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Submission to the Department of Foreign Affairs and Trade: the Indonesia-Australia Comprehensive Economic Partnership Agreement (IA-CEPA)

Complementary Medicines Australia (CMA) writes to express its strong support for the policy of Australia's engagement in trade liberalisation negotiations with the Republic of Indonesia. These negotiations are seen as an important initial step forward in building upon a long-term mutually beneficial economic relationship with our close neighbour.

CMA is the peak industry body for the complementary medicines industry, representing members throughout the value chain: manufacturers, raw material suppliers, distributors, retailers, practitioners and consultants. 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.

CMA would like to acknowledge the Government's focus on improving Australia's economic competitiveness, the commitment to a reduction in the regulatory burden on industry, and the deepening of Australia's economic ties with the major countries within the region; ties that are essential for our future prosperity.

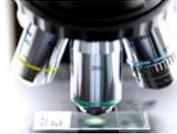
CMA also notes and strongly supports the growing focus of Australia's free trade agreement negotiations on helping to address 'behind the border' issues, and the Australian Government's goal of advocating for policy changes beyond other countries' borders in support of greater mutual understanding of national arrangements and a better interface between regulatory frameworks and those of our neighbours.

Complementary Medicines Australia

Nature - Science - Health

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Economic Contribution of Complementary Medicines Industry

Complementary medicines have been widely embraced by the Australian community, with seventy per cent of Australians regularly using a natural healthcare product. The industry generates \$4.7 billion in annual revenues and directly employs 12,700 high-skilled workers.¹ For the first time, in 2015, Australian consumers spent more of their out-of-pocket expenses on complementary medicine products than on pharmaceuticals. The growing consumer demand for complementary medicines is such that they are gaining greater attention from primary healthcare providers and policymakers.

Likewise, the growing acceptance of complementary medicines around the world is regarded as a part of consumer trend whereby consumers are proactively taking preventative measures to support their own health. The global market for complementary medicines is expected to reach US\$278 billion by 2024, from US\$122 billion in 2015.² The Asian-Pacific region is the largest market for complementary medicines products in the world.

Exporting of Australian complementary medicines has been very successful in recent years and is expected to continue to grow. Currently, over 60 per cent of Australian complementary medicines companies are engaged in exporting to 84 different countries across the globe. According to Austrade data, Australian complementary medicines export figures have more than doubled to 399.5 million in the last two years. The top 5 export countries sit in the Asian-Pacific region.³ This phenomenon has been seen largely due to Australia's 'clean and green' image and the comparative advantage for Australian complementary medicine firms of holding a well-deserved reputation for products of high quality and safety standards. This trend has boosted jobs in Australia across a range of sectors, including manufacturing, scientific evaluation and research.

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 and ageing. Given Asia is expected to see the rapid growth of an ageing demographic as well as the growth of the middle class over the next 50 years, Asian demand for Australia's high quality and high-safety complementary medicines is expected to remain very strong.

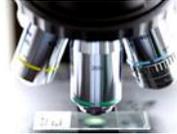
International Reputation for Quality and safety standard

Australia's complementary medicines industry is backed by a risk-based regulatory regime that is regarded as one of the strongest in the world. The regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), an arm of the Department of Health, which

¹ CMA Complementary Medicines Industry Audit June 2017, available by request.

² Grand View Research <http://www.grandviewresearch.com/industry-analysis/dietary-supplements-market>

³ CMA Complementary Medicines Industry Audit June 2017, available by request



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also regulates over-the counter, medical devices and prescription medicines. The TGA has responsibility for the oversight of product safety, quality, claims, listing, post-marketing monitoring and setting standards for manufacturing. Complementary medicines must be manufactured under pharmaceutical standard Good Manufacturing Practice (GMP) in TGA approved and licensed facilities.

Under this stringent regulatory paradigm, Australian complementary medicines are recognised as meeting the highest global standards of quality, safety and efficacy. In fact, the Australian regulatory regime for complementary medicines is such that it is viewed by most countries as the consumer protection benchmark.

Growing Demand for Complementary Medicines in Indonesia

With rapid income growth, a young population, a rising middle class, and a growing awareness of health and wellness in Indonesia, complementary medicines have been seen as highly attractive by Indonesian consumers. In 2016, the export of Australian products to the Indonesian market was valued at over AU\$1,600,000, which was 2.6 times more than the previous year.⁴

A global survey by Nielsen demonstrated that 81 per cent of Indonesian consumers are willing to spend more for food products that promote health benefits.⁵ Growing awareness of preventative medicine is particularly seen among younger middle-to high-income consumers. With increasingly busy lifestyles, unfavourable weather conditions, and marketing efforts by leading manufacturers, sales of consumer health products are expected to keep growing in Indonesia.⁶ Vitamin C supplements are the most popular single vitamin in Indonesia, with a current value growth rate of 19 per cent because of increasing pollution and extreme weather changes. Moreover, given Indonesia is the fourth most populous nation in the world, with over 50 per cent of the population under age of 30, paediatric vitamins and dietary supplements also achieved a value growth rate of 19 per cent in 2013.⁷ Due to these factors, Australia's trade in complementary medicines with Indonesia is expected to grow.

