

To:

Coordinator
Australia-India Comprehensive Economic Cooperation Agreement
Free Trade Agreements Division
Department of Foreign Affairs and Trade
RG Casey Building
John McEwen Crescent, Barton ACT 0221
Via email: indiafta@dfat.gov.au

Re: Australia-India Comprehensive Economic Cooperation Agreement (AICECA)

Complementary Medicines Australia—Submission on AICECA

Background

Complementary Medicines Australia (CMA) appreciates the opportunity to make a submission to the Department of Foreign Affairs and Trade (DFAT) in relation to the Australia-India Comprehensive Economic Cooperation Agreement (AICECA).

CMA is the leading voice and industry peak body for manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators in the Australian complementary medicines sector. CMA members represent over 80 per cent of all product sales and the full value chain of the sector in Australia. As the principal reference point for members, the government, the media and consumers, we communicate and advocate for issues that matter to the complementary medicines industry. Please refer to **Appendix 1** for more information about the CMA.

The Australian complementary medicine sector is well-established, having evolved over the last 30 years to become a world-class industry that supports research, employment and high-skilled advanced manufacturing. High domestic and international demand for Australian complementary medicine products is driving steady growth, with the industry reaching \$5.5 billion in revenues in 2021, representing a steady 1.4 per cent annual growth, despite the challenges of the COVID-19 pandemic. In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the *Therapeutic Goods Act 1989*.

CMA would like to applaud the Government's recent achievement in successfully reaching an interim agreement with India, which will place some Australian exporters in a prime position to capitalise on the world's fastest growing major economy of nearly one and a half billion consumers. Specifically, a key outcome of the AICECA was the elimination of tariff over 3, 5, 7 or 10 years on goods such as infant formula, pharmaceutical products and certain medical devices.

Complementary Medicines Australia

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CMA also would like to acknowledge that the Government's India Economic Strategy to 2035 recognises the potential opportunities for complementary medicines as value-added commodities for future growth in the Indian market, but also captures the constraints and challenges that our sector is facing, given the current policy and regulatory environment, in accessing the Indian market.

Despite these positive outcomes, as it stands, there is little direct benefit for Australia's complementary medicines industry under the interim agreement with India. Specifically, HS Code 2106.90.99, which is commonly used by Australian complementary medicines companies for exporting was excluded from tariff negotiations, resulting in tariffs associated with this code remaining at their current rate. Various complementary medicines products, such as multivitamins and other supplements, fall within HS Code 2106.90.99 and its inclusion in the AICECA would be significant in supporting the key outcomes already committed.

CMA would sincerely appreciate the Government's ongoing commitment to further negotiations on AICECA to ensure Australian complementary medicines exporters obtain preferential access to the enormous untapped Indian market, as well as to create new and wide-ranging opportunities for the sector, which is essential for the long-term prosperity of the Australian complementary medicines industry. CMA strongly believe that HS Code 2106.90.99 should be included in further tariff elimination negotiations.

Finally, CMA also would like to acknowledge the Government's ongoing commitment to strengthen export diversification as a means to foster a broader foundation for Australia's future economic engagement with the world. This initiative is crucial for the sustained growth of the Australian complementary medicines industry, particularly given that the sector is currently hugely dependant on a single market for its exports – China, which accounts for 70 per cent of Australia's CM exports. CMA strongly supports the current whole-of-Government approach to trade diversification, which includes building economic ties with India as one of its four main pillars.¹

This submission highlights four broad areas where engagement of Australia's complementary medicines industry with India could be advanced:

- Elimination of tariffs applied to HS Codes commonly used by the complementary medicine industry in exporting to India;
- Strengthening connections between Indian raw material producers and Australian complementary medicines manufacturers and the promotion of collaborative R&D;
- Negotiations for Indian recognition of Australia's world-leading regulatory regime for the manufacture of complementary medicines, such as the agreement included in Annex 7A Pharmaceuticals; and
- Creation of a distinct HS Code subcategory for Australian complementary medicines that is recognised by the Indian customs authorities.

This agreement contains scope for enhancement in bilateral trade through improved

¹ Labor's Trade Diversification Plan <https://www.alp.org.au/policies/labors-trade-diversification-plan>

access. One of the major positive steps forward provided by the Agreement is that India's and Australia's respective Therapeutic Good Regulators have agreed to work together to facilitate trade in human prescription medicines and medical devices. Specifically, both countries' regulators can utilise, as appropriate, reports from the other country's regulator in relation to the pre-market evaluation of products and Good Manufacturing Practice (GMP) inspection reports. As complementary medicines are manufactured to pharmaceutical standards in TGA-approved facilities and according to GMP, CMA believes that similar provisions to those in place for the pharmaceutical industry should also be applied to the complementary medicines sector through further negotiations.

