



Complementary Medicines Australia 2017/18 Federal pre-Budget Submission

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Introduction

Complementary Medicines Australia (CMA) is exclusively committed to a vital and sustainable complementary medicines sector and represents stakeholders across the 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 (unless specifically exempt). The term 'complementary medicines' also comprises traditional medicines, which includes traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines.

CMA conducts regular audits of the complementary medicines sector. The inaugural study started in 2011 and estimated revenues of \$1.9million. The latest full audit was conducted in 2015 when the Australian industry was estimated to be worth \$3.5 billion. This figure is expected to grow to \$4.6 billion in 2017-2018.

CMA welcomes the opportunity to provide its submission to Government with regard to the priorities for the 2017-18 Budget.

Submission Overview

CMA acknowledges and supports the continued commitment by the Australian Government to improve our nation's competitiveness on the global stage via the National Innovation and Science Agenda and the commitment to minimise unnecessary red tape for businesses. CMA welcomed the Government's announcement in September 2016, accepting the majority of the recommendations of the Review of Medicines and Medical Devices Regulation (MMDR), led by Professor Lloyd Sansom AO. In particular, industry was highly supportive of those recommendations that aimed to encourage firms to invest in conducting clinical trials to substantiate higher level therapeutic indications and health claims. CMA strongly supports the Government focus on increased research funding to spark the ideas revolution in Australia, and especially for applied research funding to encourage greater engagement and collaboration with industry. Encouraging and supporting business expenditure on research and development in complementary medicines will help Australia to capture the growing market for these goods, nationally and internationally, as well as provide significant economic and health benefits for our nation.

The Australian complementary medicines industry holds great potential to contribute further to the strength of high-skill local manufacturing, employment opportunities, research and growth in our exports. Australia is recognised as a premium brand in the complementary medicines sector, stemming from our strict quality and safety manufacturing standards. As a result of this 'clean and green' image, over 60 per cent of companies in our sector are engaged in exporting activities. Improved access to international markets will be crucial for the long term prosperity of the industry.

The Intergenerational Report from 2015 highlighted that Australia needed to make the right choices if we were to maintain and improve our standard of living, drive prosperity through increased productivity and participation, and build a strong, resilient economy.ⁱ If anything, the pressure to make the right choices in the area of health has grown since publication of that report. To achieve a productive workforce, Australia needs a healthy workforce. Unfortunately, the burden of disease in Australia and the associated economic costs are spiralling concerns, with statistics showing that half of all Australians have at least one chronic disease.ⁱⁱ Our nation's population is ageing and increasingly overweight, and is challenged by conditions such as coronary heart disease, diabetes and stroke. These are diseases that are largely preventable. An additional economic burden of disease occurs in terms of lost productivity, which means less tax revenue for the Commonwealth, State and Territory governments and increased health care costs.

In the complementary medicines sector, CMA believes that the 2017/18 Federal Budget provides an opportunity to:

1. facilitate industry growth and innovation via the implementation of the medicines and medical devices regulation (MMDR) reforms;
2. promote greater collaboration between tertiary institutions, research organisations and industry;
3. support further growth of our high-quality Australian exports; and
4. focus on building a more sustainable health system for Australia.

Noting that pre-Budget submissions must consider the Government's strong commitment to fiscal discipline and the need to minimise expenditures, the recommendations set out below propose minimal additional expenditure across the forward estimates, with potential savings of \$1.8 billion in reduced hospitalisation rates and gains in productivity.ⁱⁱⁱ

1. Progression of the Medicines and Medical Devices Regulation Reforms

Recommendation One: Facilitate industry growth and innovation via progression of the regulatory reforms recommended by the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) and accepted by Government.

The complementary medicine industry recommends the Government provides the industry regulator with additional resources to enable more comprehensive, timely and consultative development and implementation of the MMDR outcomes.

