Media Messaging

Supporting Australian Complementary Medicines

Updated: February 2017

United Voice of Industry

Globally, and in Australia, there has been an increase in attention given to the use of complementary medicines (CMs), congruent with the growing use and acceptance of these products by individuals keen to care for their general health and wellbeing. The more popular complementary medicines become with consumers worldwide, the more our industry becomes the target of sensationalist and scaremongering media headlines. The negative media is also fuelled and supported by detractors and vocal groups such as Friends of Science in Medicine (FSM).

Our industry operates within one of the most tightly regulated systems in the world, where products are manufactured to a pharmaceutical standard under Good Manufacturing Practice (GMP), and strict safety and quality regulations are enforced by the Department of Health's Therapeutic Goods Administration (TGA), ensuring that responsible, evidence-based and high quality products are available to consumers. In fact, the Australian regulatory regime for complementary medicines is such that it is viewed by most countries as the consumer protection benchmark.

Australian health products have been a success story in recent years given their growing popularity in Asia. This has boosted jobs in Australia across diverse areas such as manufacturing, scientific evaluation and research. We know that it is our high standards that are our competitive advantage, so we need to remain fiercely protective of the quality of our products and the reputation of our industry.

CMA has developed this booklet in response to the escalating level of biased and misleading media that may ultimately cause undue concern for the Australian public and potentially damage our vibrant and growing industry – so that we may respond with a united voice.

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Key Messages

Confidence in Quality

- ✓ Australia has one of the most stringent regulatory frameworks for complementary medicines in the world
- ✓ Consumers can have confidence in the quality and safety of Australian complementary medicines (AUST R and AUST L)
- ✓ Consumers should be cautious when purchasing complementary medicines online from overseas websites

Research and Evidence

- ✓ There is a compelling and growing evidence base for complementary medicines
- ✓ There is growing evidence that CMs can make a significant, cost-effective contribution to chronic diseases
- ✓ Australia has world class academic and research bodies, including two five star accredited CM research centres

Care

- ✓ Our industry is passionate about health and wellbeing
- ✓ The industry works together to protect consumers
- ✓ The TGA maintains a rigorous system for recording, monitoring and responding to adverse events for all medicines, including CMs
- ✓ Consumers should always contact their health care practitioner if they have any concerns

Contents

Growth of the Industry

A very large proportion of the Australian population, approximately 70 per cent, use complementary medicines.[i] The majority of consumers have already made their position clear – complementary medicines are paid for fully by the consumer, and the Australian complementary medicines industry is growing. While critics such as FSM might attempt to frame the growth of the industry as consumer gullibility, the simple fact is that people don't keep buying products that don't work for them.

Regulation of Australian Complementary Medicines

- **Australia has one of the most stringent regulatory frameworks for complementary medicines in the world**

- **Consumers can have confidence in the quality and safety of complementary medicines listed on the Australian Register of Therapeutic Goods (AUST R and AUST L)**

Australia has some of the most stringent regulations for the manufacture of complementary medicines, including licensing and inspecting manufacturers for supply in Australia and for export to ensure that products meet the high standard of GMP. Manufacturers of natural health care products in Australia have a respected reputation for quality and purity.

The strict Australian regulatory environment mandates that the following occur in the manufacture of complementary medicines available on the Australian market:

- Only utilise ingredients assessed as safe and allowed at safe levels by the Therapeutic Goods Administration (TGA). This is not so with overseas jurisdictions.
- The TGA mandates verification testing of all raw materials before a product is manufactured, which provides assurance to Australian consumers that they receive what's stated on the label. This is not mandatory in the US.
- Batch testing of finished products (tablets /capsules) verifies consistency and quality of the active ingredients within the label claim.
- Stability studies ensure that the product remains potent and safe throughout its shelf life.
- Product quality reviews ensure that quality data is aggregated and tracked over time, allowing the industry to identify and act on any emerging trends.
- Adverse events are rigorously captured and monitored by the TGA so that any emerging issues can be identified and addressed promptly.

Concerns with Online Purchasing

➢ **Consumers should be cautious when purchasing complementary medicines online**

Products purchased online from overseas are not subject to the same regulations as those enforced in Australia, which means there may be no surety that the product contains what it says it does. Online purchases should only be made on the recommendation of a qualified healthcare professional or from a known and reputable source.

