

Submission to the Competition Policy Review

By

Complementary Healthcare Council of Australia

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Competition Policy Review Secretariat
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1. Overview

Complementary medicines have been widely embraced by the Australian community, with two out of every three Australians regularly using a natural healthcare product. 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 chronic disease. A 2012 Market Economics report estimated that complementary medicines could save the Australian economy at least $ 7.66 billion per annum through workers having fewer sick days, visiting their general practitioner less frequently and taking less prescription medicines.[1]

The Australian complementary medicines industry generates approximately $2 billion in annual revenues and around 5500 highly skilled manufacturing jobs.[2] The global market has been estimated at $US 83 billion annually and is expected to reach close to $US 115 billion by 2015.[3] [4]

Of this, 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 sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports. However, there is still an enormous untapped potential for complementary medicines to contribute to the Australian economy in terms of:

- 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.

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 supplements. The last few years have been a time of great challenge to our industry as the TGA has embarked upon wide-ranging regulatory reforms as outlined in the document *TGA reforms: a blueprint for TGA's future*, most of which affect complementary medicines and are significant projects with overlapping agendas.[6] Industry recognises that significant work has been undertaken to date on the reforms but believes that a number of the changes have increased the regulatory burden without a corresponding improvement in protection of consumer safety or access to improved or innovative health products.

The CHC would like to acknowledge the focus on improving Australia's economic competitiveness, the commitment to a reduction in the regulatory burden on industry, and the recently announced key deliverables for the TGA of reducing red tape and participating in international harmonisation to streamline regulatory requirements.

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1 Koukoulas, S. (2012). How complementary medicines benefit the Australian Economy. Market Economics.

2 CHC Complementary Medicines Industry Audit May 2014, available by request.

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

4 Global Alternative Medicine Industry http://www.reportlinker.com/ci02242/Alternative-Medicine.html

5 CHC Industry Audit May 2011

6 TGA: www.tga.gov.au/pdf/tga-reforms-blueprint-implementation.pdf

The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the low level of risk these products represent. Our industry has the potential to significantly increase highly skilled and 'innovation rich' local manufacturing, as well as providing a significant contribution to our exports; however, in order to fulfil this potential a number of regulations and restrictions that currently prevent competition and stifle innovation need to be removed.

Light touch regulatory environment

The Australian complementary medicines industry is commonly regarded as one of the most strictly regulated in the world. Unfortunately, the recent environment of escalating red tape has contributed significantly to the difficulties faced by industry. Overly burdensome regulatory requirements have led to a stifling of product innovation, lower productivity, less job creation and minimised incentive for industry investment. The most frequently raised concern is the high price of operating in Australia (factors including small domestic market, long process time and duplication and complexity of regulations); an impost keenly felt when such regulation creates a global disadvantage for local operators to compete globally.

Whilst it is perhaps understandable that the TGA has attempted to align the regulatory requirements across the range of therapeutic goods – prescription medicines, medical devices and complementary medicines - in practice this has meant that complementary medicines have increasingly been expected to meet regulatory standards more suited to high-risk prescription medications. Examples of over-regulation of the complementary medicines industry are included below.

Proposed labelling changes

The TGA is currently proposing labelling changes for therapeutic goods that will increase costs for industry. As the CHC is unaware of issues with the existing labelling requirements for complementary medicines, any changes should only be implemented if the regulator can demonstrate the risks to consumers of maintaining the current labelling system.

Evidence requirements for advertising claims on listed complementary medicines

The TGA has recently updated the guidelines for the evidence required to substantiate the claims allowed for use in advertising of complementary medicine products. Unfortunately, the new guidelines have introduced a significant regulatory burden for companies to remain compliant with evidence substantiation for their products, and this is increasing costs and slowing innovation and efficiency. And unfortunately, the changes will not affect 'rogue' players determined to break the rules but are creating a very substantial burden for the vast majority of industry that aims to be compliant with the rules.

Process for Approval of New Ingredients

Many ingredients that are commonly used in complementary medicines in overseas jurisdictions are not available for use in listed medicines in Australia. Unless an ingredient is included on the list of available substances, an application must be made to the TGA for its inclusion. This poses a significant regulatory hurdle as it takes 1-2 years and costs a significant amount of money and time. A combination of industry information and anecdotal reporting indicate 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. This, in effect, exports jobs offshore rather than value added products.

The CHC believes that an effective way of improving Australian access to new ingredients would be the development of a fast tracked approval process for ingredients already assessed by countries with a comparable regulatory system.

Mechanisms for Increasing Competition & Innovation

Whilst the CHC recognises the key areas of focus for the Review are of Australian competition policy and removing regulations and restrictions that may impede competition, arguably in many cases the requirement is for an 'even playing field' or specific assistance for SMEs to encourage competitiveness and growth. Specific examples are included below.

Access to Stronger Health Claims

A new food standard to regulate nutrition content claims and health claims on food labels and in advertisements became law on 18 January 2013 – *Standard 1.2.7 Nutrition, Health and Related Claims*. Under this standard, 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. 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 very substantial data package, similar to that required for the registration of a new pharmaceutical drug. Registration also requires safety and toxicology data, despite the compound already being approved for use in complementary medicines sold on the Australian market (and therefore already deemed safe to be sold to consumers). The CHC would like to see a modified registration pathway that requires substantiation of evidence without the prohibitive additional cost of redundant product safety testing.

