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Consumers Health Forum of Australia

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Complementary Medicines: How well do consumers know their products?

representing consumers on national health issues

Health Voices

Health Voices is published twice each year. Each issue has a theme that promotes debate on issues of interest to health consumers, government and industry.

Readers are encouraged to write letters to CHF in response to journal articles or other issues in Australian healthcare.

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The Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers.

CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- early intervention, prevention and early diagnosis
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

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Editorial

Business is booming in complementary medicines.

The sector has experienced annual growth estimated at up to 12 per cent per annum.[1]

By 2010, sales had skyrocketed to over $1.2 billion.[2]

Consumers clearly believe there are real benefits in using complementary medicine, but what do we know about the products they are using? What safeguards are in place in terms of regulation, consumer protection and testing for quality, consistency and effectiveness?

This edition of *Health Voices* examines the issues facing consumers accessing complementary medicines.

It's a major segment of the health industry, one that is expanding.

The issues around complementary medicine are multifaceted, complex and often contestable.

Industry proponents argue that complementary medicine provides support and adds value to healthy choices, allowing consumers to self-regulate their medication based on their specific needs. Consumer activists counter that miracle cure products like *Fat Blaster* seem to undermine any credibility the industry may claim, alongside concerns around marketing, efficacy and protections for consumers, who may not fully understand the products they are taking.

So many of these products are 'scientifically formulated' and 'clinically tested', but exactly what these terms mean is often obscure.

Regulators face very real challenges including developing best practice, weighing up issues around self-regulation versus hands-on, the complexity of packaging and marketing claims, as well as being responsive to concerns from both industry and consumers.

People with chronic conditions or life-threatening diseases sometimes explore complementary medicine as a way of balancing their treatment or searching for alternatives to conventional therapy that may not be working for them.

Some consumers see taking complementary medicines as an alternative to getting medical advice which may be more costly or difficult to access.

In this issue we examine all aspects: regulation, legislation, consumer protection, efficacy and evidence as well as the use of complementary medicine in conjunction with conventional treatment.

A consistent theme is that health consumers need to be informed and know the full details of the products they are using.

Contributors to this issue include a range of voices actively engaged in the complementary medicines space.

The **Breast Cancer Network of Australia (BCNA)** outlines information and support services it provides for women diagnosed with breast cancer.

Pain Australia CEO Lesley Brydon looks at complementary medicine and chronic pain, and examines clinical use of complementary medicines and therapies to assist sufferers of chronic pain in light of evolving knowledge of pain management and asks: does it really matter if it manages the pain.

Dr Lynn Weekes, CEO of NPS MedicineWise outlines the questions consumers should be asking before choosing a complementary medicine, and the importance of considering other medications consumers might be taking when thinking about complementary medicine.

Consumer advocate **Dr Ken Harvey** outlines some deeply-held concerns regarding the efficacy, evidence and quality around complementary medicines.

New South Wales Health Quality and Complaints Commissioner Kieran Pehm outlines a unique legislative approach providing regulatory frameworks for 'unregistered' health professionals.

Parliamentary Secretary for Health and Ageing Catherine King discusses the role of government across all sections of the debate, and the role of the Therapeutic Goods Administration in working with industry, responding to consumer concerns and creating regulatory frameworks.

Australia's **Chief Medical Officer Prof. Chris Baggoley** outlines work being undertaken to review the evidence base for complementary medicine, specifically around rebates from private health funds for complementary medicines.

Dr John Skerritt and Trisha Garrett, from the **Therapeutic Goods Administration** outline the TGA regulatory process, including evidence requirements, stakeholder engagement and ensuring the claims being made are reasonable and accurate.

Australian Medical Association President Dr Steve Hambleton points out that evidence-based therapies can successfully assist a conventional treatment, however these must be considered as part of an evidence-based approach.

The Pharmacy Board of Australia Chair Stephen Marty discusses the role of pharmacists in primary care, specifically in providing community advice to people wishing to use a complementary medicine.

Finally, **Dr Deon Schoombie, Executive Director of the Australian Self Medication Industry** discusses the importance of complementary medicine in empowering consumers to decide their own healthcare needs based on their lifestyle choices, as well as giving them the ability to take proactive preventative steps.

This edition of *Health Voices* promises to be an exciting blend of perspectives – complementary medicine is here to stay, and we need to think about its role in our health care.

It's clear from our contributors that the issues associated with complementary medicine use in Australia are far from settled.

Given the size, scale and rate of expansion of this industry in recent years, CHF believes it's time for a thorough review of what consumers need to know to make informed decisions about their use of complementary medicines.

We need to move beyond market forces and vested interests, and engage in the hard discussions and debate about what place complementary medicines could or should play in our health system.

Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia.

1 Australian National Audit Office (ANAO). (2011) *Therapeutic Goods Regulation: Complementary Medicines*. Canberra.
2 Ibid

Complementary medicines and breast cancer

Breast Cancer Network Australia

Breast Cancer Network Australia

Australian research has found that more than half of Australian women with breast cancer use complementary medicines in conjunction with their conventional cancer treatments.[1] These include vitamin and mineral supplements, herbs including Chinese and Ayurveda medicines, and homeopathic remedies.

In a 2009 survey of BCNA members, women were asked about their use of, and attitude towards, complementary medicines. While some told us they don't use or believe in complementary medicines, others said they both use and recommend to other women a variety of medicines, including vitamins, herbs and green tea. We also hear anecdotally from women about their use of complementary medicines and, from time to time, women discuss them on our Online Network.

'The magic stuff I am taking is called Blue Green Algae — organically grown Klamath Lake. I also take high doses of Selenium.' — Sue

Based on our dealings with women with breast cancer over many years, we believe that many may be unaware that complementary medicines are not tested for efficacy by the Therapeutic Goods Administration, or another independent authority, before being approved for use in Australia. It is concerning that women may be using these products in the belief that they are safe and effective when we know that, to the contrary, some complementary medicines may be harmful for women being treated for breast cancer.

Seemingly innocuous vitamin supplements such as calcium, iron and vitamin C, for example, can interfere with conventional breast cancer medications and can reduce the effectiveness of cancer treatments. Other complementary medicines, including some herbal and homeopathic remedies, can also negatively interact with conventional breast cancer treatments. St John's Wort, for instance, can reduce the effectiveness of the hormone therapy tamoxifen and some chemotherapy medicines.

BCNA believes high quality research into complementary medicines, including the interactions between some of the more widely used products and conventional breast cancer treatments, and their impact on controlling symptoms and quality of life should be undertaken as a priority.

BCNA's 2009 survey of women also found that women want to be provided with information about the safety and effectiveness of complementary medicines and how particular products may affect, or interfere with, their conventional breast cancer, and other, medications.

Women who are considering using a complementary medicine should be able to find information about the product's efficacy and effectiveness, any possible side effects and any possible interactions with other medications. This information is vital in assisting women to make an informed decision about the safety and usefulness of the medication.

It would also help women to decide whether or not a medicine is good value for money. Many women struggle with the high financial costs associated with a breast cancer diagnosis. BCNA is concerned that some women may be paying for medicines that are not benefitting them or, in worst cases, for medicines that are in fact harming them or reducing the efficacy of their conventional breast cancer treatments.

'At such an emotional time, we tend to try anything in our attempt to regain health, so more accurate information would guide us to make more informed decisions.' – Jill

The public availability of this information, for example through reliable websites such as those of the Therapeutic Goods Administration or National Prescribing Service, is particularly important as we know that people using complementary medicines are often reluctant to discuss them with their treating doctors. Research undertaken by the National Prescribing Service found that nearly half of survey respondents did not discuss their use of complementary medicines with their doctor.[2]

We know anecdotally that women with breast cancer are sometimes reluctant to discuss complementary medications with their treating doctors. This may be because they don't consider them to be medicines or because they are embarrassed or fear disapproval from the doctor. It is important that women can feel confident they have someone with whom they can discuss complementary medicines, without worrying about the response they may receive.