Complementary Medicines Inclusion in Free Trade Negotiations

CMA recognises the vital importance of trade to the long-term substantial growth of our industry. This growth, based on exports, crucially supports further local investment in research and manufacturing, and job creation and job security in the industry. CMA, therefore, strongly supports the specific inclusion of Australian complementary medicines into all future free trade negotiations and regulatory framework discussions.

The global economic crisis highlighted the high degree of interdependence of economies worldwide and the degree to which growth depends on open markets. The complementary medicines industry

⁴ Austrade (2016) Annual Exports Statistics: Vitamins & Supplements. Year ended December 2016

⁵ Nutraingredients-Asia <http://www.nutraingredients-asia.com/Markets-and-Trends/Six-stand-out-functional-food-and-supplement-trends-from-Indonesia>

⁶ Austrade, Exporting Consumer Health Products to Indonesia

⁷ Euromonitor International (2014), Vitamins and Dietary Supplements in Indonesia



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.

1) Non-Tariff Measures (NTMs)

In Indonesia, complementary medicines products are regulated as either 'food supplements' or as 'processed foods' under Indonesia's Foods Law of 2012 by The National Agency of Drugs and Food Control (BPOM). 'Food supplements' includes vitamins, minerals, amino acids or other ingredients (note: derived from plants or plant) that have value and the nutritional or physiological effect in concentrated amounts.

Foreign exporters and manufacturers must comply with a multitude of licensing, registration, and approval requirements in order to import, sell, market and distribute food supplements and processed food in the market. For instance, import approval from the head of BPOM is required for each imported shipment of processed food, food additives, processing aids, and food ingredients.

Our industry is particularly concerned about the registration process, which requires a pre-assessment and assessment regime. The process is time intensive, lacks transparency and often involves inconsistent evaluations resulting in creating extra burden for Australian complementary medicines exporters. This extra bureaucratic burden has become a barrier to doing business in Indonesia for Australian exporters.

As tariff barriers continue to fall through free trade negotiations, NTMs are becoming more prominent barriers to trade. The issue with NTMs is often raised due to their opaque nature and their costs that compound along the multiple points of a supply chain, despite some NTMs having legitimate public policy objectives, including environmental protection. Many NTMs, however, restrict trade unnecessarily, or increase costs on business without additional consumer protection or biosecurity benefits, effectively acting as unjustified non-tariff barriers.

CMA believes that it is important for the negotiating parties to consider a cross-regulatory pathway, particularly based on the fact that Australian complementary medicines products are manufactured to pharmaceutical standard under GPM in TGA approved and licensed facilities, which ensures consumer protection.

2) Tariffs

Tariffs applied to Australian complementary medicines are governed by the ASEAN-Australia-New Zealand FTA (AANZFTA), which are much lower than rates from non-FTA partners. Despite this, tariffs can still be as high as 30 per cent for some products. It is vital that the agreement should allow duty free entry for all complementary medicine exports from Australia, and also should build upon the provisions and schedules in AANZFTA and adapt provisions of other trade agreements.



ASEAN members have pledged to create a regulatory framework for traditional medicines and health supplements which will create a single market and a common 'registration' regime for these products among ASEAN members. ASEAN is likely to sign the ASEAN Consultative Committee for Standards & Quality on Traditional Medicines and Health Supplements (ACCQ TTHS) this year and it is expected to formally begin its implementation in 2018.⁸ As Australia is not a member of ASEAN, we are not a participant in this initiative.

Given the current situation in ASEAN countries concerning the ACCQ TTHS, it is extremely important that Australia should negotiate with Indonesia for equivalent treatment to ASEAN countries in the handling of these products to remain competitive in the region.

Conclusion

The WHO Traditional Medicine Strategy 2014-2023 highlights the potential contribution that complementary medicines can make to health, wellness and people-centred healthcare through the appropriate integration of complementary medicines into the healthcare system. The increasing importance of the complementary medicines industry to global health can be seen in the increase in global regulatory standards and regulatory alignment, and the increase in economic and political discourses about the integration of complementary medicines with conventional medicine.

With growing awareness of health and wellness among the upper-middle-income segment, the Indonesia-Australia Comprehensive Economic Partnership Agreement (IA-CEPA) has the potential to significantly increase Australian exports of complementary medicines to Indonesia by removing or reducing regulatory and tariff controls in the Indonesian market.

Thank you for the opportunity to express our support for the Indonesia-Australia Comprehensive Economic Partnership Agreement (IA-CEPA). We would be pleased to provide further comment as required by the Free Trade Agreement Division.

Mr Carl Gibson
Chief Executive Officer
Complementary Medicines Australia

22 May 2017

⁸ Nutraingredients-Asia <http://www.nutraingredients-asia.com/Markets-and-Trends/South-East-Asia-supplement-regulations-Indonesian-trade-boss-hopeful-of-harmonisation-progress>



Appendix 1

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA is unique in representing the entire supply chain including:

- manufacturers
- importers
- exporters
- raw material suppliers
- sponsors
- wholesalers
- practitioners
- consultants
- 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.

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.

Currently there are approximately 80 TGA licenced listed medicine manufacturers in Australia, with the majority of manufacturers located in NSW.