

The background is a vibrant green color filled with various white line-art icons related to medicine and health. These icons include pills, capsules, test tubes, syringes, a heart with an ECG line, a cross, a leaf, a water drop, a flask, and molecular structures. The icons are scattered across the entire page, creating a dense, thematic pattern.

# **Complementary Medicines Australia**

2020-21 Pre-Budget Submission



**cma** Complementary  
Medicines  
Australia

**Published by:** Complementary Medicines Australia  
PO Box 450  
Mawson, ACT 2606  
Australia  
Telephone: +61 (0)2 6260 4022  
E-mail: [carl.gibson@cmaustralia.org.au](mailto:carl.gibson@cmaustralia.org.au)  
Website: [www.cmaustralia.org.au](http://www.cmaustralia.org.au)  
ABN 49 169 036 088

© Complementary Medicines Australia (2019)



Complementary Medicines Australia is the leading voice and industry body for manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. CMA members represent over 70% of all product sales and the full value chain in Australia.

As the principal reference point for members, the government, the media and consumers, we communicate about a broad issues relating to the complementary medicines industry.

CMA continues to drive a 21st Century reform agenda. The introduction of a refreshed therapeutic goods regulatory regime included the establishment of a novel intermediate pathway for listed complementary medicines with higher level therapeutic indications supported by product specific evidence. Other developments include market exclusivity for new ingredients and a data protection (information exclusivity) scheme for Assessed Listed Medicines, coordinated by the Department of Health's Therapeutic Goods Administration.

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 advanced manufacturing. High demand for complementary medicine products is driving steady growth, with the industry reaching \$5.2 billion in revenues in 2018. Over the last five years, the sector has achieved \$2 billion in growth, predominantly as a result of strong exports. Australian brands are recognised and trusted internationally, with China importing more complementary medicines from Australia than anywhere else in the world.<sup>i</sup>

Health is an indispensable prerequisite for overall well-being as well as the foundation of economic and social development. Given the ageing of our population and the increasing rates of chronic disease, it is vital that we invest in the future health and well-being of our community.

Investing in prevention and public health keeps people well and out of hospital, improving productivity and reducing pressure on the health system.

The 2020-21 Budget provides the Government with the ideal opportunity to reveal its preventive health reform vision, through evidence-based and targeted preventive health programs for a more sustainable health system in Australia.

Preventive health interventions are the most cost-effective use of our health dollars. The CMA Pre-Budget Submission sets out a range of recommendations that are achievable, affordable and will reduce costs in health care and serve to grow the economy. I am pleased to put forward CMA's recommendations regarding priorities for the 2020-21 Federal Budget.

All the best in health,

Carl Gibson,  
Chief Executive Officer

29 741 Jobs  
supported  
by CM  
Industry

6.0%  
Annual Growth  
Manufacturing  
(2014-2019)

\$5.2 Billion  
Industry  
Revenue

Exports to China  
Ranked #1 in the  
World

## Contents

Overview .....	5
Summary of recommendations: .....	5
Preventive Health for a Sustainable System .....	6
<i>Natural &amp; Complementary Therapies</i> .....	6
<i>Complementary Medicines' Role in Preventive Health</i> .....	7
Supporting Growth of Australian Exports .....	8
<i>Country of Origin "Made in Australia"</i> .....	9
<i>Trade Liberalisation</i> .....	10
<i>Ingredients Grown in Australia</i> .....	10
<i>Support Programs for Exporters</i> .....	11
Encourage & Support Innovation and Investment in Research .....	11
<i>Funding for Complementary Medicine Researchers</i> .....	11
Regulatory Framework .....	13
<i>Regulatory Reforms Implementation Leading to Unnecessary Regulatory Burden</i> .....	13
<i>Review Legislative Framework Underpinning Regulation of Therapeutic Goods</i> .....	14
<i>Regulator Resources to Develop an IT Digital Infrastructure that Supports Changing Business and Community Needs</i> .....	14
Final Word .....	15
Complementary Medicines Australia .....	16

## Overview

Complementary medicines are an important and culturally acceptable part of healthcare around the world, representing for many people an accessible, affordable way to actively contribute to their health.<sup>ii</sup> Globally, individuals are increasingly including complementary medicines within their health care options. There are many reasons for the increased uptake of these products, notably a higher priority given to living well by consumers who are embracing many forms and models of health.

