



### **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.

#### *What are complementary medicines?*

Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines (unless specifically exempt). The term 'complementary medicines' also comprises traditional medicines, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Other natural healthcare products may be regulated as foods, such as functional foods and special purpose foods, or as cosmetics, such as natural cosmetics that use herbals and botanicals.

#### *Join us*

**Together we are Stronger**

*For membership enquiries call +61 (2) 6260 4022*

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# **Australia's High Quality Complementary Medicines Industry**

***Holding Health to  
the Highest  
Standard***

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## FOREWORD BY THE CEO

**Carl Gibson**

Healthcare is a basic need worldwide. It is in all of our best interests to have access to high quality, safe and cost-effective medicines and services.

Complementary medicines play a significant role in allowing individuals to maintain a high level of physical and psychological wellness, and have the potential to assist in the reduction of the ever-increasing healthcare costs associated with preventable chronic diseases. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care. Here in Australia, it has been estimated that 70 per cent of Australians use complementary medicines to support their health and wellbeing goals.



Australia's complementary medicines industry is backed by a regulatory regime that is regarded as one of the strongest in the world. Products are manufactured to a pharmaceutical standard under Good Manufacturing Practice (GMP), and strict safety and quality regulations are enforced by the Therapeutic Goods Administration (TGA).

When a consumer purchases a product with an AUST L/R on the label, they can be confident that the product has been produced under the strictest quality and safety criteria, that the product contains what it says it does on the label, and that when taken at the dose recommended on the label it is safe to take.

## WHAT IS REQUIRED OF A QUALITY COMPLEMENTARY MEDICINE

In Australia, complementary medicines must be manufactured to medicinal standards in TGA approved and licensed facilities. Before they are marketed in Australia complementary medicines must:

- contain only ingredients that have been assessed as safe by the TGA;
- contain only ingredients at levels agreed to be safe by the TGA;
- have all active ingredients in the product tested and verified as raw materials before the product is manufactured;
- have every batch of final product tested to ensure that what is in the product is what is on the label;
- have ongoing stability trials so that the finished product is tested to demonstrate that it remains potent and safe for the entire shelf life of the product;
- have a product quality review conducted – this tracks the quality of the product over time and allows sponsors to identify and act on any issues arising over time; and
- have any adverse events monitored by the TGA so that any trends emerging with the use of specific complementary medicines can be identified and action taken quickly.



## TRANSPARENCY FOR CONSUMERS

Consumers can access information on the TGA website about therapeutic goods that have been approved for supply in Australia.

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.

By searching the ARTG information about a product, such as the sponsor's details and the intended purpose or indications, can be found.

## US SUPPLEMENT REGULATION

Periodically, the Australian media will run a story that has been produced in the US and that is about the US dietary supplements industry and the regulation of these products by the Food & Drug Administration (FDA). Often these stories ask questions about the quality and safety of supplements.

Australian and US supplements are regulated VERY differently.

In the US, vitamins and herbal supplements are regulated as dietary supplements by the FDA. In Australia, these products are regulated as complementary medicines by the TGA. The Australian regulations for complementary medicines are similar to that for pharmaceuticals and are amongst the strictest in the world.

In the US, under the FDA's *Supplement Health and Education Act 1994*, the manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. There is no approval required from the FDA before a dietary supplement is launched. It is only once a product is already on the market that the FDA has a responsibility to take action against any unsafe products.

*"The Australian public is entitled to greater information regarding the differences in regulatory regimes when the media runs US-based supplements stories. Such stories need to be placed in the correct context, and that context is that the Australian regulatory regime for complementary medicines is such that it is viewed by most countries as the consumer protection benchmark,"*

*- Mr Carl Gibson, CMA Chief Executive Officer*

## BUYING MEDICINES OVER THE INTERNET

Dietary supplements sold over the internet are unlikely to have been evaluated by the TGA, which means there is no surety that the product contains what it says it does.

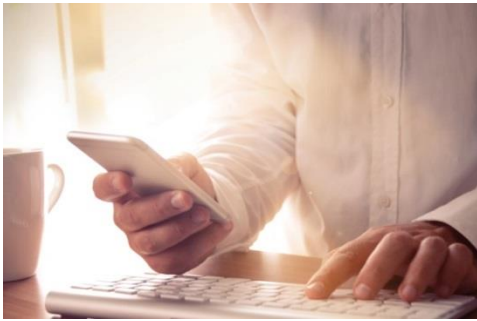
Products purchased online from overseas are not subject to the same regulations as those enforced in Australia, and therefore these purchases of supplements should only be made on the recommendation of a qualified healthcare professional or from a reputable retailer.





Products that are therapeutic 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.

