAM. Concentrating CAM research on a minority of institutions leads to the risk of CAM research being dominated by a variety of controlling interests – be they political (the heads of these institutions may prefer certain types of research be done); professional (an acupuncturist heading an institution

may be biased towards their own modality at the expense of research in others) or industry (an institution may be coerced into product development with possible financial gains as opposed to research in the practise of CAM). Authorities in the UK has decided to focus on awarding additional isolated postdoctoral fellowships and scholarships in CAM research to be determined by individual merit as opposed to focusing all resources on 'CAM Centres of Excellence' such as that at the University of Exeter[260] – the equivalent to Australia's National Institute Complementary Medicine based at the University of Western Sydney. This provides the advantage of increasing the breadth of participants and institutional expertise in CAM research whilst building capacity in this field without the risk of 'putting all the eggs in just one basket'.

6.1.4.7 CAM as a marker for general problems in medical research

These findings certainly don't excuse CAM from the obligation to develop a research base for its practise. However they do suggest that CAM may have inherent disadvantages in the current focus on evidence based practice – some of them unique and some of them related to the weakness of this approach in general.

However, there is no reason to believe that these research issues are in any way related to CAM. Rather, it may be that the controversial nature of CAM has invited closer scrutiny and uncovered issues that are applicable across medical research. For example: whilst the conventional medical community has suggested that the positive results of glucosamine may be due to financial interests affecting publication bias as all the positive trials seem to come research involving the product of one company, no analogous argument has been made to the fact that most pharmaceutical research is also industry supported[293]. A more likely reason for the positive results is the variability of CAM quality and that this product may be more effective due to increased standards of manufacture and quality. Even so, financial influence on research is by no means isolated to CAM – it is estimated that 38.7% of medical journal articles published exhibit some form of conflict of interest[292] ; CAM is criticised for not exhibiting evidence of efficacy whereas even in conventional medicine 46% of treatments have unknown efficacy and only 13% have demonstrated evidence of efficacy[275]; CAM is criticised for not following evidence based guidelines when evidence suggests that these guidelines themselves may actually have inherent weaknesses if followed dogmatically and that many established conventional therapies actually fail these same tests[273, 284-286]. There is no denying that CAM needs to sort its research house in order – but does it really need to do so any more than general medical research? Many of these problems may be more indicative of problems that need to be addressed in general to medical research methods, as opposed to CAM research specifically.

6.1.5 Utilisation of an untapped resource

Australia has a dearth of qualified health practitioners. This is particularly evident in rural areas. Complementary therapists are an untapped potential resource in these underserved areas. A national audit of rural CAM infrastructure found that there were 3419 registered CAM practitioners in rural Australia – representing approximately 35% of all primary care practitioners in these areas[294]. This represents a vast unutilised resource. Given the particular issues recruiting and retaining health professionals in rural areas[295] it makes sense to make use of resources that already exist in these areas.

Evidence also suggests that CAM may be an appropriate solution to rural healthcare delivery. It is already known that rural Australians use CAM more frequently than urban Australians[296-299] and that consultations with CAM practitioners may account for more than half of all health consultations in these areas[3]. South Australian studies found that people in more remote areas actually had greater utilisation of CAM providers than those in areas with more access to practitioners[11, 300].

Whilst these arguments could also be extended into urban regions CAM practitioners may present an existing and appropriate opportunity to addressing pertinent issues of rural healthcare delivery.

6.1.6 Dissemination of information to the public

A campaign to educate the public about such matters is needed. This would be best delivered through an existing institution such as the National Prescribing Service which has already explored this issue[301]. An online database system on the NPS or CAM Registration Board website which lists potential CAM-drug interactions is also recommended. Regulation can assist this process by increasing informed choice and ensuring minimum standards of information sources and providers.

6.2 Potential risks of regulation

6.2.1 Inhibiting of freedom of choice?

The only real risk of instigating a regulatory framework for CAM products and practitioners are possible negative impacts on consumer's freedom of choice in the market for healthcare options. However, regulation and free choice are not necessarily mutually exclusive[302]. Consumers will still be allowed to exercise their choice in a regulatory regime only they will be able to make a more informed choice than they would have in an unregulated (or self-regulated

environment). Whilst certain practitioners should gain protection of title which sets minimum barriers of entry for certain professions (“herbalist”, “naturopath” or “acupuncturist” for example) there will be no restrictions on other more generic titles – for example “natural therapist” or “complementary therapist”. Regulation is more about enabling the public to identify competent and highly trained practitioners – and making these practitioners accountable for their actions – than it is about removal of freedom to practise or freedom of choice. In this manner public health and safety can be safeguarded whilst also upholding the individual’s right to choose.

Part of any Quality Use of Medicine strategy must also include the ability for consumers to rely on the skills of health practitioners to adequately answer their questions on CAM. Ensuring minimum standards, and thereby placing barriers to entry of practice, actually encourages the consumer’s ability to make an informed opinion by giving them a mechanism by which to identify appropriate information providers.

6.2.2 Loss of holistic practice

However, integration needs to take into consideration that what the public wants is the holistic model of care and this may be lost under a regulatory regime that is overly restrictive. For this reason it is highly recommended that any integrative programs be run on salary or capitation based models of funding as opposed to the current model of fee-for-service which is open to abuse and overly restrict of best practice techniques. CAM practitioners are very much defined by the principles of their practice far more than any products they use[303] and believe that this is what ultimately delineates them from other health professionals[94]. Therefore appropriate steps must be taken to include CAM practitioners in CAM policy decision making and care exhibited to ensure any new regulatory requirements do not unnecessarily impinge upon this culture.

Criteria 6 conclusion

The benefits of promoting public safety clearly outweigh the potential negative impacts of regulation. However, care must be taken to ensure that the overall identity of CAM practice is not adversely affected.

Conclusion

The AHMAC criteria clearly demonstrate the need for further regulation of CAM in Australia. Much of this can be done within existing frameworks and national and international experience allows us valuable insight into the appropriate processes by which this can happen.

Whilst CAM undeniably presents a number of risks, it also offers a variety of opportunities to health provision in Australia. For this reason it is recommended that a detailed, objective and thorough investigation into regulation of CAM practitioners and products is commenced at the earliest convenience.

Whilst a plethora of specific recommendations could be drawn from these findings, the major recommendations can be summarised under the following principles:

- CAM products and practice have an underlying risk that requires apposite regulation be enacted. However, these risks should be placed in appropriate context and CAM should be afforded the same objectivity as other health professions in the development of any regulatory framework.
- Appropriate deterrents and penalties should be enforced for those who shirk their responsibilities and requirements under a regulatory model.
- Clearer methods of distinguishing high- and low standard CAM practitioners, products and information should be enacted. Mechanisms should be put in place that rewards those that adhere to higher standards and ensure that those of lower standards are not unfairly given equal standing.
- It is highly recommended that CAM is increasingly treated as a therapeutic modality in its own right as opposed to continuously being given 'special case' status. For these reasons it is strongly suggested that CAM be subjected to the same regulatory, evaluation and legislative requirements as other professions and therapeutic tools.
- However, as an industry in its infancy efforts should be made to build capacity in CAM, particularly in the areas of academic and research capacity. Ultimately CAM should compete on its merits alone with other health modalities.
- An appropriate regulatory framework cannot focus on CAM products alone. CAM practitioners are an integral part of the industry and most of the factors which define CAM are intrinsically linked to principles of practice rather than any particular products used
- CAM practitioners should be acknowledged as health providers and regulated accordingly to safeguard public health and safety by ensuring: minimum standards of education and appropriate levels of accountability. As those most qualified to make clinical decisions relating to CAM they should form an active part of any CAM-related legislative, institutional, research or practical decision making.
- Other health practitioners should not be prevented from practising CAM, but should abide by the same minimum standards required of CAM practitioners. Whilst other health professionals are very much respected for their areas of expertise, it lies in areas other than CAM and for this reason adequately qualified and registered CAM practitioners should be considered the default CAM providers in Australia under a regulatory model.