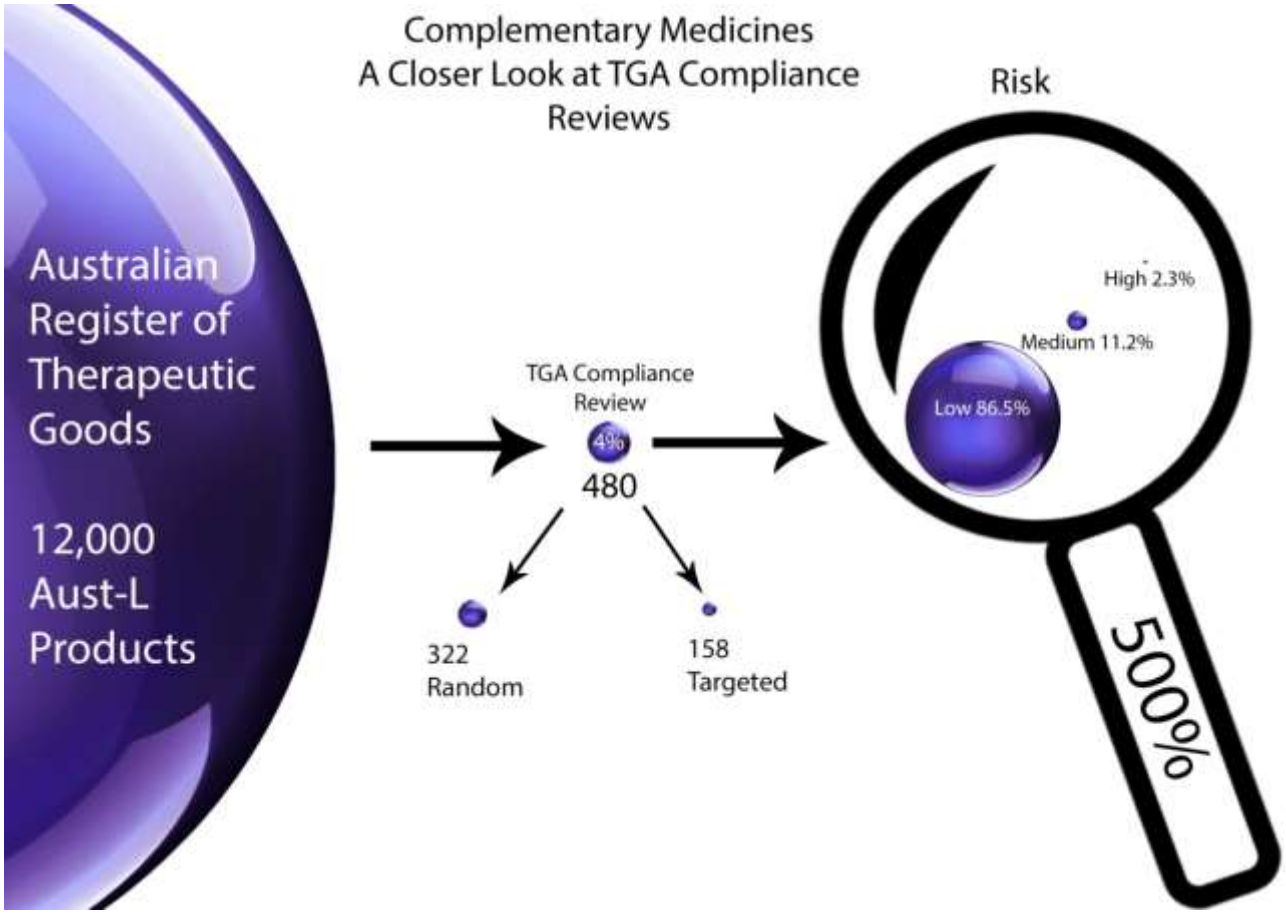
Unless specifically exempt, complementary medicines supplied in Australia are required to be entered onto the Australian Register of Therapeutic Goods (ARTG) maintained by the TGA. Unless they are included on the ARTG, complementary medicines cannot legally be imported, exported, manufactured, or supplied to consumers. Medicines that are included in the ARTG have an AUST L or AUST R number displayed on the pack.

