



# **CMA 2024-25 PRE-BUDGET SUBMISSION**

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## ABOUT COMPLEMENTARY MEDICINES AUSTRALIA (CMA)

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CMA is the peak industry body representing a diverse range of stakeholders in the \$6 billion Australian complementary medicines industry – including manufacturers, suppliers, distributors, consultants, retailers, allied health professionals and educators.

Our membership encompasses over 80% of all Australian complementary medicines market product sales, indicating a broad and influential presence throughout the industry's value chain.

We are the leading voice for our industry, representing the views of our members to Government, media and consumers.

Australia's health system is under strain, with hospitals and general practice stretched beyond capacity with increasing levels of chronic disease. Complementary medicines help reduce the risk of and relieve aspects of chronic disease but are under recognised and underutilised. Strategic Government policy to increase their recognition and use can play a significant role in easing this burden.

We welcome the opportunity to submit recommendations for the 2024-25 Budget to support the ongoing growth of our industry, contribute to the overall health and wellbeing of Australians, and boost the Australian economy.

The key recommendations outlined in this submission emphasise the importance of using complementary medicine as preventive healthcare, restoring private health rebates for natural therapies, addressing challenges in the regulatory environment, and funding research and development at a level commensurate with the sector's economic contribution.



# AUSTRALIA'S COMPLEMENTARY MEDICINE INDUSTRY

Complementary medicines are used by more than 70%<sup>1</sup> of Australians and are more likely to be used by those with tertiary education and a higher income. Complementary medicine, including traditional and integrative therapies, are recognised globally, including by the World Health Organisation, and actively recognised by governments such as Australia's large trading partners, Indonesia and China, for their effective benefit.

Australia boasts one of the world's most rigorously regulated complementary medicine product sectors and this stringent approach ensures that consumers can access responsibly formulated, evidence-based, and high-quality products. This empowers consumers to proactively integrate these options into their healthcare.

In the Western sphere, Australia is also considered to have world-leading academic institutions and manufacturing facilities, albeit currently with minimal Government support. Complementary medicine is one of the few manufacturing sectors, including medicinal manufacturing sectors, to largely remain on domestic soil.

Our sector contributes to Australia by employing nearly 40,000 people across manufacturing, logistics, research, retail, and more. The industry's robust growth, fuelled by high consumer demand, is evident with annual revenue of around \$6 billion in 2023<sup>2</sup>.

This success underscores the sector's commitment to delivering quality products to promote health and wellbeing while fostering economic opportunities and job creation, however, the next phase of growth through increased research, increasingly cost-efficient regulation, and greater community awareness is necessary.



<sup>1</sup> Complementary Medicines Australia (CMA). Consumer Sentiment Study Survey. 2022.

<sup>2</sup> NICM Health Research Institute. Securing The Future Of Complementary Medicines Manufacturing In Australia. 2023



# KEY RECOMMENDATIONS

As CMA looks toward the future, we urge the Government to actively incorporate complementary medicine in preventive health policy, enhance collaboration with the industry to support growth, and build complementary medicine-specific expertise within the regulator (TGA). In particular, we call for a continued emphasis on ensuring that regulations are risk-commensurate, fair, balanced, and do not hinder innovation or Australia's global competitiveness.



The recommendations aim to strengthen the industry's resilience, competitiveness, and ability to meet the evolving healthcare needs of the Australian population.

## CMA recommends that the Government:

1. Consult with the complementary medicines industry to incorporate the role of complementary medicine in the national preventive health strategy and agenda;
2. Prioritise removing the ban on private health insurance rebates for natural therapies;
3. Develop industry policies that support the growth of Australian complementary medicine manufacturing, including raw materials;
4. Increase funding for Austrade to facilitate increased overseas promotion and new export opportunities for Australian complementary medicine products;
5. Initiate a review by the TGA to address industry concerns related to regulations, which:
  - focuses on identifying and reassessing areas of over-regulation and inefficient regulation not commensurate with risk, and
  - aims to foster a more balanced regulatory culture that has strategies to manage risk in order to permit greater innovation and industry growth without compromising safety.
6. Provide adequate funding for the TGA to undertake all non-cost-recoverable work so these costs are not passed onto industry.
7. Provide additional funding for the Department of Health to undertake positive education campaigns relating to public health benefits of evidence-based nutritional substances and regulation of complementary medicine products.
8. Provide greater support for complementary medicine research through targeted funding and increased R&D incentives.

Further details on the implementation of these recommendations are outlined in this submission.