Consumers are urged to seek the advice of a healthcare professional before purchasing medicines. Medical guidance from the Internet should not replace consultation with a healthcare provider and should be interpreted with extreme caution.



## MONITORING SAFETY OF MEDICINES

Sometimes medicines, including complementary medicines, have unexpected and undesirable effects. The TGA has a strong pharmacovigilance program, which involves the assessment of adverse events that are reported to the TGA by consumers, health professionals, the medicines industry, international medicines regulators or by the medical and scientific experts.

Sponsors of medicines are required to report to the TGA any suspected adverse reactions for their medicines as soon as they become aware that there may be an issue.

If an adverse event to a complementary medicine is experienced, consumers should seek advice from their healthcare professional and are advised to report the adverse event to the TGA.

## FOOD MEDICINE INTERFACE

The issue of whether a particular product is regulated as a food or as a complementary medicine (a therapeutic good) by the TGA has become more complex over recent years as health claims can now be made in relation to a wider range of products, including foods.

Often, claims made about a product or the appearance of the product may suggest that it is a therapeutic good. However, the fact that health claims are made about a product does not automatically make it a therapeutic good, nor does the fact that the product comes in capsules or powders, or is labelled as a 'dietary supplement'.

The potential regulatory overlap between certain foods and medicines is referred to as the 'food-medicine interface' and regulators, manufacturers and importers all need a way to work out whether the *Therapeutic Goods Act 1989* or state or territory food legislation covers particular products.

The TGA has developed a [Food-Medicine Interface Guidance Tool](#) that can be used to help work out whether a particular product is likely to be a therapeutic good or not.



When answered in the order in which they are posed, the series of questions reflects the process by which the TGA comes to a view about whether a product at the food-medicine interface is likely to be a therapeutic good and therefore regulated as a medicine by the TGA. The Guidance Tool is only used to determine which regulatory regime applies to a product.

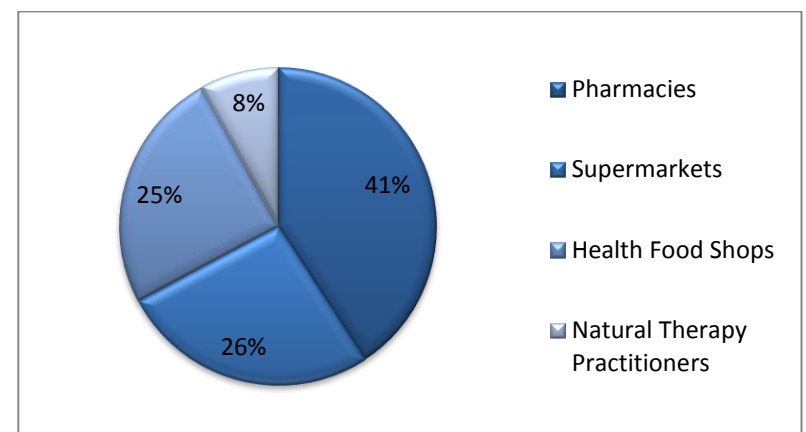


## YOUR COMPLEMENTARY MEDICINES INDUSTRY

The Australian complementary medicines industry has grown from \$2.3 billion to \$4.2 billion, with increasing acceptance and demand from consumers, both here and internationally.

In Australia, complementary medicines are sold through 5,500 pharmacies, 3,500 supermarkets and 1,500 health food stores. Data from 2015 indicates that Australian consumers still prefer to purchase their complementary medicines from pharmacies due to a large offering of product range and the availability of professional advice from the supervising pharmacist or healthcare professional.

### Place of Purchase



Roy Morgan Research, 2015. *Checking the Health of Australia's Vitamin Market*, Melbourne: Roy Morgan Research.

## ALLIED HEALTHCARE PROFESSIONALS

There are approximately 25 000 accredited complementary and alternative medicine (CAM) practitioners in Australia, and employment prospects continue to look strong for graduates.<sup>1</sup>



The complementary therapies industry is outperforming the wider economy. This is reflected by the strong growth over the past five years in industry value added (IVA), a measure of an industry's contribution to the overall economy. The IVA is forecast to grow





at a compound annual rate of 4.8% over the 10 years through 2020-21, exceeding the overall economy's forecast real GDP growth of a compound annual 2.8% over the same timeframe. <sup>ii</sup>

The World Health Organization (WHO) Traditional Medicine Strategy 2014-2023 highlights the potential contribution that complementary medicines can make to health, wellness and people-centred healthcare through the appropriate integration of complementary medicines into the healthcare system.

The increasing importance of the complementary medicines industry to global health can be seen in the increase in global regulatory standards and regulatory alignment, and the increase in economic and political discourses about integration of complementary medicines with conventional medicine.

