



**Complementary Medicines Australia
2016/17 Federal pre-Budget Submission**

January 2016

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Fast Facts on the Industry:

- 59 TGA licenced manufacturing sites in Australia
- Local manufacturing in major expansion due to overall high demand growth
- 6,000 direct high value jobs
- \$4.2bn in revenue
- Sold through 5,500 pharmacies, 3,500 supermarkets and 1,500 health food stores
- Exports to more than 26 countries including;
 - China, Taiwan, Hong Kong, South Korea
 - Singapore, Malaysia, Philippines, Vietnam, Thailand, Indonesia
 - Brazil, Canada, United States, Germany.

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1. Overview

Consumers worldwide are increasingly turning to complementary medicines as part of their desire to take control of their own health and lead longer, more active lives. In just two years the Australian complementary medicines industry has grown from \$2.3 billion to \$4.2 billion, with increasing acceptance and demand from consumers.

Australian complementary medicine exports are also booming. Over the last two years we have seen formal exports of Australian complementary medicines grow by 36%. South Korea has now overtaken New Zealand as our top export market. Exports to the Asian region have doubled, and there is continued healthy demand for Australian products, driven by the industry's reputation for products that meet the highest standards of quality and safety.

Complementary Medicines Australia (CMA) welcomes the National Innovation and Science Agenda and the Federal Government's drive to support smart ideas, create business growth, local jobs and global success. 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.

In the complementary medicines sector, the CMA believes that the 2016/17 Federal Budget provides an opportunity to:

- facilitate industry growth and innovation via progression of the deregulation agenda;
- create more high-skill, high-value jobs, bolstering Australia's competitiveness;
- support higher degrees and high level research;
- promote further growth of high-quality Australian exports; and
- build a more sustainable health system for the future and contribute to long-term cost savings, by emphasising proactive and preventive health choices.

It has been noted that Australia needs to make the right choices now if we are to maintain and improve our standard of living, drive prosperity through increased productivity and participation, and build a strong, resilient economy.¹ The key recommendations in the CMA pre-Budget submission are:

1. an appropriate and streamlined regulatory environment;
2. encouraging innovation and investment in the complementary medicines sector; and
3. improving Australia's health via a preventive focus.

¹ Australian Government. (2015). 2015 Intergenerational Report: Australia in 2055. Accessed from <http://www.treasury.gov.au/PublicationsAndMedia/Publications/2015/2015-Intergenerational-Report>

2. Budget Recommendations

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.

2.1 Recommendation 1 – Appropriate Regulatory Environment

The ability for businesses to build capacity and grow is both facilitated and constrained by the regulatory frameworks within which they must operate. An appropriate regulatory environment can increase productivity and lead to an improved allocation of resources, while poorly-designed regulation can burden firms with needless red tape and hinder entrepreneurship and innovation.

The Therapeutic Goods Administration (TGA) has responsibility for administering the federal *Therapeutic Goods Act 1989*, which provides the national framework for the regulation of therapeutic goods, including medicines and medical devices, in Australia. There are a number of aspects of the current regulatory system that are not commensurate with the low risk posed by complementary medicines. This has led to the creation of substantial regulatory and financial burden, particularly on small and medium-sized businesses. However, industry is of the firm belief that the current regulatory burden of compliance can be reduced without risking the safety and quality of complementary medicines available to Australian consumers.

CMA acknowledges the Government's Expert Review of Medicines and Medical Devices Regulation. Industry supports the goals of the review of better aligning regulatory protections with risk, and easing regulatory requirements where they do little to improve consumer protection but are a barrier to Australian business and innovation in what has become an increasingly globalised environment.

On 31 July 2015, the Expert Panel's *Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods* was provided to Government. Industry is supportive of a number of the recommendations, and in particular those that aim to encourage businesses to invest in bringing new products to the market and in conducting a greater number of clinical trials to substantiate varying levels of therapeutic indications and health claims.

The Panel has, however, made a few recommendations that would, if implemented, give rise to increased regulatory burden, especially upon SMEs, without providing additional benefit to consumer health. In particular, the Panel has recommended that sponsors be required to publish the evidence held to support all indications included in the Australian Register of Therapeutic Goods (ARTG) for each of their products. This recommendation adds substantially to the regulatory burden on businesses, and it is in stark contrast to the concept of encouraging investment in research, supporting entrepreneurship and innovation. It is also in conflict with another of the Panel recommendations, that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.