Economic Contribution of Complementary Medicines Industry

The Australian complementary medicines sector is well-established, having evolved over the last 30 years to become a world-class industry that supports research, employment and high-skilled advanced manufacturing.

The sale of complementary medicines products in Australia is now valued at \$5.5 billion, representing a steady 1.4 per cent annual growth.² This is despite the ongoing impact of the COVID-19 pandemic, which resulted in a 20 per cent drop in exports over the last two years. The industry directly employs 2,515 high-skilled workers in the Australian manufacturing sector,³ and 36,788 complementary medicine practitioners, including naturopaths and herbalists, who generate \$3.7 billion in annual revenue through the sale of natural therapy services. The industry also boasts 77 TGA-licensed finished product manufacturing sites for complementary medicines.⁴ The COVID-19 pandemic has further highlighted the importance of local medicine manufacturing. With the right Government supports, such as the national approach to strengthen modern manufacturing, our industry has the potential to flourish and help build a resilient economy into the future.

Australian complementary medicine firms hold a competitive advantage based on an international reputation for products of high quality, manufactured to strict safety standards. This reputation has driven the international demand for Australian products in recent years. Prior to the onset of the COVID-19 pandemic, the CM export market achieved phenomenal growth—going from generating \$175 million to over \$1 billion in revenue in just five years. In 2019, Australia overtook the USA as the number one exporter of complementary medicines into China⁵, where the health food market is currently valued at US\$300 billion and is projected to grow by 10 per cent every year until 2025.⁶

The size of the global complementary medicines market was US\$61.2 billion in 2020 and is projected to grow to more than double this size by 2028, to US\$128.64 billion.⁷ Demand for Australia's high quality complementary medicines is expected to remain strong in the Asian-Pacific region. Several factors underpin this expectation: the region holds the largest complementary medicines market in the world, Asian-Pacific societies are experiencing demographic changes with ageing populations and a growing middle class—which is expected to number 3.2 billion by 2030, and consumer health consciousness in the region has greatly increased with the rise of non-communicable diseases.

² Complementary Medicines Australia (2022) Australia's Complementary Medicines Industry Snapshot 2022

³ IBIS World Industry Report (2022) Vitamin and Supplement Manufacturing in Australia

⁴ Complementary Medicines Australia (2021) Australia's Complementary Medicines Industry Snapshot 2021

⁵ Zhongpeng Zhang, CCCMHPIE (2019) Development and Trade Performance of China's Nutraceutical Industry, CMA Annual Conference September 19, 2019 Sydney Australia.

⁶ Austrade (2017) Complementary Medicines in China: A guide for Australian business

⁷ Fortune Business Insights <https://www.fortunebusinessinsights.com/dietary-supplements-market-102082>



In spite of the challenges caused by the COVID-19 crisis, such as the ongoing major supply chain disruptions, the Australian complementary medicines industry is expected to continue its positive growth trajectory with revenues forecast to triple in a decade. This growth will be export driven and based on Australia's world-leading complementary medicines research and innovation and our gold-standard manufacturing practices and product safety and quality. Through this, the sector will continue to significantly contribute to the Australian economy, and will help build a resilient and competitive manufacturing base at the heart of our economy.

Australian Complementary Medicine's 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 Commonwealth Department of Health, which also regulates over-the-counter medicines, medical devices, and prescription medicines. The TGA has responsibility for the oversight of product safety, quality, post-market monitoring and setting standards for manufacturing.

In Australia, complementary medicines must be manufactured under pharmaceutical standard Good Manufacturing Practice (GMP) in TGA-approved and licensed facilities. Under this stringent medicine 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. Thus, consumers around the world seek Australian-made complementary medicines because of their exceptional quality and safety.

Our robust regulatory environment and strict manufacturing processes ensure that Australian products are renowned for quality, safety and efficacy. Our vision is to build on these foundations to ensure we continue to deliver consumers the very best products in the world.

