



Joint Submission

Productivity Commission Review of Australia's Productivity Performance 2022-23

Published by: Complementary Medicines Australia

PO Box 450

Mawson, ACT 2606

Australia

Telephone: +61 (0)2 6260 4022

E-mail: cma@cmaustralia.org.au

Website: www.cmaustralia.org.au

ABN 49 169 036 088

© Complementary Medicines Australia (2022)

Complementary Medicines Australia

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.

CMA continues to drive *'a healthy regulation for a healthy future'* agenda for the sector. The introduction of a refreshed therapeutic goods regulatory regime over recent years has included the establishment of a novel intermediate pathway for listed complementary medicines with higher level therapeutic indications, supported by product specific evidence (Assessed Listed Medicines). Other developments such as market exclusivity for new ingredients and a data protection scheme for Assessed Listed Medicines, coordinated by the Department of Health's Therapeutic Goods Administration (TGA), have advanced the sector's capabilities, and set it up for the future. However, the sector has seen years of major reviews to the pillars of our world class regulatory framework and now is the time for policy stability and certainty for business in concert with the next phase of the Government's Economic Recovery Plan.

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 medicines is driving steady growth, with the industry reaching \$5.69 billion in revenues in 2020 representing a steady 1.5% growth, despite the challenges of the pandemic.

The sector has achieved growth predominantly as a result of strong exports, even given a slight decrease in overall exports during the COVID 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, 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. Current data shows that Australians can expect a high number of years spent in ill-health in absolute terms and as a share of life expectancy. The last 24 months has made this even more apparent with the ongoing pandemic facing the nation and our global partners. Investing in prevention and public health keeps people well and out of hospital, improving productivity and reducing pressure on the healthsystem.



The Productivity Inquiry provides the Government with an opportunity to leverage preventive health reform, through evidence-based and targeted preventive health programs for a more sustainable health system and a more productive Australia. Even small improvements in managing or preventing chronic conditions can produce substantial benefits for people's wellbeing, labour markets, productivity and avoided health care costs.

The launch of the National Preventive Health Strategy 2021-2030 sees a range of positive commitments; from a 5 per cent funding of total health expenditure across all jurisdictions; the inclusion of the determinants of health, and particularly the environmental determinants of health including climate change; improved nutrition through the reduction of sugar, saturated fat, and sodium content of packaged and processed foods, and an equity focus in the strategy, with the inclusion of specific equity targets for Indigenous Australians, Australians in regional and remote areas, and Australians impacted by social and economic disadvantage.

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.

In preparing this submission the CMA has partnered with the NICM Health Research Institute (formerly the National Institute of Complementary Medicine, www.nicm.edu.au). NICM is Australia's leading authority in integrative and complementary medicine research and policy. It was co-funded by the Commonwealth Coalition Government and NSW State Labour Government in 2007 and now plays a key national role in ensuring Australians have access to reliable evidence on complementary medicines and treatments in wide use. Supported by Western Sydney University in the Westmead Health and Innovation Precinct, NICM is globally recognised for its world-class research and innovations in integrative and complementary medicine. It has been rated as an ERA 5 institute by the Commonwealth Government's *Excellence in Research for Australia* scheme since 2012, signalling research well above world standard. NICM assists the complementary medicine industry to address manufacturing challenges, capture opportunities to innovate, grow jobs and exports.

This Joint Submission sets out a range of recommendations that would enhance and complement the preventive approach already committed to by the Government and in order to further reduce costs in health care and serve to grow the economy. We are pleased to put forward these recommendations regarding priorities for the Productivity Commission Inquiry.

All the best in health,

Emma Burchell
Director Operations
Complementary Medicines Australia

Professor Dennis Chang
Director, Professor of Pharmacology
NICM Health Research Institute, Western Sydney University



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 healthcare.

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 quality, well-regulated environment for food and medicines.

Australia is a global leader in integrative and complementary medicine research and policy and is home to world-leading research institutions for complementary medicines including NICM Health Research Institute (NICM) at Western Sydney University; the National Centre for Naturopathic Medicine at Southern Cross University, and the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM) at the University of Technology Sydney.

