



COMPLEMENTARY COMPLEXITIES

Complementary medicine figures prominently in the healthcare regimen of many Australians. But the efficacy of such products, and their marketing, is widely debated.

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A FORMULATION of glucosamine hydrochloride makes a surprising appearance on the TGA's small list of registered complementary medicines – those that have undergone evaluation for safety, quality and efficacy.

According to Dr Ken Harvey, an adjunct associate professor at La Trobe University's school of public health, when challenged

last year about the evidence for the product's efficacy, the TGA noted it had been 'judged by the standards of the time' – in 1999.

"Its inclusion on the TGA list highlights a fundamental problem of TGA registration: the evaluation is usually not updated when new information becomes available," says Dr Harvey, a strident campaigner for tighter regulation of complementary medicine (CM).

While there are scientifically

evaluated CMs on the Australian Register of Therapeutic Goods (ARTG), it is difficult to distinguish the evidence-based 'wheat' from the much more voluminous hype-driven 'chaff', according to Dr Harvey.

Meanwhile, complementary and alternative medicine continues to extend its reach in the Australian health consumer marketplace. A recent national health survey, conducted by the Australian Bureau of Statistics,

found about a quarter of Australian adults affected by one or more of five conditions – diabetes, asthma, arthritis, osteoporosis, heart or circulatory problems – regularly used a complementary or alternative therapy.¹

The National Institute of Complementary Medicine values the Australian CM industry at \$1.5 billion to \$2.5 billion per annum.²

In 2010 and 2011, several reviews of the TGA were undertaken in response to health

professional and consumer concerns. These culminated in two government papers: *TGA Reforms: A blueprint for TGA's future* (December 2011) and *Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future* (July 2012).³

These documents outline a four-year timetable of incremental reform aimed at increasing the transparency of TGA regulatory processes and decisions and enhancing public

trust in the safety and quality of therapeutic goods.

While the TGA has a program of evaluating CMs, pre-market assessment of listed products is lacking and there is only limited post-marketing reviews, observers say.

Dr Harvey maintains most CMs are "unremarkable".

But he does acknowledge that we are seeing more innovative remedies whose efficacy is supported by clinical trials.

Dr Harvey singled out Floridis' Iberogast, a nine-herb mixture for irritable bowel syndrome; Blackmores' Flexagil Pain Relief Cream, a comfrey root extract for the topical treatment of sprains and osteoarthritis; and Schwabe Kaloba oral liquid, also from Blackmores, a standardised extract of *Pelargonium sidoides* for the treatment of acute bronchitis and sinusitis.

"The latter may provide a useful alternative to antibiotics which, although not indicated for acute bronchitis and sinusitis, are often prescribed," Dr Harvey says.

GPs are increasingly practising integrative medicine.

One advocate of its benefits, Dr Vicki Kotsirilos, incorporates CM into her mainstream Melbourne practice.

Most patients will leave with a 'lifestyle' prescription and, depending on the disease and the patient's choice of treatment, evidence-based complementary therapies will be used, Dr Kotsirilos says.

"For example, we use hypnosis for anxiety, acupuncture for migraines and headaches or a CM supplement if appropriate," Dr Kotsirilos says.

"We do also prescribe medication if needed."

Other CMs the practice has found to be beneficial include garlic capsules for mild hypertension, so long as it is well tolerated and there are no contraindications in the patient, such as being on warfarin.

Another example is the young woman who presents with PMS.

"I may suggest trialling the herb *Vitex agnus-castus*," Dr Kotsirilos says. "Several randomised control trials demonstrate benefit for PMS."

A patient who presents with moderate depression will be referred to a psychologist for counselling and given a lifestyle prescription.

"I may prescribe the herb St John's Wort that is supported for its use in depression... a Cochrane review of 29 randomised control trials found it was just as useful as anti-depressants with less side-effects," Dr Kotsirilos says.

There is a dearth of recent data about the incorporation of CM in Australian GPs' practices.

But a 2008 survey⁴ of more than 4000 GPs, by the National Prescribing Service (now NPS MedicineWise), indicated about 90% of GPs had recommended at least one CM in the past 12 months.

Most GPs had recommended vitamins, minerals, fish oil and glucosamine.

But more than 80% agreed CMs needed more scientific

testing before being used in conventional medicine. Only 38% felt they were confident discussing CMs with patients.

Dr Kotsirilos formerly advised the TGA as a member of the now-defunct Complementary Medicines Evaluation Committee. She believes better labelling should be key to the CM reforms.

"I believe that a suitable expert committee on the TGA could look at products individually to assess the ingredients and their level of scientific evidence," she says.

"If they are evidence-based, the TGA should consider indicating this on the label or on the bottle with some sort of symbol

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or notation to help the consumer to identify products that are evidence-based and those that are not."

There is no doubt the TGA has earned itself a reputation as a toothless tiger on CM regulation.

Dr Kotsirilos agrees that the industry needs restrictions on advertising, particularly for non-evidence-based products where inappropriate claims are made.

"If the TGA needs more support in this area, we shouldn't be criticising them, we should be supporting them and assisting them to be more powerful in their reforms and be able to act on their decision-making," Dr Kotsirilos says.

In response to the difficulties of identifying effective CMs based on their TGA listing or registration, Professor Paul Komisaroff, director of the Monash Centre for the Study of Ethics in Medicine and Society, and colleagues have set up a broad-based collaboration to foster the quality use of these products.

A management team is currently being established and the project will be underway by mid-year.

"The TGA has given in-principle support," Professor Komisaroff says.

"One of the key things in our process is to develop a database. There's currently a lot of misinformation and partial information."

GPs such as Dr Kotsirilos have clearly found some CMs to be useful and rewarding as options of treatment for diseases, but many hope the TGA reforms will assist them and the public to make more informed choices.

"I would encourage GPs to learn more about the evidence on CMs and there are now good textbooks available in Australia that can help," Dr Kotsirilos says.

"Unfortunately reliable information on the CM products is not available and is often misleading from advertisements by some sponsors."

References at medicalobserver.com.au

Complementary Medicine by numbers

- Two out of three Australians use CM each year
- Almost four times more is spent on CM (in out-of-pocket expenses) than on pharmaceuticals
- Australia's CM industry is valued at \$1.5 billion to \$2.5 billion a year
- The global market for herbal remedies is estimated at \$83 billion (excluding soy, algae and fibre)
- 3.8% of the population had consulted a CM practitioner in the previous two weeks, according to a 2006 survey by the Australian Bureau of Statistics
- At least one-third of people using CM concurrently use pharmaceuticals

Source: The National Institute of Complementary Medicine