Opportunities for India

Growing Awareness of Health and Wellness and Increasing Demand for Nutraceuticals in India

By the 2030s, India will be the 2nd largest driver of growth in the global complementary medicines market, known as nutraceuticals in India. The Indian nutraceuticals market currently accounts for almost 2 per cent of overall nutraceuticals sales across the globe and this is expected to grow to 3 per cent by the end of 2022.⁸ In dollar terms, a nutraceuticals market worth USD\$3.9 billion today is expected to grow to USD\$9.5 billion within 5 years.⁹

Several factors within India are driving this trend. These factors include, a massive and rapidly growing urban middle class, a relatively young population base, and growing awareness of health and wellness due to the rising impact of non-communicable diseases. Reflecting this growing health awareness, 75 per cent of the Indian population agrees that consuming vitamins, minerals and supplements regularly helps promote general health and wellness. Consequentially, nutraceuticals are increasingly seen as highly attractive by Indian consumers. This increasing demand is expected to accelerate in the post-COVID environment, with the easing of supply-chain disruptions and a shift towards preventative health awareness. Additionally, another important contribution to this trend is the booming growth in e-commerce, through which 50 per cent of Indian consumers are purchasing complementary medicines.¹⁰ By 2027, it is expected that 550 million Indians will be regularly shopping online.¹¹

The interim agreement with India (AICECA) will place Australian exporters in a prime position to capitalise on India's growing market and offers Australian complementary medicines companies an excellent opportunity to deepen engagement with the Indian market and Indian consumers the chance to access complementary medicines of the highest quality. This is particularly so given that India is currently only 45th for Australian complementary medicines exports, leaving much room for improvement. Once the FTA between Australia and India is in place, our exports to India are expected to grow, as the industry leverages Australia's reputation for high quality products and taps into India's health-conscious middle-class market.

Opportunities for India: Exporting Raw Materials to Australia

The AICECA offers opportunities for the Indian complementary medicines industry, too. Ayurvedic herbal materials, such as turmeric and ashwagandha, just to name a few, are widely used in various complementary medicine products developed in Australia. Australian manufacturers are also constantly looking for new raw materials for inclusion in new products,

⁸ <https://www.vitafoodsinsights.com/market-trends/nutraceutical-demand-soaring-india>

⁹ AIM Direct, Access India Market

¹⁰ Statista: Preferred purchase channels for dietary supplements or nutraceuticals in India as of March 2022
<https://www.statista.com/statistics/1182339/india-purchase-channels-for-dietary-supplements/>

¹¹ AIM Direct, Access India Market

as part of their on-going process of product research, development and innovation. Traditional medicines, such as Ayurvedic herbal medicine, are particularly highly sought after due to their long-history of well-known use in the prevention and management of various chronic conditions.

Moreover, the Indian Government has introduced an economic stimulus package under the Centrally Sponsored Scheme of National AYUSH Mission (NAM), allocating USD\$535 million to encourage the commercial cultivation of medicinal plants and their sustainable management across the country. This initiative is designed to reduce pressure on wild habitats and natural forests stemming from over harvesting.¹²

These advantages will provide Indian raw material suppliers with a great opportunity to expand their export business and substantially benefit the Indian nutraceutical industry in this area. Our sector is in an ideal position to build successful and long-lasting partnerships with India based on the mutual benefits of the AICECA.

Collaboration & Partnership: R&D, Investment

It is essential for Australia to deepen its partnership and cooperation with India for long-term mutual benefit. The CM sector is in a perfect place to align with India's needs in terms of job creation, population health improvement, and creation of a vibrant Australia-India nutraceutical R&D environment, which supports the whole economy.

NICM HRI Ayurveda Research Program

The Australian complementary medicines industry holds an exceptional reputation as a world-leader for research and development. Western Sydney University's National Institute of Complementary Medicines Health Research Institute (NICM HRI) is globally recognised for its world-class research and innovation in integrative and complementary medicine.

NICM HRI is currently undertaking an Ayurveda research program to build capacity for the evidenced-based validation of Ayurvedic medicine and aligned traditions such as Ayurveda herbal medicine, yoga and meditation. Western Sydney University was the first Australian university to sign a memorandum of understanding (MoU) with the Indian Government's Ministry of AYUSH to appoint an Academic Chair in Ayurvedic Medicine, with the aim of advancing strong collaborative opportunities with universities, research institutes and other organisations, industry and consumers within the field of Ayurveda research.

This is an excellent example that demonstrates the great potential for synergy between India and Australia, in preclinical, clinical and translational research of traditional medicine through exchanging academic knowledge and research collaboration. These important initiatives will strengthen the ties between India and Australia, between governments, researchers and industry, and bring mutual benefits for both countries.