It is significant to see Government and Industry coming together to make bold changes that will create strong, resilient, thriving and internationally competitive manufacturing businesses. With this in mind, the Government have further identified the complementary medicines sector as a priority area for growth within the Modern Manufacturing Strategy in amongst a 2, 5 and 10 year roll out.ⁱⁱ

With the implementation of the recommendations outlined in this document and more efficient operation of the Government, the Australian complementary medicines industry is expected to continue its positive growth trajectory, increasing exports, innovation-rich advanced manufacturing and research capabilities, and providing a significant contribution to the economy.

Key Statistics

The complementary medicines sector significantly contributes to the health of Australians and the broader economy via employment, advanced manufacturing, and R&D.

- **Australians accessing complementary medicine and natural therapies**

More than 70% of Australians use complementary medicines and the prevalence of use of complementary medicines has remained consistently high over time.ⁱⁱⁱ

- **Economic contribution of complementary medicine and natural therapies**

The Australian complementary medicine industry continues to outpace growth of the broader market by contributing \$5.69 billion to the economy.^{iv}

- **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.^v

- **Total spending on health in 2021–22 is estimated to be \$98.3 billion**, representing 16.7% of the Australian Government's total expenditure .^{vi}

Summary of recommendations:

These key recommendations for the Inquiry will support efficiency gains and greater investment in science, research and innovation in the industry and will complement the preventive health reform vision for Australia.

This submission outlines the major policy areas where greater investment is needed to maintain a strong and vibrant complementary medicines industry, which will deliver substantial health and economic benefits.

Recommendation 1: Healthier People

- 1.1 Improve recognition of the role of complementary medicine in preventive health, to build a more sustainable health system, enabling prevention of chronic disease, and consumer choice.
- 1.2 Support enhanced investment in complementary medicines research and translation of research into better health outcomes for all Australians
- 1.3 Government expedite restoring private health rebates for natural therapies
- 1.4 Improve the health literacy of the population to support an equitable, sustainable, health system.

Summary of recommendations:

Recommendation 2: More efficient markets, supporting Australia's Manufacturing Industry

Support growth of our high-quality Australian manufacturing sector and exports through ongoing investment and deregulation.

2.1 Modern Manufacturing Strategy and initiatives

to target funding support for SMEs

2.2 Continue to embrace international

engagement including trade, investment and

the movement of people

Summary of recommendations:

Recommendation 3: Healthy Regulatory Framework

Improve the efficient administration of the regulations of complementary medicines

- 3.1** Continue to honour the commitment to a ‘no policy change’ to the evidence guidelines for listed medicines, supporting general level and traditional medicine claims
- 3.2** Review the Legislative framework for Therapeutic Goods to simplify its structure and language (MMDR REC)
- 3.3** Continue to consult with small business to better understand the impacts of regulation on small businesses
- 3.4** Support Healthy Regulation Plan for the efficient administration of the regulations of complementary medicines

Table of Contents

Complementary Medicines Australia	3
Overview	5
Key Statistics.....	6
Summary of recommendations:	8
Preventive Health for a Sustainable Health System.....	12
Recommendation 1: Healthier People.....	12
Recommendation 2: More efficient markets, supporting Australia’s manufacturing industry.....	17
Recommendation 3: Healthy Regulatory Framework.....	19
Healthy Regulation Plan 2022-2025.....	21
Healthy Regulation Plan 2022 – Guiding principles	22
Final Word	23
Complementary Medicines Australia.....	23
NICM Health Research Institute.....	23

Preventive Health for a Sustainable Health System

Recommendation 1: Healthier People

1.1 Improve recognition of the role of complementary medicine in preventive health to build a more sustainable health system, enabling prevention of chronic disease and consumer choice

In general, it's said that Australia has one of the highest performing health systems in the world. However, in common with a number of other developed countries, Australia is 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 has become a top line priority.ⁱ

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. That's around 14 million Australians who are overweight or obese or 2 in every 3 adults, and 1 in 4 children.^{vii}

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.^{viii} Interventions to prevent overweight and obesity or reduce weight in people who are overweight or obese, and prevent diabetes, should reduce the financial burden on the health system.

Australia has committed to the World Health Organization's global target *to halt the rise in overweight and obesity*, presenting an significant opportunity to take a preventive health approach and to support the lives and futures of Australians.^{ix}

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 goes to running public hospitals (\$48 billion), which includes \$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.^x The average costs incurred by public hospitals to deliver an 'average' service to acute admitted patients ranges from \$3,300 to \$6,400.^y

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 of their health.