In BCNA's publications, including the *My Journey Kit* for women newly diagnosed with breast cancer, Hope & Hurdles for women with secondary breast cancer and the Complementary medicines page of our website, we strongly encourage women to discuss their use of complementary medicines with a member of their medical team.

In conclusion, BCNA believes more information should be made available to consumers about the safety and efficacy of complementary medicines. Consumers will then be in a much better position to make informed choices about the value of these products to them.

Breast Cancer Network Australia
www.bcna.org.au
Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We empower, inform, represent and link together people whose lives have been affected by breast cancer.
BCNA represents more than 70,000 individual members and 325 Member Groups from across Australia. We work to ensure that women diagnosed with breast cancer and their families receive the very best information, treatment, care and support possible.

1 Kremser T, Evans A, Moore A, Luxford K, Begbie S, Bensoussan A, Marigliani R, Zorbas H., *Use of complementary therapies by Australian women with breast cancer.* Breast. 2008 Aug; 17(4):387–94. Epub 2008 Jun 5.

2 National Prescribing Service *Information Use and Needs of Complementary Medicines Users Report,* December 2008

Evidence-based or Placebo effect — Does it matter if it eases the pain?

Lesley Brydon

Decades ago when I was a trainee pharmacist, valerian and belladonna were mainstream medicine. Acupuncture belonged to the Chinese and Feldenkrais was yet to emerge from Tel Aviv.

GPs wrote illegible scripts for "Tinct Valerian Ammon", for insomnia and anxiety; and "Pulv. Bismuth with Belladonna" for a stomach ulcer.

If the valerian didn't help, you got a script for phenobarbitone. There was nothing in between. Benzodiazepam and its extended family had not yet been born.

It says much for these herbal remedies that they have remained in use for centuries — with or without becoming "evidence based medicine".

The National Pain Strategy advocates the use of evidence-based, multidisciplinary treatments for managing chronic pain. However chronic pain is a complex condition that frequently resists any form of treatment. The experience of pain is highly subjective, influenced by biological, psychological and environmental factors that vary from one person to another.[1]

So it is not surprising that people with chronic pain will seek relief in different ways, frequently outside mainstream medicine, and that different therapies (or combinations of therapies) work for some people and not others.

The multidisciplinary model of managing chronic pain incorporates the use of medicines in conjunction with physical therapies and psychological strategies such as Cognitive Behavioural Therapy and Meditation.[1]

GPs and even pain specialists and rheumatologists will often prescribe complementary medicines and treatments along with prescription medications.

People with chronic musculoskeletal pain report the benefits of complementary remedies with anti-inflammatory properties such as fish oil, glucosamine, chondroitin, boswelia and various vitamin supplements, many of which are supported by clinical studies.[2]

Whilst there is limited evidence to support the use of complementary medicines for chronic pain conditions such as migraine or neuropathic pain, health professionals will frequently recommend selected treatments.

In her book *Endometriosis and Pelvic Pain* Gynaecologist and Pain Specialist Dr Susan Evans recommends magnesium for period cramps and vitex agnus castus to regulate the menstrual cycle or relieve premenstrual symptoms, through its effect on the pituitary gland[3]; and dietary changes for bowel and bladder disorders.

While many people who suffer chronic pain avoid exercise, getting the body moving is a powerful way to manage pain. There are a number of physical therapies that have proven efficacy in reducing pain symptoms.

The World Health Organisation supports the use of **acupuncture** for the treatment of neurological pain (headaches, migraines and facial neuralgia); musculoskeletal conditions (back pain, osteoarthritis, sciatica, shoulder and elbow pain) and many types of sporting injuries.

Alexander Technique (AT) is a scientifically proven method of alleviating chronic back pain[4]. AT attends to the inherent causes of loss of physical function, rather than the effects or symptoms. Patients learn to think consciously about body movements and avoid poor postural habits and neuromuscular coordination. It also helps relieve respiratory problems and asthma[5].

There is good evidence too for the Feldenkrais Method — a unique system of movement education, to assist patients understand their particular habits of thinking, feeling, sensing and acting, to improve body efficiency through increased consciousness rather than muscular strength[6].

Research shows the positive changes in biochemistry that can occur with **massage therapy**, including reduced cortisol and increased serotonin and dopamine, which can benefit patients with chronic pain, including migraine, as well as children with rheumatoid arthritis[7].

The well-known "gate-control" theory of pain developed in the 1960s by Melzack and Wall postulates that relaxation therapies including meditation and massage may be effective in "closing the gate" – that is inhibiting the transmission of noxious stimuli by stimulating the large nerve fibres that have been shown to alter pain perception.

Music and even laughter have also been shown to have a therapeutic effect[8].

Dr Damien Finness of the Pain Management Research Institute has investigated the value of the placebo effect in managing pain[9].

"Our research shows that placebo effects may occur in conjunction with any form of treatment where the mind-brain interaction works to promote the body's natural health mechanisms", says Dr Finniss.

Essentially, placebo effects change the way our brains and bodies work, complementing the effects of medical or other therapeutic treatments, often leading to a reduction in symptoms.

Dr Finniss and colleagues concluded that the placebo effect may be useful in the treatment of chronic pain, where psychosocial factors are dominant.

Dr Lisa Nissen from the School of Pharmacy at University of Queensland advocates an informed, common sense perspective to the debate about complementary therapies: "Although the evidence for most complementary medicines is limited, they may potentially benefit some people.

"So long as there is proper supervision by a trained professional to ensure there are no contra-indications and no risk of interactions with other medications the patient may be taking, then there is no harm in people taking complementary remedies."

Perhaps one of the most significant factors in managing chronic pain is the relationship between patient and practitioner and the level of collaboration that occurs between GP and other health practitioners involved in the patient's care.

"Chronic pain can be a very depressing and isolating experience, which impacts all areas of a person's life. Patients need to feel that their pain is taken seriously. They respond more positively to a practitioner who listens to them, is patient, and expresses understanding and empathy for their problem," says naturopath Amanda O'Brien.

In summary, the best practice management of chronic pain involves a multidisciplinary team approach using evidence-based treatments, which may include complementary therapies and medicines.

The challenge ahead is to incorporate this knowledge into health policies and funding models, so that where possible they may be used to pre-empt more expensive medical and surgical treatment options.

Lesley Brydon is CEO of Pain Australia. http://www.painaustralia.org.au/ Painaustralia is a national not-for-profit body established to improve the treatment and management of pain in Australia.

Painaustralia was formed in February 2011 to facilitate implementation of the National Pain Strategy (NPS), which was developed by more than 200 delegates at the Pain Summit held at Parliament House, Canberra, in March 2010.

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Making informed choices about complementary medicines

Dr Lynn Weekes

Supermarket, health food store and pharmacy shelves are packed with an array of natural, herbal and alternative medicines. So they must be safe, right?

Not necessarily. Complementary medicines like herbal supplements and vitamins are often considered less powerful than prescription medicines, but can still cause side effects in some people, and may interact with other medicines and food.

No medicine, even natural and herbal medicines, is completely free of side effects.

Complementary or natural medicines should be given the same consideration as other medicines, despite the fact that information about them can often be harder to find.

An NPS survey[1] of 1500 people in 2012 found 48% of respondents did not tell their doctor or pharmacist about other medicines they were taking the last time they received or purchased a medicine.