¹²National Medical Plants Board, Ministry of AYUSH, Government of India
<https://nmpb.nic.in/content/medicinal-plant-component>



This initiative, in the long term, could lead to more opportunities such as the establishment of joint R&D and manufacturing facilities in India, as suggested by the Australian Government in the India Economic Strategy to 2035.

Trade Barriers with India

Tariff Relief on Food Supplements (HS Code:2106.90.99)

Complementary medicine products are captured under numerous different Harmonized Commodity Description and Coding System Codes (or, Harmonized System [HS] Codes), and subject to a range of tariffs, depending on the HS Code(s) used. (Please refer to **Appendix 2** for a list of HS Codes currently used when exporting complementary medicine products to India).

With the recent signing of the interim agreement, Australian complementary medicine exporters will benefit by the elimination or reduction of tariffs on some HS Codes under which some complementary medicines sit.

Despite these positive outcomes, there is room for further improvements. **HS Code 2106.90.99**, which is currently mainly used by Australian complementary medicines companies when exporting products to India, was excluded from the tariff negotiations, resulting in tariffs associated with this code remaining at their current rate of 150 per cent. Various complementary medicines products, such as multivitamins and other supplements, fall within this HS Code.

Most import products are subject to premium pricing due to high import costs, including tariffs. By contrast, local brands are low cost, selling on average for between \$4-8. Given local Indian brands are well respected and competitively priced and India is such a price sensitive market, the current trade environment that sees tariffs applied to complementary medicines is at a significant disadvantage for engaging in trade with India for international complementary medicines businesses.

CMA strongly believe that HS Code 2106.90.99 should be included in further tariff elimination negotiations. Facilitating favorable tariff reduction on complementary medicine products will bring significant benefit to Australian complementary medicines' companies and support the greater diversification of Australia's exports.

Technical Barriers to Trade – Recognition of Australia's regulatory framework

CMA strongly supports the specific inclusion of Australian complementary medicines into all future negotiations, under Chapter 7 of the agreement, Technical Barriers to Trade (TBT).

It is recognised that the Indian regulatory framework for complementary medicines is still in the process of developing. This year, the Food Safety and Standards Authority of India (FSSAI) introduced a new set of nutraceutical regulations, which can benefit the Indian nutraceutical industry by expanding the scope for new product innovation and imports. However, there still remains a number of constraints and challenges under the current regulatory framework for "food and nutrition supplements", such as limitations on ingredient and recommended

dietary allowance (RDA) rules.¹³ Our industry is also experiencing onerous documentation requirements and bureaucracy at Indian Customs and/or FSSAI, when exporting products to India.

As noted above, Australia has a well-established regulatory framework for complementary medicines under the TGA, that sets strict standards while reducing the regulatory complexity and administrative burden for business. Australian complementary medicine products are globally recognised for their quality and safety and are highly regarded as ‘clean, green, safe and secure’.

The CM sector believes that it is reasonable for India to support and recognise the TGA’s assessment of Australian complementary medicine products that are already approved for sale in Australia, and have been safely used in Australia for decades. The export of therapeutic goods from Australia must meet requirements set out in the therapeutic goods legislation, in addition to other Commonwealth and State or Territory legislation. Export regulation supports the development and manufacture of Australian therapeutic goods and ensures that goods leaving Australia meet appropriate safety and quality standards to support public health. The FTA should reflect that such products are also safe for use in India.

Australia and India should establish a streamlined mechanism for the recognition of Australian-listed and registered complementary medicines in India. Currently, Australian complementary medicines for sale in India require registration either with the Food Safety and Standards Authority of India (FSSAI) or the Indian Ministry of Health’s Central Drug Standards Control Organisation (CDSCO), depending on the nature of the product. While registration via the FSSAI is relatively accessible and cost-effective, registration with the CDSCO is expensive and burdensome. The requirement for FSSAI, and particularly CDSCO, registration is a significant barrier for Australian complementary medicine companies. Given Australia’s gold-standard manufacturing practices—that sees complementary medicines manufactured to pharmaceutical standards in TGA approved and licensed facilities—Australian complementary medicine exporters should simply be able to provide a “certificate of listed product” or “certificate of registered product” to gain FSSAI or CDSCO approval or expedited recognition.

Furthermore, Australia is well placed to support India to draw on Australia’s TGA regulatory system to further build the India nutraceutical sector. By seeking closer alignment with the TGA approach, the Indian nutraceutical industry could unlock significant commercial opportunities at home and abroad, while ensuring product safety, efficacy and improvement in health outcomes.

