



**Complementary Medicines Australia
2015/16 Federal Pre-Budget Submission**

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**Mr Carl Gibson
Chief Executive Officer
Complementary Medicines Australia**

Published by: Complementary Medicines Australia
PO Box 450
Mawson, ACT 2606
Australia
Telephone: 02 6260 4022
Facsimile: 02 6260 4122
E-mail: carl.gibson@cmaustralia.org.au
Website: www.cmaustralia.org.au

1. Introduction

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry and is unique in representing the entire supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

Complementary medicines are an important, growing Australian industry with significant potential to expand exports. The A\$3.5 billion domestic market – which is expected to grow to \$4.6 billion in 2017-2018 – delivers jobs, supports research and local manufacturing, and provides consumers with products to keep themselves well.¹ The global market has been estimated at \$US 83 billion annually and is expected to reach close to \$US 115 billion by 2015.^{2 3}

A\$70 million per annum – The estimated value to the Australian complementary medicines industry if a light-touch regulatory environment is achieved through appropriate deregulation. This value would then be available for further investment in industry growth.

(CMA Light Touch, Right Touch Regulation for Complementary Medicines: Deregulation Today for an Innovative Tomorrow)

A\$3 billion – The net economic benefit of using evidence-based complementary medicines for four chronic disease conditions – cardiovascular disease, osteoporosis, age-related macular degeneration and depression – as reported by Frost & Sullivan in *'Targeted Use of Complementary Medicines: Potential Health Outcomes and Cost Savings in Australia'*.

In response to the Treasurer's general invitation, CMA is pleased to submit its recommendations for inclusion in the 2015-16 Budget, with the aims of economic contribution to manufacturing, research and development and, through improved population health outcomes, reducing the pressure on the Government's health budget.

2. Overview

The public embraces the use of complementary medicines, with two out of three Australians regularly using a natural healthcare product. About half of this use is in relation to the management of major chronic diseases. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional

1 National Institute of Complementary Medicine, Retrieved from:

http://www.nicm.edu.au/health_information/information_for_consumers/understanding_cm

2 The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13.

3 Global Alternative Medicine Industry, Retrieved from:

<http://www.reportlinker.com/ci02242/Alternative-Medicine.html>

medical care.⁴ However, there is still an enormous untapped potential for complementary medicines to contribute to the Australian economy in terms of both:

- cost savings – a sustainable health system needs to shift the emphasis away from a diseased-based acute-care model to a wellness model, where Australians accept a greater, proactive role in caring for their health; and
- fiscal contribution – the complementary medicines industry is one industry that, in a supportive environment, has the ability to grow exponentially and support local manufacturing, as well as providing a significant contribution to our exports.

The burden of disease in Australia, and the associated economic costs, is a progressively top-of-mind issue. Australia's population is ageing and increasingly overweight, and is challenged by conditions such as coronary heart disease, diabetes and stroke. These diseases are largely preventable.⁵ In 2013, over \$140 billion was spent on health care services, which is nearly 9.1% of Australia's total gross domestic product.⁶ An additional economic burden of disease occurs in terms of lost productivity. This means less tax revenue for the Commonwealth, State, and Territory governments and increased health care costs.

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

The complementary medicines sector has evolved into a major world class industry that supports domestic manufacturing, jobs, research and exports. Whilst manufacturing is essential to a diverse and resilient economy, and offers a disproportionately large contribution to exports and research, it is well recognised that Australia is a high-cost place to do business.⁷ For the complementary medicines industry, as for other Australian industries, putting the right regulatory

COMPLEMENTARY MEDICINES INDUSTRY SURVEY (July 2014)

\$3.5 billion complementary medicines industry revenue, expected to grow to \$4.6 billion in 2017-2018

83 per cent of complementary medicines companies are expecting to grow their business in the next 3 years

Increase to 45,000 jobs as 58 per cent of companies are expected to have a growth in employee numbers during the next three years

62 per cent of complementary medicines companies are engaged in exporting

⁴ National Institute of Complementary Medicine, (2013) , Research Priorities for complementary medicine in Australia. Retrieved from:

http://www.nicm.edu.au/_data/assets/pdf_file/0009/537840/Research_Priorities_for_CM.pdf

⁵ Australian Institute of Health and Welfare 2014. Cardiovascular disease, diabetes and chronic kidney disease— Australian facts: Prevalence and incidence. Cardiovascular, diabetes and chronic kidney disease series no. 2. Cat. no. CDK 2. Canberra: AIHW

⁶ Australian Bureau of Statistics, 2014.