One reason for this could be that people are not always aware that a complementary medicine is a medicine too. Of those surveyed, less than half considered certain vitamins and herbs to be medicines: multivitamins (23% considered it to be a medicine), echinacea (24%), and fish oil (32%). Awareness of Chinese herbal remedies as medicines was slightly higher at 41%.

Our findings also showed that complementary medicines were used by 46.3% of participants, representing just over half (53.2%) of all medicines users, 87.4% of whom used both conventional and complementary medicines. Women used more complementary medicines in the previous 24 hours than did men.

People may think that some doctors disapprove of complementary medicines, but this is not always the case. Health professionals know that many people use complementary therapies, and even if they are not convinced that all of them are effective, they will appreciate knowing about any you are taking. In order to treat the patient in the best way they can, a health professional needs to know about all the medicines a patient uses, especially if there could be an interaction between a person's medicines — including the complementary medicines.

When it comes to taking any complementary medicine — whether it's a herb, vitamin or mineral, nutritional

supplement, aromatherapy product, homoeopathic or traditional Chinese medicine — it's important to do some research on the benefits and risks first.

This is definitely not as easy as finding information about prescription and over the counter medications which undergo scientific testing and have lots of publicly available information. Complementary medicines are generally subjected to less testing and information is harder to find. There are some ways, however, to get the information you need.

Firstly you can ask your health professional.

You can also read the label and any supporting product information, but you'll probably find this is not particularly detailed.

Lastly, there are thousands of websites that provide information about complementary medicines. The difficulty with most is they are designed to sell products so you may only get information that increases their appeal. A limited number of sites provide both sides of the story, so look for websites that appear to present information in an unbiased way. Some of these include:

- Medline Plus herbs and supplements (www.nlm.nih.gov/medlineplus/druginfo/herb_All.html)
- myDR (www.mydr.com.au)
- US National Center for Complementary and Alternative Medicine (www.nccam.nih.gov)
- HealthInsite (www.healthinsite.gov.au)

Having found your information, you need to assess if it answers the following five questions. These are also suitable questions to ask your doctor, pharmacist, or other qualified health care provider to help you and your family use complementary medicines safely and effectively.

1. Is a medicine needed?

Medicines are not always the best way to treat or prevent a condition or illness. Sometimes other approaches may be more helpful.

For example, vitamin C has not been proven to prevent or reliably treat a cold, and its effect on colds has not been studied in children. Resting at home is likely to help you or your child's immune system fight the cold virus and prevent its spread to others.

Your doctor or other health professional can advise on non-medicine options for you or your family.

2. How effective is the medicine for me or my family's situation?

No medicine is a universal cure, so you need to find out how likely it is the medicine will work for you or your family.

Take fish oil supplements for example. Hundreds of studies have been conducted to determine their effectiveness in treating or preventing a variety of conditions, including some that can affect children such as attention deficit hyperactivity disorder (ADHD). But most have come back inconclusive other than for people with high triglyceride levels in their blood, heart disease or rheumatoid arthritis.

3. What are the possible side effects?

Although complementary medicines generally cause fewer side effects than prescription medicines, no medicine, however 'natural' it is, is completely free of side effects.

For example valerian — a herb sometimes used for sleep problems and anxiety — can cause headaches, excitability and vivid dreams. Echinacea — sometimes used to ward off infections and reduce the duration of colds — may worsen asthma.

4. Will it interact with other medicines or foods?

Like all medicines, complementary medicines may interact with other medicines and foods, sometimes with potentially harmful effects.

St John's wort is found in many complementary medicine products used to alleviate depression. It can interact with several commonly used prescription medicines to reduce how well they work, including oral contraceptive pills, chemotherapy and epilepsy medicines. St John's wort can also interact with some other antidepressant medicines to increase the likelihood of side effects.

5. What is the right dose for me or my family?

You need to take enough of a medicine for it to be effective. However, you don't want to take any more than you need, because doing so increases your likelihood of developing side effects, not to mention a potential waste of your money.

As with other medicines, the right dose may depend on whether the complementary medicine is for you or your child and the condition for which it is being used. Follow the recommendations given by your doctor, pharmacist or other qualified health care provider, or as provided on the medicine label or packaging — and don't be tempted to take or give more the recommended dose.

Dr Lynn Weekes is CEO of NPS: Medicinewise

Established in 1998, NPS Medicinewise enables people to make better decisions about medicines and medical tests, leading to better health and economic outcomes.

NPS Medicinewise helps health professionals keep up to date with the latest evidence and provide individuals with the tools and knowledge to make better decisions.

1 Morgan TK, Williamson M, Pirotta M, Stewart K, Myers SP & Barnes J. A national census of medicines use: a 24-hour snapshot of Australians aged 50 years and older, MJA 2012; 196 (1): 50–53)

The evidence for complementary medicines

Dr Ken Harvey

The vast majority of complementary medicines are classified by the Therapeutic Goods Administration (TGA) as listed medicines (labelled AUST L). Consumers need to be aware of the limitations of an AUST L label. Unlike registered medicines (labelled AUST R) there is no pre-market assessment of listed products. Sponsors self-certify that the ingredients are picked from a TGA approved list; that the products are manufactured in accord with good manufacturing practice (GMP) and they hold evidence supporting the claims made. Only limited post-marketing reviews are performed by the TGA.

The strength of the listing system is that consumers have some assurance of product quality and protection from unsafe ingredients. It also provides sponsors with rapid market entry at minimal cost. The weakness of the system is that many sponsors exploit the trust-based system. For example, a 2009–10 TGA post-marketing review found as many as 90 per cent of complementary medicines non-compliant with regulatory requirements[1]. The large number of upheld complaints about the promotion of complementary medicines by the Therapeutic Goods Advertising Complaint Resolution Committee provides further evidence of problems[2].

The lack of timely and significant penalties for breaches of the Therapeutic Goods Act and the Therapeutic Goods Advertising Code also encourages regulatory non-compliance. In response to consumer and health professional concerns the TGA has embarked on a 4-year program of regulatory reform[3]. It remains to be seen whether these measures will clean up the complementary medicines industry. Meanwhile, what can consumers do?

A survey by the NPS showed that the three most common sources of complementary medicines information for consumers were family and friends, the Internet and health food shop workers.[4] These information sources are of variable quality, reliability and authority.

For example a friend might say, "It worked for me" and product web sites often contain glowing testimonials. But the plural of anecdote is not evidence. There are a number of reasons why consumers (and practitioners) convince themselves that a treatment is effective when it is not. These include the natural history of disease, the placebo effect, confirmation bias (seeing what you expect to see) and cognitive dissonance (ignoring results not in accord with expectations). Endorsement of products by "celebrities" who receive multi-million payments should raise even more suspicion.[5]

In short, personal evaluation of efficacy is quick, convincing and often wrong, while double-blind, placebo-controlled clinical trials are slow, complex, and costly. However, the latter are important as they often show that initially promising results are not replicated by larger and better conducted studies.[6]

Another common claim implying benefit is that it's a "traditional medicine" with a long history of use. Traditional use has revealed many useful herbal products such as Artemisia annua for the treatment of malaria and St John's Wort for the management of mild to moderate depression. But traditional therapies have also proved to be harmful; the bloodletting that was routinely performed for centuries by the medical profession is a classic example. When clinical trials were conducted, bloodletting was shown to kill patients, not cure them. Scientific study is required. The TGA points out that claims based solely on a tradition of use should not imply efficacy.[7]

"Natural" is another advertising claim that implies that these medicines are safer (and healthier) than prescription products produced by Big Pharma. While it's true that complementary medicines are relatively low risk products, low risk does not mean no risk. For example, Echinacea can cause allergic reactions, Black cohosh has been associated with rare cases of liver failure requiring liver transplantation and St John's Wort interacts with a wide range of conventional drugs including oral contraceptives.[8] Recognition of such problems can be difficult because many patients do not tell their doctors that they are taking complementary medicines and doctors often don't ask. In addition, ineffective complementary medicines have a significant adverse effect on consumer's purses (or hip pockets) and, more importantly, they can delay or prevent the use of more evidence-based therapy.