Abbreviations used

- **AANP** American Association of Naturopathic Physicians
- **ADRAC** Australian Drug Reactions Advisory Committee
- **ANTA** Australian Natural Therapists Association
- **ANPA** Australian Naturopathic Practitioners Association
- **ATMS** Australian Traditional Medicine Society
- **CAM** **C**omplementary and alternative medicine
- **CAND** Canadian Association of Naturopathic Doctors
- **CMRB** Chinese Medicine Registration Board (Victoria)
- **GMP** Good Manufacturing Practice
- **NHAA** National Herbalists Association of Australia
- **OHE** Office of Higher Education
- **PBS** Pharmaceutical Benefits Scheme
- **TGA** Therapeutic Goods Administration

References

1 Xue C, Zhang A, Lin V, Da Costa C, Story D. Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey. *Journal of Alternative and Complementary Medicine* 2007; **13:** 643-650.

2 Australian Health Ministers' Advisory Council Criteria for Assessing the Need for Statutory Regulation of Unregulated health Occupations. Canberra: Commonwealth of Australia, 1996.

3 Sherwood P. Patterns of use of complementary health services in the South-West of Western Australia. *Australian Journal of Rural Health* 2000; **8:** 194-200.

4 Grace S, Vemulpad S, Reid A, Beirman R. CAM practitioners in integrative practice in New South Wales, Australia: A descriptive study. *Complementary Therapies in Medicine* 2008; **16:** 42-46.

5 Chow R. Complementary medicine: impact on medical practice *Current Therapeutics* 2000; **41:** 76-79.

6 Lin V, Bensoussan A, Myers S, McCabe P, Cohen M, Hill S*, et al.* The practice and regulatory requirements of naturopathy and western herbal medicine. Melbourne: Department of Human Services, 2005.

7 Australian Labor Party. Chapter Ten - Improving Health and Well-Being: A Health System that Delivers. *Australian Labor Party National Platform and Constitution*. Canberra: Australian Labor Party, 2007.

8 Federation of State Medical Boards of the United States. Model guidelines for the use of complementary and alternative therapies in medical practice: A policy document. Dallas: Federation of State Medical Boards of the United States, 2002.

9 Glisson J, Rogers H, Abourashed E, Ogletree R, Hufford C, Khan I. Clinic at the health food store? Employee recommendations and product analysis. *Pharmacotherapy* 2003; **23:** 64-72.

10 Draves A, Walker S. Analysis of the hypericin and pseudohypericin content of commercially available St John's Wort preparations. *Canadian Journal of Clinical Pharmacology* 2003; **10:** 114-118.

11 MacLennan A, Myers S, Taylor A. The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004. *Medical Journal of Australia* 2006; **184:** 27-31.

12 Barnes J. Quality, efficacy and safety of complementary medicines: fashions, facts and the future. Part I. Regulation and quality. *British Journal of Clinical Pharmacology* 2003; **55:** 226-233.

13 Callaghan M, Pye S. Best Evidence Topic 1: The effects of glucosamine on osteoarthritis of the knee joint. *Emergency Medicine Journal* 2008; **25:** 285-287.

14 Australian Consumer's Association. Spotlight on glucosamine: it's a popular alternative treatment for osteoarthritis, but does glucosamine really work? New research findings make the evidence look shaky. *Choice*, 2008; 16-20.

15 Gray H, Hutcheson P, Slavin R. Is glucosamine safe in patients with seafood allergy? *Journal of Allergy and Clinical Immunology* 2004; **114:** 459-460.

16 Villacis J, Rice T, Bucci L, El-Dahr J, Wild L, DeMerell D*, et al.* Do shrimp-allergic individuals tolerate shrimp-derived glucosamine? . *Clinical & Experimental Allergy* 2006; **36:** 1457-1461.

17 Matheu V, Gracia Bara M, Pelta R, Vivas R, Rubio M. Immediate-hypersensitivity reaction to glucosamine sulfate. *Allergy* 1999; **54:** 643.

18 Tallia A, Cardone D. Asthma exacerbation associated with glucosamine-chondroitin supplement. *Journal of the American Board of Family Practice* 2002; **15:** 481-484.

19 World Health Organisation. *WHO Strategy for Traditional Medicine 2002-2005*. Geneva: World Health Organisation, 2002.

20 But P. Herbal poisoning caused by adulterants or erroneous substitutes. *Journal of Tropical Medicine & Hygiene* 1994; **97:** 371-374.

21 Chan T, Critchley J. Usage and adverse effects of Chinese herbal medicines. *Human & Experimental Toxicology* 1996; **15:** 5-12.

22 Bensoussan A, Myers S. Towards a Safer Choice: the Practice of Traditional Chinese Medicine in Australia. Sydney: University of Western Sydney, 1996.

23 Cui J, Garle M, Eneroth P, Bjorkheim I. What do commercial ginseng preparations contain? - Letter. *Lancet* 1994; **334:** 134.

24 Stafford A. Herbal sex drive capsules tainted by dose of Viagra. *The Age*. Melbourne, 2007.

25 Mills S, Bone K. *The Essential Guide to Herbal Safety*. Edinburgh: Churchill Livingstone, 2004.

26 Pollard N. reply to: Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Medical Journal of Australia* 2008; **189:** 50-51.

27 Therapeutic Goods Administration. Guidelines for levels and kinds of evidence to support claims for non·registrable medicines, including complementary medicines, and other listable medicines. Canberra: Therapeutic Goods Adminislration, 2001.

28 Santoro A. Reply to: Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Medical Journal of Australia* 2008; **189:** 51.

29 Scientific Committee of the British Herbal Medical Association. *British herbal pharmacopoeia*, 2nd edn. Bournemouth: British Herbal Medicine Association, 1996.