Complementary medicines play a significant role in preventive health, although further research is needed to identify the most impactful areas. Whilst the value of essential supplements like folate and Vitamin D are well known, promoting self-care generally encourages people to take greater responsibility in improving their diet and ensuring adequate exercise. Exercise in various forms has demonstrable benefit in improving disease outcomes. For example, high and moderate level evidence is available for Tai Chi in preventing hypertension, in reducing pain and improving physical functioning of rheumatoid arthritis patients, in reducing the risk of osteoporotic fractures and in the multi-faceted recovery in stroke patients^{xi}. NICM and Access Economics have also shown that some complementary medicine interventions are cost-effective in disease prevention, including *St John's wort* in mild to moderate depression, omega 3 fish oils in secondary prevention of cardiovascular disease and acupuncture for low back pain.^{xii}

Recommendation 1: Healthier People**1.2 Support enhanced investment in complementary medicines research and translation of research into better health outcomes for all Australians**

A greater focus is needed on evaluating population-wide prevention initiatives, improving the health and wellbeing of the community and providing long-term savings for the health budget and greater efficiencies for the economy.

Australia has at least 58 medical research institutes (MRI) that work on a broad spectrum of human health issues.^{xiii} These institutes have a combined annual turnover of over \$1 billion pa and receive a large proportion of their research funding through NHMRC grants, state and federal government funding. However, to date not one government supported Medical Research Institute (MRI) is focused on the complementary medicine sector.

MRI research supports in part the Australian pharmaceutical manufacturing industry worth \$12.8 billion pa. The Australian complementary medicine manufacturing industry is valued at almost \$6 billion pa. All are manufactured in Australia, whilst 90% of pharmaceutical medicines sold in Australia are manufactured overseas.^{xiv} The complementary medicine manufacturing sector has its roots firmly in Australia and is a locally grown industry. However, its current research expenditure is merely \$10 million pa, with virtually none invested by Government.

Government assistance and investment in the complementary medicine industry (research, manufacturing, practice support) should be more reflective of, and commensurate with, the consumer and industry investment in this area. Government spends over \$1 billion in pharmaceutical research through the National Health and Medical Research Council (NHMRC) and Medical Research Future Fund (MRFF) each year with virtually no investment in complementary medicines. Given the size of the industry and interest by all Australians, this must be remedied. The Australian public clearly want better access – they have grown the industry and are high consumers. Government collects over \$300 million pa in GST yet none of this is returned to grow and create jobs in the sector. We seek greater Government involvement and support alongside industry, universities, philanthropy, clinicians and the community.

The global health and wellness movement, and recognition of the links between nutrition and health, has seen people take an active role in managing their own health. People with higher disposable income show an increasing demand for complementary medicines manufactured in Australia, and particularly in Asia in recognition of the significant cache of the TGA AUST listed label. In addition, recent major changes to the regulatory environment in Australia, which provide industry with scientific data (and hence marketplace) protection, will likely contribute to significant domestic R&D investment by industry along with high skilled jobs.

Australia is well placed to rapidly expand the manufacturing base for complementary medicines. We are home to some of the largest manufacturers with significant overseas exports. The international market for complementary medicines is estimated in the range of \$200B and Australia with its highly skilled manufacturing and clinical trials workforce, is well positioned to take advantage of this opportunity. The revised regulatory framework and the Government initiatives to support Australian manufacturing will serve to significantly stimulate innovation in the sector. Clinical trials are already estimated to be worth \$1 billion pa to the Australian economy.

NICM Health Research Institute can help Government support industry to address key challenges, innovate and grow jobs and exports. NICM conducts research that advances the knowledge and practice of integrative medicine and works with Government agencies to translate this evidence into better practice and guidelines. NICM has world-class specialist TGA approved laboratories, a small

manufacturing facility to serve industry, significant clinical trials expertise, preclinical pharmacology labs, conference education facilities and more. NICM assists with the education of tomorrow's experts through world-class training of next-generation health practitioners, industry-ready professionals and upskilling Australia's health workforce. NICM increases awareness in the community of ways in which complementary and lifestyle medicines improve overall health quality and safety.

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 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 future funding.

Recommendation 1: Healthier People

1.3. 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 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.^{xvii} 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.