Another problem is that herbal products consist of a complex mix of chemical ingredients. Just as all red wine is not Grange Hermitage, different products containing the same herb are not necessarily chemically or therapeutically equivalent. Variability can be caused by the use of different species or sub-species, growth conditions, methods of cultivation, the time of year and stage of growth cycle harvested, extraction methods, and formulation and storage of the finished product. Even glucosamine (used for arthritis) is available as several salts, in many different formulations and with varied evidence of efficacy from clinical trials.[9]

Unlike generic versions of prescription drugs, the TGA does not require evidence of therapeutic equivalence with proven complementary products. As a result, there is no certainty that all formulations of a generic complementary medicine, for example St John's Wort, are efficacious. Because

of this, some complementary therapists sell particular "practitioner only" products that they believe are more likely to be efficacious. However, this practice produces a clear conflict of interest and these practitioners should be asked for the evidence justifying the product they sell.

In summary, if contemplating purchasing an evidence-based complementary medicine:

1. Ask a qualified, registered health practitioner for advice, especially concerning:
   1.1. Evidence of efficacy from well conducted clinical trials concerning the specific product recommended;
   1.2. Possible side-effects and potential interactions with your existing therapy.
2. Search the Therapeutic Goods Advertising Complaint Resolution Panel (TGACRP) web site to see if complaints about a product's claims have been upheld: http://www.tgacrp.com.au/index.cfm?pageID=13
3. The National Prescribing Service (NPS) has useful information for consumers on complementary medicines as well as over-the-counter and prescription medicines: http://www.nps.org.au/.
4. The web site of the U.S. National Center for Complementary and Alternative Medicine (NCCAM), also has a lot of useful information: http://nccam.nih.gov/
5. Keep your knowledge up-to-date; many clinical trials are under way and the evidence keeps changing.
6. Finally, and most importantly, always tell your GP and other health professionals about all the medicines you are taking including complementary medicines.

Dr Ken Harvey is an Adjunct Associate Professor, School of Public Health, La Trobe University and is a member of the TGA Working Group on Regulatory Reform of Complementary Medicines.

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Regulating unregistered health practitioners —NSW experience

Kieran Pehm

NSW is currently the only State that formally regulates 'unregistered health practitioners'.

The regulation system

An unregistered practitioner is any health practitioner, who is not required to be registered under the *Health Practitioner Regulation National Law* (NSW), or who might be registered but provides services that are unrelated to their registration. This includes practitioners such as naturopaths, hypnotherapists, herbalists, massage therapists or psychotherapists.

In August 2008, a Code of Conduct for unregistered health practitioners came into effect. Professional associations in the area of complementary medicine were involved in the development of the code and have been supportive of its implementation.

The intention of the code is to set out the minimum practice and ethical standards with which unregistered health service providers are required to comply. These include the provision of health services in safe and ethical manner; having an adequate clinical basis for treatment and conducting themselves in a professional and responsible manner. There are specific prohibitions against sexual and other improper relationships with clients and against holding out as capable of curing cancer and other terminal diseases.

The code also informs consumers what they can expect from practitioners and how they can make a complaint if they believe the practitioner has breached the Code.

The NSW Health Care Complaints Commission has been given the power to deal with and investigate complaints about breaches of the Code of Conduct.

The Commission's powers

The Commission is an independent body that deals with complaints about health service providers in NSW, including unregistered practitioners.

Every complaint the Commission receives will be assessed. The aim of the assessment is to establish 1) whether there is evidence for a breach of the code, and 2) whether the practitioner poses a risk to public health or safety. If so, the Commission will investigate the complaint. If the investigation finds the complaint substantiated, the Commission can take action against unregistered health practitioners, including issuing a prohibition order and/or making a public statement.

It is an offence for an unregistered health service provider to continue to provide a health service in breach of a prohibition order.

Disciplinary actions available after investigation

The Commission has several options to deal with complaints about unregistered practitioners.

It may terminate the investigation and take no further action, where the evidence shows that there was no breach of the Code of Conduct.

Where there was a breach, but the practitioner does not pose a risk to the health or safety of members of the public, the Commission may make comments to the practitioners about how they can improve their services in the future.

If the Commission finds that that the health practitioner has breached the code of conduct, and is of the opinion that the practitioner poses a risk to the health and safety of the public, it can make a prohibition order and may also make a public statement.

The Commission publishes both public statements and prohibition orders on its website, issues a media release and notifies relevant health professional bodies.

A prohibition order may place conditions on the provision of health services to protect the public from those aspects of the person's practice that are of particular concern or danger to the public while allowing the person to continue to practice in areas that do not present a risk.

A blanket prohibition order ensures that unregistered health service providers who have practiced in a highly unethical or dangerous fashion are prohibited from providing any health services to the public.

The unregistered practitioner must advise clients of a prohibition order before treating them. A breach of the order is a criminal offence.

Increasing complaints

Since the Code of Conduct was introduced, the Commission has received an increasing number of complaints. In 2007–08, before the Code was introduced, the Commission received 32 complaints about unregistered practitioners. In 2010–11, this number increased to 104.

Despite the increase, overall such complaints represent only 4.0% of all complaints the Commission received about individual health practitioners in 2010–11.

Benefits and limitations

It is important to note that the NSW scheme is a negative licensing scheme. This means that any health practitioner, regardless of their qualifications and training, may hold themselves out to the public. It is only after investigation of a complaint that the Commission can take disciplinary action against an unregistered practitioner. The system depends on a client making a complaint, and is always reactive rather than proactive.

On the other hand, a negative licensing scheme is cost effective, as only breaches of the standards are being enforced. Also, tasking a professional complaint handling body to deal with all such complaints ensures that the complaint handling is not only cost effective, but also that standards are interpreted in a consistent manner and action taken in similar cases are comparable.

It does mean, however, that consumers need to play a very active part when considering health services from an unregistered practitioner as there is no statutory scheme of registration to ensure the quality of practice. Consumers should take care to gather information about whether the practitioner has the relevant and sufficient skills, knowledge and qualification to provide a health service. It may be helpful to see whether they are a member of an relevant professional association, which uphold certain professional standards among their members.

Outlook

The area of complementary or alternative health practice has experienced a trend towards voluntary setting of standards by professional associations. Ultimately, this may lead to more of the currently unregistered health professions becoming part of the National Registration Scheme for Health Practitioners.

As of July 2012, practitioners in traditional Chinese medicine, as well as sonographers and radiographers have become formally registered professions, bringing their regulation in line with other health professions, such as medical practitioners, dentists, nurses and midwives.

A registration scheme not only has the advantage of ensuring minimum standards regarding qualifications, skills and knowledge of practitioners, but also offers a broader range of pathways in dealing with complaints about practitioners. For example, issues of impairment or performance that do not pose a substantial risk to the health or safety of the public, may still be addressed and monitored through programs run by the registration authority.

More information

For more information about the Commission, please visit the website www.hccc.nsw.gov.au, or contact the Commission on (02) 9219 7444.

Mr Kieran Pehm is Commissioner, Health Care Complaints Commission, New South Wales Government.

The HCCC NSW acts to protect public health and safety by dealing with complaints about health service providers in NSW.

