

Australia's Complementary Medicines **Industry Snapshot 2018**



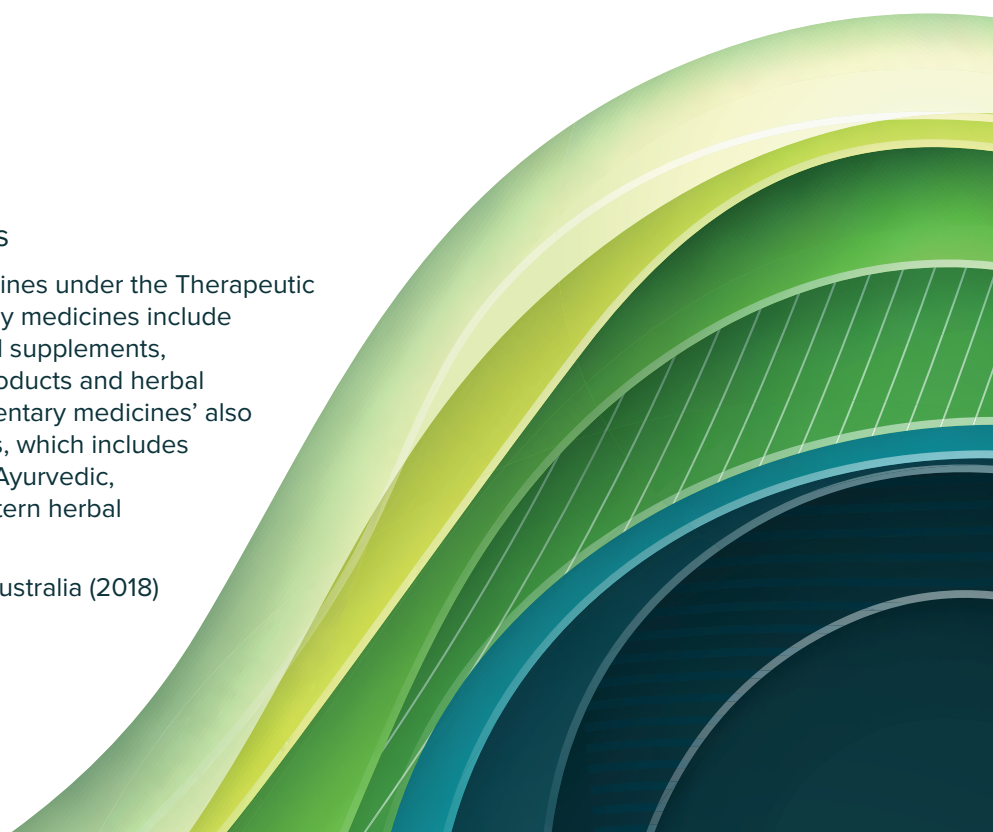
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Complementary Medicines

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. The term 'complementary medicines' also comprises traditional medicines, which includes traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines.

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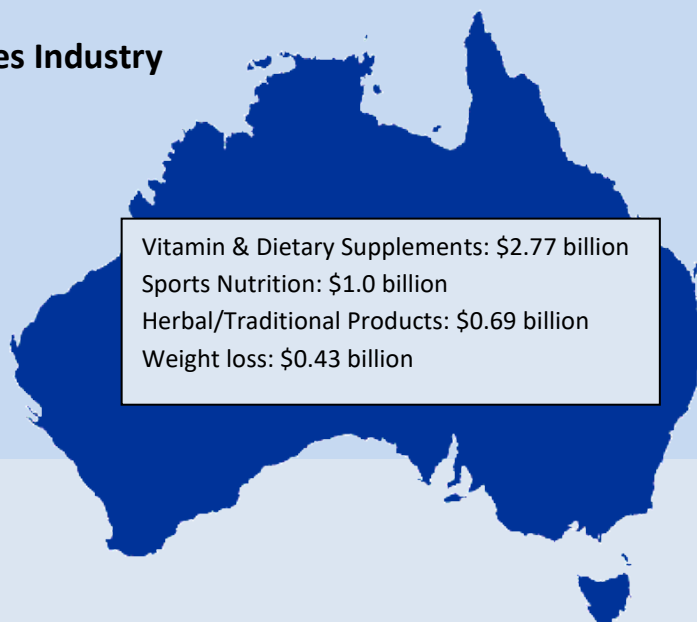