The Australian industry is fortunate to be recognised as a premium brand in the complementary medicines sector, stemming from strict manufacturing standards and Australia’s well-deserved reputation for a clean and well-regulated environment for food and medicines.

High demand for Australian complementary medicine products is driving steady growth, with the industry reaching \$5.2 billion in revenues in 2018. Over the last five years, the sector has achieved \$2 billion in growth and over 60 per cent of companies in the sector are engaged in exporting activities.<sup>iii</sup> The Australian complementary medicines industry is expected to continue its positive growth trajectory, increasing exports, innovation-rich manufacturing and providing a significant contribution to the economy.

CMA is pleased to put forward its 2020-2021 Pre-Budget submission. Our key recommendations for the Federal Budget will support investment in science and innovation in the industry and reveal its preventive health reform vision in Australia.

### Summary of recommendations:

This Pre-Budget submission outlines the major policy areas where investment is needed to maintain a strong and vibrant complementary medicines industry which can deliver substantial health and economic benefit.

**Recommendation 1:** Focus on preventive health to build a more sustainable health system for Australia

**Recommendation 2:** Support growth of our high-quality Australian exports

**Recommendation 3:** Support investment in complementary medicines research and translation of evidence into health practice

**Recommendation 4:** Review the Legislative framework for Therapeutic Goods to simplify its structure and language and develop an IT digital infrastructure that supports changing business and community needs.

*“Many countries now recognize the need to develop a cohesive and integrative approach to health care that allows governments, health care practitioners, and, most importantly, those who use health care services, to access T&CM in a safe, respectful, cost-efficient and effective manner.”*

(WHO Traditional Medicine Strategy 2014-2023).

## Preventive Health for a Sustainable System

### ***Recommendation 1: Focus on preventive health to build a more sustainable health system for Australia***

In general, it said that Australia has one of the highest performing health systems in the world. However, in common with a number of other developed countries, we are also experiencing an ageing population and increasing rates of obesity and chronic, complex health conditions. With half of all Australians already having at least one chronic disease, the need to place a stronger focus upon preventive health is becoming increasingly important.<sup>ivv</sup>

In 2017-18, two thirds (67.0%) of Australians 18 years and over were overweight or obese. The proportion of adults aged 18 years and over who were overweight or obese increased with age, relative disadvantage, and in Regional and remote Australia.<sup>vi</sup>

Overweight and obesity are associated with increased costs, beyond the individual health risks and quality of life associated with obesity, there is a huge societal and economic burden through the direct and indirect costs it generates. These costs are further increased in individuals who also have diabetes<sup>vii</sup>. Interventions to prevent overweight and obesity or reduce weight in people who are overweight or obese, and prevent diabetes, should reduce the financial burden.

Spending on health continues to grow with a total of \$161.6 billion spent on health by all governments, insurers and patients. The largest share of this spending went to running public hospitals (\$48 billion), which included \$26.4 billion to provide care for acute admitted patients (AIHW 2016). Health spend per person has grown from \$5 000 in 2006-07 to \$7 100 per person in 2015-16.<sup>viii</sup> The average costs incurred by public hospitals to deliver an 'average' service to acute admitted patients ranges from \$3,300 to \$6,400.<sup>ix</sup>

An older and sicker population can only foreshadow higher healthcare costs in the future unless there is a focus shift towards early prevention, encouraging healthy and active ageing, and supporting individuals to take control over their health.

### ***Natural & Complementary Therapies***

Natural therapies are recognised by the World Health Organization and by governments around the world as effective, appropriate and cost-effective solutions to helping people manage their healthcare. Complementary medicine practitioners emphasise nutrition, lifestyle modifications, and the importance of taking personal responsibility for health as fundamental principles for improving quality of life. Research conducted in Australia demonstrated that the total number of client consultations is estimated at 16 million annually, contributing over AUD\$1.8 billion to the economy each year.<sup>x</sup>

Amid the ongoing debate over rising out-of-pocket costs across the health sector, from the 1 April 2019, private health insurers were no longer permitted to provide cover for a wide range of natural

therapies, including naturopathy, herbal medicine, yoga and tai chi, all of which have a strong evidence base supporting their use to promote good health and wellbeing.

An analysis carried out by PricewaterhouseCoopers found that members across all levels of hospital cover who also choose ancillary benefits for natural therapies claimed \$200 per person less every year in hospital and medical costs; for members with top hospital cover it was \$430 per person less claimed if they chose ancillary benefits for natural therapies.