The Commission is an independent body that was established under the Health Care Complaints Act 1993.

NSW Public Health Regulation 2012, Schedule 3
NSW Health Care Complaints Act

CASE STUDY

Dangerous hair growth medication

The Commission investigated a self proclaimed hair regrowth specialist who possessed no formal health care qualifications, and who unlawfully possessed and supplied medication to his clients.

A number of clients of the Institute of Hair Regrowth and Beauty complained to the Commission that they suffered adverse side effects when taking medication for hair growth. The medication was supplied by Mr Sam Cohen, the owner and operator of the Institute. The medication is not approved by the Therapeutic Goods Administration for hair regrowth.

The complainants also received prescription-only medication directly from Mr Cohen.

The Commission identified a potential risk to public health and safety. The Commission started to formally investigate both Mr Cohen and the pharmacist who provided him with prescription medication.

As part of the investigation, the Commission in a joint operation with NSW Police executed a search warrant at the Institute's premises. A large amount of prescription only medication was found, as well as a significant number of prescriptions.

As Mr Cohen possessed these medications unlawfully, the Commission issued an interim prohibition order for a period of eight weeks which banned him from possessing and supplying any medication or prescriptions.

The Commission then executed a second search warrant at a pharmacy where documentation and prescriptions were found which confirmed a business relationship between the pharmacy and Mr Cohen.

Parallel to the Commission's investigation, the NSW Department of Health issued a public health warning providing advice on contraindications and risks of taking such medication for hair regrowth purposes.

After an extensive investigation, the Commission found that Mr Cohen had breached the Code of Conduct for unregistered practitioners by failing to provide health services in a safe and ethical manner.

The Commission issued a permanent prohibition order banning Mr Cohen and the Institute of Hair Regrowth and Beauty from possessing any client prescriptions and from obtaining, supplying or selling any medications. A public statement was also issued and is available on the Commission's website.

Building greater trust in our therapeutic controls

Catherine King, Parliamentary Secretary for Health and Ageing

The Therapeutic Goods Administration (TGA) is currently in the midst of great change in particular to enhance its ability to meet the growing expectations of the Australian community. As Parliamentary Secretary for Health and Ageing with responsibility for the TGA I would like to update CHF readers on the changes and what they mean for our community.

In my last contribution to CHF *Health Voices* I spoke of what we wanted to achieve at the TGA. One of these aspirations was to improve TGA's ability to communicate with the community about the role they play.

In December 2011, I was pleased to announce the Gillard Government's plan to reform the TGA to enable it to better meet the expectations of the community and industry. These reforms were informed by several important reviews of the TGA regulatory system.

A blueprint for TGA's future

The Government's vision for the TGA is outlined in *TGA reforms: a blueprint for TGA's future*. These reforms will improve the Australian community's understanding of the TGA's regulatory processes and decisions. By improving transparency, the TGA will build public trust in the safety and quality of the therapeutic goods available on the Australian market.

Therapeutic goods cover a wide range of products from prescription medicines, over-the counter medicines such as cold and flu tablets, and complementary medicines to medical devices. The reforms outlined in the blueprint relate to all these products.

Implementation will be in stages, with the TGA working closely with consumers, health professionals and industry to ensure the new regulatory

arrangements meet the needs of the community and industry. The TGA has released a detailed plan that shows how and when implementation will happen. The three-phase plan includes clear and achievable milestones up to its completion date of December 2015. The TGA will report on progress every six months, further demonstrating our commitment to enhancing its transparency.

A key recommendation of the Transparency Review was the establishment of an Australian Therapeutic Goods Advisory Council. This Council will provide broad advice to the TGA, with an emphasis on improving communications between the regulator and its three main stakeholder groups—consumers, health professionals and industry.

The new Council will be chaired by Australia's Chief Medical Officer, Professor Chris Baggoley.

As I have mentioned, the blueprint included recommendations about reforms to the regulation of complementary medicines. This work is the subject of the TGA's National Manager, Dr John Skerrit's article elsewhere in this edition of *Health Voices*.

The Transparency Review also recommended the TGA to make its adverse events database available to, and searchable by, the public in a manner that supports the safe and quality use of therapeutic goods.

I was delighted to be able to launch this online database on 1 August this year. It is now possible for everyone—consumers, health professionals and industry—to access online information about adverse events that have been reported to the TGA since 1971.

The Database of Adverse Event Notifications

The newly released database—the Database of Adverse Event Notifications (DAEN)—includes adverse event reports about prescription medicines, over-the-counter medicines sold in pharmacies and supermarkets, as well as complementary medicines such as vitamins and herbal remedies.

The term 'adverse events' has been used instead of 'side effects' because these terms describe different things. 'Adverse events' are unwanted and sometimes harmful outcomes, which may or may not be related to a medicine, where as 'side effects' are known unintended effects of a medicine or treatment (these are usually outlined in the Consumer Medicines Information contained in your medicine).

The Database currently contains around 251,000 reports of adverse events. These reports were made by consumers, health professionals and the pharmaceutical industry. This database is a great new resource provided by the TGA to make the work of the regulator more transparent and accessible to the community and to industry.

The database is searchable by the name of the medicine to see commonly reported adverse events and chronological lists of reports. It is important to know that patients cannot be identified in this listing.

It is important to understand that the information in the database, by itself, **cannot** be used to evaluate whether a medicine is safe or not. The database is **not a substitute for professional medical advice**, and should not influence a decision to stop taking a medicine. The purpose of the database is to give consumers additional information that they can discuss with their healthcare professional should they have any concerns.

When looking at the database, the number of reports cannot be used to compare the safety of two medicines. For two medicines of the same kind, the medicine used more commonly is more likely to have higher incidences of adverse event reports. As the TGA does not record how many people have taken a particular medication, the number of reports does not reflect the likelihood of an adverse event occurring.

It is also important to realise that medicines are taken by people in varying states of health. Very sick people often take lots of medicines. The adverse events reported may be related to the medicines taken, or to the illnesses suffered, or be coincidental. Just because an adverse event is recorded in the database does not mean that it is definitely related to a particular medicine.

Before taking medicines all consumers should read the Consumer Medicines Information (CMI) that comes with the prescription or pharmacist-only medicines. The CMI contains information about known side effects, as well as information on the safe and effective use of a medicine. This information can also be accessed at http://www.tga.gov.au/consumers/information-medicines-cmi.htm

Adverse event reporting

To ensure that the database remains effective it is very important that consumers and health practitioners tell the TGA about any adverse events. Current research indicates only one in fifteen adverse events are being reported. This is why I strongly encourage people to report any adverse events experiences – even if they are unsure – to the TGA or their treating health professional.

Remember this can be for prescription, over-the-counter and complementary medicines. Adverse events relating to medical devices should also be reported to the TGA. It is expected that these will eventually be included in the database.

I hope that the new database will raise awareness among both consumers and health practitioners of the importance of reporting. It would be great to see an increase in the number of reports to TGA by next year. The higher number of reports will make the picture of types and number of adverse events more complete, allowing the TGA to keep consumers and health professionals better informed.

When an adverse event is reported it is considered by experts at the TGA. These experts will then determine if any action is needed to ensure the safety of consumers.

We can all play a role in helping the TGA continue to protect health and safety, through regulation of therapeutic goods in Australia. I look forward to providing an update in 12 months to show how much further we have come in our commitment to increasing transparency and awareness of the TGA's role in Australia.

Ms King was elected to Federal Parliament in November 2001 as the Member for Ballarat and is currently Parliamentary Secretary for Health and Ageing.

Australian Government reviews private health insurance rebate for natural therapies

Professor Chris Baggoley

As part of the Australian Government's commitment to foster and promote evidence-based medicine and treatments, I have been asked to chair a review of the Government Rebate on private health insurance for natural therapies.