⁷ Australian Workforce & Productivity Agency. (2014). Manufacturing Workforce Study

environment in place will nurture, promote and enable competitiveness and innovation. The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the low level of risk these products represent. CMA acknowledges the Government's current focus on reducing regulatory red tape and welcomes the Review of Medicines and Medical Devices Regulation, led by Professor Lloyd Sansom AO.

To truly recognise the value that complementary medicines can contribute to both public health and to Australia's economy, CMA is advocating for three key Budget priorities:

1. Appropriate light touch-right touch regulatory environment
2. Improving Australia's health through a focus on preventative healthcare
3. Encouraging and supporting innovation and investment in research

3. Budget Recommendations

The 2015/16 Federal Budget provides an opportunity to refocus the approach to Australia's long term healthcare environment, and to place more emphasis upon prevention and retaining good health, rather than the costly treatment-of-disease model currently in place.

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.

3.1 Recommendation 1 – Light touch/right touch regulatory environment

Australia's Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods, including medicines, medical devices, blood products, and complementary medicines which includes vitamins, minerals and herbal substances. The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the low level of risk these products represent.

3.1.1 Timely access to new and innovative ingredients

The primary factor inhibiting the growth of the Australian complementary medicines industry is considered by industry to be the lack of availability of many dietary supplement ingredients that are commonly used in overseas jurisdictions. A new ingredient must be evaluated prior to inclusion on the list of available substances that may be used in Australia. The current application and evaluation process is costly and can take approximately 1-2 years, which is a significant investment of time and money.

As a small market in global terms, with high costs and long time frames, it is unattractive and uneconomical for multinationals to invest in the Australian market. A combination of industry information and anecdotal reporting indicates that as consumers become more product-savvy they are increasingly turning to complementary medicines bought online from overseas in order to access innovative products that contain ingredients currently not available in Australia.

CMA acknowledges the TGA's commitment to working more closely with international counterparts to identify those areas where mutual recognition may reduce resource wastage and eliminate duplication of efforts. CMA believes a fast-tracked approval process for ingredients already assessed by countries with a comparable regulatory standard is a practical and efficient way of providing the Australian market with innovative, safe, high-quality ingredients.

For novel ingredients, and submissions that contain unique data, a data protection mechanism such as that afforded under food and cosmetic regulatory frameworks should be established to provide an incentive for companies to invest in a regulatory application.

3.1.2 Complex and Unwieldy Advertising System

Advertising of complementary medicines is regulated via a complex and inefficient process. Approval for advertising is delegated by the TGA to two bodies (Complementary Healthcare Council of Australia and Australian Self Medication Industry) which often requires

advertisers wishing to advertise in broadcast and print media to seek two sets of approvals for the same advertisement. Not surprisingly, this creates inconsistencies in approvals.

Advertising complaints are heard by separate bodies, which make rulings that are often inconsistent with each other, and with the approval from the delegate(s). Obtaining prior approval to ensure advertising compliance is costly for industry but provides no certainty that an advertisement will not be the subject of complaint and subsequent sanctions from the Complaints Resolution Panel and TGA. Criticism has often been levelled at the Complaints Resolution Panel due to its lack of transparency and timeliness, limited penalties and lack of appeals process. In short, the complaints system is confusing, lacks certainty and is highly inefficient.

As the current system is costly but inefficient, advertisements for low risk complementary medicines should not require pre-approval but rather comply with best practice under the deterrent of appropriate sanctions and penalties under Australian Consumer Law. Both consumers and industry want advertising that provides accurate and adequate information about complementary medicines whilst preventing misleading claims. Reputable industry members believe that non-compliant companies should face the legal and punitive consequences available to the ACCC, which are significant compared to the current consequences of non-compliance.