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

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.

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 and allowing autonomy for private health funds to offer these services.

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, 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.

Recommendation 1: Healthier People**1.4 Improve the health literacy of the population to support an equitable, sustainable, health system.**

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 complement the National Modern Manufacturing Strategy (MMS) currently being rolled out.

Preventive health is an essential move towards improving the cost-effectiveness of the healthcare 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 Pandemic has reinforced the importance of addressing health literacy in Australia. Health literacy is the degree to which individuals have the capacity to obtain, process, understand and apply health information and services needed to make appropriate health decisions in ways which promote and maintain good health (World Health Organisation, 1998). Health literacy is a social determinant of health and equates to health equity. A sustainable communications plan is required for wellbeing and we know a good level of health literacy empowers individuals take better care of their health.

The World Health Innovations Summit (WHIS) recommends a range of strategies to address health literacy including:


- plain language and readable formats to deliver clear and concise health information.
- Adopt consistent terminology and standardize materials across the health system.
- Engage consumers in the creation of health materials.
- Use a variety of formats to distribute materials.
- Disseminate health resources and materials in places where people already congregate, not just where they receive care.
- Improve health care access for diverse, low-income, and rural communities.
- Provide information in more languages and improve access to interpreters.
- Work with community leaders and cultural groups to reach populations with limited health literacy.
- Improve cultural competency training and education.

Recommendation 2: More efficient markets, supporting Australia's manufacturing industry

Support growth of high-quality Australian complementary medicine manufacturing and exports through the Modern Manufacturing Strategy.

2.1: Modern Manufacturing Strategy to target funding support for SMEs

The Modern Manufacturing Strategy, released by the Government in October 2020, notes that manufacturing in Australia has stagnated and not enough manufacturers are scaling-up. The government and industry will grow manufacturing and create jobs by getting the economic conditions right for business, making science and technology work for industry and building national resilience.



Complementary medicines have been identified as a priority area for future growth, this can be further leverage by collaborating with the sector on specific future funding rounds.

We strongly support the whole of government approach to the Modern Manufacturing Strategy. It will leverage Australia to be recognised as a high-quality and sustainable manufacturing nation that will assist in delivering a strong, modern, and resilient economy for all Australians. It will 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 Modern Manufacturing Initiative aims to drive lasting change for Australian manufacturers and while there are no specific business size requirements, the initiative is focused on co-funding large to very large manufacturing projects. To bring businesses to scale and make them more efficient and productive, targeted funding initiatives need to leverage growth for SME's within the supply chain. In the experience of the complementary medicines sector, smaller to medium sized manufacturers have been unable to benefit significantly from the Modern Manufacturing initiatives and they are the ones that need greater assistance, particularly with enhanced digital/AI capabilities that would speed up systems and processes. Systems that would assist with productivity for the CM sector should include enhanced systems for electronic dispensing, barcoding and labelling for example, allowing staff to be available for higher impact work.

Recommendation 2: More efficient markets, supporting Australia’s manufacturing industry

2.2 : Continue to embrace international engagement including trade, investment and the movement of people

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 China 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.^{xi} The demand for complementary medicines continues to do well in China, despite the pandemic, due to an increasingly health-conscious population taking a strong interest in their health and wellbeing.

Support Programs for Exporters

Government support programs are vital to assist Australian exporters to conduct business in emerging and growing 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 (or digital presence) at the Healthplex Expo (HNC) in Shanghai 2018-2022. The HNC is the premier event for companies looking to enter the Chinese market or to raise the profile of their brands. The backing of the Australian Made Campaign Limited (AMCL), assists the Australian complementary medicines industry to fly the Aussie flag overseas. Similar support for raising brand awareness and connection phase projects in the Indian and Indonesian markets and beyond would be of key value to the sector.

Recommendation 3: Healthy Regulatory Framework

Recommendation 3.1

Continue to honour the commitment to a ‘no policy change’ to the listed medicine framework for general level and traditional medicine claims

We appreciate the significant work the Therapeutic Goods Administration (TGA) has done on the new Evidence Guidelines for Listed Medicines. The Guidelines have been under review since 2019 and are currently published (released 3 March 2022) for 4-week consultation. The 85-page document, restructures and rewords numerous parts, including clarification of several aspects.