In Australia, the regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), which has the responsibility of regulation of all therapeutic goods, including medicines and medical devices, in Australia. Despite oversight by the same regulator as medicines, it does need to be highlighted that complementary medicines do not place themselves in the same category as pharmaceutical interventions. Australian consumers understand that complementary medicines are not a replacement for prescription medicines; rather they use complementary medicines to enhance overall wellbeing and for maintenance of health. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health.

Whilst it is considered by the majority of stakeholders that it is right and proper for complementary medicines to be regulated by the TGA, and Australia's complementary medicines industry is proud to be backed by a regulatory regime that is regarded as one of the strictest in the world, the reality is that over-regulation remains one of the biggest risks to the industry. Industry supports the goals of the MMDR reforms of better aligning regulatory protections with the lower risk imposed by this sector of goods, and to ease regulatory requirements where they do little to improve consumer protection but are a barrier to business.

1.1 Regulatory Pathway to Encouraging Investment in R & D

Under the proposed new regulatory framework, there will be a third option for listing medicines onto the Australian Register of Therapeutic Goods (ARTG) where the sponsor can elect for their product, which contains ingredients already permitted in listed medicines, to undergo pre-market assessment of efficacy indications and claims. CMA has strongly supported the concept of a third, modified pathway, which will allow the ability to make higher level health claims. This will encourage and reward greater investment in research and development by industry, and be an incentive to further expand the clinical research base on complementary medicine products.

CMA looks forward to continuing collaboration with the TGA to develop and implement this third option for listing medicines and the accompanied consumer education campaign.

1.2 Removing Mandatory Approval of Advertising

The Government has accepted recommendation 55 of the MMDR, that the whole process of vetting and pre-approval of advertising of therapeutic products to the public should be stopped in favour of a more self-regulatory regime. Implementation of stronger regulator enforcement powers and the development of a sponsor education programme are expected to manage potential concerns by consumers and healthcare professionals in implementing the recommendation. CMA has supported the removal of mandatory pre-approval requirements for several reasons, including reducing unnecessary complexity for sponsors and advertisers and to minimise excessive regulatory and financial burden upon businesses.

1.3 Sponsor Education

The Government has accepted that the TGA should develop a formal education programme to provide sponsors with appropriate information and tools to assist them in understanding their obligations and enhance compliance, particularly with the reforms to advertising. Listed complementary medicines are included in the ARTG via an electronic application process that is designed to allow simple and fast access to market for low risk complementary medicines. However, to become a medicine sponsor one does not necessarily require any formal skills in relation to the associated legal, regulatory and ethical responsibilities.

CMA supports the implementation of an accreditation/licensing scheme for sponsors, as an efficient solution to ensuring that before a sponsor is able to list products on the ARTG they have undertaken a reasonable level of compliance training and will be subject to compliance monitoring. This would further engage industry and assist in the removal of regulatory burden arising from lack of understanding such as complaints handling and ongoing engagement with the regulator, whilst providing an additional level of assurance for the protection of consumers.

1.4 Industry Regulator Resources

CMA is of the view that there must continue to be genuine and appropriate consultation with industry if the TGA is to ensure a smooth transition to a renewed regulatory framework and more favourable long term outlook. Consumers and the federal health budget should be benefitting from an appropriately regulated, innovative and competitive industry.

Proposed Solutions

The following are proposed:

- Facilitation of the MMDR reforms to boost industry innovation and growth.
- Additional resources for the TGA to enable the comprehensive, timely and consultative development of the MMDR reforms.

Investment: Estimated \$AUD1 million TGA in 2017/18 and 2018/19 and cost recovered thereafter as required.

2. Research, Innovation and Commercialisation

Recommendation Two: Complementary medicines research as a priority area for funding.

CMA recommends greater support for research into the potential contribution that complementary medicines can make to health outcomes for Australians, at both the whole of system level and in relation to the most-used complementary medicines. Greater support is required to build capacity within the research community for applied research in complementary medicines, and to continue to promote greater collaboration between tertiary institutions, research organisations and industry.

2.1 Funding for Complementary Medicine Researchers

Australia has world class academic and research bodies, holding the potential to be an international leader in complementary medicines research and prioritising translational research into both commercial and health policy outcomes. Our country is extremely fortunate to be home to two world leading research institutions for complementary medicines: the National Institute of Complementary Medicines and the Australian Research Centre in Complementary and Integrative Medicine.