**Recommendation:** In light of the evidence supporting the use of complementary medicines and natural therapies for cost-effectively contributing to good health and preventing burden on the hospital system, CMA recommends that Government expedite restoring private health rebates for natural therapies.

### ***Complementary Medicines' Role in Preventive Health***

Individuals use complementary medicines as adjunctive therapy to conventional medicine, to help manage chronic disease, prevent the exacerbation of illness, and to optimise nutrition and wellbeing. There is now robust evidence in a number of areas that complementary medicines are a cost-effective way to improve health outcomes.

The 2017 McKell Institute report '*Picking the low hanging fruit: Achieving a more equitable and sustainable healthcare system*' finds that targeted evidence-based uptake of certain complementary medicines would result in notable cost savings in Australia, whilst delivering better health outcomes and greater equity.<sup>xi</sup> Through addressing some of the social determinants of health, which includes having a poor diet, complementary medicines can play a role in addressing long-term health budget pressures.

The recent introduction of Ngangkari healers, who use traditional Aboriginal methods of healing to support physical and emotional wellbeing based on 60,000 years of traditional knowledge, to South Australia's Royal Adelaide Hospital and rural health clinics<sup>xii</sup>, is testament to the Australian government's acknowledgement of the important benefits of traditional systems of medicine in Australia. The use of traditional medicines across multiple avenues of health care, provides a greater diversity in treatment options for the broader Australian population.

### ***National Preventive Health Strategy***

CMA supports the call to re-establish a National Preventive Health Agency to evaluate natural and complementary therapy interventions at a population level, an important step towards placing good health at the centre of policy making in Australia. A fundamental aim of health policy should be to prevent disease and reduce ill health so that people remain as healthy as possible for as long as possible.

*"Tackling the growing personal, social and economic burden of chronic illness is imperative, especially in a country with an ageing population. Prevention is increasingly being seen as a crucial means of reducing this burden."*

(Australia: The Healthiest Country by 2020)

Australia is uniquely positioned in the world to capitalise on our research and manufacturing

capabilities to demonstrate and better understand the value of traditional and complementary healing systems to Australia's diverse community.

Preventive health is also an essential move towards improving the cost-effectiveness of the health care system, by enhancing Australians' health and quality of life, and reducing preventable illness. In the case of complementary medicines, a thoughtful and rigorous strategy, coordinated by the preventive health body, would further demonstrate the cost-effectiveness and health benefits of complementary medicines for contributing to improved public health.

**Recommendations:**

- Re-establish a national preventive health agency to implement and evaluate population-wide prevention initiatives, improving the health and wellbeing of the community and providing long-term savings for the health budget.
- Reinststate the private health rebate for natural therapies, in light of the evidence supporting the use of these natural therapies.

## Supporting Growth of Australian Exports

### ***Recommendation 2: Support growth of our high-quality Australian complementary medicine exports***

Trade with international markets is crucial for the long-term prosperity of the Australian complementary medicines industry. Australian products are well recognised as a premium brand in the complementary medicines sector, due to our strict quality and safety manufacturing standards and Australia's global reputation for clean and safe products and its trusted regulatory agencies.

With Australian products increasingly popular in overseas markets, notably across Asia and the Western Pacific region, our industry holds the ability to continue its positive growth trajectory, growing our advanced manufacturing sector, boosting Australian jobs as well as stimulating scientific evaluation and research.

The Asia-Pacific region is the largest market for complementary medicines products in the world. Given the ageing population and growth of the middle class, demand for Australia's high quality complementary medicines is expected to remain strong. By 2030, the Asia-Pacific region will have 3.2 billion middle class consumers. Large demand is expected in the areas of health and aged care, natural preventive care and high-quality food products.

In 2019 Australia overtook the USA as the number one importer of complementary medicines into China. The opportunities offered by the Chinese market are extensive, with the health-food market alone – which includes vitamins and minerals, herbal extracts and Traditional Chinese Medicine – currently valued at US\$30 billion and projected to grow by 10 per cent every year until 2025.<sup>xiii</sup>



CMA welcomed the news that China will expand its free trade zones and extend its cross-border e-commerce policy, providing a stable policy and more certainty and confidence for e-commerce rules for imported products. The Chinese Government has made health a priority, with the “Healthy China 2030” (HC 2030) vision being central to all policy making<sup>xiv</sup>. It will include a focus not only on medical services for patients visiting doctors, but a holistic approach, including education, lifestyle, services and the environment. China is encouraging and promoting the development of a diverse medical service and health industry as it tackles the challenge of an aging society.

