

Complementary Healthcare Council of Australia

Response to the ANZTPA Discussion Paper "Description of a possible joint regulatory scheme for therapeutic products under ANZTPA, January 2013"

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1. Introduction

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the Complementary Medicine industry and presents the views of the entire supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. These entities range in size from multinationals through to smaller regional-based business (typically SMEs).

A primary objective of the Complementary Healthcare Council of Australia (CHC) is to ensure appropriate risk-based legislative provisions that allow consumers to have confidence in the safety, quality and efficacy of Complementary Medicine products.[1] Therefore, the CHC can only conditionally support the implementation of an Australian-only Complementary Medicines Framework for Australia New Zealand Therapeutic Products Agency (ANZTPA) and this support is conditional upon the development of rules that are appropriate to Complementary Medicine (CM) products.

Manufacturers of CMs in Australia use the same technologies and operate under the same Code of Good Manufacturing Practice (GMP) as the Australian pharmaceutical industry.

Sponsors similarly operate under the same Act, with similar regulatory processes, as the pharmaceutical industry.

The CM Industry currently provides substantial employment opportunities, whilst developing a range of technical and vocational skills, through innovation, research and the utilisation of complex technologies, despite increasing global competitiveness and regulatory pressures.

The ANZTPA joint framework will need to:

- Apply the principles of minimum effective regulation, endorsed by the Council of Australian Governments (COAG);
- Better understand the burden and impact inappropriate regulations have on industry;
- Move away from an overly prescription medicine approach to regulations for CMs;
- More effectively communicate regulations and regulatory changes with industry; and
- Help build compliance capability as a function of business resilience and success.

There are two key drivers for the CM industry underpinning this position, the need for CM appropriate regulation, and those of economic pressures, respectively.

1.1 CM Appropriate Regulation

The CHC believes the key to reform for our industry is the adoption of a more appropriate model of CM regulation that takes in account risk management. Excessive bureaucratic burden is encroaching on an industry that has seen the use of ambiguous (at best) Listed medicine post-market statistical data to drive a range of performance reviews and subsequent Blueprint Reform Recommendations.[2]

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[1] In this document, the term "Complementary Medicine" (CM) is a collective term that includes products referred to as complementary or alternative medicines (e.g. herbal medicines, homoeopathic medicines), traditional medicines (e.g. Indigenous Australian, Chinese and Ayurvedic medicines) and therapeutic dietary supplements (e.g. vitamins, minerals and amino acids). Note that Complementary Medicines is also expressed as Natural Health Products (Canada), Natural Health and Supplement Products (New Zealand) and other international variations.

[2] "…the recent data is based on small sample sizes, making it difficult to gauge the magnitude of non-compliance with any precision", ANAO Audit Report No. 3 2011, p. 16.

Under the *Therapeutic Goods Act 1989*, CMs[3] are positioned as a subset of pharmaceuticals[4], a position that the CHC actively seeks to change. The CM Industry in Australia maintains that CMs are neither foods nor pharmaceuticals, and therefore should be defined separately in the *Act*, to ensure they are regulated as low-risk medicines in their own right.

With globalisation and increased commercial and economic pressures across national boundaries – the Australian CM manufacturing sector is under pressure to remain competitive and relevant. The key factors impacting its ongoing viability include the entry of low labour cost countries into the Australian market via supply of bulk products destined to be packed locally, and fully-finished products, all intended to be sold in the local Australian market.

ANZTPA will have a significant impact on the CM industry and whilst some of this could be positive it is expected that some will be detrimental. It is important that companies operating both in New Zealand and Australia, as well as the Australian-only industry, have a significant input into the development of the joint regulatory environment.

Overall, the CHC believes that if progressed along the lines of the current regulatory framework, ANZTPA will be excessively onerous, complex and unworkable for the CM industry, and recommends extensive consultation be undertaken prior to any implementation. The Discussion Paper contains a number of explicit and implicit proposed changes, including new concepts and requirements, which will have an unbalanced effect on the Australian CM Industry with significant impact, most notably economic, on industry members and therefore consumers.

1.2 Economic Pressures

- Smaller businesses are being progressively forced out of the industry due to the high costs of regulation.
- There is currently a large cost differential associated with manufacture and supply of CMs between Australia and New Zealand. New Zealand is becoming a more attractive manufacturing base.
- This will become more pronounced when ANZTPA comes into effect with the Natural Health and Supplement Products (NHSP) Bill expecting to only recover partial costs. The Australian industry would have some relief from this inequitable situation if government could reduce the cost burden of uncompetitive taxes and inefficient regulation. One of the most frequently raised industry concerns (by Sponsors and Manufacturers) is the high cost of operating in Australia. An impost keenly felt when regulation creates additional burdens to export business.
- Inappropriate and inconsistent risk management has for some time caused substantial problems for the industry. Australian sponsors of therapeutic goods are at a distinct disadvantage in international markets due to competition from markets that do not apply such a strict liability regime as Australia. The Australian CM industry fully supports appropriate standards of safety, quality and efficacy, however, the current legislative environment for CMs has inflated the risk basis for managing these medicines; noting that the *Therapeutic Goods Act* also regulates high risk pharmaceutical and over-the-counter medicines and devices. Complementary medicine is unique in that it is based on a long term wellness model and it should be governed in its own right, separate from pharmaceuticals that

[3] TGA Definition: medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are referred to as 'Complementary Medicines'. These are regulated as medicines under the *Therapeutic Goods Act 1989* (the Act). Complementary Medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines. Located at http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

[4] In this document, the term “pharmaceuticals” is a collective term that includes Prescription Medicines and Over-the-Counter (OTC) Medicines, i.e.: pharmaceutical drugs, in classic terminology.

are focused on addressing the disease model. The removal of the influence of the pharmaceutical sector (high risk stakeholders) from the risk management of CMs will allow for more appropriate standards to be developed for the CM industry.