Given the potential benefits of complementary medicines as a tool towards health promotion and disease prevention, CMA believes that this should be a priority area for research funding. For every dollar invested in Australian health research and development, \$2.17 in health benefits is returned.^{iv} Potential gains also include costs avoided due to less people using the health care system, and indirect gains such as productivity gains, avoided carer costs, welfare and disability costs, and foregone taxation revenues.^v

2.2 Promoting Stronger Ties between Tertiary Institutions and Industry

CMA acknowledges and strongly supports the Government focus on increased research funding to spark the ideas revolution in Australia, and especially for applied research funding to encourage greater engagement with industry. CMA applauds the recent announcement of a funding boost by \$76 million, including \$50 million from the National Innovation and Science Agenda, to drive greater collaboration between researchers, industry and businesses.^{vi}

Australia has a well-developed complementary medicine research sector; however, it is insufficiently supported given the size of the Australian industry and the level of consumer use. A recent study by the National Institute of Complementary Medicine (NICM) showed that Australia has 160 lead investigators working on 295 complementary medicine research projects, and over \$30 million is being invested in research. Despite these figures, NICM also found that while Australia's use of complementary medicines is increasing, investment in complementary medicines research has been decreasing. Less than one per cent of National Health and Medical Research Council (NHMRC) funds have been allocated to complementary medicine research over the last decade. In this context, there is a need to encourage industry support of the research effort in Australia.

2.3 Market Protection

In the case of the complementary medicines industry, one of the major barriers for firms to investing in research and development is that there is currently little incentive due to a lack of data protection and/or market exclusivity. This is because, for many complementary medicines, their individual ingredients have traditional medicinal uses and are already in the public domain. As a result, sponsors who undertake research to support their products are not provided with any form of protection. A competitor may be able to make similar claims about their product without incurring the expense of research. This has led to sponsors typically relying on research conducted elsewhere, or a history of traditional use, in the sale and distribution of complementary medicines in Australia. This has also resulted in very little Australian innovation in this area, despite extensive potential and opportunities for new product development.

Industry recommends that a stakeholder working group be convened to develop and implement mechanisms of protecting innovation and new research data. The 2015 Expert Panel's *Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods* recommended that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation, noting the cross government responsibility for innovation policy. Whilst this aligns with the National Innovation and Science Agenda, the Panel did not propose specific recommendations in favour of any particular mechanism to protect innovation. Implementing formal IP protection mechanisms to incentivise innovation within the regulatory framework is likely to provide the greatest reward for investment in research and development.

The current process for new ingredient applications does not recognise or protect the investment by innovators who research and develop new ingredients to be used in listed complementary medicines. CMA proposes that a period of market exclusivity be introduced for new complementary medicine ingredients entering the Australian market, and that a three-year period of intellectual property protection is introduced for scientifically supported indications based on new clinical investigations in the complementary sector.

Proposed Solutions

The following are proposed:

- Targeted additional support for complementary medicine research groups on top of the current miniscule funding allocation.
Investment: \$500,000 each year for three years
- A stakeholder working group develop and implement mechanisms of protecting innovation and new research data in order to improve incentives for industry to invest in R & D.
- An industry reference group to help Government to shape additional tertiary education frameworks.
- A three-year period of IP protection be introduced for scientifically supported indications.
- A period of market exclusivity be provided for new complementary medicine ingredients entering the Australian market.

Investment: Secretariat costs to be absorbed by Department of Industry and TGA

Three: Supporting Growth of Australian Exports

Recommendation Three: Support further growth of our high-quality Australian complementary medicines exports.

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.

Access to international markets is crucial for the long term prosperity of the complementary medicines industry. Consumers worldwide have confidence in our products, and Australia exports to more than 26 countries including Singapore, Hong Kong, Korea, Malaysia, South Africa, Indonesia and Japan. The Australian industry has been a success story in recent years due to a growing demand for our complementary medicine products in Asia.