Products that are medicinal in nature but not listed on the ARTG may not have been made under GMP principles, and may not meet the quality and safety standards expected by Australian consumers. Such products may have elevated levels of heavy metals, pesticides, or microbial contaminants, as these are not screened for in many countries. They may also contain low levels of stated herbal active ingredients, the wrong herb entirely, or be adulterated with other unknown ingredients.

Non-compliance

The TGA's performance statistics reports do not currently categorise non-compliance issues into risk categories. This is providing industry critics with the ability to misrepresent the true level of non-compliance and the subsequent risk to consumers.

CMA has developed an infographic that puts the numbers into perspective (below) by separating non-compliance issues into high, medium and low risk. Of the 12000+ Aust-L products on the ARTG the TGA reviewed 480 (4 percent) in the period of July 2015- June 2016. Of these, 322 were random and 158 were targeted reviews. The higher rate of non-compliance in targeted reviews reflects that these reviews were initiated by the TGA due to an expected non-compliance concern that had been previously identified.



A past statistic that is also often quoted indicated that 90% of the listed complementary medicines reviewed against the regulations as part of an audit were found to be non-compliant. This statistic is misleading. The audit was looking at a very small number of products and these figures included products that were targeted for review of listing compliance. The 90% statistic encompassed a number of minor issues including missing full stops and wrong font size in labelling, and subsequently 97% of the instances of non-compliance were corrected.

Lack of Evidence

- **There is a compelling and growing evidence base for many complementary medicines**
- **There is growing evidence that CMs can make a significant, cost-effective contribution to chronic diseases.**

- **Australia has world class academic and research bodies, including two five star accredited CM research centres.**

Any blanket statement that complementary medicines aren't supported by scientific evidence simply cannot be accepted. A quick search of one database (PubMed) for any particular popular herb will produce dozens of scientific studies linking these products to research on a wide range of health conditions. A significant amount of scientific research has been conducted looking at the direct health benefits of using complementary medicines, forming part of an ever-developing evidence profile.

Claims that supplements are unproven are often made by a vocal minority which maintains an old fashioned, paternalistic approach to healthcare. The attitude falls short of the integrative model of care that will ultimately allow consumers to use complementary medicines in an effective, safe and respectful manner.

Australian CM Research

Australia has world class academic and research bodies, including two five star accredited CM research centres.

Australia is very lucky to be home to two world leading research institutions for complementary medicines: the National Institute of Complementary Medicines and the Australian Research Centre in Complementary and Integrative Medicine, both five star accredited research centres.

Cost-effectiveness

There is growing evidence that complementary medicine can make a significant, cost-effective contribution to chronic diseases.

A 2014 Frost & Sullivan report '*Targeted Use of Complementary Medicines: Potential Health Outcomes and Cost Savings in Australia'* shows robust links between several of the more well-known complementary medicines with reduced risk of a secondary disease event among high-risk groups, and with major potential healthcare cost savings. The report examined the use of six complementary medicines across four chronic disease conditions – cardiovascular disease (CVD), osteoporosis, age-related macular degeneration and

depression – all of which contribute heavily to the national burden of illness in Australia. Large cost savings were identified, especially for the use of calcium and vitamin D by women aged over 50 who had been diagnosed with osteoporosis or osteopenia. For these conditions alone, the report estimated that between 2015 and 2020 an average annual hospitalisation cost of A$922 million could be potentially saved, along with gains in productivity of A$900 million – a net gain of A$1.8 billion.

A 2013 US study '*Smart Prevention – Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements*', found the use of key dietary supplements, including omega-3s, B6, B12 and folic acid, could reduce hospitalisation costs by $US billions per year.

GPs Interest in CMs

The high usage rates by Australian consumers have led to 90 percent of medical practitioners expressing an interest in increasing their understanding of complementary medicines.

World Health Organisation

The *WHO Traditional Medicine Strategy 2014-2023* stresses the importance of traditional medicines to the totality of health care, improved health and patient autonomy. Complementary medicines have a long history of use in health maintenance and in disease prevention and treatment, particularly for chronic disease.