CMA endorses that the current advertising regulatory standards are upheld (such as compliance with the *Therapeutic Goods Advertising Code*) but recommends removal of onerous regulatory burden through abolishing the current pre-approvals and complaints systems.

3.1.3 Advertising Claims on Complementary Medicines

At this stage, the pathway for a complementary medicine to be able to make stronger health claims is via the registration process; a process that requires a substantial data package, similar to that required for the registration of a new pharmaceutical drug. This is a major regulatory hurdle and impediment to companies investing in clinical trials. The evidence base required for making indications/claims on natural medicines needs to be commensurate with the low risk associated with these products.

CMA suggests a modified registration pathway for products that contain compounds that are included on the TGA's list of permitted ingredients for complementary medicines (and are therefore already deemed safe to be sold to consumers). A modified registration application would require less substantiation with regard to safety and toxicology testing, but must provide evidence of efficacy (clinical trials) in relation to the proposed higher therapeutic claims.

The recently updated guidelines for the evidence required to substantiate indications for use in listed medicines has increased the regulatory burden for product sponsors. Compliance with evidence substantiation has significantly increased industry costs, slowing innovation and efficiency. The updated guidelines will not stop the small number of companies determined to break the rules, but have created a substantial burden for reputable companies that aim to be compliant with the rules.

As an example, the current evidence requirements, especially for weight loss, biomarker claims and other scientific indications, are disproportionately excessive to the claims that are available. It is important that the evidence required and the claims that are available allow for a level playing field with food regulations. Under a new standard, *1.2.7 Nutrition, Health and Related Claims*, foods are able to make stronger health claims (such as lowering high cholesterol) – while having both lower manufacturing and evidence requirements – than complementary medicines listed on the Australian Register of Therapeutic Goods.

3.1.4 Protection of Innovation via Regulatory Mechanisms

There is no intellectual property protection for a large proportion of complementary medicine products regulated by the TGA, which creates a disincentive to innovate or bring new products to market. Unfortunately, this means that businesses are less likely to reinvest in their Australian operations and drives manufacturing, and research and development, offshore.

A solution is to develop regulatory protection to incentivise innovation in listed medicines and ingredients in the place of standard IP protection. In 2003, in a report to the Parliamentary Secretary to the Minister for Health and Ageing, the Expert Committee on Complementary Medicines in the Health System recommended that, “the TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.”⁸

As an example, the TGA could apply a period of non-disclosure to data used in the assessment of applications for new substances and products – for a sufficiently long enough period for innovative companies to recoup the cost of development and the meeting of regulatory requirements prior to competitors being able to use that data. Industry has previously recommended a suitable timeframe for the application of exclusivity to be for a period of 3 to 5 years.

⁸ <http://www.tga.gov.au/pdf/archive/committees-eccmhs-report-031031.pdf>

3.1.5 Proposed Solutions

The following are proposed:

- *Increase the number of new substance applications to the TGA by investing in review and analysis of new ingredients where assessments have been made in countries with comparable regulatory systems.*
- *Remove onerous regulatory burden through abolishing the current pre-approvals and complaints systems.*
- *A TGA-Industry Working Group to consider options to encourage industry investment, such as protection of new substance innovation.*

Cost: Absorbed by TGA in 15/16 and 16/17 and cost-recovered there-after

3.2 Recommendation 2 – Improving Australia’s Health via a Preventative Focus

The escalating costs associated with ageing and the growing burden of disease in Australia are a major challenge for government, private health insurers and individuals. 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.⁹

3.2.1 Cost-effectiveness of Complementary Medicines

A recently published 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 \$922 million could be potentially saved, along with gains in productivity of \$900 million.

*See Appendix 1, Frost & Sullivan Infographic,
Reproduced with permission from ASMI*

A 2013 US study ‘*Smart Prevention – Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements*’, also conducted by Frost & Sullivan, found the use of key dietary supplements, including omega-3s, B6, B12 and folic acid, could reduce hospitalisation costs by \$US billions per year. And a 2009 Access Economics report, ‘*Cost effectiveness of complementary medicines*’, commissioned by the National Institute of Complementary Medicine, found that the use of St John’s wort for mild to moderate depression 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

⁹ Frost & Sullivan. (2014). Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia

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.