The demand for complementary medicines is growing rapidly in China due to an increasingly health-conscious population taking a strong interest in their health and wellbeing.

### ***Country of Origin “Made in Australia”***

In 2017 changes to the Australian Consumer Law (ACL), including the safe harbour test of ‘substantial transformation’, meant that as an unintended consequence the majority of complementary medicines no longer qualified to be labelled as ‘Made in’ Australia. This had flow-on effects for the ability of business to use the green and gold Australian Made (AMAG) logo<sup>1</sup> and the quality assurances that this claim provides domestic and global consumers.

After a 2019 Country of Origin taskforce, the Government has now enshrined in legislation new protections for the complementary medicine industry. The amendment to the regulations titled, *The Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019*, effective 18 December 2019, ensures access to Australian origin claims and eligibility for the Australian Made logo for all complementary medicines meeting the newly legislated example.

Complementary Medicines Australia supported the government taskforce recommendation (2019) that products that are manufactured in Australia should continue to be eligible for access to the ‘Made in’ Australia logo. Using Australian GMP production of the finished medicinal product should be the benchmark to protect industry and support businesses to compete in overseas markets.

The ability to use a consistent logo and branding in the form of the ‘Made in’ Australia offers Australian business a competitive advantage in international markets and confers that the products were manufactured in Australia to the highest safety specifications.

A joint media release ‘Claiming back Australian Made for complementary medicines’ by the Hon Karen Andrews MP, Minister for Industry, Science and Technology, and Assistant Treasurer the Hon Michael Sukkar MP, formally announcing these measures also foreshadowed possible further label changes, such as a bar chart to be consistent with the (mandatory) requirements around labelling for food.

The business certainty that has been provided in the updated Regulations<sup>2</sup> is welcomed and now needs to remain stable for a reasonable period of time without further label amendments posed on a compliant industry.

---

<sup>1</sup> Registered certification trademark and Australia's most trusted, recognised and widely-used country of origin symbol AMCL.

**Recommendation:**

- Business certainty provided in the updated Regulations<sup>2</sup> needs to remain stable for a reasonable period of time without further label amendments posed on a compliant industry.

***Trade Liberalisation***

CMA strongly supports the growing number of free trade agreements to which Australia is a signatory, and the growing focus on helping to address ‘behind the border’ issues. Continued trade liberalisation will present sizeable opportunities for the Australian complementary medicines industry as the sector is well positioned to compete for emerging opportunities.

The Regional Comprehensive Economic Partnership (RCEP) is a regional free trade agreement that seeks to build on Australia’s existing relationships with 15 Indo-Pacific countries. Once signed and entered into force, RCEP will deliver substantial new trade and investment opportunities for Australia in the Indo-Pacific region). Prime Minister Morrison and Leaders from 14 other RCEP countries (excluding India) announced on 4 November 2019 at the annual summit in Bangkok that RCEP’s text negotiations had concluded.

Over 98% of Australian Complementary Medicines are exported in the RCEP countries, led by China (56%), Hong Kong (14%) and New Zealand (11%). While bilateral trade agreements provide Australian exporters with a more competitive framework in these three countries, an overarching multilateral trade agreement would further improve the CM industry through a consistent set of Rules of Origin, improved dialogue channels for reducing non-tariff barriers with members, and a unified set of rules across region concerning capital flows, intellectual property and data protection and collection.

**Recommendation:** The Australian Government focus on securing some of the objectives of the Australia-India Comprehensive Economic Cooperation Agreement (CECA) through the RCEP and return to CECA negotiations once RCEP is concluded.

***Ingredients Grown in Australia***

AgriFutures (formerly RIRDC) identifies and nurtures research, innovation and collaborative efforts to support new and emerging opportunities for rural industries. This includes support of the emerging Australian seaweed industry, tea tree oil, and native plants such as wattle seed, Kakadu plum and native pepper. An opportunity exists to increase the market capacity for ‘Australian Grown’ raw materials for medicinal herbal ingredients, underpinned by Australia’s ‘clean and green’ branding and reputation for quality. CMA proposes targeted funding for AgriFutures to work with the Australian complementary medicines industry, supporting additional research and commercialisation to fully capture the opportunity of locally grown ingredients.