Australia's Complementary Medicines Industry

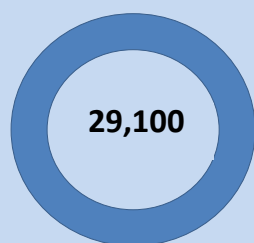
\$4.9

Billion Revenue (AUD)

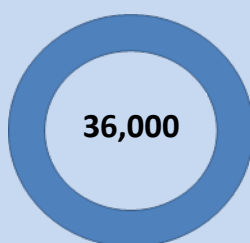
\$2.0 billion Growth over 5 Years



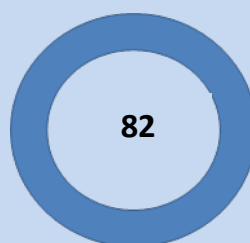
Vitamin & Dietary Supplement (VDS) category alone has doubled over the last 10 years



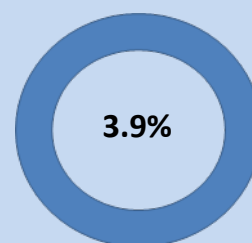
Jobs supported by the complementary medicines industry



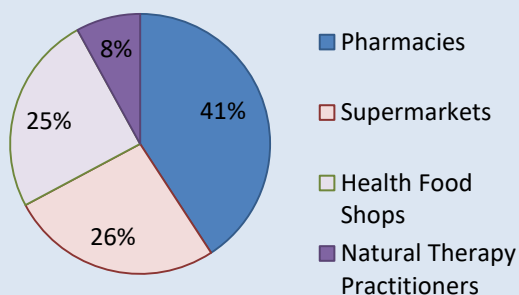
Natural health practitioners



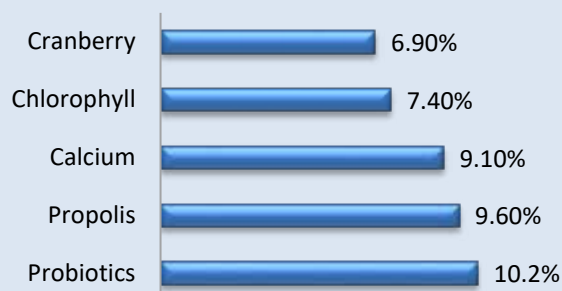
Manufacturers, paying \$170 million in wages



2017 expected annual growth rate for manufacturing sector



Complementary medicines are sold through 5,500 pharmacies, 3,500 supermarkets and 500 health food stores.



The top 5 fastest growing dietary supplement ingredients 2016/17



8.1 Million regular consumers in Australia

The top 5 dietary supplement categories by share in 2016/17

General Health	17.6%
Heart Health	13.7%
Joint	13.6%
Digestive	9.0%
Women's Health	8.0%

71

New ingredients approved in 2017, driving development of innovative new products

Note from the CEO



I am delighted to present this snapshot of the Australian complementary medicines industry, which shares the key findings from CMA's 2018 Industry Audit and provides a brief overview of the regulatory environment for complementary medicines manufactured and provided for sale in Australia.

The sector is well-established, having evolved over the last 30 years to become a world-class industry that supports research, employment and high-skilled manufacturing. High demand for complementary medicine products is driving steady growth, with the industry reaching \$4.9 billion in revenues in 2017. Over the last five years, the sector has achieved \$2 billion in growth, predominantly as a result of our strong exports. Over 60 per cent of companies in our sector are engaged in exporting activities, and numerous Australian brands are recognised and trusted internationally.

The Australian government has committed to fostering a regulatory environment that is supportive of innovation. Recent, ongoing regulatory reforms have the goals of minimising the regulatory and administration burden for businesses, whilst ensuring the timely access to quality therapeutic goods for consumers. As a part of this commitment, the regulator has approved the use of many new active and excipient ingredients for use in listed medicines, including 71 new ingredients in 2017. This will support the industry to innovate further and formulate new products to meet consumer demand.

The Australian complementary medicines industry is expected to continue its positive growth trajectory, increasing innovation-rich manufacturing and providing a significant contribution to our country's exports.

A handwritten signature in black ink, which appears to read 'Carl Gibson'.