The Review process began on 1 July 2012 and is being managed by the Department of Health and Ageing. I am to chair the purpose formed 'Natural Therapy Review Advisory Committee'. The Committee will comprise members with expertise in evidence, drawn from the fields of natural therapy, the registered professions, consumers and health insurance. The NHMRC will play an important role in the process.

The Review will undertake examination of those natural therapies which, through their inclusion in private health insurance general treatment products, attract taxpayer subsidy via the government PHI rebate.

The rebate assists with the cost of private health insurance for low and middle income earners who hold a complying health insurance policy. The level of rebate received is dependent on the age and income level of recipients. The majority of recipients receive the rebate as a 30 per cent premium reduction. The benefits paid for natural therapies currently amount to approximately 0.8% of the total benefits that are paid under private health insurance. For 2010–11, natural therapies attracted around $87 million in benefits, equating to about $27 million in subsidy from the rebate. Nearly all private health insurers offer natural therapies under their general treatment policies.

As part of the Review, consultations will occur with service providers, consumers, professional bodies and private health insurers to clarify the levels of evidence available in support of claims for the clinical effectiveness of natural therapy treatments. There will be a comprehensive literature review outlining the evidence available for the clinical effectiveness and safety of the investigated therapies, which will be considered by the Advisory Committee.

Based on the eventual findings of the Review, decisions will be made to ensure that only natural therapies identified as clinically effective and safe will remain eligible for coverage by private health insurers as part of health insurance policies that attract the rebate. As announced in the 2012–13 Budget, the rebate changes are expected to be implemented from 1 January 2014. From that date, the Australian Government will introduce, through regulation, a list of natural therapies that will continue to receive the rebate.

Natural therapies investigated by the Review will include, for example, treatments such as aromatherapy, remedial massage, homeopathy, iridology, kinesiology, reiki and rolfing.

Services that can be subsidised under Medicare and health professionals regulated under the National Registration and Accreditation Scheme will not be affected by the measure. These include acupuncture, audiology, Chinese medicine, chiropractic, dental, diabetes education, dietetics, exercise physiology, occupational therapy, osteopathy, physiotherapy, podiatry, psychology, services provided by Aboriginal health workers, speech pathology, medical, nursing including mental health and midwifery services, and optical.

Consumers will still be able to purchase natural therapy products, but private health insurers will only be able to pay benefits for those natural therapies found by the Review to be clinically effective and safe.

All Australians will benefit from this measure. Taxpayers are currently subsidising services and treatments without evidence that they are effective. Removing the rebate for 'natural therapies' not underpinned by a robust evidence base will be a win for taxpayers and the health sector alike. Consumers will benefit from the reassurance they gain from knowing that the natural therapies services they purchase through private health insurance have a proven and credible evidence base.

Regularly updated information about the Review is available on the Department's website at: http://www.health.gov.au/internet/main/publishing.nsf/Content/CurrentIssues

Professor Chris Baggoley is Chief Medical Officer for the Australian Government and is the principal medical adviser to the Minister and the Department of Health and Ageing.

Prior to his appointment Professor Baggoley was the Chief Executive of the Australian Commission on Safety and Quality in Health Care. He was a former Chief Medical Officer and Executive Director with the South Australian Department of Health, amongst a range of senior appointments.

Strengthening the evidence requirements for listed complementary medicines

John Skerritt and Trisha Garrett, Therapeutic Goods Administration.

Complementary medicines –a growth industry

Some two-thirds of all Australians use complementary medicines. Market growth has been estimated at between three and twelve percent a year and the Australian industry is valued at $1.5 – 2.5 billion per annum. There are currently about 10,000 complementary medicines are on the ARTG.

Why does TGA regulate complementary medicines?

In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are referred to as 'complementary medicines'. Complementary medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines. Any complementary medicine product for which therapeutic claims are made must be listed or, registered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia.

The TGA regulates complementary medicines to ensure quality, safety and that indications and claims on product labels are evidence-based. While the majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, many are indicated for maintaining health and well being, or the promotion or enhancement of health. Commensurate with their low risk, the majority of complementary medicines have been listed on the ARTG via a streamlined, automated process.

There is increased public scrutiny of the efficacy of complementary medicines with calls for increased rigour of evidence requirements to support therapeutic indications made for these medicines. At the same time, TGA recognises that the regulatory burden on sponsors should be commensurate with the low risk profile of listed medicines.

TGA reforms: A blueprint for TGA's future

The 'Blueprint' was released by Parliamentary Secretary Catherine King in December 2011 and an implementation plan published in July 2012. It details a package of reforms in response to recent reviews, including those that examined the regulation of complementary medicines.

An essential element of a regulatory program is the "guidance" given to industry and sponsors intending to list or register a medicine on the ARTG. The guidance document allows them to understand what is required of them and the consequences of not meeting those requirements. It lessens the risk of non-compliant products reaching the marketplace where consumers bear the risks of that non-compliance. The Auditor General's report on complementary medicines regulation called for the TGA to complete and publish updated key guidance materials – and we are well underway in doing so.

Evidence requirements

The Act requires that at the time of listing, sponsors must certify that they hold information or evidence to support any claim that the applicant makes relating to the medicine. However, the type and level of evidence required is not currently specified in the law. This means that sponsors may base their certification on whatever evidence they believe is appropriate. From the information collected in post-listing compliance reviews conducted in 2009–10, 57% (or 89) of the listed complementary medicines reviewed for evidence failed to meet evidence requirements.

The Evidence Requirements document provides sponsors with information on regulatory requirements including guidance on evidence they are required to hold to support indications made for listed complementary medicines. To provide for greater consistency and to enable enforcement it is intended that evidence requirements be embedded in the regulations.

In April 2012, the TGA opened a consultation seeking submissions on the first draft of the Evidence Requirements. A summary of issues identified from the submissions and the TGA's response was published on the TGA website. A revised version of the Evidence Requirements incorporating many issues raised by stakeholders was released in August for further consultation and to inform the Regulatory Impact Statement required before requirements can be potentially embedded in the regulations. An implementation plan with transitional arrangements for sponsors to meet the requirements will form part of this process. The first part of the revised document outlines evidence requirements for sponsors of listed medicines, and the second provides additional guidance regarding how these requirements may be achieved.

It is proposed that listable indications should be described as a nominated effect on a target biological process or clinical condition. To support this two alternative approaches may be taken. The first is to propose scientific indications that are efficacy-based, and proven through clinical trials or broader clinical experience and described in the refereed literature. For the cited study to be relevant, it will need to demonstrate equivalence in therapeutic use, doses and route of administration and similarly characterised active ingredients with a comparable method of preparation. The second approach, use of traditional indications, relate to a tradition of use in a particular paradigm. Claims cannot be made that imply efficacy, reference specific pharmacological effects or relate to serious health conditions. Evidence provided also needs to be directly relevant to the target population, traditional health benefit and traditional context.

Supporting the changes are proposed improvements in the integrity of the listing system through use of coded indications to limit use of inappropriate claims on the ARTG. Currently, TGA is working with an industry and consumer working group to agree the list of indications before wider consultation leading to anticipated amendments to legislation.

The revised approach provides increased flexibility whilst ensuring that the review of evidence is performed appropriately.

Continuing strong stakeholder engagement

Improvements in compliance with evidence requirements are an important component of improving public confidence in listed complementary medicines. However, the TGA recognises that in order to improve compliance a multi-faceted approach is required and other elements of the reform agenda, including increasing the transparency and effectiveness of post-market compliance reviews and implementing enhanced processes for investigating advertising breaches for complementary medicines will progress over the next year.

