Complementary Healthcare Council of Australia



The Complementary Healthcare Council's

2012/13 Federal Pre-Budget Submission

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1. Complementary Healthcare Council

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the Complementary Medicine (CM) Industry. The CHC is unique in representing the entire supply chain including; manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. We are the principal reference point for our members, the government, the media and consumers to communicate about issues relating to the complementary medicine industry.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals.

Complementary medicines comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines. Complementary medicines are generally available for self selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. 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[1].

There are 254 complementary medicine companies in Australia generating around $2 billion in annual revenues[2]. In Australia the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Production of complementary medicines in Australia is a substantial industry with 59 TGA approved manufacturing facilities nationally.

Not surprisingly, half the adult population of Australia will purchase a complementary medicine product at least every quarter. The majority (75%) of consumers can name the exact CM product they purchase and why.[4]

Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at higher rates than domestic consumption.[5]

The CHC develops and manages a series of codes of conduct to which its members comply, and to which CHC promotes compliance with amongst all industry participants. This includes operating to the highest regulatory and ethical standards when sourcing, manufacturing and marketing complementary medicines.

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1 Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

2 CHC Complementary Medicines Industry Audit May 2011, available by request.

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

4 My Opinions Research for CHC May 2011

5 CHC Industry Audit May 2011

The CHC has five Board-level committees focused on critical industry issues: manufacturing and trade, innovation, regulatory policy, marketing and communications, and retailing. Additionally, the CHC has 11 working groups representing sectors of the supply chain, focused on operational-level issues.

2. Industry issues

Over the last few decades the complementary medicine sector has evolved from something akin to a 'cottage industry' to a major industry subject to a tight regulatory regime, which requires complex supply chains, clinical trials, global marketing, and export acumen. While this transformation is unambiguously positive, it has brought with it a set of policy challenges which need to be addressed if the industry is to continue to employ highly-skilled workers in the manufacturing sector, and maintain recent export momentum.

Three key policy challenges for the Industry are described below. These are challenges which are considered by the industry to be critical and which require addressing in the short-to-medium term.

2.1 Recognition of population health benefits

The contribution made by complementary medicines to improving population health outcomes is supported by a large and constantly growing evidence base; this is particularly the case for major products like multi vitamins, vitamin B, and fish oil, which together account for approximately 50 per cent of complementary medicine sales in Australia.

There are about 10 000 such medicines available on the Australian market, of which only about 200 are in the higher risk 'registered' category; the remainder are in the lower- risk 'listed' category. There are about 3000 sponsors of listed and registered complementary medicines; the sponsor generally is the marketer and may also be the manufacturer, importer or exporter of the medicine.

The evidence suggests that key products are more cost-effective in dealing with minor conditions than the available pharmaceutical medicines on the market[6] (for some the cost differential is up to 70 per cent) and their efficacy has been recognised by the National Health and Medical Research Council (NHMRC). These medicines are also widely considered to offer a means of managing chronic conditions associated with greater life expectancy[7]. The Commonwealth Government has acknowledged that for far too long the health system has focused on treating people after they become unwell, and this has resulted in vast social and economic costs associated with chronic disease[8].

Yet policy makers remain reluctant to accommodate a role for complementary medicines in the preventive health agenda. For example, there is no acknowledgment of the preventive health benefits of complementary medicines within the work-plan of the new Australian National Preventive Health Agency (ANPHA).

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[6] NICM http://www.nicm.edu.au/content/view/159/276/

[7] WHO Traditional Medicine Strategy 2002-2005, Geneva, 2002, p. 2, available from http://www.who.int/medicines/publications/traditionalpolicy/en/

[8] Australian Government: Taking Preventative Action. A Response to Australia: The Healthiest Country by 2020, the report of the National Preventative Health Task Force. http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/6B7B17659424FBE5CA25772000095458/$File/Foreward.pdf

There is a real and immediate role for complementary medicines in achieving the Government objectives set out in *Australia: the healthiest country by 2020* through primary and secondary prevention of illness, and by encouraging and empowering all Australians to take better care of their health[9].

General practitioners recognise the role played by complementary medicines. A survey conducted by the National Prescribing Service in 2008 found that 90 per cent of GPs had recommended complementary medicines to their patients. However, around 92 per cent of doctors expressed a need for more education and research in the complementary medicines field.