Carl Gibson
Chief Executive Officer
Complementary Medicines Australia

Industry Snapshot Key Findings

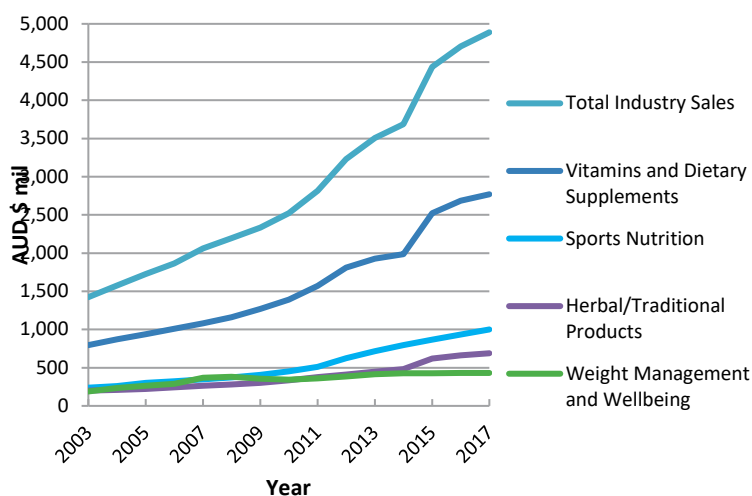
Industry Growth

The Australian complementary medicines industry has now reached sales of \$4.9 billion, having doubled over the past 10 years.ⁱ

The industry has experienced \$2 billion in growth in the previous 5 years.ⁱⁱ

The sector is strongly export focused, with over 60 per cent of Australian complementary medicine companies involved in exporting.ⁱⁱⁱ

Total Industry Sales



Sales Channels

Domestic consumers in Australia can purchase complementary medicines from a variety of sales channels, including:

Health food stores: There are more than 500 specialised health food stores with an extensive range of natural health products.

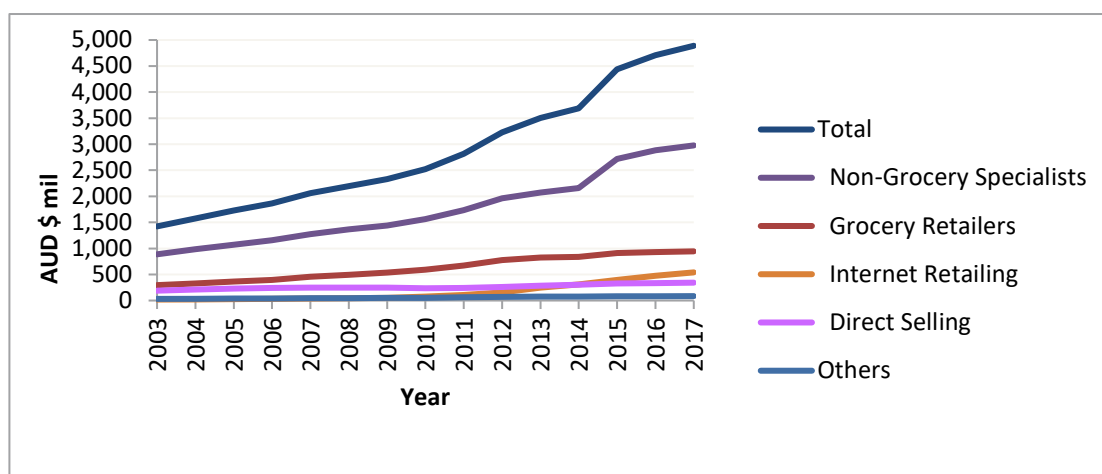
Pharmacies: Most Australian pharmacies have a store section for complementary medicines, where consumers can obtain professional healthcare advice from the pharmacist and in-store health professionals.

Supermarkets: Australian chain supermarkets, such as Coles and Woolworths, stock an extensive range of vitamins and minerals, supplements and other health products.

Online shopping: This is the fastest growing purchasing channel, with 14.3 per cent growth over the 2016-2017 period.^{iv}

The most popular channels are pharmacy, discount pharmacy and health food stores.^v

Sales by Channel



Top 5 Fastest Growing Supplement Ingredients	
Ingredient	2016-17 % Growth
Probiotics	10.2
Propolis	9.6
Calcium	9.1
Chlorophyll	7.4
Cranberry	6.9

Source: Euromonitor International (2017) ^{vi}

Top 5 Largest Supplement Categories by Market Share	
Category	2016-17 % Share
General Health	17.6
Heart Health	13.7
Joint Health	13.6
Digestive	9.0
Women's Health	8.0

The number of Australian consumers who used a complementary medicine on a regular basis in 2015 was 8.1 million, up 22.7 % from 6.6 million in 2011. ^{vii}

Employment

On the basis of research conducted by Remplan in 2016, the Australian complementary medicines industry is estimated to have supported 29 100 jobs in 2017, including 13 200 direct highly skilled jobs across the product supply chain. ^{viii}

The high demand for Australian natural health products has boosted jobs in the complementary medicines sector in Australia across a range of areas, including manufacturing, scientific evaluation and research.