The TGA have stated it is *‘important to note that there are no policy changes in the proposed revised guidance’* and it *‘will not change existing requirements to substantiate indications’*. However, industry have identified some significant changes to requirements, policy, interpretation, volume of documentation, and other expectations that will require changes to evidence packages, one of the highest impact changes to the listed medicine framework.

Many of the changes are not perceived as commensurate to risk and are in direct conflict with the over-arching goals of the expert Medicine and Medical Devices Regulation (MMDR) reform; to reduce duplicative and unnecessary red-tape. While we note the TGA consultation statement *‘it is inevitable that some clarifications may appear to be a change... due to previous lack of clarity’*; many identified changes are not due to lack of clarity but appear a distinct change.

If the guidelines were to be implemented as they currently stand, it would result in significant policy changes and regulatory impact including removal of indications or products, and potential allegations of lack of efficacy in compliance reviews. In summary, this risks undermining the intended framework that helps consumers in safely interpreting the evidence whilst allowing economic growth in Australia. These are the themes of changes industry are concerned about, and the government are asked to honour its long-standing commitment of no policy change to the evidence for listed medicine guidelines as part of the current review.

Industry requests a commitment to not creating distinct, up-regulatory changes, especially those changes that fundamentally undermine the intended nature and purpose of the listed medicine framework to reasonably be able to communicate supported product physiological effects in non-specific indications including health maintenance claims and nutritional indications.

Recommendation 3.2:

Review the Legislative framework for Therapeutic Goods to simplify its structure and language

The Government accepted the principle of the Medicine and Medical Devices Regulation (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. 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.

Recommendation 3.3

Continue to consult with small business to better understand the impacts of regulation on small businesses

Australia must remain competitive and be able to attract people to start and operate their business. Australia has slipped four rungs on the IMD World Competitiveness Yearbook, which compares the performance of 64 different nations, sinking back to 16th place for government efficiency (Australia ranked 15th on this metric last year) when scored against 330 different criteria.^{xviii}

The unique characteristics of and challenges facing small business should be considered in the design of regulation. Appropriate consultation with small business will be required to properly understand the impacts of regulation on small business, particularly where small businesses are a significant share of the regulated population.

Given small businesses have less capacity to distil regulatory requirements and high compliance cost structures, policy makers should remove any unnecessary complexity in regulatory requirements and associated guidance.

Recommendation 3.4

Support principles of a Healthy Regulation Plan for the efficient administration of the regulations of complementary medicines

Appropriate regulation protects consumers and makes markets function more efficiently by improving consumer confidence and reducing search costs. Reducing red tape and unnecessary compliance measures will make it easier for businesses to do business.

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.

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. 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 now been completed

The main objectives of the MMDR panel were to: identify areas of unnecessary, duplicative, or ineffective regulation that could be streamlined, and aimed to identify areas of regulation where a more risk-based approach could be adopted to more appropriately align regulation with the risk posed by regulated products. This is consistent with the need for Australia to remain competitive on the global stage.

Industry has cooperated with the implementation of the MMDR 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.

The Expert Panel reviewed the complementary medicines 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 has a stated commitment to reducing red tape and unnecessary regulation, making it easier for businesses to invest, create jobs and grow the economy.

Despite this, 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. A healthy regulation plan is required.

Healthy Regulation Plan 2022-2025

Deregulation and removing duplication is a key driver of the MMDR, the Modern Manufacturing Strategy (MMS) and the 2020 Deregulation Taskforce. The sector is striving for a Healthy Regulation Plan to support the original guiding intent of the MMDR reforms and to reduce unintended burden on the sector from poor policy application.

A Healthy Regulation Plan is required to address this expanding area in order for the Australian industry to continue to do well and play its part in the recovery and re-building phase, post pandemic.

In addition, the Healthy Regulation plan aims to complement the Government's deregulatory commitments to support a strong, resilient and future proof manufacturing sector. The below 10 guiding points are the summary outline of a plan that will be fleshed out in conjunction with work already underway with the medicine's regulator.

Priority items for the sector relate to item 1-4 which address ingredients, Good Manufacturing Practice (GMP) and supporting the growing probiotic industry.