30 Schmidt M, Eich J, Kreimeyer J, Betti G. Anbau der Teufelskralle. Ein Projekt in Namibia zur Sicherung der pharmazeutischen Qualität. *Deutsch Apotheker-Zeitung* 1998; **138:** 4540-4549.
31 Peltz K, Penman K, Lehmann R. Devil's claw authentication by HPLC. *Herbal Medicine: Practice and Science International Convention*. Brisbane, 1999.
32 Awang D. Siberian ginseng toxicity may be case of mistaken identity. *Canadian Medical Association Journal* 1996; **155:** 1237.
33 Grayer R, Kite G, Goldstone F, Bryan S, Paton A, Putievsky E. Infraspecific taxonomy and essential oil chemotypes in sweet basil, Ocimum basilicum. *Phytochemistry* 1996; **43:** 1033-1039.
34 Hudaib M, Speroni E, Di Pietra A, Cavrini V. GC/MS evaluation of thyme (Thymus vulgaris L.) oil composition and variations during the vegetative cycle. *Journal of Pharmaceutical and Biomedical Analysis* 2002; **29:** 691-700.
35 Stahl-Biskup E. Essential oil chemistry of the genus Thymus-a global view. In: Stahl-Biskup E, Sáez F, (eds.) *Thyme, the genus Thymus*. London: Taylor and Francis, 2002; 75-124.
36 Dinchev D, Janda B, Evstatieva L, Oleszek W, Aslani M, Kostova I. Distribution of steroidal saponins in Tribulus terrestris from different geographical regions. *Phytochemistry* 2008; **69:** 176-186.
37 Linde K, Barrett B, Wölkart K, Bauer R, Melchart D. Echinacea for preventing and treating the common cold. *Cochrane Database Systematic Review* 2006.
38 Wills R, Stuart D. Levels of active constituents in manufactured Echinacea products. *Chemistry in Australia* 1998; **9:** 17-19.
39 Bilia A. Ginkgo biloba L.: A workshop report. *Fitoterapia* 2002; **73:** 276-279.
40 Vlad S, LaValley M, McAlindon T, Felson D. Glucosamine for pain in osteoarthritis: why do trial results differ? *Arthritis & Rheumatism* 2007; **56:** 2267-2277.
41 Molyneux S, Florkowski C, Lever M, George P. The bioavailability of coenzyme Q10 supplements available in New Zealand differs markedly. *New Zealand Medical Journal* 2004; **117:** 1-6.
42 Meier B. The extraction strength of ethanol/water mixtures commonly used for the processing of herbal drugs. *Planta Medica* 1991; **57:** 26.
43 Adverse Drug Reactions Advisory Committee. Traditional Indian (Ayurvedic) and Chinese medicines associated with heavy metal poisoning. *Australian Adverse Drug Reactions Bulletin* 2007; **26:** 1.
44 Smith P. Investigation launched into drug kickbacks. *Australian Doctor*, 2006.
45 Masters S. The medical profession and the pharmaceutical industry: when will we open our eyes?: Letters. *Medical Journal of Australia* 2004; **181:** 458-459.
46 Carroll A, Honnef T. Create a Wellness Practice: Healthy patients and a healthy business. *Metagenics Practice Seminar*. Brisbane, 2008.
47 Turner A. Your practice - Your business. *Natural Therapies Expo*. Brisbane, 2008.
48 Carroll A, Honnef T. Create a Wellness Practice: Healthy patients and a healthy business. *Metagenics Practice Seminar*. Brisbane, 2007.
49 Smith C, Martin K, Hotham E, Semple S, Bloustien G, Rao D. Naturopaths practice behaviour: provision and access to information on complementary and alternative medicines. *BMC Complementary and Alternative Medicine* 2005; **5**.
50 Department of Industry Tourism and Resources. Australian Complementary Medicines Industry: A Preliminary Study. Canberra: Department of Industry, Tourism and Resources, 2006.
51 Mills S, Bone K. *Principles and Practice of Phytotherapy*. Edinburgh: Churchill Livingstone, 2000.
52 Bensoussan A, Myers S, Wu S, O'Connor K. Naturopathic and Western herbal medicine practice in Australia-a workforce survey. *Complementary Therpies in Medicine* 2004; **12:** 17-27.
53 Therapeutic Goods Administration. Therapeutics Goods Administration Summary: Other Therapeutic Products. In: Wardle J, (ed.). Canberra, 2008.
54 McGuire T, Moses G. Increasing The Frequency, Quality And Breadth Of Adverse Drug Reaction (ADR) Reporting By Consumers And Health Professionals - "The ADR Project". *Australian Conference on Safety and Quality in Health Care*. Perth, 2003.
55 Moses G. Increasing the frequency, quality and breadth of adverse drug reaction reporting by consumers and health professionals. *School of Pharmacy*. Brisbane: University of Queensland, 2005.
56 World Health Organization. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Geneva: World Health Organization, 2004.
57 Roughead E. The nature and extent of drug-related hospitalisations in Australia. *Journal of Quality in Clinical Practice* 1999; **19:** 19-22.
58 Thomas E, Studdert D, Runciman W, Webb R, Sexton E, McWilson R*, et al.* A comparison of iatrogenic injury studies in Australia and the USA I: context, methods, casemix, population, patient and hospital characteristics *International Journal for Quality in Health Care* 2000; **12:** 371-378.
59 Almeida J, Grimsley E. Coma from the health food store: interaction between kava and alprazolam. *Annals of Internal Medicine* 1996; **125:** 940-941.
60 Moulds R, Malani J. Kava : herbal panacea or liver poison? *Medical Journal of Australia* 2003; **178:** 451-453.
61 Gow P, Connelly N, Hill R, Crowley R, Angus P. Fatal fulminant hepatic failure induced by natural therapy containing Kava. *Medical Journal of Australia* 2004; **178:** 442-443.
62 Currie B, Clough A. Kava hepatotoxicity with Western herbal products: does it occur with traditional kava use? *Medical Journal of Australia* 2003; **178:** 421-422.

63 Pittler M, Ernst E. Kava extract for treating anxiety. *Cochrane Database of Systematic Reviews* 2003**:** CD003383.
64 Stargrove M, Treasure J, McKee D. *Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategies*. St Louis: Mosby, 2007.
65 Niggemann B, Grüber C. Side-effects of complementary and alternative medicine. *Allergy* 2003; **58:** 707-716.
66 Katzung B. *Basic & Clinical Pharmacology*. New York: Lange Medical Books, 2004.
67 Drug Utilisation Sub-Committee Drug Utilisation Database. Top 10 Drugs. *Australian Prescriber* 2006; **29:** 167.
68 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 1. *Journal of Complementary Medicine* 2007; **6:** 82-86.
69 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 2. *Journal of Complementary Medicine* 2007; **6:** 86-89.
70 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 3. *Journal of Complementary Medicine* 2007; **6:** 72-75.
71 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 4. *Journal of Complementary Medicine* 2007; **6:** 72-75.
72 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 5. *Journal of Complementary Medicine* 2007; **6:** 61-67.
73 Braun L, Cohen M. Drug-Complementary Medicine Interactions: Part 6. *Journal of Complementary Medicine* 2007; **6:** 64-68.
74 Izzo A, Ernst E. Interactions between herbal medicines and prescribed drugs. A systematic review. *Drugs* 2002; **61:** 2163-2175.
75 Hu Z, Yang X, Ho P, Chan S, Heng P, Chan E*, et al.* Herb-drug interactions: a literature review. *Drugs* 2005; **65:** 1239-1282.
76 Thien F. Chamomile tea enema anaphylaxis. *Medical Journal of Australia* 2001; **175:** 54.
77 But P. Need for correct identification of herbs in herbal poisoning. *Lancet* 1993; **341:** 637.
78 Boon H, Kachan N. Natural health product labels: is more information always better? *Patient Education & Counseling* 2007; **68:** 193-199.
79 Silva C, D'Cruz D. Pyridoxine toxicity courtesy of your local health food store - Letter. *Annals of the Rheumatic Diseases* 2006; **65:** 1666-1667.
80 See K, Lavercombe P, Dillon J, Ginsberg R. Accidental death from acute selenium poisoning. *Medical Journal of Australia* 2006; **185:** 388-389.
81 World Health Organization. General guidelines for methodologies on research and evaluation of traditional medicine. Geneva: World Health Organization, 2000.
82 Welsh S. The use of complementary medicines by inpatients at St Vincent's Hopsital. *Australian Journal of Hospital Pharmacy* 2001; **31:** 111-113.
83 Snape L. Report on Complementary Medicine/Complementary Therapy Use Survey. Penrith: Wentworth Area Health Service Complementary Therapies Committee, 2004.
84 Williams N. Naturopaths warned over bad medicine. *Daily Telegraph*. Sydney, 2004.
85 Turnbull S. Court rules 'natural justice'. *Northern Star*. Lismore, 2008.
86 Munro C. Unsafe health practices blamed on 'soft' law. *The Sun-Herald*, 2005.
87 Davies L. Without regulation the alternatives can be fatal. *The Daily Telegraph*. Sydney, 2005.
88 Khoury R. Re: Paul Perret investiation results. Personal Communication edn. Brisbane, 2008.
89 New South Wales Legislative Assembly. New South Wales Parliamentary Debates (Hansard). 2005; 20547.
90 Dowsley A, McRae S. Accused still in job Rape charges undisclosed. *Herald Sun*. 1st edn. Melbourne, 2006; 9.
91 Gaynor L. Naturopath guilty of sex assaults. *The Herald-Sun*. Melbourne, 2008.
92 Milton J. The impact of complementary therapy on mainstream practice. *International Journal of Palliative Nursing* 2006; **12:** 121-122.
93 Cohen M, Penman S, Pirotta M, Da Costa C. The Integration of Complementary Therapies in Australian General Practice: Results of a National Survey. *Journal of Alternative & Complementary Medicine* 2005; **11:** 995-1004.
94 Wardle J. Complementary and alternative medicine consumption, provision and integrated healthcare delivery: An examination of the perceptions and experiences of naturopaths in rural areas. *School of Population Health*. Brisbane: University of Queensland, 2007.
95 Easthope G, Tranter B, Gill G. Normal medical practice of referring patients for complementary therapies among Australian general practitioners. *Complementary Therapies in Medicine* 2000 Dec; **8:** 226-233.
96 Poynton L, Dowell A, Dew K, Egan T. General practitioners' attitudes toward (and use of) complementary and alternative medicine: a New Zealand nationwide survey. *New Zealand Medical Journal* 2006; **119:** U2361.
97 Thomas KJ, Coleman P, Nicholl JP. Trends in access to complementary or alternative medicines via primary care in England: 1995-2001 results from a follow-up national survey. *Family Practice* 2003 Oct; **20:** 575-577.
98 Brienza R, Stein M, Fagan M. Delay in obtaining conventional healthcare by female internal medicine patients who use herbal therapies. *Journal of Women's Health & Gender-Based Medicine* 2002; **11:** 79-87.
99 Cohen M, Eisenberg D. Potential physician malpractice liability associated with complementary and integrative medical therapies. *Annals of Internal Medicine* 2002; **136:** 596-603.
100 Weir M. Regulation of Complementary and Alternative Medicine Practitioners. *Law In Context* 2006; **23**.
101 Tuohy W, Silkstone W. Call for control on alternative medicine. *The Age*. Melbourne, 2002.