Higher risk registered products, such as pharmaceuticals, some OTC and registered complementary medicines are fully assessed by the TGA for safety, quality and efficacy, which means a substantial timeframe of at least 1-2 years before products are available on the market. Listed medicines must only contain ingredients that have been approved by the TGA as being of low risk, and are not required to be pre-assessed by the TGA for efficacy, which allows for a sensible timeframe to market. The Panel has proposed that for the majority of complementary medicines a prominent disclaimer be placed on all promotional materials to the effect that the efficacy claims for the product have not been independently assessed. A requirement for negative labelling on complementary medicines is not a global practice, and is therefore likely to be detrimental to the exports and international reputation of Australian complementary medicines.

In parallel to the negative disclaimer, the Panel has also proposed the option of sponsors choosing to have the evidence supporting a product evaluated prior to market access, thus allowing a positive disclaimer “efficacy claims have been independently assessed” or similar. This concept is further supported by the recommendation for an increase in the number of post-market listing compliance reviews conducted by the TGA that should, upon successful completion, allow the use of the positive disclaimer if desired. In acknowledging support for encouraging investment in research, the positive disclaimer should be the only one implemented to avoid unintentional regulatory burden and consumer confusion over the regulatory framework for lower risk products.

The CMA submission to the Panel detailed those areas where regulation of complementary medicines could be improved to enhance productivity and competitiveness, whilst ensuring consumer access to high quality, safe and effective products. Please find below a summary of the complementary medicines industry’s top recommendations. With the implementation of these recommendations, our industry expects to save approximately \$70 million per annum, which could be better spent towards research and development and innovation.²

2.1.1 Timely Access to New and Innovative Ingredients

A 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. Unless an ingredient is included on the TGA’s list of permissible ingredients³, an application is required for evaluation of the substance for its inclusion. This process includes a quality and safety dataset and is a significant regulatory hurdle that can take approximately 1-2 years for the application to be evaluated – a significant investment of time and money.

CMA recognises the Panel recommendation of allowing the submission of unredacted evaluation from a comparable regulator and the suggestion for development, with industry, of legislative timeframes for evaluation of new ingredients. The work of the TGA’s Business Process Reform towards targeted and predictable timeframes is also acknowledged, and we look forward to our continued collaboration in this area.

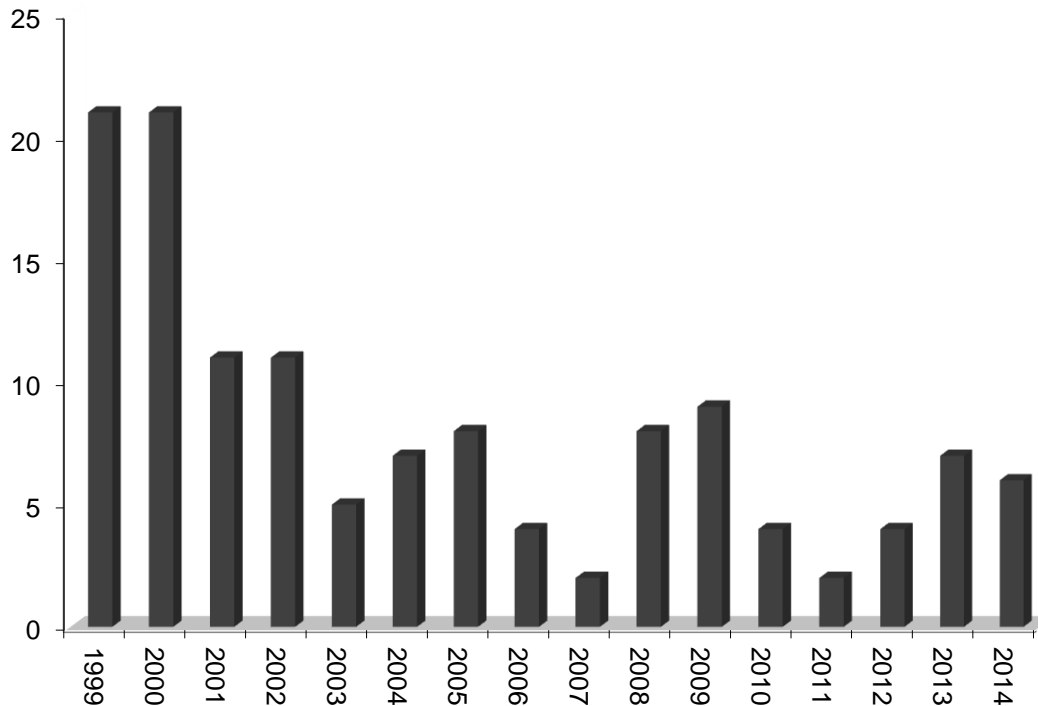
CMA believes a fast-tracked, abbreviated approval process for ingredients already assessed by countries with a comparable regulatory standard is a practical and efficient way of providing the Australian market with innovative, safe, high-quality ingredients.