**Recommendation:** Targeted funding for AgriFutures to work with the Australian complementary medicines industry, supporting research and commercialisation of locally grown ingredients.

### ***Support Programs for Exporters***

CMA believes that government support programs are vital to assist Australian exporters to conduct business in emerging and growth markets, and in terms of provision of advice, capacity building and expediting export opportunities. Maintaining Austrade as a strong organisation is vital to Australia's economy, as are the continued efforts by the Department of Foreign Affairs and Trade to support Australian firms in building strong international networks.

Austrade and DFAT's Australia-China Council have provided instrumental support for the complementary medicine industry in building engagement with Chinese stakeholders, a notable example being the strong presence of Australian brands at the CMA Australian Pavilion at the Healthplex Expo in Shanghai, the premier event for companies looking to enter the Chinese market or to raise the profile of their brands. Similar support for raising brand awareness in the Indian and Indonesian market would be of great value.

#### **Recommendations**

- The Australian Government secure some of the objectives of an Australia-India Comprehensive Economic Cooperation Agreement (CECA) through the Regional Comprehensive Economic Partnership (RCEP)
- Targeted funding for AgriFutures to collaborate with the Australian complementary medicines industry to increase locally grown ingredients.
- Maintain current investment in Austrade to support Australian exporters and enhance Australia's global competitiveness.

## **Encourage & Support Innovation and Investment in Research**

***Recommendation 3: Support investment in complementary medicines research and translation of evidence into health practice***

Australia holds a unique opportunity to build capacity in a world-leading complementary medicine research sector and to contribute to informed healthcare choices around the globe.

### ***Funding for Complementary Medicine Researchers***

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.

A principal complementary medicine research institute in Australia, the NICM Health Research Institute has created a broad network of significant research partnerships with international organisations, including a number of prestigious universities, hospitals and other agencies in China, Asia, Europe and the US. The NICM Health Research Institute has recently moved to the Westmead precinct, one of the largest health, education, research and training precincts in the Southern Hemisphere. The research facilities and capabilities of Australia in the field of natural and complementary therapies are the envy of the world, but funding is needed to capitalise on and cement this reputation.

Australia also boasts excellent research centres outside of the university sector, such as the Endeavour College of Natural Health, The National Institute of Integrative Medicine (NIIM) 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. In collaboration with universities and other medical bodies, NIIM conducts research into the safety and efficacy of integrative medicine and complementary therapies for the prevention, detection and treatment of disease and boasts Australia's largest integrative medical centre, the NIIM Clinic. 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.

Just a few examples of recently published research include nutrition and supplementation, probiotics and internal gut health, yoga, natural pain relief methods during childbirth, and the benefits of exercise in mental health. A Cochrane Review, published in November 2018, 'Omega-3 fatty acid addition during pregnancy' showed that there's high quality evidence for omega-3 supplementation being an effective strategy for preventing preterm birth, the leading global cause of death in children under the age of 5 years.<sup>xv</sup>

For every dollar invested in Australian health research and development, \$2.17 in health benefits is returned.<sup>xvi</sup> Given the potential benefits of complementary medicines as a tool towards preventive health, and that we now have world-class facilities poised to take flight in this important research area, complementary medicines research should be a priority area for funding.

**Recommendations:**

- Beyond the general need for increased funding support for public health research in Australia, CMA recommends that particular areas of research priority include targeted additional support for complementary medicine research groups.

## Regulatory Framework

***Recommendation 4: Review the Legislative framework for Therapeutic Goods to simplify its structure and language and develop an IT digital infrastructure that supports changing business and community needs***

The Australian complementary medicines industry operates within one of the most highly regulated systems in the world. This ensures that 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.

In Australia, the regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), part of the Health Products Regulation Group (HPRG) within the Department of Health. The TGA is committed to contributing to Australia's health system by protecting the health and safety of the community through delivering a world class, efficient and timely regulatory system for therapeutic goods.<sup>xvii</sup>

### ***Regulatory Reforms Implementation Leading to Unnecessary Regulatory Burden***

In 2016 the Australian Government supported the majority of the recommendations to the Review of Medicines and Medical Devices Regulation (MMDR), which identified ways to improve access to therapeutic goods for consumers and remove unnecessary red tape for industry whilst maintaining the safety of therapeutic goods in Australia. CMA would like to acknowledge the significant work that has been undertaken to date by the TGA on the MMDR reforms. Implementation of the Government Response to the MMDR Review has largely been completed, with the exception of certain complementary medicines and medical devices reform.