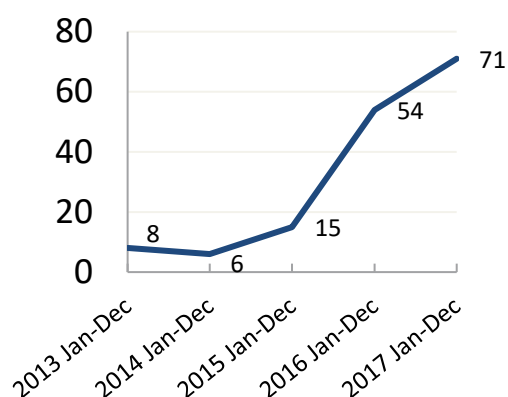
Manufacturing Sector

The sector has a growing number of trusted brands, and substantial manufacturing capability and capacity. Australian manufacturing of complementary medicines is expected to continue to expand, with an expected annual growth rate of 3.9% in 2017 building upon the strength of our high-skilled manufacturing. ^{ix}

There are 82 manufacturers, paying \$170 mil in wages at an average of \$65,500^x

Over the last three years, the regulator has approved the inclusion of greater than 100 new active and excipient ingredients on the List of Permissible Ingredients. 71 new ingredients were approved in 2017. ^{xi xii}

To support further research and development in the sector, a period of regulatory protection for propriety research and clinical trials is soon to be established.



New Ingredient Approvals

Note from the President



The Australian complementary medicines industry is proud to belong to a global sector that supports individuals and communities to better care for their health. Sales of complementary medicines are steadily increasing across the globe as consumers seek ways to proactively manage their health. Regulatory standards between countries are becoming more aligned, and there is greater discourse about the integration of complementary medicines with conventional medicine as recognition grows regarding the links between optimal nutrition and health.

The provision of high quality products is fundamental to the goal of the Australian complementary medicines industry of enhancing consumers' health. The Australian industry is fortunate to be recognised as a premium brand in the complementary medicines sector, stemming from our strict manufacturing standards and Australia's well-deserved reputation for a clean and well-regulated environment for food and medicines. In Australia, the regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), which has the responsibility of regulation of all therapeutic goods, including medicines and medical devices. Our regulatory system is seen as one of the most stringent in the world.

Evidence is growing in a number of areas that complementary medicines offer a valuable and cost-effective way to improve health outcomes. Complementary medicines research is essential for continuing to establish the safety and efficacy of complementary medicines, to contribute to understanding best practice for integrative health care, and to develop innovative new products. Australia has formidable complementary medicines research institutions that hold an international reputation for excellence.

The Australian complementary medicines industry, with high quality products supported by one of the most rigorous regulatory frameworks in the world and exceptional research institutions, has much to offer – quite simply, the best of natural health.

Dusko Pejnovic
President
Complementary Medicines Australia

Australian Research & Development Capabilities

Australia is fortunate to be home to world-leading research institutions for complementary medicines, including the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM) at the University of Technology Sydney, and the NICM Health Research Institute (NICM) at Western Sydney University.



ARCCIM is an outstanding public health and health services research centre focusing on traditional, complementary and integrative health care and brings together experts in epidemiology and health economics. Its work has received substantial government funding, including prestigious research fellowships from the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC).

Case Study: NICM Health Research Institute



A principal complementary medicine research institute in Australia, NICM Health Research Institute, is soon to move to the Westmead precinct, which is one of the largest health, education, research and training precincts in the Southern Hemisphere.

This is a unique opportunity to build capacity for a robust complementary medicine sector in Australia and internationally, and to contribute to informed healthcare choices.