It is appropriate for the Minister for Health and Ageing to direct the ANPHA to include the role of complementary medicines in its preventative health action plan. The CHC acknowledges that further and ongoing research is required to reinforce the current extensive evidence base for complementary medicines. Indeed, one of the most challenging aspects of regulating complementary medicines, which also affects the transparency of the regulatory system as a whole, is the public availability of evidence relating to efficacy of complementary medicines[10]. The ANPHA should, from within current resources, fund a multi-year research project on the preventive health benefits of complementary medicines. This Health Economics related activity should be undertaken in consultation with industry and consumers and should provide cost / benefit analyses as to the population health outcomes and the Federal budget savings from consumer use of complementary medicines as a key part of the preventive health action plan.

2.2 Industry Regulation can control but not stifle innovation

The Australian complementary medicines industry is commonly regarded as one of the most tightly regulated in the world. Regulation of the complementary medicine industry in Australia is similar to and administered by the same regulator as that for pharmaceutical and over the counter medicines as well as medical devices. A distinct difference however, is that the complementary medicines industry does not enjoy the innovation incentive or IP protection enjoyed by the big Pharmaceutical companies. Nor does it have funding by the Government or the financial backing of the large Pharmaceutical companies.

For example, while substantial intellectual property rights are attached to new drugs developed by pharmaceutical companies, there is no such protection for new products developed by the complementary medicines industry. Limited regulatory protections, which provide market exclusivity for new complementary medicines supported with scientific evidence are available in other jurisdictions, most notably China.

Should an Australian complementary medicine company choose to list a new product there is no certainty regarding the timelines for approval of an application. This is in contrast to the model used in the pharmaceutical approval process where there is a statutory period of time within which the review of the application must take place.

9 Australia: the healthiest country by 2020 Discussion Paper, http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/discussion-healthiest

10 The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, p. 18.

The regulatory process for therapeutic goods in Australia is wrapped in copious red tape. There are more than 150 compliance regulations scattered across 16 different guidelines. The Australian National Audit Office (ANAO) has recommended that these regulations be streamlined and guidance documents for industry updated and completed expeditiously[11].

The process of launching a new product is expensive, time consuming, lacks procedural certainty and – even if successful - does not confer any market exclusivity for the applicant company. This stifles innovation, reduces health care options, and threatens the competitiveness of Australian exports. It is believed there are many substances and compounds that are used overseas safely with major population health benefits, that could be introduced in Australia, under a rigorous yet "innovation neutral" regulatory regime. There are already well known Indigenous Medicine substances such as Tea Tree, Eucaluptus and Emu oils, and most recently Kakadu Plum has been the subject of intensive research and development and scientific trials as to efficacy for a range of conditions. It is estimated there are hundreds more yet to be catalogued, researched and trialled as to their potential impact on population health outcomes and commercial opportunity, locally and in international markets.

The numbers of approvals through the Advisory Committee for Complementary Medicines (ACCM) for new substances, as permitted ingredients, has fallen from an average of around 20 per year in the late 1990s to just 4 in 2010. It is believed this is primarily due to the negative factors outlined above.

2.3 The lack of an industry framework

The complementary medicines industry directly employs around 5000 highly skilled workers and approximately $200 million in GST revenue is collected by the Federal Government each year on the sale of complementary medicines.

However there is little direct investment in the industry by Government. Less than one per cent of NHMRC funding supports complementary medicine research, yet statistics show complementary medicines are ~ 12.5% of the total medicines and devices industry. There is also no targeted support for export facilitation or skills maintenance or traineeships.

It is acknowledged that a number of Federal Government programs exist that could be tapped to address some of these gaps, but what is needed is an overarching complementary medicines industry policy to guide public investment decisions and give taxpayers confidence that targeted support is appropriately framed.

An Industry Plan could be developed under the auspices of the Manufacturing Roundtable process. But regardless of the modality, the development of a comprehensive three-year plan for the complementary medicines industry with time-bound priority actions would be a low-cost, valuable investment for Government. A similar state-based manufacturing industry action plan is under preparation in NSW[12].

[11] The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, p. 19-20.

[12] NSW Government Industry Action Plans: Manufacturing. http://www.business.nsw.gov.au/doing-business-in-nsw/industry-action-plans

3. 2012/13 Pre-Budget recommendations

The 2012/13 Federal Budget provides an opportunity to begin addressing the policy challenges faced by the complementary medicines industry.

Noting the guidance in the Treasurer's media release that pre-Budget submissions should consider the Government's strong commitment to fiscal discipline and the need to minimise expenditures, the recommendations set out below propose only moderate additional expenditure across the forward estimates.