² CMA, Light Touch Right Touch for Complementary Medicines

³ [Therapeutic Goods \(Permissible Ingredients\) Determination No.1 of 2015 - F2015L02094](#)

Availability of new ingredients for use in complementary medicines over time (please see table below).

TGA Listing Notices 1999 - 2014



<http://www.tga.gov.au/listing-notices>

2.1.2 Complex and Unwieldy Advertising System

Currently, advertising of complementary medicines is regulated via a complex and inefficient process. Approval for advertising is delegated by the TGA to two bodies which often requires advertisers to seek two sets of approvals across a media campaign. Not surprisingly, this creates inconsistencies in approvals and additional costs for industry.

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). 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.

In alignment with the Panel recommendations, 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.

Recognising that implementation of significant changes may take some time, CMA asks that consideration is given to making an interim variation to the way that the pre-approvals services are

classified, which would address the main concern of the industry in providing a one stop shop for clearance of marketing campaigns. Modern marketing campaigns now utilise a wide range of marketing channels (not just traditional print and broadcast) and the areas of regulatory clearance are becoming more blurred with the advancement of technology such as digital outdoor marketing screens. CMA, the advocacy arm of the Complementary Healthcare Council of Australia, suggests separate contracts be offered and negotiated for the provision of pre-approvals services for AUST-R and AUST-L advertising pre-approvals (including exempt therapeutic goods such as homeopathics), rather than for traditional print and broadcast. This would provide the vast majority of advertisers with a one stop clearance house for pre-approvals, ensure consistency of decision making, as well as providing some equitability in the fees charged for advertising pre-approvals service. This suggestion would also benefit the TGA, offering efficiencies in administration, reviews, appeals and reporting.

2.1.3 Advertising Claims on Complementary Medicines

Many complementary medicines have the ability to be used for conditions that require a higher level of health claim than currently allowed, but are unable to advertise this information. 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 supports the Panel recommendation for three pathway options by which sponsors may enter their product in the ARTG, which should include a modified registration pathway that would enable a higher level of health claim. This pathway 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.

2.1.4 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.*
- *Implement registration pathway options that encourage industry investment in further research and product innovation.*
- *Remove onerous regulatory burden through abolishing the current pre-approvals and complaints systems.*

Cost: Absorbed by TGA in 2016/17 and 2017/18

2.2 Encouraging Innovation and Investment in the Complementary Medicines Sector

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. It is an industry that holds great potential to grow exponentially and to contribute further to the strength of high-skill local manufacturing and exports. To leverage the accumulated knowledge, capabilities and a strong international branding for excellence, Australian complementary medicines businesses need the ability to invest in research and development, and to drive networks into global markets.

2.2.1 Incentives for Research & Development

Business expenditure on research and development in Australia remains lower than the OECD average, being 1.24% of GDP in 2012 compared to the OECD average of 1.63%.⁴ In the case of the complementary medicines industry, one of the major barriers to investing in research and development is that there is currently little incentive due to a lack of data protection and/or market exclusivity. The provision of regulatory or administrative protection is a possible solution. As an example, since 1992, China has provided administrative protection of between 7 and 30 years for traditional Chinese medicines.⁵

The recently published 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, although the Panel did not propose how this should be achieved. Industry recommends that a stakeholder working group be convened to develop and implement mechanisms of protecting innovation and new research data. Encouraging business expenditure on research and development in complementary medicines will help Australia capture the growing market for these goods, nationally and internationally, as well as provide significant economic and health benefits for Australians.

2.2.2 Support for complementary medicines researchers

As recognised by the National Innovation and Science Agenda, Australia has been poor at translating research into commercial outcomes and is falling behind on measures of commercialisation and collaboration, consistently ranking last or second last among OECD countries for business-research collaboration.

Australia has world class academic and research bodies, and holds the potential to be an international leader in complementary medicines research and translation 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, both five star accredited research centres. A third centre is being established, based out of La Trobe University in Melbourne, which is a collaborative centre focused specifically on the modern, GMP

⁴ National Institute of Complementary Medicine. (2015). Highlighting complementary medicine research.

⁵ National Institute of Complementary Medicine. (2015). Highlighting complementary medicine research.

processed products in complementary medicines and the relevant nutritional research and clinical trials: the Australian Nutraceutical Science and Education Centre.