The new home of NICM Health Research Institute, a landmark heritage building in the heart of the Westmead precinct, will include:

- 5,000 m² of research, teaching, clinical space for 100+ staff and research students
- Expansion of clinical trials platform
- Expansion of TGA herbal analysis, R & D, pharmacology laboratories
- Integrative medicine clinic and dispensary
- Conference facilities
- Expansion of NICM education and training program



NICM has created a broad network of significant research partnerships with international organisations in government and industry, including a number of prestigious universities, hospitals and other agencies in China, Asia, Europe and the US. NICM's strong credentials in Chinese medicine are well recognised and form the foundation for two major partnerships with China Academy of Chinese Medicine Sciences and Beijing University of Chinese Medicine. NICM is also working with a number of industry partners in China to advance evidence based analysis focusing on quality, safety, efficacy, and effectiveness of Chinese herbal medicines.

Australia also boasts excellent research centres outside of the university sector, such as the Endeavour College of Natural Health and the Blackmores Institute. The Endeavour College of Natural Health is a leading higher education provider for complementary and integrative healthcare, in part due to the value placed upon practice-relevant research. The Blackmores Institute, the academic and professional arm of Blackmores Limited, was established in 2012 with a vision to improve and promote the quality use of natural medicine via a focus on research and education.

Australian Regulation of Complementary Medicines

The Australian regulatory regime for complementary medicines is such that it is viewed internationally as the consumer protection benchmark.

Regulated under Australian law

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods, including prescription medicines, vaccines, medical devices, and complementary medicines such as vitamins, minerals and herbal products.

Based in Canberra, the TGA is responsible for administering the activities prescribed under the Therapeutic Goods Act 1989, the same Act under which it was established. The Act provides for a national system of controls relating to the quality, safety, efficacy, performance and timely availability of therapeutic goods used in Australia or exported from Australia. These controls are risk-based, with a tiered system for the regulation of all medicines, including complementary medicines.

Australian Register of Therapeutic Goods (ARTG)

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.

Information held in the ARTG includes:

- product name and formulation details
- sponsor (company) and manufacturer details

The vast majority of CMs are in the lower risk *listed* category, and there are about 140 products in the higher risk *registered* category.

Listed Medicines

- ❖ Usually considered to be low-risk medicines
- ❖ Products with well-known ingredients, usually with a long history of use
- ❖ The majority are self-selected by consumers and used for self-treatment
- ❖ Must display an 'AUST L' number on the label as proof of listing on the ARTG
- ❖ May only make health claims permitted for use in listed medicines
- ❖ Must comply with all legislative requirements relating to quality, safety and efficacy

Registered Medicines

- ❖ Medicines assessed as having a higher level of risk must be registered
- ❖ Rigorous and detailed assessment, including comprehensive evaluation of safety, quality and efficacy
- ❖ Must display an 'AUST R' number on the label as proof of registration; high-risk registered products include prescription medicines
- ❖ Registered complementary medicines are products that are higher risk than listed medicines, based on their ingredients or the indications made for the medicine

Strict Manufacturing Standards

In Australia, complementary medicines must be manufactured in accordance with the principles of the PIC/S Guide to Good Manufacturing Practice GMP in TGA approved and licensed facilities.

PIC/S GMP addresses requirements relating to quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall, and self-inspection.

Recent Regulatory Reforms

Recognising the need for an appropriate and contemporary regulatory environment the Government announced the Review of Medical and Medical Devices Regulation Review (MMDR) in 2014.