# THE ROLE OF COMPLEMENTARY MEDICINE IN PREVENTIVE HEALTH

Primary healthcare in Australia is under considerable strain. Hospitals and general practice are stretched beyond capacity, and this is compounded by rising rates of obesity and chronic disease, and an ageing population. With half the population dealing with at least one chronic disease<sup>3</sup>, there's a need to recalibrate the focus from acute care to preventive health.

Preventive health measures can play a significant role in easing the healthcare burden, and complementary medicines are a fundamental element in this. Preventative health has been proven to result in better health outcomes, which delivers not only a positive impact on the health and wellbeing of Australians, but financial benefits for the Government.

The complementary medicines industry promotes holistic health, strongly emphasising lifestyle modifications, regular exercise and healthy practices as primary interventions. Complementary medicines play a crucial role in supplying essential nutrients that may be lacking in diets, thereby contributing to overall health and preventing deficiencies that could potentially lead to health issues.

Empowering well-informed health consumers is integral to improving outcomes and fortifying the population's resilience, ensuring the long-term sustainability of essential healthcare services.

This approach enhances health resilience, promotes proactive health measures, improves the management of health conditions, and ultimately reduces expenditures on essential health services.

The National Preventive Health Strategy is a foundational framework for proactive healthcare in Australia, designed to bring about systemic changes for optimal outcomes across the population. The role and contribution of complementary medicine (and associated health practitioners, such as naturopaths) should be acknowledged.



## Recommendation #1:

The Government should consult with the complementary medicines industry to incorporate the role of complementary medicine in the national preventive health strategy and agenda



### Vitamin shortfalls

95% of Australians don't consume the recommended daily intake of fruit and vegetables<sup>4</sup>.



### Nutritional support

Up to 95% of Australians have a low vitamin D intake, with implications for physical, psychological and immune health<sup>5</sup>.



### Antioxidant protection

Research indicates that supplementing with vitamins A, C, and E and other antioxidant compounds can reduce the onset of eye-related diseases and potentially slow the progression of certain eye conditions<sup>6</sup>.



### Stress management

Managing stress is essential for overall mental and physical wellbeing and prevention of chronic illness. Supplementing with evidence-based nutrients creates improvements in chronically stressed people<sup>7</sup>. Researched herbal products can assist the body in adapting to stress<sup>8</sup>.



### Pregnancy nutrition

Multiple evidence-based nutrients are considered critically necessary for healthy baby physical and brain development, not only during pregnancy, but before pregnancy occurs. Some of these nutrients must be taken in supplemental form for assurance of effect<sup>9</sup>. Many Australians don't meet the recommended daily intake for these nutrients on a dietary basis, including iodine<sup>10</sup> and long-chain omega-3s<sup>11</sup>.



### Sleep support

Insufficient sleep has been linked to a higher risk of developing chronic conditions such as heart disease, diabetes, and obesity<sup>12</sup>. Herbal supplements are traditionally used to support healthy sleep patterns. Studies also suggest that insufficient levels of certain nutrients in the body may be linked to troubled sleep and insomnia<sup>13</sup>.

<sup>3</sup>Australian Institute of Health and Welfare, Australian Burden of Disease Study, 2023

<sup>4</sup>Australian Bureau of Statistics. Dietary Behaviour – Latest Release. 2022.

<sup>5</sup>Dunlop, E., Boorman, J. L., Hambridge, T. L., McNeill, J., James, A. P., Kiely, M., Nowson, C. A., Rangan, A., Cunningham, J., Adorno, P., Atyeo, P., & Black, L. J. "Evidence of low vitamin D intakes in the Australian population points to a need for data-driven nutrition policy for improving population vitamin D status." *Principles of Nutrition and Dietetics*, vol. 36, no. 1, 2023, pp. 203-215.

<sup>6</sup>Evans, Jennifer R., and John G. Lawrenson. "Antioxidant Vitamin and Mineral Supplements for Slowing the Progression of Age-Related Macular Degeneration." *Cochrane Database of Systematic Reviews*, vol. 9, no. 9, 2023, CD000254.

<sup>7</sup>Pickering, Gisèle, et al. "Magnesium Status and Stress: The Vicious Circle Concept Revisited." *Nutrients*, vol. 12, no. 12, 2020, 3672.

<sup>8</sup>National Institute of Health Office of Dietary Supplements. "Ashwagandha: Is it helpful for stress, anxiety, or sleep? Fact Sheet for Health Professionals."

<sup>9</sup>Sulistyoningrum, Dian, et al. "Study Protocol for a Randomised Controlled Trial Evaluating the Effect of Folic Acid Supplementation beyond the First Trimester on Maternal Plasma Unmetabolised Folic Acid in Late Gestation." *BMJ Open*, vol. 10, no. 11, 2020, e040416.

