



cma Complementary
Medicines
Australia

Media Messaging

Australian Complementary Medicines



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A Healthy Industry

In Australia and globally, consumers are increasing including complementary medicines (CMs) within their health care options. There are many reasons for the increased popularity of these products, notably a higher priority given by individuals to health promotion and wellbeing as reflecting a more multicultural Australia which embraces many forms and models of health and healing. With this increased in popularity comes an increased scrutiny by main stream media and critics of the sector. Though criticism can be healthy, increasingly our industry has become the target of ill-informed and biased reporting that is too often sensationalist and scaremongering notably by fringe groups such as the Friends of Science in Medicine (FSM).

The truth is that the Australian regulatory regime for complementary medicines is considered by many countries as being innovative and forward thinking, a potential benchmark for consumer protection. Rather than being lacking, the Australian complementary medicines 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). This ensures that not only do consumers have access to responsible, evidence-based and high quality products and the ability to make informed choices about including them within their health care options.

The Australian complementary medicines industry is not only a good news story about people's health but also the national economy with Australian health products increasingly popular in overseas markets notably Asia and the Western Pacific region. This has boosted jobs in Australia across the sector notably in product manufacturing, as well as stimulated scientific evaluation and research. We know that it is these high standards and appropriate regulations that are our competitive advantage. Not only to protect the Australian complementary medicines sector but also support Australians in making healthy choices, 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, inaccurate 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.



Carl Gibson
Chief Executive Officer



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

A Healthy Industry.....	2
Key Messages.....	3
Growth of the Industry.....	4
Regulation of Australian Complementary Medicines.....	4
Online Buyer Beware: Concerns with Online Purchasing.....	5
Industry Funded Research.....	8
Green Tea & Liver Toxicity.....	9
Black Cohosh.....	10
Other Commentary.....	10

Growth of the Industry

A very large proportion of the Australian population, approximately 70 per cent, use complementary medicines within their health care options. They have already made their position clear with – complementary medicines paid for fully by the consumer, a fact reflected in the Australian complementary medicines industry continued growing. Critics such as fringe group Friends of Science in Medicine may attempt to frame the growth of the industry as consumer gullibility. The simple fact is that people invest in complementary medicine products as part of their daily health and wellness regime because they work for them.

Regulation of Australian Complementary Medicines

- **Australia has one of the most stringent regulatory frameworks for complementary medicines in the world supporting consumers in making informed health decisions.**
- **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 one of the most developed, robust and strictest regulations for the manufacture of complementary medicines in the world. This regulatory approach demands that manufacturers are licensed and inspected and follow the highest standard of GMP not only for products for the Australian market but also for those exported overseas. Manufacturers of complementary medicines in Australia have a well-deserved and respected reputation for quality and purity worldwide bar none.

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

- Use only ingredients assessed as safe and allowed at safe levels by the Therapeutic Goods Administration (TGA).

- 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.
- Batch testing of finished products (tablets /capsules) verifies consistency and quality of the active ingredients within the label claim.
- Product labels provide consumers with information that supports them in making informed choices in selecting these products
- Ensure that advertising and promotional material is accurate and truthful
- 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.
- Potential adverse events are identified, monitored and analysed by the TGA so that any emerging issues can be identified and addressed promptly.

Online Buyer Beware: Concerns with Online Purchasing

- **Consumers should buy complementary medicines approved by the TGA and be cautious when purchasing complementary medicines online**

Few overseas jurisdictions have regulations for complementary medicines that are stringent and robust as those in Australia. This means that products not approved by the TGA and purchased online from overseas are not subject to the same high level of scrutiny with no surety that the product contains what it says it does on the label. In an increasing number of cases, the product may contain the wrong ingredient, contaminated with pollutants and heavy metals and even be intentionally adulterated with undeclared pharmaceutical drugs. Consumers should be very wary about making purchases online and only on the recommendation of a qualified healthcare professional or from a known and reputable source. Simply put it is always best to buy complementary medicines approved by the TGA.