Criticism of Industry Funded Research

There is a long history of engagement between philanthropic organisations, industry and universities in medical discovery and knowledge building. Partnerships between private organisations and universities are a longstanding and necessary part of research – Australian taxpayers cannot and should not be required to fund all research.

Less than one per cent of National Health and Medical Research Council (NHMRC) funds have been allocated to complementary medicine research over the last decade. In this context, it is easy to see the importance of industry support of the research effort in Australia.

As noted in the Australian 2013 McKeon *Strategic Review of Health and Medical Research*, private research funding from industry and philanthropic sources has always been an important contributor to health and medical research. Effective health and medical research depends upon industry and philanthropic funding, with most medical research institutes accounting for 30 per cent or more of their funding sources from private funding.

As long as research is rigorous and oversights are in place through ethics committees and university policies, these partnerships are vital for research.

Fish Oil Quality

Fish oil supplements are tightly regulated in Australia – the TGA undertakes routine testing to monitor compliance, including long-term stability testing in relation to oxidation.

Omega-3 oil supplements are regulated by the TGA in Australia and Medsafe in New Zealand and both regulators have quality standards in place that the industry has to adhere to (GMP); including meeting label claim on EPA/DHA content and long-term stability testing relative to a set quality standard for oxidation.

Background

A study, published in the journal *Scientific Reports* in January 2015 found that most (29/32) fish oil products sold in New Zealand contained lower levels of omega-3 than their labels claimed. This study has been raised in subsequent media reporting on fish oil supplements.

The authors also found that 30 out of 36 supplements analysed for oxidation exceeded the p-Anisidine Value (pAV) and 18 of the 36 exceeded recommended total oxidation value (Totox) thresholds. About half of the supplements analysed were manufactured in Australia.

Experts from the Global Organization for EPA and DHA Omega-3s (GOED) and the Omega-3 Centre were highly suspicious of the nature of the results and queried the study methodology and handling of samples. Both GOED and O3C have written to the journal.

- The TGA publishes specific compositional guidelines that lay out the test methods and appropriate acceptance criteria for ingredients in listed complementary medicines. The authors of this paper did not use the TGA-approved European Pharmacopeia or British Pharmacopeia methods for measuring EPA and DHA content and appear to have modified the approved methods for measuring oxidation.
- There is no international industry standard for reporting EPA+DHA content on labels and it wasn't clear from the article if the different reporting methods were considered.
- It is important to note that analyses must be done immediately, before the oils oxidise. The authors describe their collection method to include combining the contents of 8-24 capsules, and from the pooled sample measuring in triplicate for PV, AV, Totox and fatty

acid concentration. Generally, high PV's suggest the oils were oxidised upon opening the capsule.

Industry has previously raised concerns with the TGA that two different methodologies could be used to quantify DHA and EPA, namely mg/g of triglycerides (using a reference standard) or as a percentage under the curve (g/100 g of fatty acids; area normalisation method). These different methodologies generate different results when calculating the content of EPA and DHA used in fish oils in listed medicines. To provide clarity, the TGA compositional guidelines specify the methodology to be used in determining DHA and EPA content.

In 2010, on the back of a 2008 Choice study on fish oil label claims, the TGA conducted a listing compliance review on this issue and found the inconsistencies. However, it concluded that on the basis of the general level of compliance with stated label claims for content of EPA and DHA in fish oils observed in the survey, and lack of specific incidences of non-compliance reported to the TGA, there was at the time insufficient evidence to suggest that consumers were being misled as to the dose, quality and efficacy of fish oil.

TGA analyses performed in 2015 after the New Zealand study was published have again also showed that 15 products were all compliant for EPA/DHA content, PV and pAV. The TGA noted that additives may interfere with the pAV measurement. The Omega-3 Centre has, in 2016, overseen analyses of further ANZ products by an independent laboratory using standard methods. All 10 products analysed were compliant for EPA/DHA content and PV and 8/10 were compliant for pAV. Two samples are being retested for pAV.