Healthy Regulation Plan 2022 Guiding Principles for Complementary Medicines

- 1 • Enshrine GMP exemption on processed materials in Listed medicines
- 2 • Support ingredient access and stimulate new Australian ingredient manufacturing businesses
- 3 • Enshrining longstanding PIC/S GMP risk concessions in an instrument.
- 4 • Support for the growing Australian probiotic industry with appropriate policy.
- 5 • Remove & streamline duplicative eligibility requirements for listed medicines.
- 6 • Commitment to reducing onerous, complex regulation in all areas inc labelling, advertising
- 7 • Reallocate some cost recovered resource to centralised safety systems.
- 8 • Support State/Territory approach to reducing unnecessary burdens.
- 9 • AUST L(A) fit for purpose review.
- 10 • Shared approach to compliance monitoring and commitment to non-misleading reporting.

Final Word

In light of the next phase of the Government's Economic Recovery Plan, 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.

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. More information is available at www.cmaustralia.org.au

NICM Health Research Institute

NICM Health Research Institute (formerly the National Institute of Complementary Medicine) is Australia's leader in integrative and complementary medicine research and policy. Seed funded by the Commonwealth Government and NSW State Government, NICM plays a key national role in ensuring Australians have access to reliable evidence on complementary medicines and treatments in wide use. As an ERA 5 ranking institute, NICM is globally recognised for its world-class research and innovations in integrative and complementary medicine. NICM assists the complementary medicine industry to address manufacturing challenges, capture opportunities to innovate, grow jobs and exports. More information is available at www.nicm.edu.au

- ⁱ Zhongpeng Zhang, CCCMHPIE (2019) Development and Trade Performance of China's Nutraceutical Industry, CMA Annual Conference September 19, 2019 Sydney Australia.
- ⁱⁱ Department of Industry, Science, Energy and Resource, Medical Products National Manufacturing Priority road map: <https://www.industry.gov.au/data-and-publications/medical-products-national-manufacturing-priority-road-map/road-map-at-a-glance>
- ⁱⁱⁱ Steel, A. et al. (2018). Complementary medicine use in the Australian population: Results of a nationally-representative cross-sectional survey. *Scientific reports*, 8(1), 17325. <https://doi.org/10.1038/s41598-018-35508-y>
- ^{iv} CMA Industry Audit 2021: <https://cma.mailscampaign.com/flipit-double-page/>
- ^v Australian Government. (2015). New stats reveal 50% of Australians battling disease. Accessed from <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediaref-yr2015-ley100.htm>
- ^{vi} Budget Strategy and Outlook: Budget Paper No. 1: 2021–22, pp. 161–16 Commonwealth of Australia 2021.
- ^{vii} Australian Bureau of Statistics 2019. National Health Survey: first results, 2017–18. Cat. no. 4364.0.55.001. Canberra: ABS
- ^{viii} 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
- ^{ix} *World Health Organization 2013. Global Action Plan for the Prevention and Control of NCDs 2013–2020. World Health Organization. Geneva, Switzerland.*
- ^x Australian Institute of Health and Welfare (2018) Australia's health 2018: in brief. Cat. no. AUS 222. Canberra: AIHW.
- ^{xi} Guo-Yan Yang, Jennifer Hunter, Fan-Long Bu et al. Determining the safety and effectiveness of Tai Chi: A critical overview of 210 systematic reviews of controlled clinical trials, 01 July 2021, PREPRINT (Version 1) available at Research Square [<https://doi.org/10.21203/rs.3.rs-661503/v1>]
- ^{xii} Cost-effectiveness of complementary medicines report (2010) Access Economics Pty Limited https://www.westernsydney.edu.au/nicm/health_information/health_economics/cost_effectiveness_of_complementary_medicines_report
- ^{xiii} Association of Australian Medical Research Institutes: <https://www.aamri.org.au/medical-research-institutes>
- ^{xiv} Financial Review (2022) Australia dangerously dependent on medical imports, <https://www.afr.com/politics/federal/australia-dangerously-dependent-on-medical-imports-20200217-p541ej>
- ^{xv} 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.
- ^{xvi} Access Economics. (2008). Exceptional Returns: The Value of Investing in Health R&D in Australia
- ^{xvii} McKell Institute (2017). Picking the low-hanging fruit: Achieving a more equitable and sustainable health care system. Equity Economics, Sydney.
- ^{xviii} <https://www.imd.org/centers/world-competitiveness-center/rankings/world-competitiveness/>

Case example: 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>