¹³ Nutra Ingredients-aisa.com <https://www.nutraingredients-asia.com/Article/2022/04/20/India-s-new-nutrapolicies-to-benefit-NPD-and-imports-FSSAI-s-ex-director>

Future Consideration

Creation of Complementary Medicines Specific HS code

As discussed above, Australian complementary medicines businesses currently use various HS Codes when exporting complementary medicines to India. There are a range of tariffs applied to exporters, depending on the HS Codes used, which are ultimately determined by the customs authorities in India at the time products arrive at the border. This situation can create confusion and lead to determinations by the local customs authority that are unfavourable to Australian CM exports.

For instance, HS Code 2106, including HS Code 2106.90.99, can be used for complementary medicine products, but also applies to products such as custard, masala powder and flavours. HS Code 3004 is applied to pharmaceuticals product, however, is also used by Australian complementary medicines exports for exporting to India. At Indian customs, these products are often held up because customs officials expect products exported under this Code to be registered with the CDSCO and not FSSAI, under which most Australian complementary medicines are registered. Given the confusing nature of HS Codes, Australian CM products can be held up by Indian customs officers who demand further explanation as to why a given product has been exported under a specific HS Code and Australian complementary medicine companies have experienced days or weeks of delays before their products clear customs.

CMA members have experienced Indian customs officials recommending Australian complementary medicines exports to use HS Code 2936: *Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent (PROVITAMINS, VITAMINS AND HORMONES)*, for export to India. This Code, however, can only be used for singular ingredients and bulk shipments.

As the above demonstrates, there are no clear rules for HS classification for complementary medicine products, and the determination of HS Codes is uncertain depending on the importing country customs authority's decision. This is also due to the nature of complementary medicines, which consist of various ingredients in various forms. Moreover, any of the Code groups that can be used do not necessarily align to what health supplements or nutraceuticals are defined as in the importing country. Due to the ambiguity of the HS classification system for complementary medicines, it is possible that Australian exporters may be given erroneous HS Codes for their commodities, inadvertently determined by the local customs.

CMA believes that the creation of a HS Code specifically for listed and/or registered complementary medicines, including vitamins mineral and nutritional supplements and herbal supplements, will reduce these risks and provide the industry with much greater business confidence and certainty.

Any changes to HS Codes must go through the World Customs Organization (WCO), which represents 183 customs administrations around the world and develops and maintains HS Codes. WCO updates the HS Code every 5 years after a review process, with the latest round of updates having been completed recently. The Harmonized System consists of around 5000 six-digit product categories that are common for all countries. Countries typically sub-divide these codes further to eight digits or more. These subcategories may not be the same in all countries even if the product is the same. According to DFAT, 'ultimately, it is the importing country customs authority that determines if a product is correctly classified at the time it arrives at the border'.¹⁴ The creation of a new subcategory eight-digit HS Code for complementary medicines that is mutually recognised by Australia and India could provide a means to expedite market entry rather than through the more comprehensive and complicated WCO review process.

Setting up an Australian complementary medicines specific HS Code could be extremely beneficial to India, as well, since they would be able to be confident in the highest-quality of Australian complementary medicines and also be able to differentiate our products from those of other countries.

¹⁴ Department of Foreign Affairs and Trade, 'What is my HS Code?', <https://ftaportal.dfat.gov.au/help/hs-code>.

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 77 TGA licenced and listed medicine manufacturers in Australia, with the majority of manufacturers located in NSW.

The latest Industry Audit can be accessed here: [Australia's Complementary Medicines Industry Snapshot 2022](#)

List of HS codes for complementary medicine products

HS Code	Definition
1504.20.20	Fish lipid oil
2008.93.00	Cranberries (Vaccinium macrocarpon, Vaccinium oxycoccos Vaccinium vitis idaea)
2106.1	Protein concentrates and textured protein substances
2106.90.99	Other "Food supplements"
3004.50.20	Preparations of minerals and their supplements
3004.50.31	Of vitamin A
3004.50.32	Of vitamin B1 and B2 and their salts thereof
3004.50.33	Of vitamin B9
3004.50.34	Of vitamin B12
3004.50.35	Of vitamin C
3004.50.36	Of vitamin D
3004.50.37	Of vitamin E
3004.50.39	Other
3004.50.90	Other
3004.9	Other Medicine Out Up For Retail Sale
3304.99.10	Face Cream
3507.90.99	Other