Fish Oil Evidence

A study, published in the journal *Heart, Lung and Circulation,* found a trend towards no beneficial effect in consumption of omega-3 long-chain polyunsaturated fatty acids (EPA and DHA) for the prevention of cardiovascular disease (CVD), which contrasted with previous studies regarding fish oil and its effects on CVD. The study prompted the National Heart Foundation to review its dietary and supplementation advice in relation to fish oil.

The research paper concluded that people should eat two or three servings of fish (including oily fish) a week, and acknowledges that supplements will provide people who don't eat enough fish with marine-sourced Omega-3s.

According to the Natural Medicines Database, fish oil has also been associated with health benefits for conditions ranging from hypertriglyceridemia, joint health, arthritis and osteoporosis, eye health, prevention of cognitive decline, to skin conditions such as psoriasis.

Green Tea & Liver Toxicity

- **Consumers are reminded to only purchase complementary medicines that are listed or registered on the ARTG, where they are well regulated, and not online from overseas.**

- **The presence of an AUST L or AUST R number on the medicine label is an important safeguard.**

Consumers should always follow label instructions and warning statements. If consumers desire more information about a medicine they are able to use the unique identifying AUST number to look up the product on the ARTG or ask their health care professional.

The TGA maintains a rigorous system for recording, monitoring and responding to adverse events for all medicines, including complementary medicines.

Clinical pharmacologist Professor Ric Day, from St Vincent's Hospital in Sydney, said liver toxicity cases are unusual and could happen with prescribed medications as well. In his view, the risks of taking supplements are quite low as they have been given a wide level of exposure in the population.

Background

A 26-year-old man had reported using two dietary supplements for a 1-week period 10 weeks prior to hospital presentation – a whey protein powder which was not listed on the ARTG containing, among other ingredients, green tea (*Camellia sinensis*) and a weight loss supplement containing 70% *Garcinia cambogia.* In the absence of any alternate cause of liver toxicity, an adverse event notification was made to the TGA. The two supplements were tested for heavy metals and pharmaceutical adulterants; however, no unexpectedly high levels of these substances were detected.

The TGA is continuing to investigate the report it received relating to the BSC protein powder and liver failure as part of a larger investigation into this issue, noting that the TGA has not received any other reports of liver failure with this product. The results will be made public if there is sufficient evidence of a safety issue to warrant further action.

The TGA, like other regulatory agencies around the world, monitors the safety of medicines marketed in Australia to contribute to a better understanding of their possible adverse effects. This is known as pharmacovigilance and is routine for all medicines, including prescription, OTC and complementary medicines.

The TGA monitors the safety of medicines marketed in Australia using:

- reports of adverse events;
- sharing of information with other regulatory agencies;
- sharing of information with Australian state and territory health authorities;
- Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs); and
- reviews of literature.

Black Cohosh

The Therapeutic Goods Administration (TGA) reviewed the safety of Black cohosh (*Cimicifuga racemosa*) in 2005 following reports of possible liver problems internationally and in Australia. While the risk of liver toxicity associated with Black cohosh is rare and idiosyncratic, the TGA expert advisory group determined that Black cohosh, while still suitable for use in complementary medicines, required a warning statement to be included on medicine labels.

The TGA maintains a publicly accessible catalogue of approved ingredients for listed medicines; the *Permissible Ingredients Determination No 1, 2016* includes the below statement as a legislative requirement for Black cohosh:

> (BCOHOSH) *'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'*

The TGA maintains a rigorous system for recording, monitoring and responding to adverse events for all medicines, including CMs.

DNA Barcode Testing

The New York Attorney General (AG) was heavily criticised a year ago for inappropriately using DNA barcode testing on finished herbal products. DNA barcoding is an innovative technology that can have a role in testing raw materials, but was the wrong test for finished products.

Other Commentary

Concerns of people megadosing on supplements:
Vitamins are essential in your diet for good health. Though, as with anything, too much of any food, too much of any supplement can be harmful.

Supplements are a waste of money:
There is a compelling and growing evidence base for many complementary medicines.
With continued investment in complementary medicine research the translation of evidence into clinical practice and relevant policy will benefit the health of all Australians.

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing members across the supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality. CMA is the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

[i] Macquarie University (2015) Consumer Behaviour Fact Book, March 2015 pp 228-239