<sup>10</sup>Hynes, Kristen L., et al. "Women Remain at Risk of Iodine Deficiency during Pregnancy: The Importance of Iodine Supplementation before Conception and Throughout Gestation." *Nutrients*, vol. 11, no. 1, 2019, 172.

<sup>11</sup>Middleton, Dian, et al. "Omega-3 Fatty Acid Addition during Pregnancy." *Cochrane Database of Systematic Reviews*, 2018, no. 11, CD003402.

<sup>12</sup>Grandner, Michael A., et al. "Sleep: Important Considerations for the Prevention of Cardiovascular Disease." *Current Opinion in Cardiology*, vol. 31, no. 5, 2016, pp. 551-565.

<sup>13</sup>Arab, Arman, et al. "The Role of Magnesium in Sleep Health: A Systematic Review of Available Literature." *Biol Trace Elem Res*, vol. 201, no. 1, 2023, pp. 121-128.





## PRIVATE HEALTH INSURANCE REBATES FOR NATURAL THERAPIES

In 2019, the previous Australian Government removed private health insurance rebates for a variety of natural therapies (such as naturopathy, yoga, Pilates and tai chi). These therapies encouraged Australians to adopt healthier lifestyles and exercise, which studies show can help take pressure off the healthcare system.

The prohibition of these therapies from private health insurance in Australia differs to experiences overseas. Insurers are required to cover naturopathic services in several US states and Canadian provinces, as well as countries such as Germany and Switzerland by virtue of their effectiveness.

Naturopathy is also incorporated into publicly-subsidised aspects of the Brazilian and Indian national health systems for similar reasons. While Australian insurers are now prohibited from inclusion of these therapies in certain conditions, health systems such as the UK NHS mandate their inclusion as a first-line form of care.


Studies show therapies such as naturopathy effectively translate evidence-based preventive health approaches into real and sustained behavioural and lifestyle changes in patients<sup>14</sup>.

These therapies are not intended to cure severe diseases but rather to support overall health and wellbeing. We know that when people adopt healthier lifestyles, they are less of a burden on the health system, and this reduces costs for both insurers and the Government<sup>15</sup>.

With one in two Australians grappling with chronic diseases, strategic investment in funding for complementary medicines and natural therapies could substantially alleviate the burden of illness and stress on the health system.

By removing the blanket ban on private health insurance rebates for natural therapies, more Australians would be financially incentivised to incorporate these therapies into their lifestyle and improve their health, lessening their dependence on the healthcare system.

Private health insurers are also calling for the ban to be removed because of the demonstrated positive impact these therapies can have on people's health.



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**In Australia, integrating a post-surgical naturopathic wellbeing clinic for cardiac patients at a major Australian teaching hospital improved postoperative heart function and attendance at rehabilitation, which reduced the need for high-intervention postoperative medical support by 40%.**

**Recommendation #2:**

**The Government prioritise removing the ban on private health insurance rebates for natural therapies.**

This will have no cost to Government but taking pressure off the health system will result in savings and other associated benefits.

It should be up to private health insurers to determine which benefits they want to offer to their members.

<sup>14</sup>Myers SP, Vigar V. The State of the Evidence for Whole-System, Multi-Modality Naturopathic Medicine: A Systematic Scoping Review. J Altern Complement Med N Y N. 2019 Feb;25(2):14168.

<sup>15</sup>Wardle J, Steel A, Casteleijn D, Bowman D (2019). An evidence-based overview of naturopathic practice in Australia. Australian Journal of Herbal and Naturopathic Medicine 31(1):9-13

# CONTRIBUTION TO THE AUSTRALIAN ECONOMY AND ADVANCED MANUFACTURING

By promoting preventive health measures, complementary medicines help manage healthcare costs, indirectly benefiting the economy. The sector further contributes to Australia's economic growth, through advanced manufacturing, jobs, exports and research initiatives.

Complementary medicines are an Australian manufacturing success story, worth over \$6 billion per year, and Australia is the largest exporter of complementary medicines to many international markets, including China. Products are highly sought-after due to their impeccable reputation for quality, safety and efficacy.

The international market for complementary medicine stands at an impressive \$200 billion and Australia holds a particularly advantageous position due to its highly skilled manufacturing capabilities that comply with the Pharmaceutical Inspection Co-operation Scheme (PICS) and Good Manufacturing Practice (GMP) standards.

The complementary medicine sector drives research and development, advancing scientific and medical knowledge.