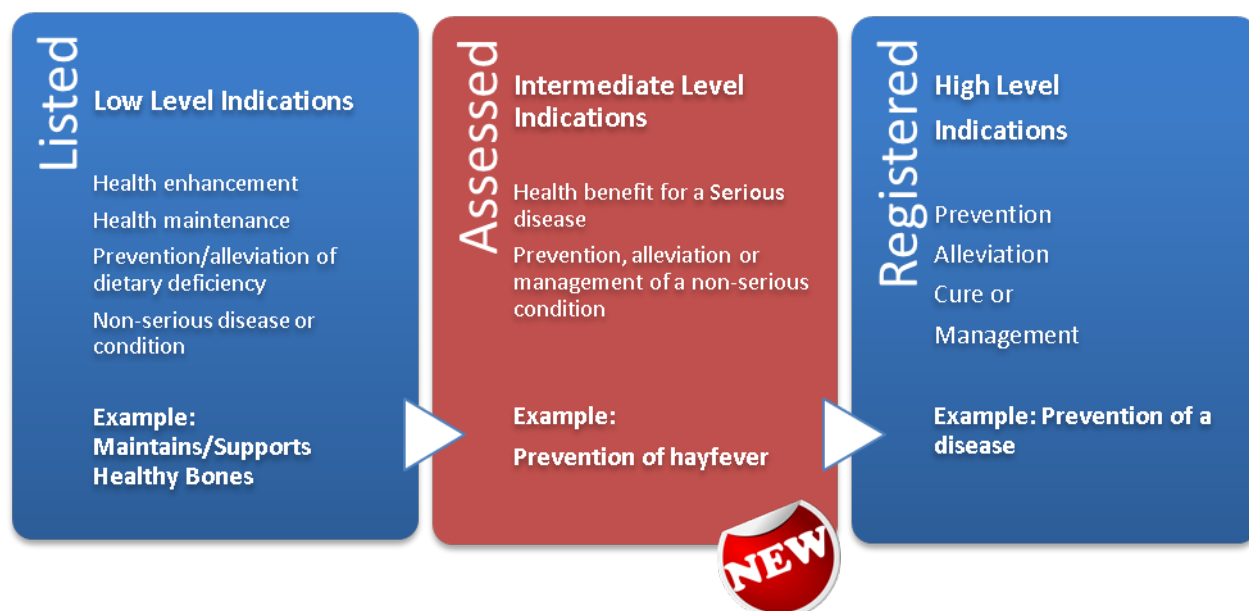
The MMDR was established by then Prime Minister, Tony Abbott, to identify areas of unnecessary regulation that could be streamlined and opportunities to enhance the regulatory framework so that Australia continues to be well-positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

The Australian Government accepted the majority of the Review recommendations. Amendments are steadily being made to the *Therapeutic Goods Act 1989* to support the implementation of the Government's response to the Review recommendations.



New Assessment Pathway for Complementary Medicine:

A recent reform to the regulatory system is the addition of a new pathway for listing a product on the Australian Register of Therapeutic Goods (ARTG). This pathway will allow for pre-market assessment for a product to make a specific higher level health claim or claims. The pathway also introduces a much needed mechanism for regulatory protection for propriety research and clinical trials.



Permitted Indications:

The government accepted the Review recommendation for the introduction of a list of 'Permitted Indications' for low-risk Listed complementary medicines. This creates a definitive list of indications from which sponsors must exclusively draw and will help reduce inadvertent non-compliance. The industry has been working with the TGA to ensure that the list is comprehensive.

Advertising & Complaints System:

The current advertising pre-approval system will be phased out over a two year period. The regulatory changes also include the establishment of a streamlined complaints system within the TGA. The decision to provide, through the regulator, a single body to manage all complaints is expected to help deliver consistency in decision-making, compliance and appropriate enforcement.

Regulatory Alignment

The TGA has active working relationships with many international agencies and overseas regulators, and has emphasised building institutional relationships to streamline both imports and exports. The TGA is committed to contributing to Australia's health system through best practice regulation of health products, and safeguarding the health of consumers through effective, timely and risk proportionate regulation of therapeutic goods.^{xiii}

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

Published by: Complementary Medicines Australia

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ⁱ Euromonitor International Australia, *Complementary Medicines Market Data 2016-2017*. 2018: Euromonitor International Australia.

ⁱⁱ *ibid*

ⁱⁱⁱ Complementary Medicines Australia, *Complementary Medicines Industry Survey*. 2014.

^{iv} Euromonitor International Australia, *Complementary Medicines Market Data 2016-2017*. 2018: Euromonitor International Australia.

^v *ibid*

^{vi} Euromonitor International. (2017). *Dietary Supplements In Australia*. Sydney: Euromonitor International

^{vii} Roy Morgan. (2015). Checking the health of Australia's vitamin market [Press release]

^{viii} Remplan, *Economic Impact Analysis: Nutraceutical Science and Innovation Program*. 2016.

^{ix} Euromonitor International Australia, *Complementary Medicines Market Data 2016-2017*. 2018: Euromonitor International Australia.

^x IbisWorld, *Vitamin and Supplement Manufacturing in Australia: Market Research Report*. 2017.

^{xi} Therapeutic Goods Administration, *Performance statistics report: July 2015 to June 2017*. 2018.

^{xii} Therapeutic Goods Administration, *Half Yearly Performance Snapshot, 1 July to 31 December 2017*. 2018.

^{xiii} Therapeutic Goods Administration (2017) Therapeutic Goods Administration Business Plan 2017-18