Encouraging Research through Data Protection

Data protection is a well-established methodology in the regulatory systems of most developed countries, including Australia, to provide adequate incentive for product innovation, recognising that significant investment is required to generate and provide data to gain regulatory approval. However, for the complementary medicines industry, the commercial reality of 'no patent protection' to recoup research and clinical trial costs has limited the incentive to invest in new/improved research and limited clinical trials being conducted to provide scientific evidence for complementary medicines. In this area, complementary medicines are always at a disadvantage compared to pharmaceuticals.

In most cases, complementary medicines are not patentable because an application for a standard patent may be rejected if the invention is merely a mixture of known ingredients. Further, the general intellectual property laws do not necessarily protect the types of information that may be sought to be protected.

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."[7] The CHC would like to see this happen.

Low Volume Turnover (LVT) Scheme for Therapeutic Goods

The TGA is currently conducting a policy and operational review of the low value turnover exemption scheme (LVT) that waives the fees for low value turnover products in order to increase innovation and support manufacturers of low volume products, start-up companies and small herb growers. Recent analysis of the usage of the scheme indicates that it currently benefits larger companies (the three largest being related to the manufacture of generic medicines) and not the intended audience. Small business uptake of the scheme has been low due to the

[7] http://www.tga.gov.au/pdf/archive/committees-eccmhs-report-031031.pdf

administrative burden. Industry supports retention of a limited scheme that entitles SMEs, the original intended beneficiaries of such a policy, to benefit, with the suggestion of reducing the administrative burden.

Free Trade Agreements

The global economic crisis highlighted the high degree of interdependence of economies worldwide and the degree to which growth depends on open markets.[8] The complementary medicines industry recognises the importance of a strategic, collaborative approach to International market engagement, via leveraging our strengths, facilitating strong commercial ties and opening up opportunities, especially within the Asian region. The CHC also notes and strongly supports the growing focus of Australia's FTA negotiations on helping to address the 'behind the border' issues, and the Australian Government's goal of advocating for policy changes beyond other countries' borders in support of greater mutual understanding of national arrangements and a better interface between regulatory frameworks and those of our neighbours.[9]

China's growing economy and expanding consumer base cannot be overlooked or ignored. However, costly and confusing regulations and incongruent timelines mean there is no clear path to market. A recent report by the US-China Health Products Association in conjunction with the US Department of Commerce calculated the costs of lost business due to China's confusing thicket of regulations at $8.37 billion in lost potential exports and about 2800 lost jobs. [10] By simple calculation this equates to approximately $ 1 billion lost exports for Australian complementary medicines. Given the unique mix of GMP manufacturing, permitted ingredients and strict regulation it is not untoward to expect recognition and fast track access for Australian products outbound to the Chinese market place – which they enjoy inbound to the Australian market.

With Australia engaged in a number of FTA negotiations, and recognising the vital importance of trade to the long-term substantial growth of our industry, the CHC is currently developing a strong argument for the specific inclusion of Australian complementary medicines into FTA negotiations/regulatory recognition discussions.

Conclusion

It is widely accepted that a country's competitiveness is the key driver for sustaining prosperity and raising the wellbeing of its citizens. In other words, a more competitive economy is one that is likely to grow faster over time. The complementary medicines industry has much to offer in terms of contribution to the preventative health agenda, personal productivity levels, growth of our economy and to Australia becoming an 'innovation-rich' and competitive country.

The Australian complementary medicine industry is commonly regarded as one of the highest quality, yet most heavily regulated in the world, and, in recent years, has been subjected to regulatory burdens more appropriate to high-risk pharmaceutical products. Removing the 'one size fits all' approach through a review of the current regulatory reforms is critical to ensuring the sustainability of the industry and maintaining an innovative and competitive market that is able to meet consumer demands.

Removal of over-regulation will help the Australian complementary medicines industry to gain its position as a leading Australian industry sector and exporter.

[8] Global Competiveness Report 2013-14
[9] Asian Century White Paper, p209
[10] http://uschinahpa.org/wp-content/uploads/2014/05/Export-Potential-Report-2014-05-23.pdf

Appendix 1

Complementary Healthcare Council of Australia

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the complementary medicines industry. The CHC is unique in representing the entire supply chain including:

- manufacturers
- importers
- exporters
- raw material suppliers
- sponsors
- 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 include vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. The term 'complementary medicines' also comprises traditional medicines, including Traditional Chinese Medicines, Ayurvedic and Australian Indigenous medicines.

Currently there are approximately 60 TGA licenced listed medicine manufacturers in Australia, with the majority of manufacturers located in NSW. The Australian Register of Therapeutic Goods indicates there are over 3000 product sponsors. Complementary medicines can be either listed or registered in Australia; registered medicines have their marketing claims pre-approved and can make higher level claims (for example linking to serious disease through biomarker risk reduction such as lowering cholesterol). However, due to the cost and complexity of registration, the number of evaluated registered complementary medicines on the market numbers approximately 30.

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.[11]

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