The industry creates a wide range of well-paid, highly skilled jobs, employing nearly 40,000 people across manufacturing, logistics, research, retail, and more. Additionally, using local herbs and ingredients supports Australian agriculture and encourages sustainable farming practices.

Australian companies must remain competitive by excelling in product quality, innovation, and strategic market positioning. Opportunities exist for companies investing in research and innovation to develop new and unique products. Formulations backed by scientific evidence continue to differentiate products in the market.

The ability to adapt to various regulatory landscapes and align with global trends positions Australia's complementary medicine industry as a robust and competitive player in the international arena.







There is potential to capture a greater share of the rapidly expanding global market, but the industry currently faces a range of barriers which hinder growth. These include:

- ◆ insufficient grant funding for research and development
- ◆ heavy reliance on imported raw materials, creating supply chain vulnerabilities
- ◆ acute skills shortages
- ◆ high manufacturing costs compared to overseas
- ◆ growing competition from overseas brands<sup>16</sup>

Addressing these barriers is essential for Australia's complementary medicines industry to grow. Strategic measures and support from the Government can bolster the industry across both domestic and international markets.

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**With adequate Government investment, there is the potential for Australian manufacturers to triple industry revenues by 2032<sup>17</sup>.**

**Recommendation #3:**

**The Government should develop industry policies that support the growth of Australian complementary medicine manufacturing, including raw materials.**

**Recommendation #4:**

**The Government should increase funding for Austrade to facilitate increased overseas promotion and new export opportunities for Australian complementary medicine products .**



<sup>16</sup>NICM Health Research Institute. Securing The Future of Complementary Medicines Manufacturing In Australia. 2023

<sup>17</sup>NICM Health Research Institute. Securing The Future of Complementary Medicines Manufacturing In Australia. 2023

# REGULATORY ENVIRONMENT

Australia's complementary medicine sector is arguably the most highly regulated in the world. These stringent regulations by the Therapeutic Goods Administration (TGA) ensure product safety and quality underpinned by evidence-based claims, making our products desirable to international buyers.

Ongoing and appropriate regulation on safety, quality and efficacy is essential for ensuring Australian complementary medicines maintain a high standard and competitive global reputation.

Whilst high Australian standards permit some price premium, this is not unlimited. Current aspects of regulation do not always reflect the low-risk nature of the products involved, and local businesses face the challenge of meeting the compliance costs which many overseas competitors do not. This creates restrictions and financial imbalances, resulting in delayed time to market and reduced competitiveness.

Increasing regulatory expectations over recent years and further red flags of increasing regulation in coming years risks Australian businesses becoming priced out as an exporter to global markets.

To remain competitive and ensure companies have sufficient resources for ongoing innovation, Australia needs risk-appropriate regulation for complementary medicines governed by senior staff with a strong background in complementary medicines who can

sensitively understand and navigate any risk while appropriately creating incentivised and accessible innovation.

Further, to be able to focus compliance efforts on genuinely significant areas of safety, quality, and matters of claims and advertising that are verifiably untrue or misleading which have the potential to create a lack of level playing field for complying industry, while preventing resource wastage on less significant matters.

The TGA has flagged a future major review of fees and charges, which must ensure a regulatory review to remove areas of ineffective regulation while ensuring remaining regulation remains efficient across the market and low-cost. High-fee, low-to-no risk requirements for products must be appropriately removed or streamlined to minimise regulatory burden and promote regulatory cohesion and compliance.

It is critical that the sector has greater transparency on and greater consultation about the way that cost-recovered resources are utilised for regulatory compliance purposes. Through greater consultation with industry, the TGA can ensure that compliance expenditure is targeted to necessary areas without a high compliance expenditure resulting in little to no difference to the marketplace or consumers.

The current TGA direction appears to be significantly increasing staffing levels without a commensurate level of identified risk, which creates an ineffective high-cost, low-outcome environment.

**The level of regulation must highly targeted with influence by CM-specific staff members and consultation with industry to cost-efficiently manage low-risk complementary medicines**

## **Recommendation #5:**

**The Government should initiate a review by the TGA to address industry concerns related to regulations, which:**

- **focuses on identifying and reassessing areas of over-regulation and inefficient regulation not be commensurate with risk, and**
- **aims to foster a more balanced regulatory culture that has strategies to manage risk in order to permit greater innovation and industry growth without compromising safety.**

**This process should consider:**

### **Efficiency Improvement**

- Advocate for streamlining both regulatory processes and fees and charges to eliminate unnecessary burdens on the industry.
- Promote a more agile and responsive regulatory approach with increased alignment with industry dynamics.
- Aim to foster an environment of innovation and competition within the complementary medicines sector through clarity, accessibility and affordability of regulatory pathways.

