

The background is a solid green color with a repeating pattern of white line-art icons. These icons include various medical and scientific symbols such as pills, capsules, test tubes, beakers, a heart with an ECG line, a microscope, a cross, a leaf, a water drop, and molecular structures.

Complementary Medicines Australia

Pre-Budget Submission 2021-22



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Complementary Medicines Australia is the leading voice and industry body for manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. CMA members represent over 80% of all product sales and the full value chain in Australia. As the principal reference point for members, the government, the media and consumers, we communicate and advocate for the issues that matter to the complementary medicines industry.

CMA continues to drive ‘a healthy regulation for a healthy future’ agenda for the sector. The introduction of a refreshed therapeutic goods regulatory regime included the establishment of a novel intermediate pathway for listed complementary medicines with higher level therapeutic indications supported by product specific evidence. Other developments include market exclusivity for new ingredients and a data protection scheme for Assessed Listed Medicines, coordinated by the Department of Health’s Therapeutic Goods Administration. We have 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 Morrison 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 medicine products is driving steady growth, with the industry reaching \$5.2 billion in revenues in 2018. Over the last five years, the sector has achieved \$2 billion in growth, predominantly as a result of strong exports. Australian brands are recognised and trusted internationally, with China importing more complementary medicines from Australia than almost anywhere else in the world.ⁱ

Health is an indispensable prerequisite for overall well-being as well as the foundation of economic and social development. Given the ageing of our population and the increasing rates of chronic disease, it is vital that we invest in the future health and well-being of our community. The last 12 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 health system.

The 2021-22 Budget provides the Government with the ideal opportunity to reveal its preventive health reform vision, through evidence-based and targeted preventive health programs for a more sustainable health system in Australia.

Preventive health interventions are the most cost-effective use of our health dollars. The CMA Pre-Budget Submission sets out a range of recommendations that are achievable and will reduce costs in health care and serve to grow the economy. I am pleased to put forward CMA’s recommendations regarding priorities for the 2021-22 Federal Budget.

All the best in health,

Carl Gibson,
Chief Executive Officer

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Overview

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

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

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

Key statistics

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

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

Approximately 70% of Australians use complementary medicines¹ and the prevalence of use of complementary medicines and natural therapies modalities has remained consistently high over time².

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

The Australian complementary medicine industry continues to outpace growth in the broader market by contributing \$5.2 billion to the economy².

- **The role of complementary medicine and natural therapies in preventative health**

Approximately 50% of Australians suffer from some kind of chronic condition, many of which are preventable and it is estimated that in 2020 the Australian Government will spend over \$80 billion on medical care², though with the ongoing impacts of the COVID-19 pandemic, spending is likely to surpass this figure. Complementary medicine and natural therapies

¹ CMA Industry Audit 2019: http://www.cmaustralia.org.au/resources/Documents/CMA-INDUSTRY_AUDIT-V4.pdf

² 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>

practitioner services are widely accessed and valued by the Australian public, and represent a considerable contribution to preventative care.

CMA is pleased to put forward its 2021-2022 Pre-Budget submission. Our key recommendations for the Federal Budget will support investment in science and innovation in the industry and reveal its preventive health reform vision in Australia.

Summary of recommendations:

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

- **Recommendation 1:** Focus on preventive health to build a more sustainable health system for Australia.
- **Recommendation 2:** Support growth of our high-quality Australian manufacturing sector and exports.
- **Recommendation 3:** Support investment in complementary medicines research and translation of evidence into health practice.
- **Recommendation 4:** Support the guiding principles of CMA's Healthy Regulation Plan 2021, to be further developed in conjunction with the regulator.

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

(WHO Traditional Medicine Strategy 2014-2023).

Preventive Health for a Sustainable System

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

In general, it'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, we are also experiencing an ageing population and increasing rates of obesity and chronic, complex health conditions. With half of all

Australians already having at least one chronic disease, the need to place a stronger focus upon preventive health has become a top line priority. ^{iv}

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. ^{vi}

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

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

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

Natural & Complementary Therapies

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

Recommendation: In light of the evidence supporting the use of complementary medicines and natural therapies for cost-effectively contributing to good health and preventing burden on the

hospital system, CMA recommends that Government expedite restoring private health rebates for natural therapies.

