



Complementary Medicines Australia

Pre-Budget Submission 2023-24

27 January 2023

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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 80% 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 and advocate for the issues that matter to the complementary medicines industry.

The sector is well-established, having evolved over the last 30 years to become a world-class industry that supports a 30,000 workforce in research and high-skilled advanced manufacturing. High demand for complementary medicine products is driving steady growth, with the industry reaching \$5.5 billion in revenues in 2021 representing a steady 1.4% growth, despite the challenges of the pandemic.

Australian brands are recognised and trusted internationally, with China importing more complementary medicines from Australia than almost anywhere else in the world.ⁱ

As Complementary Medicines Australia celebrates 50 years of promoting preventive health and wellness, it is a timely reminder of how indispensable health is as a 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. The last few years has made this even more apparent. Investing in prevention and public health keeps people well and out of hospital, improving productivity and reducing pressure on the health system.

The 2023-24 Federal Budget provides the Government with the opportunity to unveil its integrated, preventive health reform vision, through evidence-based and targeted preventive health programs encompassing complementary approaches for a more sustainable health system in Australia.

Preventive health interventions are the most cost-effective use of health dollars and there is significantly more that can be done over a long-term strategy to enhance preventive health and wellbeing outcomes, including the contribution of cost-effective, efficacious complementary medicines.

The CMA Pre- Budget Submission sets out a range of pillars that would enhance and complement the preventive approach already committed and in order to further reduce costs in health care and serve to grow the economy. I am pleased to put forward CMA's recommendations regarding priorities for the 2023-24 Federal Budget.

All the best in health,



Carl Gibson
Chief Executive Officer



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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. 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.

It is significant to see Government making bold changes that will create strong, resilient, thriving and internationally competitive manufacturing businesses. With this in mind, the Government has established the National Reconstruction Fund (NRF), which is a significant step in rebuilding Australia's industrial capability.

However, advancing complementary medicine manufacturing (which is a significant Australian industry), has not been called out as a priority area for growth, unlike the previous Modern Manufacturing strategy.

With the right support, the Australian complementary medicines industry is expected to continue its positive growth trajectory, increasing exports, innovation-rich advanced manufacturing and providing a significant contribution to the economy.

Key Statistics

The complementary medicine and natural therapies sector significantly contributes to the health of Australians and the strength of the broader economy via employment, manufacturing and the supply chain.

Australians accessing complementary medicine and natural therapies

More than 70% of Australians use complementary medicines and the prevalence of use of complementary medicines and natural therapies modalities has remained consistently high over time².

Economic contribution of complementary medicine and natural therapies

The Australian complementary medicine industry continues to outpace growth in the broader market by contributing \$5.5 billion to the economy².

The role of complementary medicine and natural therapies in preventative health Approximately 50% of Australians suffer from some kind of chronic condition, many of which are preventable. Heralding the call for an increased focus on prevention rather than just cure.

The latest Australian Institute of Health & Welfare (AIHW) report, The Australian Burden of Disease Study 2022, back this up and shows that a portion of the burden of disease, as a measure of the years of healthy life lost from living with, or dying from disease and injury, is preventable due to modifiable risk factors.

Summary of Recommendations

Our key recommendations for the Federal Budget will support investment in science and innovation in the industry and complement the preventive health reform vision for Australia.

- **Recommendation 1:** Recognise the role of complementary medicine in preventive health, to build a more sustainable health system for Australia:
 - Focus on evaluating population-wide prevention initiatives, improving the health and wellbeing of the community and providing long-term savings for the health budget.
 - Reinstate the private health rebate for natural therapies, in light of the evidence supporting the use of these natural therapies.

- **Recommendation 2:** Support growth of our high-quality Australian manufacturing sector and exports through ongoing investment and deregulation.
 - Leverage complementary medicine as a priority area for future growth by collaborating with the sector on specific future funding rounds.
 - Liaise with the medicines regulator on key manufacturing principles applied to complementary medicines that could be cost offset to help scale up and build future capacity for the sector.
 - Targeted funding for AgriFutures to work with the Australian complementary medicines peak body and industry, to support research and commercialisation of locally grown ingredients.
 - Expand investment in Austrade to enable Austrade to continue providing fee-free support to Australian exporters and enhance Australia's global competitiveness.

- **Recommendation 3:** Support investment in complementary medicines research and translation of evidence into health practice.
 - The Government should support medical research in the complementary medicines sector.