## A FOCUS ON QUALITY

The provision of high quality products is fundamental to the goal of the Australian complementary medicines industry of enhancing consumers' health. Our industry recognises that we must continue to strive for quality, rather than simply ensuring we meet regulatory compliance.



Through the work of CMA and the vigilance of local manufacturers and other interested parties, the Australian industry has a strong focus on quality. An industry quality improvement process has been developed, our relationship and liaison with the TGA has never been stronger, and quality remains at the heart of industry educational events.

*Every business that operates within our industry holds a vital stake in ensuring that ours is an industry that provides products of the highest quality for both the Australian market and for our exports. I am delighted to see that Australia is acting as a global leader and building on the strength of our strong global branding for excellence."*

- Mr Dusko Pejnovic, CMA Board President

To ensure that our industry is informed and forewarned about global developments and any possible quality issues with raw materials, CMA supports the pivotal work undertaken by the American Botanical Council in relation to the Botanical Adulterants Program. The Program informs the industry worldwide about the most common causes of both intentional and unintentional adulteration, and provides the tools for product sponsors to combat those causes of unintentional adulteration when developing or reviewing strategies for minimising risk.

CMA is also a member of the International Alliance of Dietary/Food Supplement Associations (IADSA), an organisation that has regional and national regulatory programs in many parts of the world, scientific programs to address relevant and often challenging issues for policy makers, and a technical program focused on continuing to build quality in manufacturing of supplements.



## GROWING EXPORTS

Over 60% of Australian complementary medicine companies are engaged in exporting and the number of firms looking to export is growing rapidly. Our industry exports to more than 26 countries including;

- China, Taiwan, Hong Kong, South Korea
- Singapore, Malaysia, Philippines, Vietnam, Thailand, Indonesia
- Brazil, Canada, United States, Germany.

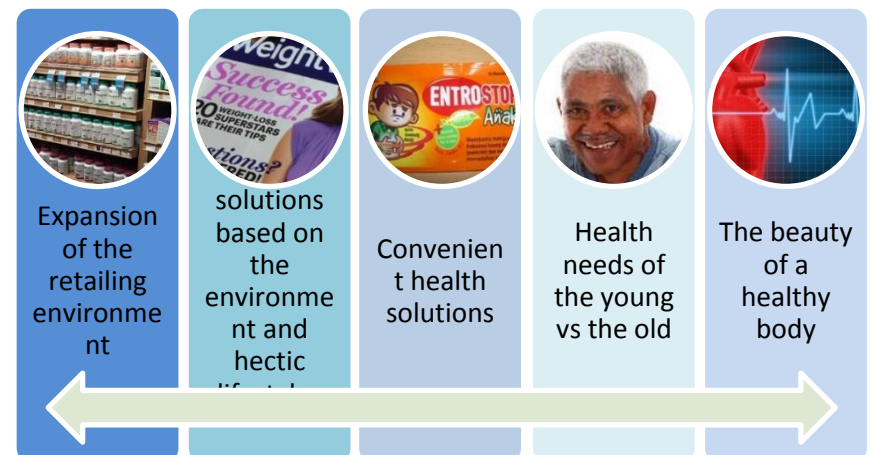
Recent Austrade data shows Australian complementary medicines exports to Asia have more than doubled in the last year. <sup>iii</sup> Over the last two years we have seen formal exports of Australian complementary medicines grow by 36 per cent.

## GLOBAL TRENDS

Products offered by the Australian complementary medicines industry, which range from herbals to vitamins and minerals to nutritionals and functional foods, align with a number of the top global trends for 2016, <sup>iv</sup> which include:

- challenging ageing for an optimal mature lifestyle;
- consumers shopping for control over their lives,
- creative single spenders fusing luxury with counterculture;
- mental wellbeing matters;
- a better world as a mainstream goal; and
- greener food to cut waste and feel safer.

### Factors Driving Growth in the Asia Pacific Region



Cox, E., 2015. *Consumer Health Global Overview*. Sydney, Euromonitor International.

Australians are choosing to be more proactive and adopting a greater role in caring for their health, and the use of complementary medicines is a core element of this. The Australian complementary medicines industry, with high quality products supported by one of the most rigorous regulatory frameworks in the world, has much to offer – quite simply, the best of natural health.



<sup>i</sup> Osborne, G. (2014). Job prospects look decidedly healthy. Sun Herald, Sydney.

<sup>ii</sup> IbisWorld. (2016). Alternative Health Therapies in Australia: Market Research Report <http://www.ibisworld.com.au/industry/default.aspx?indid=1914>

<sup>iii</sup> Austrade (2015) Annual Export Statistics: Vitamins & Supplements. Year ended June 2015

<sup>iv</sup> Kasriel-Alexander. D. (2016). Top 10 Global Consumer Trends for 2016. Euromonitor International.