3.2.2 Proposed Solutions

The following are proposed:

- *The convening of an Industry & Department of Health taskforce to develop an integrated health policy that includes the contribution of complementary medicines in preventative health.*
- *Industry & National Prescribing Service to develop education and training programs to assist doctors, pharmacists and other healthcare professionals with complementary medicines knowledge.*

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

3.3 Recommendation 3 – Encouraging Innovation and Investment in Research

The relatively high Australian dollar, slow growth across the economy, intense global competition and a focus on sustainable production have placed pressure on Australian manufacturing.¹⁰ In spite of this, the complementary medicines industry contributes to employment opportunities and development of a range of technical and vocational skills through innovation, research and the utilisation of complex technologies. The complementary medicines industry is one industry that, in a supportive environment, has the ability to grow exponentially and continue to support local manufacturing, as well as providing a substantial contribution to our exports.

3.3.1 Manufacturing & Incentives for Research & Development

Manufacturing is one of the main sources of innovation in Australia, and while the sector makes up just eight per cent of the economy, it is responsible for a quarter of all investment in R&D. Whilst the current R&D tax incentive assists in the development of intellectual property, it has little capacity to encourage subsequent commercialisation.

CMA supports the Export Council of Australia's proposed Australia Innovation and Manufacturing Incentive (AIM), designed to support local manufacturers to retain competitiveness and to cultivate innovation. Rather than a direct subsidy, the incentive would see the government provide tax relief based on the retention of intellectual property and manufacturing in Australia. The incentive would be offset against a company's tax bill, thereby linking it directly to commercial success and resulting in no upfront government outlay.

See Appendix 2, Australia Innovation and Manufacturing Incentive (AIM)

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3.3.2 Support for Australian Exporters

Australia's CM exports were worth over A\$200million in 2013, with dietary and vitamin supplements alone accounting for a large and growing share. Almost half were destined for East and South East Asia which are fast growing retail markets for these products. A number of factors contribute to the rapidly growing demand for Australian complementary medicines in the Asia Pacific region – a well-deserved reputation for high safety standards and high quality products, coupled with a growing middle class and ageing population. It is expected that by 2030 Asia will be home to the majority of the world's middle class; an increasingly wealthy and mobile group of people that will account for about 60 percent of

¹⁰ Australian Workforce & Productivity Agency. (2014). Manufacturing Workforce Study

global middle class consumption. This large demand for a range of goods and services will include health and aged care, natural preventative care and high-quality food products.¹¹

Estimates indicate that Indonesia, for example, had around 74 million middle-class consumers in 2012, expected to double by 2020. This implies that about 8 million to 9 million people will enter the middle class in Indonesia each year.¹² The growth in consumption of vitamin and dietary supplements across the Asia Pacific is forecast to remain high – for example, in Indonesia growth is expected to be 9 per cent per year.¹³

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.

3.3.3 Innovation through Evidence

Australia has an important resource in its academic and research bodies, with the potential to be an international leader in complementary medicines research. We have formidable complementary medicines research leaders that hold a national and international reputation.

Australia is fortunate to be home to two of the world's best research institutions for complementary medicines: The National Institute of Complementary Medicines and The Australian Research Centre in Complementary and Integrative Medicine, both five star accredited research centres.

Funding for complementary medicines research is essential to continue to scientifically establish the safety and efficacy of complementary medicines, to contribute to understanding best practice for integrative health care, and to develop innovative new products. However, at this stage, minimal support is provided through National Health and Medical Research Council (NHMRC) funding and Australia has one of the lowest rates of investment in research into complementary medicines.¹⁴

There is currently little or no incentive for industry to support the development of complementary medicines if there is no possibility of data protection and/or market exclusivity. By comparison with the United States of America and the United Kingdom,

¹¹ <http://www.asiaeducation.edu.au/verve/resources/australia-in-the-asian-century-white-paper.pdf>

¹² ITS Global (2014) Advancing Market Access for Complementary Medicines in Australia

¹³ ITS Global (2014) Advancing Market Access for Complementary Medicines in Australia

¹⁴ National Institute of Complementary Medicine, (2013) , Research Priorities for complementary medicine in Australia.