3.1 Recommendation 1 – Industry Plan

The Federal Government should prepare an industry plan for the complementary medicines sector. The Plan would act as a 'roadmap' showing where the industry is currently positioned and best directions for optimal development. Importantly, it will provide practical mechanisms for the complementary medicines industry to address the key industry issues outlined above as to improving population health outcomes and enhancing Innovation, Manufacturing, Job Creation and Exports in an Industry that has grown substantially over the last decade. [13] The Plan would have a 'how to' approach to the complementary medicines industry's challenges and opportunities. It would be developed by a working group chaired jointly by a senior officer within the Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE) and a nominee of the CHC and would include other Government Agencies to ensure whole-of-Government agreement. The industry plan would be finalised by the end of 2012 and would cover the three year period 2013-2015.

The Plan should consider, among other things:

- Mechanisms to facilitate market exclusivity for a period of time to encourage innovation and support ongoing clinical trials.
- Strategic policy directions to invest an approximately relevant proportion of NHMRC funding towards complementary medicines (complementary medicines are ~12.5% of the total medicines and devices sector).[14]
- Access to appropriate industry support schemes including export development and import replacement.
- A package of measures to support development and retention of skilled manufacturing positions.
- Options for supporting further research and development.
- Measures to streamline current regulatory arrangements.

Cost: Nil – secretariat costs to be absorbed by DIISRTE

[13] Euromonitor Vitamins and Dietary Supplements in Australia July 2011
[14] Euromonitor Consumer Health in Australia July 2011

3.3 Recommendation 2 – Clinical Trial Partnership

Consumers, Health Professionals, Industry and Government have a shared interest in reinforcing and enhancing the sound scientific evidence base that demonstrates the efficacy of complementary medicines. Clinical trials are expensive and the results of such trials currently lack intellectual property protection for Complementary Medicines in contrast to other Medicines. We propose a major four–year clinical trial partnership for Complementary Medicines which examines the preventive health benefits of a select group of CMs in the treatment of specific chronic and preventive health conditions. Such a partnership would require significant scoping but is expected to pilot trials, and follow on trials would be subject to existing best practice and CM relevant protocols, sample sizes and be subject to independent peer review. A fund established for joint Government and industry funding of projects, conducted through local universities, done to the highest relevant standards and published in peer-reviewed journals, has gathered extremely significant industry support.

Ideally, initial pilot trials should proceed alongside the development of the Industry Plan called for in recommendation 1 and be linked to the regulatory changes agreed as a result of those discussions which we anticipate would be phased in across a three-year timeframe concluding in 2015.

The cost of establishing a clinical trial partnership could be expected to be in the vicinity of around $15.5 million over four years. Industry would contribute 50 per cent of this cost including all costs in the first year.

Cost: Nil in 12/13 and $3.5 million in 13/14 and 14/15, and $500,000 in 15/16.

3.2 Recommendation 3 – Support traditional indigenous medicines

Indigenous Australians have used medicinal plants and food for thousands of years. Research demonstrating the effectiveness of other traditional medicines around the world (Western, Chinese, Ayurvedic and American) is building. Aside from a small amount of work undertaken by the Indigenous Bio-resources Research Group at Macquarie University, very little has been done to catalogue traditional knowledge in this field. Even less work has been done to ensure the intellectual property rights of Indigenous Australians are protected if products become commercialised. Consistent with the World Health Organisation's 2008 Declaration on Traditional Medicines, the Australian Government should take concrete steps to research, catalogue and protect traditional indigenous medicines. Two actions are proposed.

First, funding should be provided to undertake a comprehensive stock-take of specific indigenous medicines in consultation with traditional owners. The cost associated with undertaking this work is estimated at $600,000 over two years. This work would build on preliminary research already undertaken at Macquarie University and could be coordinated and managed by the CHC as the independent peak body, together with relevant organisations, on behalf of Industry and traditional owners.

This should then lead to a position where analysis of the key substances leads to pilot clinical trials being undertaken on those key substances.

Cost: $300,000 each year in 12/13 and 13/14.

Second, the Federal Government should allocate $700,000 over four years commencing 2012/13 to support the 'Australian Indigenous Medicines' initiative – a research and development activity being sponsored by the CM Industry and managed by the CHC as the independent peak body to bring evidence-based indigenous medicines to market with intellectual property in the products vesting with traditional owners. The Federal Government contribution would include funding of two indigenous cadetships to assist with development, marketing and community outreach, as part of the specific indigenous medicines research stock-take project undertaken 'on country'.

Cost: $100,000 in 12/13 rising to $200,000 a year from 13/14 to 15/16.