The main objectives of the MMDR were to improve the timely and safe access to quality therapeutic goods for consumers, whilst ensuring that any legislative framework is commensurate with the risk of such goods, and to minimise the regulatory and administration burden for business. This is consistent with the need for Australia to remain competitive on the global stage. Industry has cooperated with the implementation of these reforms with the intent that they are to be de-regulatory in nature.

Whilst it is recognised that reforms create additional work for both the regulator and for businesses, unnecessary burden has been created for the CM sector due to the staggered time frames for implementation of the numerous changes required to legislative instruments. This creates a level of complexity and financial burden for industry, particularly for smaller and medium sized entities.

The Expert Panel reviewed the CM sector with a view that the Industry Innovation and Competitiveness Agenda indicated that *'a lower cost, business friendly environment with less regulation'* is critical to achieving the outcome of maintaining global competitiveness. The Coalition Government is committed to reducing red tape and unnecessary regulation, making it easier for businesses to invest, create jobs and grow the economy. The Deregulation Taskforce announced July

2019 by the Assistant Minister to the Prime Minister and led by the Treasurer will drive improvements to the design, administration and effectiveness of government regulation to ensure it is fit for purpose. The Taskforce includes for example 'reducing regulatory burden for food manufacturers with an initial focus on exporting'. A better regulatory environment will help businesses lower their costs, save time and improve their competitiveness.

In light of these priority areas, the TGA implementation of a number of the MMDR recommendations has instead resulted in a significant increase in red-tape due to increasing complexity of requirements across all areas: Manufacturing & GMP; Labelling; Advertising; and evidence review and interpretation.

### ***Review Legislative Framework Underpinning Regulation of Therapeutic Goods***

The Government accepted the principle of MMDR Recommendation 28; that the Australian Government undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, including a review of the *Therapeutic Goods Act 1989* and associated Regulations in their entirety, with a view to simplifying its structure and language to achieve a more user-friendly approach.

CMA believes it is crucial to implement the intent of this recommendation in light of the TGA's increasing compliance and enforcement actions to provide a fair opportunity for all businesses, and a level playing field for smaller businesses with lower financial resources. To increase enforcement in an exceedingly complex and non-user-friendly framework, without fulfilling the recommendation to make the legislation more simplified and user-friendly, is putting the 'cart before the horse' and providing an extremely difficult regulatory environment that will see international competitors with less red tape complexities take competitive advantage of critical overseas markets.

As the recommendation suggested, an assessment should be made on the need for a more comprehensive review of the legislative framework underpinning the regulation of therapeutic goods. As demonstrated by legislative reforms by NICNAS, a new and simplified legislative scheme is possible and achievable.

### ***Regulator Resources to Develop an IT Digital Infrastructure that Supports Changing Business and Community Needs***

Complementary medicines supplied in Australia, unless specifically exempt 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. As the vast majority of complementary medicines are in the lower risk AUST L category, sponsors access the TGA's eBusiness portal to include, update or amend product listings.

Under the MMDR, the TGA has established a list of 'permitted indications' from which sponsors must exclusively draw from when listing an AUST L product on the ARTG. This, among other changes to eBusiness, has led to an increasingly overwhelmed, extremely slow and unpredictable IT system. For businesses that routinely update numerous listings, the loss of productivity with IT glitches can be

significant. In response to the changing business environment, innovation to improve business processes through the better use of the data provided by stakeholders and improved data analytics is required.

The TGA annual budget is approximately \$165 million and operated predominantly on a cost recovery basis. The regulatory costs are recovered through fees and charges levied on sponsors and manufacturers of therapeutic goods. An activity based costing model is used to calculate the relevant costs for each activity undertaken.

The TGA are committed to an ongoing program of business improvement focussed on transparency of regulatory decision-making, increased efficiencies in business processes and a more strategic approach to the use of information technology to support regulatory operations<sup>xvi</sup>.

In light of these priority areas, additional investment from reserves is required for the TGA to modernise their existing legacy systems to build a more agile, integrated system that would serve to better meet the changing business and security needs of its users.

The Department of Agriculture for example has moved forward with the build of an agile new biosecurity system interconnecting the platform with existing legacy systems to improve information flows across the department and to better support staff to make biosecurity risk decisions. The new data analytics capability was funded with \$15.9 million from the 2016 federal budget to improve the way the department manages biosecurity risks.