Complementary Medicines' Role in Preventive Health

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

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

Case example: The recent introduction of Ngangkari healers, who use traditional Aboriginal methods of healing to support physical and emotional wellbeing based on 60,000 years of traditional knowledge, to South Australia's Royal Adelaide Hospital and rural health clinics^{xii}, is testament to the Australian government's acknowledgement of the important benefits of traditional systems of medicine in Australia.

The use of traditional medicines across multiple avenues of health care, provides a greater diversity in treatment options for the broader Australian population.

National Preventive Health Strategy

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

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 invested into.

Preventive health is an essential move towards improving the cost-effectiveness of the health care system, by enhancing Australians' health and quality of life, and reducing preventable illness. In the case of complementary medicines, a thoughtful and rigorous strategy, coordinated by the preventive health body,

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

(Australia: The Healthiest Country by 2020)

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

Recommendations:

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

Supporting Growth of Australian Manufacturing and Exports***Recommendation 2: Support growth of our high-quality Australian complementary medicine manufacturing and exports***

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.

“Australian manufacturing will not grow if broader economic conditions are not right. These are the critical building blocks necessary to attract investment, boost business opportunities and deliver a strong recovery. This is principally a role for government.”

“We are removing unnecessary regulation and reducing business compliance costs. We are focused on lifting the performance of our regulators to reduce the time and effort spent by businesses on unnecessary red tape.”

CMA strongly supports 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 helps to deliver 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.

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

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

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

In 2019 Australia overtook the USA as the number one importer of complementary medicines into China. The opportunities offered by the Chinese market are extensive, with the health-food market alone – which includes vitamins and minerals, herbal extracts and Traditional Chinese Medicine – currently valued at US\$30 billion and projected to grow by 10 per cent every year until 2025.^{xiii} CMA welcomed the news that China will expand its free trade zones and extend its cross-border e-commerce policy, providing a stable policy and more certainty and confidence for e-commerce rules for imported products. The Chinese Government has made health a priority, with the “Healthy China 2030” (HC 2030) vision being central to all policy making^{xiv}. It will include a focus not only on medical services for patients visiting doctors, but a holistic approach, including education, lifestyle, services and the environment. China is encouraging and promoting the development of a diverse medical service and health industry as it tackles the challenge of an aging society.

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

Recommendation:

- Continued support for the whole of government approach to the Modern Manufacturing Strategy, along with the inclusion of sector specific expertise on the Modern Manufacturing Advisory Panel.

Country of Origin “Made in Australia”

In 2017 changes to the Australian Consumer Law (ACL), including the safe harbour test of ‘substantial transformation’, meant that as an unintended consequence the majority of complementary medicines no longer qualified to be labelled as ‘Made in’ Australia. This had flow-on effects for the ability of business to use the green and gold Australian Made (AMAG) logo³ and the quality assurances that this claim provides domestic and global consumers.

After a 2019 Country of Origin taskforce, the Government has now enshrined in legislation specific protections for the complementary medicine industry. The amendment to the regulations titled, *The*

³ Registered certification trademark and Australia's most trusted, recognised and widely-used country of origin symbol AMCL.

Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019, effective 18 December 2019, ensured continued access to Australian origin claims. While the passage of the *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020* on 10 December 2020, now prescribes, by law, processes of substantial transformation, rather than providing an example of a process that results in substantial transformation and therefore strengthens Australian Made representations for all complementary medicines meeting the newly legislated example. The passage of these Regulations represents years of work for the Complementary Medicines industry and provides stronger protections for industry by strengthening Country of Origin laws.

Complementary Medicines Australia advocated for and supported the government taskforce recommendation (2019) that products that are manufactured in Australia should continue to be eligible for access to the ‘Made in’ Australia logo. Using Australian GMP production of the finished medicinal product should be the benchmark to protect industry and support businesses to compete in overseas markets. The ability to use a consistent logo and branding in the form of the ‘Made in’ Australia offers Australian business a competitive advantage in international markets and confers that the products were manufactured in Australia to the highest safety specifications.

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

The business certainty that has been provided in the updated Regulations² is welcomed however this now needs to remain stable for a reasonable period of time without further label amendments posed on a compliant industry.

Recommendation:

- Strengthening Country of Origin laws has been provided in the updated Regulations² and the policy intent has been achieved.
- Imposing additional information standards such as a mandatory label bar chart on the sector would jeopardise the uptake of the new legislated scheme and risk the Australian made competitive advantage as part of the economic recovery plan.