### **Thorough Regulatory Review**

- Conduct a review of regulatory focus not commensurate with the actual risks or relevance to safety, quality or efficacy.

### **Collaboration Enhancement**

- Enhance collaboration between TGA and the industry by fostering improved consultation mechanisms, particularly the utilisation of cost-recovered resources.
- Enable a clearer understanding of areas requiring regulatory focus and those that do not.

### **Expertise Prioritisation**

- Prioritise the development of Complementary Medicine-specific expertise within the relevant TGA Branch.
- Ensure a more nuanced and industry-aware approach to regulation through specialised knowledge.

Non-discretionary TGA functions encompass a wide variety of activities that cannot be cost recovered, including activities relating to illegal products, and general consumer education activities. Where there is not enough direct Government funding, the remaining is absorbed through levied fees and charges imposed on the industry. This should not occur as it is an unfair burden on the entire Australian medical and healthcare products industry.

## **Recommendation #6:**

**The Government should provide adequate funding for the TGA to undertake all non-cost-recoverable work so these costs are not passed onto industry.**

It is also important that the Australian public has awareness of the TGA's regulatory work and understands the strict requirements in place to help ensure safety, quality and efficacy of products. This will help to provide consumers with greater confidence, education and information about products.

## **Recommendation #7:**

**The Government should provide additional funding for the Department of Health to undertake positive education campaigns relating to the public health benefits of evidence-based nutritional substances and regulation of complementary medicine products.**



# INNOVATION, RESEARCH AND DEVELOPMENT

Research and development (R&D) is critical to supporting the future of Australia's complementary medicines sector, and Australia is home to several world-class institutions researching areas including herbal medicine, natural products, and integrative health.

Despite the sector's large economic contribution fuelled by consumer recognition of the benefit of complementary medicines, little to none of this finds its way back to direct funding of research and development. For example, by way of NHRMC grants into efficacy trials and epidemiological studies relating to complementary medicines.

Investment in R&D enables clinical trials and scientific studies to ensure continued effectiveness and safety in complementary medicines. This also fosters and retains consumer trust and innovation within the regulatory framework.

R&D also plays a pivotal role in establishing quality standards for manufacturing processes, raw materials, and final products.

Collaborative research between the industry and the broader healthcare community also creates new and improved opportunities for patient care, which for complementary medicines, are almost always low-cost and cost-effective interventions.



Despite the industry's commitment to research and development, a lack of Government funding commensurate with the sector's contribution to the economy currently hinders industry growth and market potential through limiting access to more specific evidence-based claims.

Limited grant funding from the Government deters companies from co-investing in the innovation which is critical to widening the efficacy base for consumers and health professionals to effectively use in the arsenal against chronic health conditions.

Clearer funding pathways and targeted funding for R&D are critical for fostering innovation creating significant health benefits for Australians, and to more clearly establish Australia as a world-class leader in complementary medicine manufacturing, research and development.



## **Recommendation #8:**

**The Government should provide greater support for complementary medicine research through targeted funding and increased R&D incentives.**

More specifically, to unlock the full potential of Australia's complementary medicines industry, CMA urges the Government to:

### **Establish Dedicated Research Funding Streams**

- Create specific funding streams dedicated to complementary medicine research.
- Engage Stakeholders and Experts

### **Engage Stakeholders and Experts**

- Collaborate with experts from the industry, research institutions, and healthcare professionals to identify priority areas for research.

### **Promote Interdisciplinary Research**

- Encourage interdisciplinary collaboration among complementary medicine researchers, pharmacologists, clinicians, and relevant experts.

### **Target-Specific Health Challenges**

- Align funding opportunities with pressing health challenges and public health priorities addressable through complementary medicine research (e.g., chronic conditions such as obesity, mental wellness).

### **Enhance Public-Private Partnerships**

- Facilitate partnerships between government agencies, research institutions, and private industry to leverage additional funding and resources.

### **Promote Translation and Implementation Research**

- Prioritise funding for research translating scientific findings into practical applications.
- Explore the implementation of evidence-based complementary medicine approaches in healthcare settings.

### **Enhance Public Awareness and Education**

- Promote public awareness of the importance of complementary medicine research through targeted communication strategies.
- Educate healthcare professionals, policymakers, and the public about the potential benefits and risks of complementary medicine through informational campaigns.

### **Government Support for Complementary Medicine Research**

- Implement strategic measures and incentives for innovation, skill development, and supply chain resilience.
- Bolster the industry's competitiveness domestically and internationally.
- Foster collaboration and proactive solutions to overcome challenges.
- Realise ambitions for sustainable growth and continued success.



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