Retrieved from:

http://www.nicm.edu.au/data/assets/pdf_file/0009/537840/Research_Priorities_for_CM.pdf

research infrastructure for complementary medicines in Australia is not well developed. Research validates and supports innovation and informs good government policy, and there is a need for dedicated government funding for complementary medicines research.¹⁵

3.3.4 Proposed Investment

The following are proposed:

- *Implement the Australia Innovation and Manufacturing Incentive (AIM)*
Cost: Offset against a company's tax bill; no upfront government outlay
- *Maintain current investment in Austrade to support Australian exporters and enhance Australia's global competitiveness*
- **Cost: Retain funding; no additional cost**
- *Restoration of support for complementary medicine research groups.*
Cost: \$500,000 each year for three years

¹⁵ Complementary Medicines in the Australian Health System: Expert Committee on Complementary Medicines in the Health System Report to the Parliamentary Secretary to the Minister for Health and Ageing; September 2003

4. Conclusion

Complementary medicines play a significant role in allowing individuals to maintain a high level of physical and psychological wellness, and have the potential to assist in the reduction of the ever-increasing healthcare costs associated with preventable chronic diseases. The Australian health system has traditionally focused on illness, but there are increasing pressures for health funding to focus on wellness and wellbeing to prevent people from coming into the health system later in life with chronic diseases.

Health policy in Australia does not yet recognise the contribution of complementary medicines and a significant gap exists in the translation of the existing evidence base into integrative medical practice. CMA believes there is a requirement for further 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.

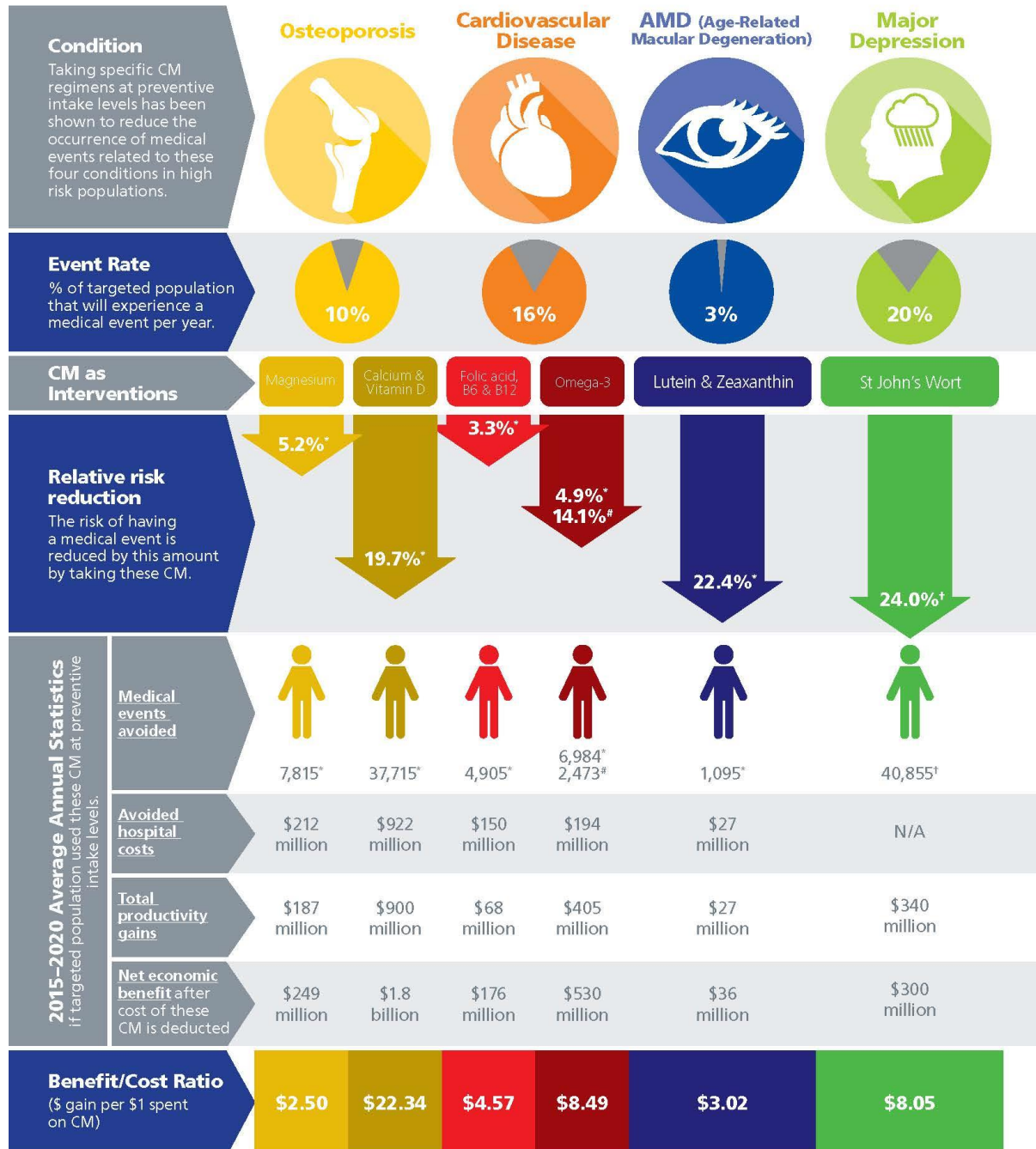
Removal of over-regulation will help the Australian complementary medicines industry to gain its position as an innovative and competitive market that is able to meet growing consumer demands, and support of complementary medicines research will help the industry to gain its position as a leading Australian industry sector and exporter.