Trade Liberalisation

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

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

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

Recommendation:

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

Ingredients Grown in Australia

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

Recommendation:

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

Support Programs for Exporters

CMA believes that government support programs are vital to assist Australian exporters to conduct business in emerging and growth markets, and in terms of provision of advice, capacity building and expediting export opportunities. Maintaining Austrade as a strong organisation is vital to Australia’s

economy, as are the continued efforts by the Department of Foreign Affairs and Trade to support Australian firms in building strong international networks.

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

Recommendation:

- Maintain current investment in Austrade to support Australian exporters and enhance Australia's global competitiveness.

Encourage & Support Innovation and Investment in Research***Recommendation 3: Support investment in complementary medicines research and translation of evidence into practice***

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

Funding for Complementary Medicine Researchers

Australia is fortunate to be home to world-leading research institutions for complementary medicines including; the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM) at the University of Technology Sydney, the NICM Health Research Institute (NICM) at Western Sydney University and the National Centre for Naturopathic Medicine at Southern Cross University, focusing on evidence-based natural medicine and its important role in healthcare.

Australia also boasts excellent research centres outside of the university sector, such as the Endeavour College of Natural Health, The National Institute of Integrative Medicine (NIIM) and the Blackmores Institute. The Endeavour College of Natural Health is a leading higher education provider for complementary and integrative healthcare, in part due to the value placed upon practice-relevant research. In collaboration with universities and other medical bodies, NIIM conducts research into the safety and efficacy of integrative medicine and complementary therapies for the prevention, detection and treatment of disease and boasts one of Australia's largest integrative medical centres, the NIIM Clinic. The Blackmores Institute, the academic and professional arm of Blackmores Limited, was established in 2012 with a vision to improve and promote the quality use of natural medicine via a focus on research and education.

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

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

Regulatory Framework

Recommendation 4: Review the Legislative framework for Therapeutic Goods to simplify its structure and language

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. ^{xvii}

Regulatory Reforms Implementation Leading to Unnecessary Regulatory Burden

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

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 these 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 CM sector with a view that the Industry Innovation and Competitiveness Agenda indicated that *'a lower cost, business friendly environment with less regulation'* is critical to achieving the outcome of maintaining global competitiveness. The Coalition Government is committed to reducing red tape and unnecessary regulation, making it easier for businesses to invest, create jobs and grow the economy. The Deregulation Taskforce announced July 2019 by the Assistant Minister to the Prime Minister and led by the Treasurer will drive improvements to the design, administration and effectiveness of government regulation to ensure it is fit for purpose. The Taskforce includes for example *'reducing regulatory burden for food manufacturers with an initial focus on exporting'*. A better regulatory environment will help businesses lower their costs, save time and improve their competitiveness.

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

CMA's Healthy Regulation Plan 2021

Deregulation and removing duplication is a key driver of the MMDR, the Modern Manufacturing Strategy (MMS) and the 2020 Deregulation Taskforce. The CMA's Healthy Regulation Plan 2021 is being developed to support the original intent of the MMDR reforms and to reduce unintended burden on the sector from poor policy application.

In addition, the plan is being developed to complement the Government's deregulatory drivers to support a strong, resilient and future proof manufacturing sector. The below 10 guiding points are the summary outline of the plan that will be fleshed out in 2021 in conjunction with work already undertaken with the medicine's regulator. Priority items for the sector relate to item 1-3 which address ingredients and GMP and do not conflict with other Country of Origin (COO) changes already mentioned in this submission.

CMA's Healthy Regulation Plan 2021 – Guiding principles

- 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.

Review Legislative Framework Underpinning Regulation of Therapeutic Goods

The Government accepted the principle of MMDR Recommendation 28; that the Australian Government undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, including a review of the *Therapeutic Goods Act 1989* and associated

Regulations in their entirety, with a view to simplifying its structure and language to achieve a more user-friendly approach.

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

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

Recommendations:

- Support the guiding principles of CMA's Healthy Regulation Plan 2021, to be further developed in conjunction with the regulator.
- Provide the TGA with specific funding to undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods.

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 over their health.

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

CMA appreciates the opportunity to offer its recommendations regarding priorities for the 2021-22 Federal Budget.

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body representing the whole of the complementary medicines value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators.

CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines. The term 'complementary medicines' also comprises traditional medicines, which includes traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines.



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