Critically, the TGA will continue to improve its focus on communication and education — especially with consumers.

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and through administering the Therapeutic Goods Act 1989 is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products.

General practice and complementary medicines

Dr Steve Hambleton

The use and promotion of so-called complementary medicines has been a big issue for the AMA and the medical profession for some time, especially in the last decade or so as complementary medicine practitioners have in many places actively set themselves up to compete with GPs.

While complementary medicine is an issue for general practice to monitor and assess on its merits, it also requires serious consideration by consumers and regulators.

It is appropriate that complementary medicines be judged on research, evidence and efficacy, and that practitioners be qualified, registered and properly regulated.

The AMA has strong views about complementary medicine, not all negative, which I set out below.

The term 'complementary medicine' refers to both complementary medicines and therapies.

Complementary medicine includes a wide range of products and treatments with therapeutic claims that are not presently considered to be part of conventional medicine.

Complementary medicines include herbal medicines, some vitamin and mineral supplements, other nutritional supplements, homeopathic formulations, and traditional medicines such as ayurvedic medicines and traditional Chinese medicines.

Complementary therapies include acupuncture, chiropractic, osteopathy, naturopathy and meditation.

The use of complementary medicine in Australia is considerable and increasing.

The AMA recognises that evidence-based aspects of complementary medicine can be part of patient care by a medical practitioner.

However, there is limited high quality efficacy evidence regarding most complementary medicine.

'Unproven' or poorly tested complementary medicines and therapies can pose a risk to patient health, either directly through misuse or indirectly if a patient defers seeking medical advice.

Children are a vulnerable population group. Due to the complexities of diagnosing and treating illness in children, a medical practitioner should inform any diagnosis and ongoing treatment plans, including the use of complementary medicine.

Research

There are varying levels of evidence presented for complementary medicines. The least reliable is testimonial. Just because it 'works' for a high profile person does not mean it will work for you.

The most reliable is scientific research in the form of a randomised controlled trial to validate complementary medicines and therapies for efficacy, safety, and quality so that practitioners and consumers can evaluate the potential benefits and any adverse effects.

Even at this level of reliability your medical practitioner will ask: "Do the population characteristics in the study match the characteristics of the patient in front of me?"

The next test is price. Does the price justify the benefit versus the risk? In other words, is it cost effective?

Medical practitioners

Medical practitioners are trained to interpret the quality and reliability of the levels of evidence that exist for all medicines, including complementary medicines and therapies, to help you make an informed choice.

Your medical practitioners may specifically ask you whether you are considering or using complementary medicines or therapies in order to allow appropriate consideration of the potential interactions between therapies in the management of your medical treatment.

Consumers

The AMA believes that consumers should also have access to accurate information and education about the level of evidence for complementary medicines and therapies in order to make well-informed choices.

This should include the risks and opportunity costs of delaying conventional treatment.

It is the AMA view that consumer information and education should stress the importance of continuing to consult your medical practitioners in relation to medical conditions and health concerns.

It is important that patients inform their medical practitioner about any complementary medicines or therapies they are using, as there are quite a few known adverse interactions.

Regulation

The majority of complementary medicines do not meet the same standards of safety, quality and efficacy as mainstream medicines because they are not as rigorously tested.

The AMA believes it is essential that there be clear and true statements—including accurate labelling — regarding the standards of evidence relied upon when complementary medicines make health claims.

Accordingly, Government agencies such as the Therapeutic Goods Administration (TGA) and educational bodies such as the National Prescribing Service should ensure information on the safety, quality, efficacy and cost effectiveness of complementary medicines is readily available to consumers, medical practitioners and complementary practitioners.

Consumers and all health practitioners should also ensure that they promptly report any adverse events they suspect are caused by a complementary medicine to the TGA.

The TGA should then collate and make available the information about adverse events in order to improve the information that is reaching patients about the potential risks.

There should also be appropriate regulation of complementary medicine practitioners and their activities.

These regulations should ensure that complementary medicine practitioners cannot claim expertise beyond their scope of practice.

The AMA believes that non-registered health and complementary medicine practitioners should be required by law to observe a code of practice, including that they must not provide care that is outside their experience or training.

There should be sufficient sanctions for breaching the code, such as a ban on practice.

There should be a national public register of non-registered health and complementary medicine practitioners who are the subject of a banning order in their State or Territory.

The AMA also has concerns that the use of titles such as Doctor or Dr, without qualification, by non-medical health practitioners carries the significant risk that members of the public will believe they are consulting a medical practitioner when they are not.

Regulation of advertising

The AMA has also made its position on advertising clear to the Government in the light of some of the direct-to-consumer advertising that we have observed.

We believe that direct-to-consumer advertising must not:

- exploit patients' vulnerability or lack of medical or health-related knowledge;
- attempt to induce unjustified fear or concern in patients/consumers regarding their own health in order to increase demand for the advertiser's products or services;
- encourage inappropriate self-diagnosis or treatment or in any way discourage patients from seeking the advice of their medical practitioner;
- attempt to promote an unreasonable expectation as to the applicability or efficacy of the advertised product or service;
- create inappropriate use of the goods or services;
- make unsubstantiated claims; or
- be false, misleading, or deceptive.

When complementary becomes conventional

Many of the medicines that we use today have come about when the scientific method was applied to a 'complementary' product.

A great example is Artemisinin, which is a Chinese herb effective against malaria. The scientific method applied to this has led to the purification of one of the world's most important anti-malarial pharmaceutical products.

The AMA does have an open mind on the use of complementary medicines or therapies, but cautions that extra vigilance is required to assess the level and quality of evidence, both positive and negative that exist, before consumers choose to use them.

Dr Steve Hambleton is President of the Australian Medical Association.

The place of complementary medicines in community pharmacy: Ethics and Responsibilities

Stephen Marty

The Australian regulatory regime for approval of medicines is a bit like the curate's egg – good in parts. The good part is the process for registering all prescription medicines and conventional non-prescription medicines. Medicines that have undergone this process will have been individually evaluated (except for some older products) and the label will show the symbol "AUST R" followed by the number in the Australian Register of Therapeutic Goods (ARTG). Less satisfactory is the part of the regime that allows many products to be sold in Australia without having been individually evaluated. It applies to most vitamin, mineral and herbal substances, as well as some miscellaneous items such as shark cartilage, amino acids and glucosamine. This part of the regime is called Listing and products so sold are recognised by the symbol "AUST L" on the label followed by the ARTG number. The public cannot be expected to know the meaning of "AUST R" and "AUST L" and a way needs to be found to educate them accordingly. One suggestion is the addition of a disclaimer that would say words to the effect that "this product has not been evaluated by Australian health authorities". At least that statement might stimulate consumers to ask questions or do their own research. Not surprisingly, a statement of this kind is unlikely to be welcomed by manufacturers. While the statement is, of itself, true, it could suggest that the product is somehow suspect even though it might be quite respectable.

There are vitamin and mineral products on the market which contain doses of essential vitamins and minerals that function purely as supplements to the diet. But what about those vitamin and mineral products which also contain multiple herbal substances? It would be an Olympian exercise to conduct a clinical trial to show which ingredients or a combination of them each contributes meaningfully to an improved therapeutic outcome. And at what doses and how are the improvements measured?