Currently, Australia has one of the lowest rates of investment in research into complementary medicines and there is minimal support provided through National Health and Medical Research Council (NHMRC) funding.⁶ Research validates and supports innovation and informs good government policy, and there is a need for dedicated government funding for complementary medicines research.⁷

2.2.3 Support for Higher Degrees

Human capital – talent and skills – is seen as one of the key pillars of the National Innovation and Science Agenda that will allow the transformation of Australia’s economy and global competitiveness. In line with this, the focus to improve Australia’s ability to translate our research into practice must have a foundation of teaching new practitioners with the most up-to-date and research-based knowledge.

Approximately 70 percent of Australians use complementary medicines, mostly alongside conventional medical treatments to help improve their health and wellbeing, with about half of this use being in relation to the management of major chronic diseases. The community expects health practitioners to be highly trained, to provide information and guidance, and be able to make informed decisions in the best interests of patient health.

It is important that funding be maintained to Australia’s tertiary institutions for higher degrees and high-level research in complementary medicines, to contribute to both a STEM-strong economy and to public health.

2.2.4 Support for Australian Exporters

Whilst Australia’s exporters are increasingly competing with companies from around the world, the Australian complementary medicines industry has the comparative advantage of holding a well-deserved reputation for high safety standards and high quality products.

Unlike in some other jurisdictions, the Australian regulation of complementary medicines as *medicines* facilitates their integration within mainstream medicine, both locally and around the world.⁸ 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.

It has been projected that by 2030, there could be close to 3.2 billion middle-class consumers in the Asia Pacific region.⁹ Ernst & Young estimate that as many as 500 million Chinese could become

⁶ National Institute of Complementary Medicine, (2013)-, Research Priorities for complementary medicine in Australia. http://www.nicm.edu.au/_data/assets/pdf_file/0009/537840/Research_Priorities_for_CM.pdf

⁷ 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

⁸ National Institute of Complementary Medicine. (2015). Highlighting complementary medicine research

⁹ The Treasury. (2015). 2015 Intergenerational Report: Australia in 2055. p 94. Accessed from <http://www.treasury.gov.au/PublicationsAndMedia/Publications/2015/2015-Intergenerational-Report>

middle class over the coming decade.¹⁰ A large demand is expected in the areas of health and aged care, natural preventive care and high-quality food products.¹¹

Our industry has significant potential to expand exports and needs to be in a position to capitalise on these market opportunities. CMA would like to acknowledge the Government's focus on deepening Australia's economic ties with countries within our region, ties that are essential for our future prosperity. We also strongly support a focus of Australia's FTA negotiations on helping to address 'behind the border' issues. In China, for example, onerous testing and licensing requirements inhibit market access for complementary medicine products and limit investment in the Chinese market, particularly for products which make health claims. Continued trade liberalisation in our region will present sizeable opportunities for the Australian complementary medicines industry.

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.

2.2.5 Proposed Solutions

The following are proposed:

- *A stakeholder working group be convened to develop and implement mechanisms of protection for innovation and new research data and investigate opportunities for regulatory/ administrative protections for R & D for complementary medicines*
Cost: Absorbed by TGA in 2016/17 and 2017/18
- *Maintain current investment in Australia's tertiary institutions for higher degrees in the field of complementary medicines studies*
Cost: Retain funding; no additional cost
- *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

¹⁰ ITS Global (2014) Advancing Market Access for Complementary Medicines in Australia

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

2.3 Recommendation 3 – Improving Australia’s Health via a Preventive Focus

The burden of disease in Australia, and the associated economic costs, is a progressively top-of-mind issue, with recent statistics showing that half of all Australians have at least one chronic disease.¹² 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. In 2013, over \$140 billion was spent on health care services, nearly 9.1% of Australia’s total gross domestic product. Yet Australia’s spending on preventive health is low by OECD standards.

The Productivity Commission published the research paper *Efficiency in Health* in April 2015 to outline a number of options for efficiency gains that could be delivered without changing the existing framework and funding structures of the health system. A key finding was that Australia needs to invest more in preventive health to reduce the burden on disease and to achieve better value from limited health resources.¹³

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. Person-centred health care, and the appropriate focus on prevention in the Australian health system, is a vital element of the vision of improved health.

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.¹⁴

2.3.1 Cost-effectiveness of Complementary Medicines

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.

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

¹² 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>

¹³ Productivity Commission. (2015). Efficiency in Health. Accessed from <http://www.pc.gov.au/research/completed/efficiency-health/efficiency-health.pdf>

¹⁴ Frost & Sullivan. (2014). Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia

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.

2.3.3 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.*

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

3. 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. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care.

