



Industry Action Plans
c/o: Innovation Unit
NSW Trade & Investment
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Re: NSW Government Manufacturing Industry Action Plan: Complementary Medicines

Thank you for providing the opportunity for the complementary healthcare industry to comment on the NSW Government Manufacturing Industry Action Plan, dated 21 October 2011.

The Complementary Healthcare Council (CHC) is the peak industry body exclusively committed to a vital and sustainable complementary medicines industry (CM Industry). Our members include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers.

The Complementary Medicines market is worth ~AUS\$1.9 billion in revenues and the industry claims ~5000 highly skilled direct manufacturing jobs, ~60,000 indirect jobs and exports to more than 20 countries¹ including Hong Kong and China - where ingredients are also sourced and products imported back to Australia. Currently there are approximately 59 TGA licenced Listed medicine manufacturers in Australia, with the majority of CM product manufacturers located in NSW. The Australian Register of Therapeutic Goods indicates there is approximately over 3000 product sponsors.

Pharmaceutical product manufacturing in Australia has at best plateaued and from many accounts is in decline. Large multinational organisations are shifting processing facilities to countries with lower cost profiles or larger domestic markets or in order to consolidate global product supply centres of excellence (such as in Japan).

Complementary Medicine product manufacturing in Australia uses the same technologies and adheres to the same Therapeutic Goods Administrations (TGA) Good Manufacturing Practices (GMP)(GMP) and regulatory processes as the Pharmaceutical Industry. The CM Industry continues to grow and provide substantial employment opportunities whilst developing a range of technical and vocational skills through innovation, research and the utilisation of complex technologies, despite an increasing number of global competitive pressures.

¹ The Complementary Healthcare Councils [Complementary Medicines Industry Audit 2011](#).

The key factors to the success of the complementary medicine manufacturing sector to date include the following:

- The stringent pharmaceutical/regulatory requirements for manufacturing complementary medicine products in Australia compared to most other countries where these products are considered to be functional foods, with reduced adherence to processing requirements and/or quality.
- The confidence of the Australian public, as well as export destinations, in the regulated quality of Australian CM manufactured products.
- The stringent regulatory requirement to monitor the quality of various herbal, active and raw materials used in the complementary medicine manufacturing processes.
- The somewhat unique and innovative product development profiles of a large range of complementary medicine products in the Australian market.
- The ability to access and approve, through the existing regulatory process, an ongoing stream of new herbal and active materials for various therapeutic applications.
- The depth and breadth of medicinal research, science and teaching across the higher education sector – including 41 Complementary Medicine programs.
- Increasing recognition by the general public and sections of the mainstream medical profession that complementary medicine products have a major role to play in preventative health and the wellbeing of consumers across broad age groups and a wide variety of mainstream illnesses and conditions.

NSW represents the largest proportion of the CM manufacturing and marketing industry in Australia.

With globalisation and increased commercial and economic pressures across national boundaries – the Australian complementary medicines manufacturing sector is under pressure to remain competitive and relevant. The key factors impacting its ongoing viability include the following:

- Entry of low labour cost countries into the Australian market via supply of bulk finished products destined to be packed and sold in the local Australian market
- Proliferation of TGA registered/approved manufacturing plants in these countries with little or no effective subsequent monitoring or control of regulated processes post initial approval by the regulator
- Disproportionally long (between 3-9 month) overseas GMP Audit advance warnings to overseas manufacturers due to visa, cost recovery and other commercially driven considerations allowing for a variety of pre Audit, temporary and or unmonitored rectifications and plant/technology changes to take place without the regulator being aware or capable of realistically assessing these – in direct contrast to the “spot audits” implemented on domestic manufacturers
- Access by overseas competitors to (in many cases) unregulated and substantially cheaper herbal, active and raw materials in their own countries of origin reducing the final costs of finished goods
- An increasingly high overhead compliance burden for local manufacturers in regard to a wide variety of labour, OH&S and environmental requirements across local, state and federal government departments
- An increasingly slow, costly and cumbersome new product/active approval process via the regulator
- Support and various financial subsidies by governments in these countries to their manufacturers in regard to building local manufacturing facilities, processing technologies and various export incentives

- No legal requirement in Australia to declare country of origin/manufacture for complementary medicine and other pharmaceutical products in order to allow Australian consumers to make decisions with regard to purchase options based on perceived quality and or support for Australian manufactured products. Australia is one of the few industrialised nations that do not have this as a standard legal labelling requirement.
- The current strength of the Australian dollar in relation to most other trading currencies.
- The growing practice of overseas TGA approved manufacturers to use Australia as a subsidised dumping ground for specific products in order to be able to claim export into one of the most respected and regulated markets in order to facilitate other product sales into the substantially larger European and North American markets.

Global competition is a given in any industry sector, including the complementary medicine manufacturing industry, which acknowledges that it should not be an exception.

It is not expected that Australia can be immune or isolated from the rest of the world. In the interest of the Australian Government and industry stakeholders, as well as improving population health outcomes, the Industry recommends the following to ensure the growth trajectory of the local complementary medicine product manufacturing industry;

- Minimising “un-level playing fields”, especially from the point of view of TGA-GMP regulatory compliance (manufacturing processes as well as material actives and components for overseas versus local manufacturing players.
- Ensuring that consumers have the information to make informed choices in regard to labelling of products with country of origin or manufacture. If this is a requirement for the most basic of food products, fresh fish, processed goods and clothing – one would expect that therapeutic products should have at least the same legal requirement?
- Ensuring local CM manufacturers and sponsors are informed of available support programs and incentives, such as those offered by the Federal and State Governments for:
 - Export development
 - Import replacement
 - Manufacturing productivity.
- Recruit, train and up-skill employees in these ‘high knowledge – high skill’ local industries.
- Investing in new facilities, technologies and Research & Development to further grow and develop the complementary medicines industry.

If you have any questions on this submission, please feel welcome to contact the CHC.

Yours sincerely



Dr Wendy Morrow
Executive Director

Appendix 1 NSW MANUFACTURING INDUSTRY ACTION PLAN OVERVIEW

By September 2012, the Manufacturing Industry Taskforce will submit to the Deputy Premier an Industry Action Plan that:

1. Outlines a vision and 10 year development strategy for the industry, including 2 year and 5 year goals.
2. Articulates a way forward to achieve the vision, including priority issues to be addressed (including, but not limited to, skills, regulations and regulatory barriers, innovation and productivity, R&D, infrastructure and policy reform).
3. Proposes ways to build stakeholder engagement and commitment in delivering long-term industry development needs.
4. Identifies drivers for and barriers to growth and innovation in the industry (including those caused by Government practices, as well as identifying specific issues facing regional businesses and SMEs).
5. Identifies and validates the key domestic, Asia-Pacific and global trends, opportunities and challenges for the industry's development (including for regional NSW and small business development).
6. Develops detailed recommendations and rationale of the strategies and actions proposed to be undertaken by industry, industry associations, educational and research institutions, and Government to encourage sector growth, enhance productivity and innovation, improve export performance and, where required, facilitate structural adjustment.
7. Identifies key performance indicators, progress and outcome metrics, clear benchmarks and timeframes for major initiatives.
8. Clearly identifies roles and responsibilities for the delivery of the Industry Action Plan's recommendations, and outlines mechanisms to oversee and report on the progress of its implementation.