Whilst Australia's exporters are increasingly competing with companies from around the world, the Australian complementary medicines industry has the advantage of holding a well-deserved reputation for high safety standards and high quality products. This reputation has led to a rapidly growing demand for Australian complementary medicines in the Asian region, and is coupled with a growing middle class and ageing population that embraces complementary medicines. The Asia Pacific region is predicted to be the most promising market for complementary and alternative medicines in the years to come.^{vii}

In 2015, the market in China for vitamins and dietary supplements reached RMB 109 billion (US\$16.3 billion). By 2020, China's population is expected to reach 1.4 billion, of which 248 million will be aged 60 years and above.^{viii} Australian health foods have a strong reputation among Chinese consumers, thanks to Australia's 'clean and green' reputation. However, there are only a few Australian health food brands selling offline in China due to the complex CFDA registration processes, and the high costs and timeframes associated with registration.

For our industry, it is very important for Australia to continue to pursue trade liberalisation, and to support Australian businesses via trade delegations, provision of advice, capacity building and expediting export opportunities.

Proposed Solutions

The following are proposed:

- Maintain current investment in Austrade to support Australian exporters and enhance Australia's global competitiveness.
- Build on the momentum of the ChAFTA and continue to pursue trade liberalisation in the Asian region.

Investment: Retain Austrade funding - no additional cost

4. Focus on a Sustainable Health System

Recommendation Four: Focus on building a more sustainable health system for Australia.

There is a need for cooperation and collaboration between policy makers, researchers, industry and health professionals to ensure complementary medicines are a future component of policy contributing to the overall health of all Australians.

4.1 Preventive Health Role of Complementary Medicines

A fundamental aim of any health system is to prevent disease and reduce ill health so that people remain as healthy as possible for as long as possible. There is a real and immediate role for smarter preventive health. This is not limited to, but certainly includes, the use of complementary medicines for primary and secondary prevention of illness, and encouraging and empowering all Australians to take better care of their health. Integrative health care, and the appropriate focus on prevention in the Australian health system, is a vital element of the vision of improved health.

A healthy diet and regular physical activity are important factors in maintaining a healthy lifestyle. Unfortunately, the Australian Bureau of Statistics (ABS) found that only 5.1 per cent of the adult population met the recommended intake of fruit and vegetables.^{ix} Just recently, patients at Sydney's Westmead hospital have been found to have scurvy, a disease that is caused by a lack of vitamin C and that is associated with old-world sailors. It is perhaps not surprising that vitamin D, iron with vitamin C, and multivitamins with minerals are frequently recommended by general practitioners.^x

Complementary medicine users exhibit healthier lifestyles, with more exercise, less smoking and better diets.^{xi} The majority of complementary medicines are paid for fully by the consumer and alongside their widespread use, this demonstrates that Australians are willing to invest in improving their health and want to have an active role in their healthcare. The growing consumer demand for products and services that fall outside of orthodox prescription medicines should not be ignored; rather consumer empowerment and integrated healthcare should be vital elements of health in Australia.

4.2 Cost Effectiveness of Complementary Medicines

A significant amount of scientific research has been conducted looking at the direct health benefits of using complementary medicines, and numerous studies demonstrate that many of these medicines have a positive effect on reducing the risk of a secondary disease event.^{xii}

Clinical indications and claims made by complementary medicines are not always trivial and include osteoporosis, childhood bronchitis, secondary prevention of cardiovascular events, aspects related to metabolic disease, dementia and other major Australian national health priority areas. Improved integration of evidence based complementary medicines may not only improve health outcomes, but impact significantly on national health costs as described below.