**Recommendations:**

- Provide the TGA with funding to modernise existing legacy systems to build a more agile, integrated system, including an upgraded eBusiness support system.
- Provide the TGA with specific funding to undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods.

**Final Word**

In a supportive business environment, 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.

There is now robust evidence in a number of areas that complementary medicines are a valuable and cost-effective way to improve health outcomes. An ageing population and increasing rates of chronic disease foreshadow higher healthcare costs in the future unless there is a focus shift towards early prevention, encouraging healthy and active ageing, and supporting individuals to take control over their health.

To fully realise the contribution that complementary medicines can make to the health of our communities, research is essential for continuing to establish their safety and efficacy, to contribute to understanding best practice for integrative health care, and to develop innovative new products. The Australian complementary medicines industry, with high quality products supported by one of the most rigorous regulatory frameworks in the world and exceptional research organisations, has much to offer – quite simply, the best of natural health.

CMA appreciates the opportunity to offer its recommendations regarding priorities for the 2020-21 Federal Budget.

### **Complementary Medicines Australia**

Complementary Medicines Australia (CMA) is the peak industry body representing the whole of the complementary medicines 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.

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.





- 
- <sup>i</sup> Zhongpeng Zhang, CCCMHPIE (2018) Development and Trade Performance of China's Nutraceutical Industry, CMA Annual Conference September 19, 2018 Sydney Australia.
- <sup>ii</sup> Commonwealth of Australia (2017) Complementary Medicines Industry Capability Report.
- <sup>iii</sup> Complementary Medicines Australia (2018) Australia's Complementary Medicines Industry Snapshot 2018
- <sup>iv</sup> Australian Government. (2015). New stats reveal 50% of Australians battling disease. Accessed from <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley100.htm>
- <sup>v</sup> McKell Institute (2017). Picking the Low-Hanging Fruit. Achieving a More Equitable and Sustainable Health Care System.
- <sup>vi</sup> Commonwealth of Australia (2019) Australian Bureau of Statistics, National Health Survey: First Results, 2017-18.
- <sup>vii</sup> Crystal Man Ying Lee, Brandon Goode, Emil Nørtoft, Jonathan E. Shaw, Dianna J. Magliano & Stephen Colagiuri (2018) The cost of diabetes and obesity in Australia, *Journal of Medical Economics*, 21:10, 1001-1005, DOI: 10.1080/13696998.2018.1497641
- <sup>viii</sup> Australian Institute of Health and Welfare (2018) Australia's health 2018: in brief. Cat. no. AUS 222. Canberra: AIHW.
- <sup>ix</sup> Australian Institute of Health and Welfare (2018) Hospital Performance: Costs of acute admitted patients in public hospitals from 2012–13 to 2014–15. Canberra: AIHW.
- <sup>x</sup> The Practitioner Research and Collaboration Initiative (PRACI) <https://praci.com.au>
- <sup>xi</sup> McKell Institute (2017). Picking the low-hanging fruit: Achieving a more equitable and sustainable health care system. Equity Economics, Sydney.
- <sup>xii</sup> Hanifie S, 2018 Ngangkari healers: 60,000 years of traditional Aboriginal methods make headway in medical clinics, ABC News, 28 March 2018 <https://www.abc.net.au/news/2018-03-28/aboriginal-healers-complementary-medicine-finds-its-place/9586972>
- <sup>xiii</sup> Austrade (2017) Complementary Medicines in China: A guide for Australian business
- <sup>xiv</sup> Tan, X., Liu, X. & Shao, H. 2017, "Healthy China 2030: A Vision for Health Care", *Value in Health Regional Issues*, vol. 12, pp. 112-114
- <sup>xv</sup> Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. *Cochrane Database of Systematic Reviews* 2018, Issue 11. Art. No.: CD003402. DOI: 10.1002/14651858.CD003402.pub3.
- <sup>xvi</sup> Access Economics. (2008). Exceptional Returns: The Value of Investing in Health R&D in Australia.
- <sup>xvii</sup> Therapeutic Goods Administration (2019) Therapeutic Goods Administration Business Plan 2019-20
- IbisWorld, (2018) Vitamin and Supplement Manufacturing in Australia: Market Research Report. Available at: <https://www.ibisworld.com.au/industry-trends/specialised-market-research-reports/consumer-goods-services/vitamin-supplement-manufacturing.html> (Accessed: 14 January 2019).