Claims purporting to relieve symptoms or the underlying pathology of serious conditions such as memory loss, or vague allusions to heart health should be viewed sceptically. And even if studies are available, how robust are they both statistically and clinically? Stringing together a number of scientific observations and isolated biochemical facts to produce a good looking theory does not necessarily mean that a clinical benefit will follow. Among the worst offenders are products purporting to help in weight loss.[1] Some AUST L products have good data to support their efficacy; a prime example being sunscreens. There are others which have evidence to support their use, even if that evidence is equivocal. An example is glucosamine. [2,3] But should a person be denied access to glucosamine if he or she finds conventional anti-inflammatory drugs produce unwanted gastrointestinal effects, are contraindicated or perhaps interact with other medicines? Fish oils are also AUST L and here too, recent literature seems to be hedging its bets.[4] Thus, we find within the AUST L classification another curate's egg made up of "good" and "bad" and all points in between. In other words, for AUST R medicines, the Government is the main gatekeeper. It has done the work for us. For AUST L products, the Government is only a partial gatekeeper having been satisfied that the products are safe and are made under acceptable conditions of manufacture. It is therefore incumbent on pharmacists and other health professionals to also act as gatekeepers, especially in regard to claims for efficacy.

Listed medicines may be purchased from pharmacies, supermarkets or health food shops. In supermarkets, customers are on their own, while in health food shops they are likely to be advised by someone without any scientific training. In the case of pharmacies, there is a pharmacist present who has the scientific tools to be able to distinguish between fact and wishful thinking but he or she is also dependent on sales revenue to run the business. There is thus a tension between the two, especially at a time when many pharmacies are going into receivership in the face of lower profit margins under the Pharmaceutical Benefits Scheme and higher operating costs.

The Pharmaceutical Society of Australia's Code of Ethics states, in part:

1. **A pharmacist recognises the health and wellbeing of the consumer as their first priority.** A pharmacist will utilise expert knowledge....
2. **A pharmacist pays due respect for the autonomy and rights of consumers and encourages consumers to actively participate in decision-making.**

Thus, Article 1 makes clear that pharmacists, irrespective of their financial circumstances, must "utilise expert knowledge". Ideally, that knowledge is gained by reference to peer-reviewed publications. However, the perfect clinical trial has yet to be reported and even respected authorities may disagree. A lack of evidence does not automatically mean that there is a lack of efficacy. The appropriate clinical trials might not have been conducted.

A pharmacist should make a reasonable judgement on whether an AUST L product should be supplied, be it on the pharmacist's own motion or in response to a person seeking advice. What is important is that pharmacists

keep abreast of the current science and communicate the pros and the cons of complementary medicines to a person seeking the advice, which may include a comment that scientific studies are either absent or poor. What pharmacists need to do is carefully consider their ranges of AUST L products and exclude those whose therapeutic claims are exaggerated, unfounded or just absurd and those whose formulations are irrational. The public would also be assisted if there were a sign near the shelves where complementary medicines are stored informing them of the deficiency of the AUST R regime together with an invitation to ask for advice.

Stephen Marty is Chair of the Pharmacy Board of Australia.

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Complementary medicines and self medication

Dr Deon Schoombie

It is almost impossible to overstate the significance of complementary medicines to Australia's health landscape.

Millions of Australians have embraced complementary medicines as a way of treating short term ailments, managing chronic conditions, or just staying healthy.

In particular, the place of complementary medicines in the area of preventative health has helped to stimulate a widespread community desire for improved health, fitness and wellbeing.

It has been a truly landmark shift as complementary medicines have forged their rightful place in our health system.

Of course, it has not been without its hiccups.

As in any industry, there have been those who have sought to exploit the newfound appetite for a healthier lifestyle to market products that don't meet appropriate standards.

As the peak industry body representing non-prescription products, including over-the-counter (OTC) and complementary medicines, the Australian Self-Medication Industry (ASMI) has taken an active role in these developments.

As the size of the industry and its reach have grown, so too have the challenges in nurturing a sector in which consumers can have trust and confidence.

ASMI works closely with members from the complementary medicines sector and with the Therapeutic Goods Administration (TGA) to support a regulatory framework that is both commensurate to the risk posed by these medicines, and which protects consumers, and engenders trust in the products they use.

As an organisation that supports an evidence-based approach to the evaluation and regulation of medicines, we have been up-front in supporting measures that would provide consumers more information and guidance on those complementary medicines that are proven effective.

We were very pleased that the TGA recently agreed to publish on its website the full list of "Registered" (AUST R) complementary medicines – those that have been fully evaluated for quality, safety and efficacy.

This provides consumers with a clear, transparent means of seeing which products have been put to the test.

We think more could be done. Given that the vast majority of complementary medicines are not "Registered", but "Listed" (AUST L), there is scope to help consumers better understand the evidence and health claims that are made.

Put simply, all health claims made about complementary medicines should be supported with evidence.

The 2011 report of the Australian National Audit Office (ANAO) made a series of recommendations to strengthen regulation of complementary medicines, including increased post-market surveillance, together with penalties and sanctions as deterrents against non-compliance. ASMI supports these measures.

Reform is also needed to address the lack of data protection on the evidence required to support applications for registration of complementary medicines. This will help to encourage research that will generate the evidence necessary to build confidence and rigour in the sector.

In recent months, the TGA has embarked on a number of new initiatives to both address the evidence claims that can be made for complementary medicines, and highlight the steps that will be taken to ensure compliance with the rules.

We welcome the broad thrust of these measures because they are central to building greater consumer confidence in the industry.

In terms of health claims made for complementary medicines, ASMI supports a strong and effective framework based on the following:

- Clear, published guidelines.
- Retaining the existing self-regulatory processes within a broader co-regulatory system.
- A system that applies to all advertisers regardless of membership of any industry association.
- A system that applies to all advertising regardless of the medium employed or the audience targeted.
- Timely, consistent and transparent complaints mechanisms.
- Effective sanctions.

We have all seen the damage that is done when products with lurid health claims tarnish the reputation of responsible sections of the industry. We can't afford to sit by and see a small minority of manufacturers deceive consumers and undermine the vast majority of responsible complementary medicine manufacturers.

ASMI will continue to press for a strengthened framework for advertising controls, as well as appropriate sanctions, penalties and complaints handling processes.

If we don't get these fundamentals right, we put a great deal at risk. One thing we do know is that some 75% of Australians have used complementary medicines.

Consumers have made it very clear that they see a distinct role for complementary medicines as part of an integrated approach to personal health. They want GPs, pharmacists and other healthcare professionals to assist them in making the right choices.

Complementary medicines also form a central part of a shift to a health system that is based on the principle of "self care" – where individuals are encouraged to take greater personal control of their health. Complementary medicines play a key role in such things as minor ailments, chronic conditions, and preventative health.

Examples include the use of dietary vitamin and mineral supplements for those with vitamin or mineral deficiencies. Calcium supplementation, for instance, is a well-tested and widely available option for increasing bone density and reducing the risk of fractures, especially in older people.

In 2007 ASMI received Government funding to manage an independent research project in relation to complementary medicines. The Australian study found that calcium, and calcium in combination with Vitamin D, was associated with a 12% reduction in fractures of all types including hip, vertebrae and wrist.

There is a strong body of evidence to support the use of fish oil supplements in providing primary and secondary prevention in patients with cardiovascular disease.

Research undertaken by Deloitte Access Economics identified savings of approximately $4.2 billion through avoidance of disease burden and premature life loss as a result of the preventative use of fish oils in patients with heart disease.

Complementary medicines are now embedded in the daily lives of scores of Australians. They are no longer the fringe, but a key plank of a well-rounded approach to health and well-being.

This measure of consumer confidence is precious, and needs to be respected.

We recognise the pivotal place of complementary medicines, and remain strong adherents of measures that build a robust and viable industry that all Australians can trust.

Dr Schoombie is executive director of the Australian Self Medication Industry (ASMI). ASMI is the peak body representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products in Australia.

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