- **Recommendation 4:** Support the appropriate regulation of complementary medicines and provide direct funding to the Therapeutic Goods Administration (TGA) to cover work outside of the direct cost recovered framework.
 - Provide specific funding to the TGA to undertake services that are currently unfunded public good activities mandated through legislation/policy but that cannot be attributed to ARTG sponsors and should not be cost-recovered by industry.
 - Provide the TGA with specific funding to undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods.
 - Establish a separate Office of Complementary Medicines within the TGA

Preventive Health for a Sustainable Health System

Recommendation 1: Recognise the role of complementary medicine in preventive health, to build a more sustainable health system for Australia

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 for a stronger focus upon preventive health has become a top line priority.^{ivv}

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.^x

The previous government banned private health insurers from offering rebates 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.

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 remove the ban on 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 option 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.^{xi} Through addressing some of the social determinants of health, which includes having a poor standard diet, complementary medicines can play a role in addressing long-term health budget pressures.

Case example: 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^{xii}, 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

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. This approach would unite strongly if it were to be a priority area of focus into the Government’s National Reconstruction Fund and associated sovereign capability uplifts.

Preventive health is 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, would further demonstrate the cost-effectiveness and health benefits of complementary medicines contributing to improved public health.

“The Strategy recognises that around 38% of the chronic disease burden could be prevented through a reduction in modifiable risk factors, and emphasises that preventive action must focus on the all influencing factors that impact on health to ensure health equity is achieved for priority populations.”

(National Preventive Health Strategy, December 2021)

Recommendation:

- Focus on evaluating population-wide prevention initiatives, improving the health and wellbeing of the community and providing long-term savings for the health budget.
- Reinstate the private health rebate for natural therapies, in light of the evidence supporting the use of these natural therapies.

Supporting Growth of Australian Manufacturing and Exports

Recommendation 2: Support growth of our high-quality Australian complementary medicine manufacturing and exports

CMA strongly supported the whole of government approach to the then Modern Manufacturing Strategy as it would leverage Australia to be recognised as a high-quality and sustainable manufacturing nation that helps to deliver a strong, modern and resilient economy for all Australians. It aimed to also support continued confidence of Australian made complementary medicines longer term, along with the inclusion of sector specific expertise on the Modern Manufacturing Advisory Panel.

The launch of the National Reconstruction Fund, calls out medical science as a focus area but does not specifically recognise the success and significance of complementary medicine manufacturing in Australia.

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. Expansion in Vietnam, Indonesia and India are a key focus and opportunity for the industry. Further negotiation and prioritisation on removing and reducing tariffs related to HS Codes for complementary medicine trade with India will be a significant step forward for Australia.

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 China market remain 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.^{xiii} The demand for complementary medicines continues to do well in China due to an increasingly health-conscious population taking a strong interest in their health and wellbeing.

Recommendation:

- Leverage complementary medicine as a priority area for future growth by collaborating with the sector on specific future funding rounds.
- Liaise with the medicines regulator on key manufacturing principles applied to complementary medicines that could be cost offset to help scale up and build future capacity for the sector.

Ingredients Grown in Australia

AgriFutures 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, native pepper, among others.

Recommendation:

- Expand investment in Austrade to enable Austrade to continue providing fee-free support to Australian exporters and enhance Australia’s global competitiveness.

An opportunity exists to increase the market capacity for ‘Australian Grown’ raw materials for medicinal herbal and other 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 and their end use.

The CMA position statement on climate action supports a circular economy approach and a promising opportunity exists to assist primary producers in Australia and simultaneously expand agricultural waste conversion into high-value products. For example, a range of nutraceuticals, health-promoting foods and pharmaceutical and high-performance materials can be produced using compounds diverted from other industries.

Recommendation:

- Targeted funding for AgriFutures to work with the Australian complementary medicines peak body and industry, to support research and commercialisation of locally grown ingredients.

Support Programs for Exporters

CMA believes that government support programs and services are vital to assist Australian exporters enter and expand in emerging and growth markets, and in terms of provision of advice, capacity building and expediting export opportunities.

In recent months, Austrade has provided instrumental support to aide our sector’s diversification efforts into emerging markets such as South-East Asia. Maintaining market share and navigating market challenges in China has required local intelligence and advice which Austrade offices in-country have been able to provide to Australian complimentary medicine businesses – intelligence proven to be challenging for businesses to gather given covid lockdown policies.

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 pre-covid 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.

Continuing to build Brand Australia through brand awareness activations in new and emerging markets including India, Indonesia and beyond would be of substantial value to the sector. Recent CMA export webinars canvassed the opportunities of government led, industry delegations to India that specifically tapped into Australia’s complementary medicine advantage and proposition to the Indian market.