A 2014 Frost & Sullivan report '*Targeted Use of Complementary Medicines: Potential Health Outcomes and Cost Savings in Australia*' shows robust links between several of the more well-known complementary medicines with reduced risk of a secondary disease event among high-risk groups, and with major potential healthcare cost savings. The report examined the use of six complementary medicines across four chronic disease conditions – cardiovascular disease (CVD), osteoporosis, age-related macular degeneration and depression – all of which contribute heavily to the national burden of illness in Australia. Large cost savings were identified, especially for the use of calcium and vitamin D by women aged over 50 who had been diagnosed with osteoporosis or osteopenia. For these conditions alone, the report estimated that between 2015 and 2020 an average annual hospitalisation cost of A\$922 million could be potentially saved, along with gains in productivity of A\$900 million – a net gain of A\$1.8 billion.

A 2013 US study '*Smart Prevention – Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements*', found the use of key dietary supplements, including omega-3s, B6, B12 and folic acid, could reduce hospitalisation costs by \$US billions per year. In addition, a 2010 Access Economics report, '*Cost effectiveness of complementary medicines*', commissioned by the National Institute of Complementary Medicine, found that the use of omega-3 fish oils for secondary prevention of heart disease could provide significant cost savings to the Australian health budget.

These reports begin to demonstrate the potential savings offered by complementary medicines as a means to combat unsustainable health care costs, and as a means for high-risk individuals to reduce their chances of having to deal with potentially costly disease-related events. However, to date the contribution that complementary medicines can make to individual and community health in Australia has failed to be included in health policy and practice. Government recognition of this potential contribution is vital, as is more research to further inform how complementary medicines can contribute to funding choices in the broader context of national health.

Proposed Solutions

The following is proposed:

- The convening of an Industry & Department of Health taskforce to develop an integrated health policy that includes the contribution of complementary medicines in preventive health.

Investment: Secretariat costs to be absorbed by Department of Health, CMA and Industry

Conclusion

The growth in consumer demand for complementary medicines has been consistently strong, and the sector is expected to continue to show solid growth in the future, both in Australia and internationally. As is the case in Australia, consumers in Asia have been using complementary medicines as part of a proactive approach to healthcare, becoming more confident in self-selection and willing to take preventive measures to support their health. This demand has resulted in the industry becoming a significant pillar in preventive healthcare, contributing to Australian manufacturing, research, domestic jobs and exports. Encouraging business expenditure on research and development in complementary medicines will help Australia capture the growing market for these goods, as well as provide significant economic and health benefits for Australians.

Complementary medicines are an important and often underestimated part of the Australian health system. They are increasingly being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care. CMA believes that Australia's future prosperity hinges on our ability to support a healthy workforce, encourage the translation of research into commercial outcomes, and ensure a business environment that allows Australian firms to be innovative, flexible and competitive.

ⁱ Australian Government. (2015). 2015 Intergenerational Report: Australia in 2055. Accessed from <http://www.treasury.gov.au/PublicationsAndMedia/Publications/2015/2015-Intergenerational-Report>

ⁱⁱ Australian Government. (2015). New stats reveal 50% of Australians battling disease. Accessed from <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-lev100.htm>

ⁱⁱⁱ Frost & Sullivan. (2014). Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia

^{iv} Access Economics. (2008). Exceptional Returns: The Value of Investing in Health R&D in Australia.

^v Deloitte Access Economics (2011). Returns on NHMRC funded Research and Development, Australian Society for Medical Research.

^{vi} Australian Government (2016). Backing Australia's researchers for the ideas of the future. Media Release from Minister for Education and Training.

^{vii} Geriatric Complementary and Alternative Medicines (CAM) Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2016 – 2024 - <http://www.digitaljournal.com/pr/3079260>

^{viii} Austrade (2016) The Health and Aged Care Industry in China: A guide for Australian business.

^{ix} ABS (2015) National Health Survey: First Results 2014-15.

^x Britt H, Miller GC, Henderson J, Bayram C, Harrison C, Valenti L, Pan Y, Charles J, Pollack AJ, Wong C. , Gordon J. (2016). General practice activity in Australia 2015–16. General practice series no. 40. Sydney: Sydney University Press, 2016.

^{xi} NICM (2015) Australian Government rebate on Private Health Insurance for Natural Therapies: Highlighting complementary medicine research.

^{xii} Frost & Sullivan. (2014). Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia