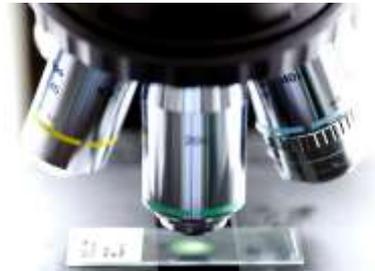




**chc**

Complementary  
Healthcare Council  
of Australia



## **A Future for the Complementary Medicines Industry**

**The Complementary Healthcare Council continues to advocate for an overarching Complementary Medicine Industry Framework that brings together innovation, manufacturing, appropriate regulation, research and health policy, needed to ensure sustainability of this important industry.**

## **The Complementary Medicines Industry**

- comprises at least 400 companies;
- ranges from multinationals through to smaller regional-based business (SMEs);
- ~ \$2 billion in annual revenues;
- supports more than 26,000 practitioners;
- employs around 5,000 people in highly-skilled manufacturing jobs;
- indirectly supports a further 60,000 jobs.

### **Exports**

- valued around \$200 million;
- to more than 20 countries in Southeast Asia, Europe and the Americas; and
- continues to grow at higher rates than domestic consumption.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using botanicals. Complementary medicines also comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines.

## **Executive Summary**

*The strategic framework described in this Advocacy Agenda provides a statement of commitment to the provision of a coherent, synergistic approach to sustainable growth in the Complementary Medicines Industry in Australia.*

*To achieve its goal of a sustainable, vibrant, compliant industry that holds its place in consumer health, the Complementary Medicines industry has prioritised four areas needing action.*

## **Appropriate Regulatory Environment**

### **Improving Consumer Health**

### **Innovation through Evidence**

### **Opportunities for Growth**

# Complementary Medicines require different regulation from Pharmaceutical Medicines

## Complexity of products:

- Multiple ingredients
- Complex formulations

## Evidence:

- is mostly traditional;
- scientific data is continually emerging;
- target populations must be 'healthy' yet supporting scientific data is in diseased populations (it is not feasible to conduct studies in healthy people);
- products are low risk in terms of safety.

## Lack of Data Protection:

- Patents not applicable to natural ingredients;
- Generated evidence is not protected by IP rules.

## Has led to:

- Complexity of regulation;
- Cost of regulation;
- Inappropriateness of medical model of evidence;
- Innovation restricted to marketing due to difficulties in bringing new ingredients to Australia and evidence restrictions.

## Priority 1: Appropriate Regulatory Environment

### Strategic Rationale

*An appropriate regulatory environment is required for a viable and competitive complementary medicines industry. The current environment of escalating regulatory red tape contributes significantly to the difficulties faced by industry.*

In fact, Australia has already one of the most highly regulated complementary medicines industries in the world. Even now, the regulatory environment causes significant financial impact, particularly on small and medium-sized enterprises (SMEs) that are being progressively forced out of the industry. The most frequently raised concern is the high cost of operating in Australia; an impost keenly felt when regulation creates additional burdens to export business. The burden will be felt even more with the introduction of the Australian New Zealand Therapeutic Products Agency (ANZTPA), due to the large cost differential associated with manufacture and supply of Complementary Medicines between Australia and New Zealand.

Excessive regulatory red tape stifles job creation, reduces investment, lowers innovation and lessens productivity. The Productivity Commission has estimated that reducing the burden of unnecessary red tape could generate as much as \$12 billion in extra gross domestic product per year.

### Government Action Needed

The CHC is advocating for the Australian Government to:

- ensure an appropriate Regulatory Framework for Complementary Medicines that remains adaptable to community and industry expectations;
- preserve an Office of Complementary Medicines Authorisation, and ensure Complementary Medicine-relevant Legislation;
- review the implementation of the current regulatory reforms to ensure appropriate 'light touch' regulation;
- support the development of a Complementary Medicine specific Code of Good Manufacturing Practice.

### Benefits include:

- clarity for industry, the regulator and consumers;
- clear and transparent regulation with appropriate parameters for listed and registered Complementary Medicines;
- assistance with building compliance capability as a function of business resilience and success;
- an innovative and sustainable industry.

# Complementary Medicines are an Integral Component of Consumer Healthcare

The supply of complementary medicines and complementary healthcare products comprises an important and integral component of health care delivery to the community; products that are available for personal selection and dispensing by healthcare professionals. Not surprisingly, half the adult population of Australia purchase a complementary medicine product at least every quarter.

Well-informed Australian consumers, in taking responsibility for their health and wellbeing, are keen to access innovative new products, even if this means ordering these products on-line from international sources.

It is an unfortunate side effect of the high regulatory standard in Australia that the introduction of new and innovative products, with the potential to contribute to population health has been almost eliminated by bureaucratic red tape.

## Priority 2: Improving Consumer Health

### Strategic Rationale

*There is a real and immediate role for Complementary Medicines in contributing to primary health through primary and secondary prevention of illness, creating healthy communities and businesses, and by encouraging and empowering all Australians to take better care of their health.*

The establishment in 2011 of the Australian National Preventive Health Agency (ANPHA) was recognition by the Government that prevention in the first instance beats cure when a problem occurs. However, the contribution of Complementary Medicines is absent from their agenda.

Complementary Medicines offer low-risk, efficacious interventions that can prevent or delay the onset of a wide range of chronic diseases that place a huge burden on the Australian community. Already, there is strong evidence of the important role of St John's Wort, Fish Oils, Vitamin D, Calcium and Glucosamine Sulphate in the prevention and management of cardiovascular disease, osteoporosis and osteoarthritis.

There is enormous potential for Complementary Medicines to demonstrate savings from disease prevention and health promotion. More research is urgently needed for economic analysis to help guide individuals, industry and Government spending on health. Research and education on the safe, effective and rational use of consumer and Government spending on Complementary Medicines must be a priority.

### Government Action Needed

The CHC is advocating for the Australian Government to:

- commit to a Complementary Medicine Policy Position that includes the significant contribution of Complementary Medicines in preventative health;
- allocate funding toward Complementary Medicine research and education in preventative healthcare;
- formally acknowledge and incorporate Indigenous Medicines into strategies to address the 'Close the Gap' target.

### Benefits include:

- realisation of the role of Complementary Medicines in improving public health;
- reduction of the burden of disease;
- contribution to easing the health cost burden on the Australian economy.

## Priority 3: Innovation through Evidence

### Strategic Rationale

*Australia has an important resource in its academic and research bodies, with the potential to be an international leader in Complementary Medicine research.*

*Currently less than 1% of NHMRC funding supports complementary medicine research yet statistics show Complementary Medicines are approximately 12.5% of the total medicines and devices industry.*

A viable, innovative and responsible complementary medicines industry is dependent on research to support quality, safety, efficacy, and cost effectiveness, and to develop new products. There is currently little or no incentive to support the development of complementary medicines if there is no possibility of data protection and/or market exclusivity. By comparison with the United States of America and the United Kingdom, research infrastructure for complementary medicine in Australia is not well developed.

There needs to be a greater incentive for R&D that allow for industry exclusivity or first-to-market advantage. Through Food Standards Australia New Zealand (FSANZ), the Australian Food Industry can now make health claims that link to serious disease through biomarker risk reduction. These claims incorporate a first- to-market advantage, offering companies returns from investment in research and development while allowing the certainty afforded by the pre-approval process.

### Government Action Needed

The CHC is advocating for the Australian Government to:

- ensure strategic policy directions to invest a proportion of NHMRC funding towards Complementary Medicines;
- support the National Institute of Complementary Medicine as an Australian Complementary Medicines specific agency;
- provide support to empower Indigenous Australians with commercialisation of their traditional knowledge – funding should be provided to undertake a comprehensive stocktake of indigenous medicines in consultation with traditional owners.

### Benefits include:

- maximised health gains and economic efficiency for the benefit of all Australians;
- further demonstration of the ability of Complementary Medicines to help deliver preventative health objectives.

## National Institute of Complementary Medicine

The National Institute of Complementary Medicine (NICM) was established to provide leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians.

The establishment of NICM followed the 2003 recommendation by the *Expert Committee on Complementary Medicines in the Australian Health System* that the Government has a social responsibility to fund complementary medicine research, given the high community use of complementary medicines and therapies.

NICM reached the end of its initial funding period in 2009. Additional funding is required if NICM is to continue to work closely with industry, disease foundations, health insurers, and research and government stakeholders to create better linkages, identify research and regulatory priorities and translate research into practice.

## Priority 4: Opportunities for Growth

### Strategic Rationale

*Whilst offering significant population health benefits, the Complementary Medicines Industry currently faces a number of barriers to growth. Industry has identified potential pathways to promote innovation and a sustainable industry whilst upholding the vital objectives of a sustainable regulatory environment.*

Currently, clinical trials involving complementary medicines must only be conducted in healthy populations, severely limiting the ability to achieve meaningful results.

In addition, current processes for new substance approval and product development are expensive, time consuming, lack procedural certainty and, even if successful, do not confer any market protection.

These barriers severely limit the type and level of evidence that can be gathered to support efficacy claims, and restrict industry's ability to substantiate the health benefits of their products.

Australian manufacturers need Government support to take advantage of the opportunities surrounding the Asian Century. In particular, assistance with exporting Australian-branded and indigenous medicines would greatly increase the contribution that the Australian Complementary Medicines industry can make in this arena.

### Government Action Needed

The CHC is advocating for the Australian Government to:

- support a Government-Industry Working Group to consider positive regulatory reform that promotes innovation in consumer health.

Possible solutions for improving industry competitiveness include, for example:

- *Complementary Medicine appropriate product registration pathway to incentivise registration;*
- *mechanisms to facilitate market exclusivity (data protection);*
- *mutual recognition with comparable overseas regulators;*
- *access to appropriate industry support schemes including export development and import replacements;*
- *targeted support for export facilitation, skills development and/or traineeships.*

### Benefits include:

- Australian consumers having access to high quality, safe, effective and readily available Complementary Medicines;
- a sustainable and innovative industry - with less reliance on marketing as the only form of innovation.

## The Complementary Medicines Industry Peak Body

The Complementary Healthcare Council of Australia is the peak industry body for the Complementary Medicines Industry. The CHC is unique in representing the entire supply chain from: manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. We are the principal reference point for members, the Government, the media and consumers to communicate about issues relating to the Complementary Medicine industry.

The CHC develops and manages codes of conduct to which its members comply, and to which CHC promotes all industry participants to comply. This includes operating to the highest regulatory and ethical standards when sourcing, manufacturing and marketing complementary medicines.



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# Complementary Medicine Industry Action Priorities

## **Priority 1: Appropriate Regulatory Environment**

Specific regulatory requirements recognised and levelled appropriately  
ANTZPA and international regulatory environment – mutual recognition

Barriers to Entry – Licensing of Sponsors, product pre-evaluation

Enabler for Priorities 2, 3 and 4 to work effectively

## **Priority 2: Improving Consumer Health**

Complementary Medicines included in Health Policy

Contributing to the Preventive Health Agenda

Recognition of Existing Evidence

Registration of Complementary Medicine Practitioners

Role of Universities in Teaching Complementary Medicine

## **Priority 3: Innovation through Evidence**

Research and Building Evidence

Innovation and Evidence

Sequester Funding for Complementary Medicine Research

Communication of Evidence to Practitioners & Consumers

Data Protection

New Substances and Formulations

Boosting Research & Development

## **Priority 4: Opportunities for Growth**

Export 'Clean and Green'

The Asian Century

Indigenous Medicine

Manufacturing Competitiveness

Workforce Development