Encourage & Support Innovation and Investment in Research

Recommendation 3: Support investment in complementary medicines research and translation of evidence into 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, the NICM Health Research Institute (NICM) at Western Sydney University and the National Centre for Naturopathic Medicine at Southern Cross University, focusing on evidence-based natural medicine and its important role in healthcare.

Australia also boasts excellent research centres outside of the university sector.

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.^{xv}

For every dollar invested in Australian health research and development, \$2.17 in health benefits is returned.^{xvi}

Given the preventive health benefits of complementary medicines, and that Australia has world-class facilities in this important research area, complementary medicines research should be a priority area for future funding.

Recommendation:

- The Government should support medical research in the complementary medicines sector

Healthy Regulatory Framework

Recommendation 4: Support the appropriate regulation of complementary medicines through and provide direct funding to the Therapeutic Goods Administration (TGA) to cover work outside of the direct cost recovered framework

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.

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. ^{xvii}

Regulatory Reforms Implementation Leading to Unnecessary Regulatory Burden

In 2016, the Australian Government supported the majority of the recommendations from 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.

Industry cooperated with the implementation of the reforms with the intent that they were to be de-regulatory in nature, 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.

However, the TGA implementation of a number of the MMDR recommendations 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.

Continuing Cost Pressures

Significant Budget pressures remain for the TGA, particularly around the cost of fee-free services and reform costs.

Non-discretionary TGA functions encompass a wide verity of activities that are currently not appropriately cost-recovered under the agreed model, including significant compliance, enforcement and litigation actions. The result being where there is not enough direct Government funding, the remaining is to be absorbed by levied fees and charges imposed on the regulated industry.

Many of the large costs associated with TGA compliance, enforcement and litigation actions are a result of those that operate largely outside of the regulated system, including where products are not appropriately registered on the ARTG or represent an illegal food type product.

Further to this, a recent government decision has indicated that the second phase of the Digital Transformation of the TGA would be cost recovered by the regulated industry rather than originally proposed as "government investing \$12 million over four years to digitise, transform and modernise the TGA's business systems and infrastructure'. The effects of this change will be keenly felt by and require extensive consultation with industry sectors.

In addition, costs associated with the TGA's recent move in Canberra from Symonston to Majura should not be passed onto industry. This should be funded entirely by Government.

Industry should not be forced to fund activities of the TGA which do not relate to the regulation of industry. The government should provide adequate funding to the TGA for these activities.

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. Plain English guidelines are also a pillar supported by the World Health Innovations Summit (WHIS) recommendations and strategies to address health literacy.

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.

For the regulator to increase enforcement activities in an exceedingly complex and non-user-friendly framework, without fulfilling the recommendation to make the legislation more simplified and user-friendly, results in an extremely difficult regulatory environment that will see international competitors with less red tape obtain competitive advantage in critical overseas markets.

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.

Fit for purpose structure in TGA

CMA is calling for a Distinct Office of Complementary Medicines to be established within the Department of Health by splitting from the existing combined 'TGA Office of Over-the-Counter Medicines & Complementary Medicines'.

By doing so, this will enable a 'fit for purpose' Office staffed with people with a relevant preventive health and natural therapies skill set and a capability and culture that would harness an appropriate risk-based approach to the sector without the need to establish a distinct a separate regulatory body for CMs.

This should avoid unnecessary impact on the budget. This proposal is aligned with the Governments' better regulation agenda and would support an approach that acknowledges complementary medicines as a high value-add group identified for growth opportunities as we focus on an Australian made future.

It is not seen in lowering standards, safety or quality of the products in the industry in any way. It is seen as helping the industry build on the \$1 Billion+ export success story by maintaining high quality exports of complementary medicines.

The establishment of a distinct Office of Complementary Medicines would allow for tailored performance measures and reporting processes that are appropriate to the complementary medicines sector. It would begin to address the long-expressed concern of industry of misleading reporting of listed medicine compliance statistics to Government and consumers.

Recommendation:

- Provide specific funding to the TGA to undertake services that are currently unfunded public good activities mandated through legislation/policy but that cannot be attributed to ARTG sponsors and should not be cost-recovered by industry.
- Provide the TGA with specific funding to undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods.
- Establish a separate Office of Complementary Medicines within the TGA

Final Word

In light of the next phase of the Government’s move to “reform and renewal”, the Australian complementary medicines industry has the capacity 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 of 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 2023-24 Federal Budget.

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