Apart from the very few types of products specifically exempt, all complementary medicines supplied in Australia are required to be entered onto the Australian Register of Therapeutic Goods (ARTG). The ARTG is maintained and updated by the TGA. Unless they are included on the ARTG, complementary medicines cannot legally be imported, exported, manufactured, or supplied to consumers. All medicines, including complementary medicines, on the ARTG have an AUST L or AUST R number displayed on the pack.



Therapeutic goods not listed on the ARTG may not have been made under GMP principles. This means that they 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 including pharmaceutical drugs.

Evidence

- **The use of complementary medicines is supported by many different forms and types of evidence**
- **There is a compelling and growing scientific evidence base for many complementary medicines**
- **In addition to clinical evidence, there is growing evidence that CMs can make a significant, cost-effective contribution to chronic diseases.**
- **Australia has world class academic and research sector, including two five star accredited CM research centres**

As the range of complementary medicines is diverse, so is the evidence to support their safe and effective use. This means that products may be supported by traditional evidence such as traditional Chinese medicine and Ayurvedic medicine, data from population and observational studies as well as increasingly as with conventional drugs from randomized controlled clinical trials

A preliminary search of any of the mainstream medical databases such as (PubMed) will produce hundreds of positive scientific studies linking these products to research on a wide range of health conditions. The number of clinical studies and other scientific research is growing forming part of an ever-developing evidence profile and play an important role in stimulating research and innovation in the market place. Any blanket statement that the complementary medicine sector is not supported by scientific evidence is patently untrue.

Claims that supplements are unproven are typically made by a vocal minority who see the randomised controlled trial as the only rather than one important way to evaluate a product's efficacy. The attitude of "one size fits" all does not reflect the diverse types of complementary medicines nor consumers' desire to use many forms of complementary medicines from many types of health and healing. In reality it is often not a question of the amount of evidence but rather the type of evidence provided and ensuring that it provides the consumer with the information to make an informed choice about its use.

Australian Complementary Medicine Research



Australia has world class academic and research sector working internationally working in many different complementary medicine disciplines.

Two of these centres, the National Institute of Complementary Medicines (NICM) and the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM), have been awarded five star accreditation. More information on their work can be found at www.westernsydney.edu.au/nicm and www.uts.edu.au

Cost-effectiveness

In addition to growing clinical research, 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.



This is not the only supporting research with 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 year¹

¹ <https://www.crnusa.org/resources/smart-prevention-health-care-cost-savings-supplements>

GPs Interest in CMs

The high usage rates by Australian consumers have led to 90 per cent 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.

Industry Funded Research

Across all disciplines, 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. It is unreasonable and unfair that Australian taxpayers should be required to fund all research.



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.

It was estimated that 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, support for independent, objective and relevant from the Australian complementary medicine is essential for the sector as well as the health care of Australians.

The Australian complementary medicines industry is committed to funding and supporting cutting edge and innovation. As such, the industry sector is currently investing \$32 million, with 160 researchers working on 295 projects.

Research be independently conducted. Australian Universities and colleges have a world renowned track record for rigorous policies and procedures that prevalent any hint of partisanship.

Green Tea & Liver Toxicity

- Consumers should 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.

A case study

In a case documented in the Medical Journal of Australia; a 27-year-old man from Geraldton, nearly died in 2016 after he drank a pre-workout protein shake and consumed a weight-loss supplement he purchased online. The products included – 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*.

Within a week, he was experiencing severe fatigue and jaundice. The symptoms persisted two months later, so he took himself to hospital, where he was diagnosed with liver failure and needed an emergency liver transplant.

In the absence of any other potential causes 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 European Food Safety Authority assessed the safety of green tea supplements from dietary sources and in April 2018 determined that Green tea extracts may cause liver damage.

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.

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.

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