Our industry has the ability to significantly increase highly skilled and innovation rich local manufacturing, as well as providing a significant contribution to our exports. Regulatory/administration protections are important to encourage businesses to invest in research and development. Along with greater support for complementary medicines researchers and tertiary level training, this would greatly support the translation of the evidence to commercialisation and integrative medical practice.

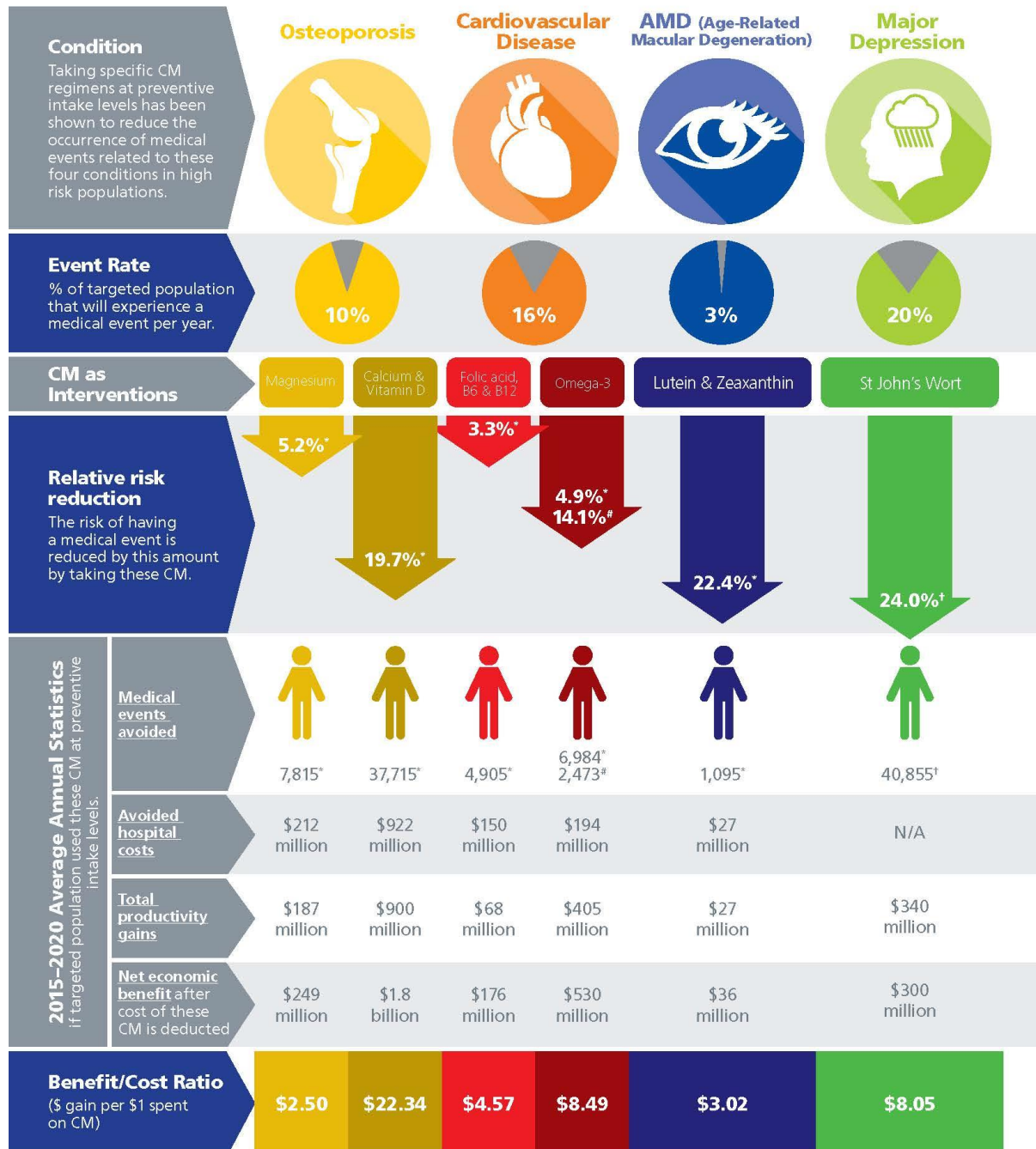
CMA believes there is a requirement for further cooperation and collaboration between policy makers, researchers, industry and health professionals to ensure complementary medicines are a future component of policy contributing to the overall health of all Australians.

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

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing members across the 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.

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, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Traditional and long-term use is taken into account in establishing safety as a medicine. Other natural healthcare products may be regulated as foods, such as functional foods and special purpose foods, or as cosmetics, such as natural cosmetics that use herbals and botanicals.