Appendix 1

Health Care Cost Savings

TARGETED USE OF COMPLEMENTARY MEDICINES

A new economic report in Australia shows that taking specific complementary medicines (CM) can provide significant positive health outcomes and cost savings, by reducing hospitalisations and increasing productivity. The report looks at six complementary medicines regimens across four conditions in a targeted population of Australian adults who have the specific conditions or are at high risk for the disease.



Source: Targeted Use of Complementary Medicines: Potential Health Care Outcomes & Cost Savings in Australia – Frost & Sullivan.

Notes: *Hospital Separations, #Attributed deaths, †Successful Diagnostic Transitions.

©ASMI (Australian Self Medication Industry)

Appendix 2

Export Council of Australia

Trade Policy Recommendations 2013/14: International competitiveness begins at home
Developed in conjunction with Cook Medical Pty Ltd

Australian Innovation and Manufacturing Incentive (AIM)

Nearly one million Australians are employed in manufacturing, contributing more than \$106 billion to the economy per year. Manufacturing is one of the main sources of innovation in Australia. While the sector makes up just 8% of the economy, it is responsible for a quarter of all investment in R&D. Patent development and manufacturing are different sides of the same coin. A constant push-pull operates, whereby innovation in product design (R&D) encourages innovation in manufacturing processes, and innovation in processes encourages innovation in product design.

Once production is sent offshore, company engineers and scientists no longer engage with the manufacturing process, during which potential improvements to a product are identified. Designs cannot be amended correspondingly, and as a result they may be under-designing compared to the competition.

For this reason, the Harvard Business School advises against the separation of R&D and manufacturing.

Whilst the current R&D tax incentive undoubtedly promotes the development of Intellectual Property (IP), it does little to encourage the capitalisation of this IP through the commercialisation and manufacturing processes, thus inadvertently stifling the potential for innovation and employment creation.

The AIM incentive, designed to support manufacturers, is the logical next step to maintaining our competitiveness and cultivating innovation.

Rather than a direct subsidy, the incentive would see the government provide tax relief based on the retention of IP and manufacturing in Australia. One possibility is for Australian companies to receive an incentive equivalent to 2% of sales on locally manufactured products, for which they hold patents/licenses. The incentive would be offset against a company's tax bill, thereby linking it directly to commercial success and resulting in no upfront government outlay.

The AIM incentive also has the potential to attract new investment from overseas, as well as keeping 'home-grown' manufacturing within the country.

An excellent example of this kind of model working in practice is provided by the UK. GlaxoSmithKline has recently invested over \$800m in new operations there. By the company's own admission, this was due to the fact that the UK government introduced "Patent Box" legislation, which came into effect in April 2013.