102 Koren G, Oren D, Rouleau M, Carmeli D, Matsui D. Comparison of verbal claims for natural health products made by health food stores staff versus pharamacists in Ontario, Canada. *Canadian Journal of Clinical Pharmacology* 2006; **13:** 251-256.
103 Buckner K, Chavez M, Raney E, Stoehr J. Health food stores recommendations for nausea and migraines during pregnancy. *Annals of Pharmacotherapy* 2005; **39:** 274-279.
104 Mills E, Ernst E, Singh R, Ross C, Wilson K. Health food store recommendations: implications for breast cancer patients. *Breast Cancer Research* 2003; **5:** 170-174.
105 Brazier N, Levine M. An evaluation of the quality of herbal product information provided by health food store retailers and pharmacists in a Canadian city. *Canadian Journal of Clinical Pharmacology* 2002; **9:** 108-109.
106 Harvey K, Korczak V, Marron L, Newgreen D. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. *Medical Journal of Australia* 2008; **188:** 21-25.
107 Offord L. Grab a slice of the wellness pie. *Australian Journal of Pharmacy* 2006; **87:** 48-49.
108 Day A. The complementary medicine market. *Australian Journal of Pharmacy* 2005; **86:** 457-458.
109 Expert Committee on Complementary Medicines. Complementary medicines in the Australian health system: Report to the Parliamentary Secretary to the Minister for Health and Ageing. Canberra: Commonwealth of Australia, 2003.
110 Australian Taxation Office. GST and acupuncture, naturopathy and herbal medicine services. Canberra: Australian Taxation Office, 2006.
111 Adverse Drug Reactions Advisory Committee. Adverse reactions to complementary medicines. *Australian Adverse Drug Reactions Bulletin* 2005; **24:** 1.
112 Bensoussan A, Myers SP, Wu SM, O'Connor K. Naturopathic and Western herbal medicine practice in Australia-a workforce survey. *Complementary Therapies in Medicine* 2004 Mar; **12:** 17-27.
113 Roughead E, Barratt J, AL G. Medication-related problems commonly occurring in an Australian community setting. *Pharmacoepidemiology & Drug safety* 2004; **13:** 83-87.
114 Weir M. Regulation of Complementary and Alternative Medicine: An International Perspective. *Medicine and Law* 2006; **25:** 673-685.
115 Evans S. The story of naturopathic education in Australia. *Complementary Therapies in Medicine* 2000; **8:** 234-240.
116 Robinson A, Cooper S. Trusted Information Sources: The Preferred Option for Complementary and Alternative Medicine Users. *Complementary Health Practice Review* 2007; **12:** 120-138.
117 Braun L, Cohen M, Braun G. Communication and Knowledge of Complementary Medicines by Hopsital Doctors and Pharmacists. *International Congress on Complementary Medicine Research*. Sydney, 2008.
118 Braun L, Cohen M. Use of Complementary Medicine by Surgical Patients - Undetected and Undersupervised. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
119 Braun L. Complementary Medicines in Hospitals: Don't Ask, Don't Tell. *6th International Conference on Phytotherapeutics*. Canberra, 2007.
120 van Haselen RA, Reiber U, Nickel I, Jakob A, Fisher PAG. Providing Complementary and Alternative Medicine in primary care: the primary care workers' perspective. *Complementary Therapies in Medicine* 2004 Mar; **12:** 6-16.
121 Braun L, Cohen M, Braun G. Hospital Doctors and Pharmacists Attitudes, Perceptions, Interest and Use of Complementary Therapies. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
122 Cohen M. CAM practitioners and "regular" doctors: is integration possible? *Medical Journal of Australia* 2004; **180**.
123 Milden SP, Stokols D. Physician's attitutdes and practivces regarding complementary and alternative medicine. *Behavioral Medicine* 2004; **30:** 73-82.
124 Kemper KJ, Gardiner P, Gobble J, Woods C. Expertise about herbs and dietary supplements among diverse health professionals. *BMC Complementary & Alternative Medicine* 2006; **6**.
125 Adams K, Cohen M, Eisenberg D, Jonsen A. Ethical considerations of complementary and alternative medical therapies in conventional medical settings. *Annals of Internal Medicine* 2002; **137:** 660-664.
126 Levine SM, Weber-Levine ML, Mayberry RM. Complementary and alternative medical practices: training, experience, and attitudes of a primary care medical school faculty. *Journal of the American Board of Family Practice* 2003 Jul-Aug; **16:** 318-326.
127 Giannelli M, Cuttini M, Da Frè M, Buiatti E. General practitioners' knowledge and practice of complementary/alternative medicine and its relationship with life-styles: a population-based survey in Italy. *BMC Family Practice* 2007; **8**.
128 Borgeault L. Physician's attitudes toward patients' use of alternative cancer therapies. *Canadian Medical Association Journal* 1996; **155:** 1679-1685.
129 O'Beirne M, Verhoef M, Paluck E, Herbert C. Complementary therapy use by cancer patients. Physicians' perceptions, attitudes, and ideas. *Canadian Family Physician* 2004 Jun; **50:** 882-888.
130 Bensoussan A, Myers S, Carlton A. Risks associated with the practice of traditional Chinese medicine. *Archives of Family Medicine* 2000; **9:** 1071-1078.
131 Blackmores. Blackmores Health and Wellbeing Survey. Sydney: Blackmores, 2002.
132 Busse J, Heaton G, Wu P, Wilson K, Mills E. Disclosure of natural product use to primary care physicians: a cross-sectional survey of naturopathic clinic attendees. *Mayo Clinic Proceedings* 2005; **80:** 616-623.

133 Berman B, Bausell R, Lee W. Use and referral patterns for 22 complementary and alternative medical therapies by members of the American College of Rheumatology: results of a national survey. *Annals of Internal Medicine* 2002; **162:** 766-770.
134 Hyodod I, Eguchi K, Nishina T. Perceptions and attitudes of clinical oncologists on complementary and alternative therapies. *Cancer* 2003; **97:** 2861-2868.
135 Leach M. Orthodox use, or misuse, of complementary & alternative medicine. *Journal of Complementary and Integrative Medicine* 2006; **4**.
136 Cohen M. Challenges and Future Directions for Integrative Medicine in Clinical Practice. *Evidence Based Integrative Medicine* 2005; **2:** 117-122.
137 Adams J. Direct integrative practice, time constraints and reactive strategy: An examination of GP therapists' perceptions of their complementary medicine *Journal of Management in Medicine* 2001; **15:** 312-323.
138 Naidu S, Wilkinson J, Simpson M. Attitudes of Australian Pharmacists Toward Complementary and Alternative Medicines. *Annals of Pharmacotherapy* 2005; **39:** 1456-1461.
139 Barnes J, Abbot N. Experiences with complementary
remedies: a survey of community pharmacists. *Pharmaceutical Journal* 1999; **263:** 37.
140 Ernst E. Complementary medicine pharmacists? *Pharmaceutical Journal* 2004; **273:** 197-198.
141 Dolder C, Lacro J, Dolder N, Gregory P. Pharmacists' use of and beliefs about alternative medicines. *American Journal of Health System Pharmacy* 2003; **60:** 1352-1357.
142 Koh H, Teo H, Ng H. Pharmacists' patterns of use, knowledge and attitudes toward complementary and alternative medicine. *Journal of Alternative & Complementary Medicine* 2003; **9:** 51-63.
143 Hutchinson S, Mitchell K, Hansford D, Stewart D. Community pharmacists' views and experiences of counter-prescribing in pregnancy. *International Journal of Pharmacy Practice* 2001; **9:** 15-21.
144 Brown C, Barnes J, Shah S. Community pharmacists' actions when patients use complementary and alternative therapies with medications. *Journal of the Americane Pharmacy Association* 2005; **45:** 41-47.
145 Howard N, Tsourounis C, Kapusnik-Uner J. Dietary supplement survey of pharmacists: personal and professional practices. *Journal of Alternative & Complementary Medicine* 2001; **7:** 667-680.
146 Semple S, Hotham E, Rao D, Martin K, Smith C, Bloustien G. Community pharmacists in Australia: barriers to information provision on complementary and alternative medicines. *Pharmacy World Science* 2006; **28:** 366-373.
147 Triller D, Snitkoff G. Survey of herbal retailers: Comparison of pharmacist and non-pharmacist involvement. *Journal of Herbal Pharmacotherapy* 2001; **1:** 35-34.
148 Braun L. Pharmacists and complementary medicines: don't ask, don't tell, don't know? *Australian Journal of Pharmacy* 2007; **88:** 58-59.
149 Brophy E. Does a doctor have a duty to provide information and advice about complementary and alternative medicine? *Journal of Law & Medicine* 2003; **10:** 271.
150 Weir M. Obligation to advise of options for treatment - medical doctors and complementary and alternative medicine practitioners. *Journal of Law & Medicine* 2003; **10:** 296-307.
151 Cohen M, Eisenberg D. Potential physician malpractice liability associated with complementary and intergrative therapies. *Annals of Internal Medicine* 2002; **136:** 596-603.
152 Ipp D. Review of the law of negligence: A final report. Canberra: Commonwealth of Australia, 2002.
153 Kerridge I, McPhee J. Ethical and legal issues at the interface of complementary and conventional medicine. *Medical Journal of Australia* 2004; **181:** 164-166.
154 McGroder v Maguire. Sydney: New South Wales Court of Appeal, 2002.
155 Adverse Drug Reactions Advisory Committee. Black cohosh and liver toxicity - an update. *Australian Adverse Drug Reactions Bulletin* 2007; **26:** 1.
156 Grant v. Pharmative, LLC 452 F.Supp.2d 903. *United States District Court*. Omaha, 2006.
157 Anonymous. Poisoned comfrey tea warning. *Pharmaceutical Journal* 1983; **230:** 173.
158 Winslow LC, Shapiro H. Physicians want education about complementary and alternative medicine to enhance communication with their patients. *Archives of Internal Medicine* 2002; **162:** 1176-1181.
159 Theodoropoulos I, Manolopoulos K, Von Georgi R, Bohlmann M, Munstedt K. Physicians and complementary and alternative medicine cancer therapies in Greece: a survey. *Journal of Alternative & Complementary Medicine* 2005 Aug; **11:** 703-708.
160 Sikand A, Laken M. Pediatrician's experience with and attitudes toward comlplementary/alternative medicine. *Archives of Pediatric and Adolescent Medicine* 1998; **152:** 1059-1064.
161 De Smet P. Health risks of herbal remedies. *Drug Safety* 1995; **13:** 81-93.
162 System ECoCMitH. Complementary Medicines in the Australian Health System. Report to the Parliamentary Secretary to the Minister for Health & Ageing. Canberra: Commonwealth of Australia, 2003.
163 Therapeutic Goods Administration. Review of Drugs Poisons & Controlled Substances Legislation: A Council of Australian Governments Review. Final Report Part A. Canberra: Commonwealth of Australia, 2001.
164 Therapeutic Goods Administration. Therapeutic Goods Order No. 69 - General requirements for labels for medicines. *Commonwealth of Australia Gazette* 2001; **GN36**.
165 Therapeutic Goods Administration. Australian Regulatory Guidelines for Complementary Medicines – Part IV. In: Administration TG, (ed.). Canberra: Therapeutic Goods Administration, 2005.
166 Hinde S. Herbal Potions to be Regulated. *Sunday Herald Sun*. Melbourne, 2006.

167 Sykes K. Re: Regulation of naturopaths. In: Wardle J, (ed.). Melbourne: Department of Human Services, 2007.
168 House of Lords Select Committee on Science and Technology. Sixth Report, Complementary and Alternative Medicine: HL Paper 123. London: Her Majesty's Stationary Office, 2000.
169 Health Services Development Unit. Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland. Dublin: Department of Health and Children, 2002.
170 White House Commission on Complementary and Alternative Medicine Policy. United States of America White House Commission on Complementary and Alternative Medicine Policy Final Report Washington, DC, 2002.
171 Australian Medical Association. AMA Position Statement: Complementary Medicine. Canberra: Australian Medical Association, 2002.
172 Frenkel MA, Borkan JM. An approach for integrating complementary-alternative medicine into primary care. *Family Practice* 2003 Jun; **20:** 324-332.
173 O'Brien K. Complementary and alternative medicine: the move into mainstream health care. *Clinical & Experimental Optometry* 2004 Mar; **87:** 110-120.
174 Emslie M, Campbell M, Walker K. Changes in Public Awareness of, Attitudes to, and Use of Complementary Therapy in North-East Scotland: Surveys in 1993 and 1999. *Complementary Therpies in Medicine* 2002; **10:** 148-153.
175 Media Release: Call for Government Monitored Self Regulation (GMSR) of complementary medicine practitioners. Sydney: Australian Traditional Medicine Society, 24 July 2008.
176 Media release: Call for self regulation. *Australian Traditional Medicine Society*. Sydney, 14 Aug 2008.
177 Media release: Media on registration. *Australian Traditional Medicine Society*. Sydney, 20 Sept 2007.
178 Khoury R. Submission to the Joint Parliamentary Committee on the Health Care Complaints Commission Inquiry Into the Regulation or Registration of Traditional Chinese Medicine. Sydney: Australian Traditional Medicine Society, 2005.
179 Khoury R. Submission to the NSW Committee on the Health Care Complaints Commission on the Review of the Unregistered Health Practitioners: The Adequacy and Appropriateness of Current Mechanisms for Resolving Complaints Report (1998). Sydney: Australian Traditional Medicine Society, 2006.
180 Australian Traditional Medicine Society. Submission to the Senate Community Affairs References Committee Inquiry Into Services and Treatment Options for Persons with Cancer. Sydney: Australian Tradtitional Medicine Society, 2005.
181 Khoury R. Submission to the Department of Health Discussion Paper on the Regulation of Practitioners of Chinese Medicine in Western Australia June 2005. Sydney: Australian Traditional Medicine Society, 2005.
182 Australian Naturopathic Practitioner's Association. Australian Naturopathic Practitioners Association Practitioner Database. Australian Naturopathic Practitioners Association, 2007.
183 Eisenberg D, Cohen M, Hrbek M, Grayzrl A, Van Rompay J, Cooper R. Credentialing complementary and alternative medical providers. *Annals of Internal Medicine* 2002; **137:** 137.
184 Fisher P, Van Haselen R, Hardy K, Berkovitz S, McCarney R. Effectiveness gaps: a new concept for evaluating health service and research needs applied to complementary and alternative medicine. *Journal of Alternative & Complementary Medicine* 2004; **10:** 627-632.
185 Kure C, Tarasuik J, Lloyd J, Stough C. An Open Clinical Trial Comparing The Effects Of Remotiv ® (Hypericum perforatum; Ze117) And Nicotine Replacement In The Management Of Smoking Cessation. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
186 Kasper S, Schubert H. Ginkgo Biloba Extract EGb 761® In Dementia: Response Rates, Numbers Needed To Treat And Numbers Needed To Harm. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
187 Yam W, Wilkinson J. A Survey Of Acupuncture In Stroke Rehabilitation. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
188 Pittler M, Guo R, Ernst E. Hawthorn Extract For Treating Chronic Heart Failure: Cochrane Review. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
189 Holubarsch C. Crataegus Extract WS® 1442 Reduces Cardiac Death In Patients With Congestive Heart Failure NYHA class II-III: The SPICE Trial. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
190 Maddon T. Health Economics: How The Wellness Model Supports Sound Economic Management In Australia. *3rd International Congress on Complementary Medicine Research*. Sydney, 2008.
191 World Health Organization. Ottawa Charter for Health Promotion. Geneva: World Health Organization, 1986.
192 Walker B, Muller R, Grant W. Low Back Pain in Australian Adults: The Economic Burden. *Asia Pacific Journal of Public Health* 2003; **15:** 79-87.
193 Herman P, Szczurko O, Cooley K, Mills E. Cost-effectiveness of naturopathic care for chronic low back pain. *Alternative Therapies in Health and Medicine* 2008; **14:** 32-39.
194 Szczurko O, Cooley K, Busse J, Seely D, Bernhardt B, Guyatt G*, et al.* Naturopathic care for chronic low back pain: a randomized trial. *PLoS ONE* 2007; **2:** e919.
195 Willison K, Williams P, Andrews G. Enhancing chronic disease management: a review of key issues and strategies. *Complementary Therapies in Clinical Practice* 2007; **13:** 232-239.
196 Navarro A, Voetsch K, Liburd L, Giles H, Collins J. Charting the future of community health promotion: recommendations from the National Expert Panel on Community Health Promotion. *Preventing Chronic Disease* 2007; **4:** 1-7.
197 Kelner M, Wellman B. Health care and consumer choice: Medical and alternative therapies. *Social Science and Medicine* 1997; **45:** 203-212

198 Lofgren H, De Boer R. Pharmaceuticals in Australia: developments in regulation and governance *Social Science and Medicine* 2004; **58:** 2397-2407.
199 Contacos C, Barter P, Sullivan D. Effect of pravastatin and omega-3 fatty acids on plasma lipids and lipoproteins in patients with combined hyperlipidemia. *Arteriosclerosis and Thrombosis* 1993; **12:** 1755-1762.
200 Durrington P, Bhatnagar D, Mackness M. An omega-3 polyunsaturated fatty acid concentrate administered for one year decreased triglycerides in simvastatin treated patients with coronary heart disease and persisting hypertriglyceridemia. *Heart* 2001; **85:** 544-548.
201 Grekas D, Kassimatis E, Makedou A, Bacharaki D, Bamichas G, Tourkantonis A. Combined Treatment with Low-Dose Pravastatin and Fish Oil in Post-Renal Transplantation Dislipidemia. *Nephron* 2001; **88**.
202 Yokoyama M, Origasa H, Matsuzaki M, Matsuzawa Y, Saito Y. Effects of eicosapentaenoic acid on major coronary events in hypercholesterolemic patients (JELIS): a randomized open-label, blinded endpoint analysis. *Lancet* 2007; **369:** 1090-1098.
203 Department of Health and Aging. Australian Statistics on Medicines 2008. Canberra: Department of Health and Aging, 2008.
204 Malsch U, Kieser M. Efficacy of kava-kava in the treatment of non-psychotic anxiety, following pretreatment with benzodiazepines. *Psychopharmacology* 2001; **157:** 277-283.
205 Poyares A, Guilleminault C, Ohayon M, Tufik S. Can valerian improve the sleep of insomniacs after benzodiazepine withdrawal? *Progress in Neuropsychopharmacology and Biological Psychiatry* 2002; **26:** 539-545.
206 Smedley F, Bowling T, James M, Stokes E, Goodger C, O'Connor O*, et al.* Randomized clinical trial of the effects of preoperative and postoperative oral nutritional supplements on the clinical course and cost of care. *British Journal of Surgery* 2004; **91:** 983-990.
207 Den Hond E, Peeters M, Hiele M, Bulteel V, Ghos Y, Rutgeerts P. Effect of glutamine on the intestinal permeability changes induced by indomethacin in humans. *Alimentary Pharmacology & Therapeutics* 2001; **13:** 679 - 685.
208 Muriel P, Rivera-Espinoza Y. Beneficial drugs for liver diseases. *Journal of Applied Toxicology* 2008; **28:** 93-103.
209 Jarvill-Taylor K, Anderson R, Graves D. A Hydroxychalcone Derived from Cinnamon Functions as a Mimetic for Insulin in 3T3-L1 Adipocytes. *Journal of the American College of Nutrition* 2001; **20:** 327-336.
210 Braun L, Cohen M. *Herbs & Natural Supplements: An evidence-based guide*. Sydney: Elsevier, 2007.
211 Hippisley-Cox J, Coupland C. Risk of myocardial infarction in patients taking cyclo-oxygenase-2 inhibitors or conventional non-steroidal anti-inflammatory drugs: population based nested case-control analysis. *British Medical Journal* 2005; **330:** 1366.
212 Hippisley-Cox J, Coupland C, Logan R. Risk of adverse gastrointestinal outcomes in patients taking cyclo-oxygenase-2 inhibitors or conventional non-steroidal anti-inflammatory drugs: population based nested case-control analysis. *British Medical Journal* 2005; **331:** 1310-1316.
213 Burgess C, Holman C, Satti A. Adverse drug reactions in older Australians, 1981-2002. *Medical Journal of Australia* 2005; **182:** 267-270.
214 Braun L. Being Sensible about Interactions. *Journal of Complementary Medicine* 2007; **6:** 5.
215 Smallwood C. The Role of Complementary and Alternative Medicine in the NHS: An Investigation Into the Potential Contribution of Mainstream Complementary Therapies to Healthcare in the UK. London: FreshMinds, 2005.
216 Australian Institute of Health and Welfare. Australia's Health 2008. Canberra: Australian Institute of Health and Welfare, 2008.
217 Maxion-Bergemann S, Wolf M, Bornhoft G, Matthiessen P, Wolf U. Complementary and alternative medicine costs - a systematic literature review. *Forschende Komplementarmedizin* 2006; **13:** 42-45.
218 Smith T, Smith B, Ryan M. Prospective investigation of complementary and alternative medicine use and subsequent hospitalizations. *BMC Complementary and Alternative Medicine* 2008; **8:** 19.
219 Ernst E. The efficacy of Phytodolor for the treatment of musculoskeletal pain - a systematic review of randomized clinical trials. *Natural Medicine Journal* 1999; **2:** 14-17.
220 Long L, Soeken K, Ernst E. Herbal medicines for the treatment of osteoarthritis: a systematic review. *Rheumatology* 2001; **40:** 779-793.
221 Barrett B, Vohmann M, Calabrese C. Echinacea for upper respiratory infection. *Journal of Family Practice* 1999; **48:** 628-635.
222 Melchart D, Linde K, Fischer P, Kaesmayr J. Echinacea. *Cochrane Database Systematic Review* 2000; **2:** CD000530.
223 Gaster B, Holroyd J. St John's wort for depression: a systematic review. *Archives of Internal Medicine* 2000; **160:** 152-156.
224 Kim H, Streltzer J, Goebert D. St. John's Wort for depression. A meta-analysis of well-defined clinical trials. *Journal of Nervous and Mental Disease* 1999; **187:** 532-538.
225 Szegedi A, Kohnen R, Dienel A, Kieser M. Acute treatment of moderate to severe depression with hypericum extract WS 5570 (St. John's Wort): A randomised controlled double blind noninferioritytrial versus paroxetine. *British Medical Journal* 2005; **330:** 530.
226 Whiskey E, Werneke U, Taylor D. A systematic review and meta-analysis of Hypericum perforatum in depression: a comprehensive clinical review. *International Clinical Psychopharmacology* 2001; **16:** 239-252.
227 Birks J, Grimley E, Van Dongen M. Ginkgo biloba for cognitive impairment and dementia. *Cochrane Database Systematic Reviews* 2002; **4:** CD003120.

228 Pittler M, Ernst E. Ginkgo biloba extract for the treatment of intermittent claudication: a meta-analysis of randomized trials. *American Journal of Medicine* 2000; **108:** 276-281.
229 Ernst E, Pittler M. Ginkgo biloba for dementia: a systematic review of double-blind, placebo-controlled trials. *Clinical Drug Investigations* 1999; **17:** 301-308.
230 Ernst E, Chrubasik S. Phyto-anti-inflammatories: a systematic review of randomized, placebo- controlled, double-blind trials. *Rheumatoid Disease Clinics of North America* 2000; **26:** 13-27.
231 Wegener T, Lüpke N. Treatment of patients with arthrosis of hip or knee with an aqueous extract of devil's claw (Harpagophytum procumbens DC.). *Phytotherapy Research* 2003; **17:** 1165-1172.
232 Pittler M, Schmidt K, Ernst E. Hawthorn extract for treating chronic heart failure: meta-analysis of randomized trials. *American Journal of Medicine* 2003; **114:** 665-674.
233 Tauchert M. Efficacy and safety of crataegus extract WS 1442 in comparison with placebo in patients with chronic stable New York Heart Association class-III heart failure. *American Heart Journal* 2002; **143:** 910-915.
234 Zapatero J. Selections from current literature: effects of hawthorn on the cardiovascular system. *Journal of Family Practice* 1999; **16:** 534-538.
235 Pittler M, Ernst E. Horse chestnut seed extract for chronic venous insufficiency. *Cochrane Database of Systematic Reviews* 2005; **4:** CD003230.
236 Tiffany N, Boon H, Ulbricht C, Basch E, S B, Barrette E*, et al.* Horse chestnut:a multidisciplinary clinical review. *Journal of Herbal Pharmacotherapy* 2002; **2:** 71-85.
237 Boyle P, Robertson C, Lowe F, Roehrborn C. Meta-analysis of clinical trials of permixon in the treatment of symptomatic benign prostatic hyperplasia. *Urology* 2000; **55:** 533-539.
238 Debruyne F, Koch G, Boyle P, Da Silva F, Gillenwater J, Hamdy F*, et al.* Comparison of a phytotherapeutic agent (Permixon) with an alpha-blocker (Tamsulosin) in the treatment of benign prostatic hyperplasia: a 1-year randomized international study. *European Urology* 2002; **41:** 497-507.
239 Preuss H, Marcusen C, Regan J, Klimberg I, Welebir T, Jones W. Randomized trial of a combination of natural products (cernitin, saw palmetto, B-sitosterol, vitamin E) on symptoms of benign prostatic hyperplasia (BPH) *International Urology and Nephrology* 2001; **33:** 217-225.
240 Wilt T, Ishani A, MacDonald R. Serenoa repens for benign prostatic hyperplasia. *Cochrane Database of Systematic Reviews* 2002; **3:** CD001423.
241 Hamre H, Becker-Witt C, Glockmann A, Ziegler R, Willich S, Kiene H. Anthroposophic therapies in chronic disease: the Anthroposophic Medicine Outcomes Study (AMOS). *European Journal of Medical Research* 2004; **9:** 351-360.
242 Slade K, Chohan BP, Barker PJ. Evaluation of a GP practice based homeopathy service. *Homeopathy: the Journal of the Faculty of Homeopathy* 2004 Apr; **93:** 67-70.
243 Manga P, Angus D. Enhanced Chiropractic Coverage Under OHIP as a Means of Reducing Health Care Costs: Attaining Better Health Outcomes and Achieving Equitable Access to Health Services. Ottawa: University of Ottawa, 1998.
244 Deloitte & Touche. Impact of Delisting Chiropractic Services: Final Report. Toronto: Deloitte & Touche, 2004.
245 Noe B. Vermont Car Dealers Help to Quantify the Benefits of Naturopathic Care. *21st Annual Conference of the American Association of Naturopathic Physicians*. Portland, 2006.
246 Herman P, Craig B, Caspi O. Is complementary and alternative medicine (CAM) cost-effective? a systematic review. *BMC Complementary and Alternative Medicine* 2005; **5:** 11.
247 Canter P, Coon J, Ernst E. Cost effectiveness of complementary treatments in the United Kingdom: systematic review. *British Medical Journal* 2005; **331:** 880-881.
248 Hulme C, Long A. Square pegs and round holes? A review of economic evaluation in complementary and alternative medicine. *Journal of Alternative & Complementary Medicine* 2005; **11:** 179-188.
249 Meenan R. Developing appropriate measures of the benefits of complementary and alternative medicine. *Journal of Health Services Research and Policy* 2001; **6:** 38-43.
250 Meade T, Dyer S, Browne W, Townsend J, Frank A. Low back pain of mechanical origin: randomised comparison of chiropractic and conventional treatment. *British Medical Journal* 1990; **300:** 1431-1437.
251 Baron R, Campbell S. Benefits of integrating naturopathic medicine in the workplace: an introductory report. *Journal of Naturopathic Medicine* 1997; **7:** 104.
252 Clark J. Capacity to produce pharmaceutical products from agriculture. *New food and pharmaceutical products from agriculture*. Canberra: Rural Industries Research and Development Corporation, 2002.
253 Baer H. The drive for legitimation in Australian naturopathy: Successes and dilemmas *Social Science and Medicine* 2006; **63:** 1771-1783.
254 NSW Department of Health IB. Guidelines and Information on the operation of mutual recognition in NSW. *Information Bulletin* 1995; **93**.
255 Nieuwenhuysen J, Williams-Wynn M. *Professions in the Marketplace: An Australian Study of Lawyers, Doctors, Accountants, and Dentists*. Melbourne: Melbourne University Press, 1982.
256 Lin V, Gillick D. Is registration of Chinese medicine protecting public health and safety? *Health Issues* 2006; **88:** 20-24.
257 National Health and Medical Research Council. Total NHMRC research funding for all new and continuing awards each calendar year. Canberra: National Health and Medical Research Council, 2008.
258 Department of Health and Aging. Complementary medicine gets a boost: media release. Canberra: Department of Health and Aging, 2008.

259 Bensoussan A. Complementary medicine: searching for the evidence. *Australian Family Physician* 2000; **29:** 1129-1133.
260 Chen H, Ma B, Grant A. Research funds for complementary medicine: Letter. *Lancet* 2001; **357:** 1982.
261 Bensoussan A, Myers S, Cooke M, Cheras P. Review of Complementary Medicine in NSW: Report to the Ministry for Science and Medical Research. Sydney: Ministry for Science and Medical Research, 2005.
262 Kaptchuk T, Stason W, Davis R, Legedza A, Schnyer R, Kerr C. Sham device v inert pill: randomised controlled trial of two placebo treatments. *British Medical Journal* 2006; **332:** 391-397.
263 Herbert J, Gaudiano B. Introduction to the special issue on the placebo concept in psychotherapy. *Journal of Clinical Psychology* 2005; **61:** 787-790.
264 Fava M, Evins E, Dorer D, Schoenfeld D. The Problem of the Placebo Response in Clinical Trials for Psychiatric Disorders: Culprits, Possible Remedies, and a Novel Study Design Approach. *Psychotherapy and Psychosomantics* 2003; **72:** 115-127.
265 Hancock M, Maher C, Latimer J, McAuley J. Selecting an appropriate placebo for a trial of spinal manipulative therapy. *Australian Journal of Physiotherapy* 2006; **52:** 135-138.
266 Cleophas T, Van der Meulen J, Kalmansohn R. Clinical trials: specific problems associated with the use of a placebo control group. *British Journal of Clinical Pharmacology* 1997; **43:** 219-222.
267 Smith D. The case against cure-alls. *Sydney Morning Herald*. Sydney, 2008.
268 Pirotta M. The application of RCTs for CAM: methodological challenges. In: Adams J, (ed.) *Researching complementary and alternative medicine*. London: Routledge, 2008.
269 Tonelli M, Callahan T. Why alternative medicine cannot be evidence-based. *Academic Medicine* 2001; **76:** 1224-1225.
270 Cohen M. Evidence and CAM research. In: Adams J, (ed.) *Researching complementary and alternative medicine*. London: Routledge, 2008.
271 Scientific Committee of the British Herbal Medical Association. *British herbal pharmacopoeia*, 1st edn. Bournemouth: British Herbal Medicine Association, 1983.
272 Bradley P. British Herbal Compendium. 2nd edn. Bournemouth: British Herbal Medical Association, 2006.
273 LeLorier J, Grégoire G, Benhaddad A, Lapierre J, Derderian F. Discrepancies between Meta-Analyses and Subsequent Large Randomized, Controlled Trials. *New England Journal of Medicine* 1997; **337:** 536-542.
274 Hardern RD, Leong FT, Page AV, Shepherd M, Teoh RCM. How evidence based are therapeutic decisions taken on a medical admissions unit? . *Emergency Medicine Journal* 2002; **20:** 447-448.
275 BMJ Clinical Evidence. How much do we know? , 2008.
276 Radley D, Finkelstein S, Stafford R. Off-label Prescribing Among Office-Based Physicians. *Archives of Internal Medicine* 2006; **166:** 1021-1026.
277 Howe M. Starved of attention: A desire for a less rushed and more holistic approach is driving the increase in patietns consulting complementary practitioners. *Australian Doctor*, 2005.
278 McColl A, White P, Field J. General practitioners' perceptions of the route to evidence based medicine: a questionnaire survey *British Medical Journal* 1998; **316:** 361-365.
279 Adams J. General practitioners, complementary therapies and evidence-based medicine: the defence of clinical autonomy *Complementary Therapies in Medicine* 2000; **8:** 248-252.
280 Tomlin Z, Humphrey C, Rogers S. General practitioners' perceptions of effective health care. *British Medical Journal* 1999; **318:** 1532-1535.
281 Schattner H, Fletcher R. Research evidence and the individual patient *Quarterly Journal of Medicine* 2003; **96:** 1-5.
282 Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 2003; **362:** 1225-1230.
283 Haynes R, Devereaux P, Guyatt G. Clinical expertise in the era of evidence-based medicine and patient choice. *Evidence-Based Medicine* 2002; **7:** 36-38.
284 Turner E, Matthews A, Linardatos E, Tell R, Rosenthal R. Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy. *New England Journal of Medicine* 2008; **358:** 252-260.
285 Roelofs P, Deyo R, Koes B, Scholten R, van Tulder M. Non-steroidal anti-inflammatory drugs for low back pain. *Cochrane Database of Systematic Reviews* 2007**:** CD000396.
286 West R, Sohal T. "Catastrophic" pathways to smoking cessation: findings from national survey. *British Medical Journal* 2006; **332**.
287 Loefler I. Evidence based medicine. *British Medical Journal* 2004; **328:** 842.
288 Sackett D. Evidence based medicine: what it is and what it isn't *British Medical Journal* 1996; **312:** 71-72.
289 English J. Honest Research - Rapid response to: Should NICE evaluate complementary and alternative medicine? . *British Medical Journal* 2007; **334:** 506.
290 Ernst E. What's the point of rigorous research on complementary/alternative medicine? *Journal of the Royal Society of Medicine* 2002; **95:** 211-213.
291 Linde K, Willich S. How objective are systematic reviews? Differences between reviews on complementary medicine. *Journal of the Royal Society of Medicine* 2003; **96:** 17-22.
292 Friedman L, Richter E. Relationship between conflicts of interest and research results. *Journal of General and Internal Medicine* 2004; **19:** 51-56.

293 Reginster J. The efficacy of glucosamine sulfate in osteoarthritis: Financial and nonfinancial conflict of interest *Arthritis & Rheumatism* 2007; **56:** 2105-2110.
294 Wardle J, Adams J. Complementary therapists: a potential healthcare resource in rural areas underserviced by conventional medical resources. *Rural Health Conference*. Bendigo, 2008.
295 Humphreys J, Jones J, Jones M, Hugo G, Bamford E, Taylor D. A critical review of rural medical workforce retention in Australia. *Australian Health Review* 2001; **24:** 91-102.
296 Adams J, Sibbritt D, Easthope G, Young A. The profile of women who consult alternative health practitioners in Australia. *Medical Journal of Australia* 2003; **179:** 297-300.
297 Wilkinson JM, Simpson MD. High use of complementary therapies in a New South Wales rural community. *Australian Journal of Rural Health* 2001 Aug; **9:** 166-171.
298 Sibbritt DW, Adams J, Young AF. A longitudinal analysis of mid-age women's use of complementary and alternative medicine (CAM) in Australia, 1996-1998. *Women & Health* 2004; **40:** 41-56.
299 Brems C, Johnson ME, Warner TD, Roberts LW. Patient requests and provider suggestions for alternative treatments as reported by rural and urban care providers. *Complementary Therapies in Medicine* 2006 Mar; **14:** 10-19.
300 Eckert K, Taylor A, Wilkinson D. Does health service utilisation vary by remoteness?: South Australian population data and the Accessibility and Remoteness Index of Australia. *Australian and New Zealand Journal of Public Health* 2004; **28:** 426-432.
301 Easton K. Complementary medicines: attitudes and information needs of consumers and healthcare professionals. Sydney: National Prescribing Service, 2007.
302 Lewis J, Strom B. Balancing safety of dietary supplements with the free market. *Annals of Internal Medicine* 2002; **136:** 616-618.
303 Pizzorno J, Murray M. *Textbook of Natural Medicine*. London: Elsevier, 2005.

Author:

Jon Wardle **BHSc(Naturopathy) MPH**

Jon Wardle is a practising naturopath in Brisbane and Clinical Lecturer and Researcher at the Australian College of Natural Medicine and University of Queensland. He is currently completing doctorate studies looking at the role of complementary medicine in filling healthcare gaps in medically underserved rural areas. He is founding director of the Naturopathy Foundation, founding member of the Network of Researchers of the Public Health of Complementary and Alternative Medicine (NORPHCAM) and research collaborator on the Australian Longitudinal Study on Women's Health and Hunter Community Study. He is currently developing and co-editing an evidence-based practical text entitled Clinical Naturopathy for Elsevier and is a regular health columnist for various Queensland newspapers. He is heavily involved in clinical and public health research projects at the University of Queensland, University of Newcastle, Mater Hospital as well as various projects nationally and internationally.