- Australian CM manufacturers are also suffering. Manufacturing is increasingly being carried out overseas (with product imported back into Australia), as compliance with Australian regulations becomes too difficult and costly on-shore. Australian contract manufacturers are finding it increasingly difficult to compete with overseas manufacturers. Anecdotal evidence also suggests that overseas business are not being attracted to Australia as the current regulatory requirements are considered one of the most burdensome of western nations; being too difficult and costly compared to other countries. Further details can be provided.

2. Executive Summary

- No investigation has been conducted on the impact of the Australia New Zealand Therapeutic Products Agency on the Australian Complementary Medicine Industry, in light of the introduction of the Natural Health and Supplement Products Bill in New Zealand.

- The Complementary Healthcare Council of Australia is concerned that the New Zealand initiative to legislate New Zealand Complementary Medicines outside of the Australia New Zealand Therapeutic Products Agency. This potentially means that the Australian Complementary Medicine industry will be pushed further into the pharmaceutical model of regulation, designed to cater for high-risk pharmaceutical medicines. Complementary Medicines are not high-risk pharmaceutical medicines.

- Those Complementary Medicines that may fit into the higher risk streams should be regulated as Complementary Medicines, not Over-the-Counter products.

- The CHC is supportive of the New Zealand initiative to develop specific legislation for its CM industry, which will provide appropriate, light-touch regulatory oversight of CM production and supply. In light of this initiative, Australia should develop specific legislation for its CM industry that will also provide appropriate, light-touch regulatory oversight of CM production and supply.

- The Complementary Healthcare Council is concerned that the proposed Australia New Zealand Therapeutic Products Agency will exacerbate an already un-level playing field for many Australian Complementary Medicine companies.

- The Complementary Healthcare Council of Australia strongly advocates a fee for service cost recovery policy, set to a maximum percentage of operating costs and capped for industry contributions. The ongoing reviews of cost recovery policy should occur as industry-specific discussion.

- There is no evidence that the Australia New Zealand Therapeutic Products Agency, as described in the Discussion Paper, will provide any benefit to consumers of Complementary Medicines. The Australia New Zealand Therapeutic Products Agency should establish an appropriate risk model for Complementary Medicines, one which measures the cost of compliance against community benefit.

The CHC will continue to work towards the establishment of these principles with the TGA and the new Australia New Zealand Therapeutic Products Agency (ANZTPA):

- The CHC supports a simplified Listing system that is commensurate with a small business economy.
- The CHC supports GMP appropriate to the manufacturing requisites of the Complementary Medicine Industry and specifically, its substances.
- Administrative oversight of the Act and Regulations by regulators with knowledge and understanding of Complementary Medicines and the Complementary Medicines industry.
- The CHC Board of Directors would be pleased to attend a meeting to discuss the ANZTPA implementation strategy, the consultative process, and to further discuss the issues of concern expressed by the CHC.

3. CHC Position on High-Level Issues

3.1 CHC Position on ANZTPA

The Complementary Healthcare Council of Australia is concerned that the New Zealand initiative to legislate New Zealand Complementary Medicines outside of the Australia New Zealand Therapeutic Products Agency. This potentially means that the Australian Complementary Medicine industry will be pushed further into the pharmaceutical model of regulation, designed to cater for high-risk pharmaceutical medicines. Complementary Medicines are not high-risk pharmaceutical medicines.

- Industry understands the importance of 'Brand TGA' to the recognition of high-quality, high standard products and the premium that can be attached to a gold-standard benchmark.
- However, inappropriate regulation is being imposed on substances that physically cannot comply. Currently in Australia, CM manufacturers must comply with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) requirements, but several exemptions are required as PIC/S is designed for pharmaceutical medicines and is not directly applicable to CM substances/products. Exemptions include, but are not limited to: release for sale; quantified by input; stability testing; product quality reviews; process validation; supplier qualification; and sampling and testing.
- Therefore, although it appears to make good sense for Australian and New Zealand Agencies to work together and share resources and systems, with the initiative to legislate New Zealand CMs outside of ANZTPA, it is impossible to comment on the impact of this system on the Australian CM industry, in light of the ongoing Blueprint reform work. There is legitimate concern that the pace of implementation and the commencement of up to five major project consultations at one time, means that it is impossible for industry (and potentially the Office of Complementary Medicines) to fully evaluate the impact of the changes.[i]
    - Excessive bureaucratic burden is encroaching on the Australian industry that has seen use of ambiguous statistical data to direct a range of ANAO Performance Reviews and subsequent Blueprint Recommendations.[ii]
        - For example: the bureaucratic burden of evidence required to support the indications for Listed medicines has recently been significantly increased. The CHC believes that increased requirements, in the absence of evidence of any specific consumer safety concern, do not constitute best practice regulation. The CHC does however, support more stringent enforcement action against companies that have made little or no attempt to comply with the regulations, or where a true safety concern is identified.
- Further regulation of CMs as pharmaceuticals will not result in higher consumer confidence in either the regulator or the industry. It presents a more complicated system – with additional exemptions and inclusions – in an already complex environment.

Additional ANZTPA Issues for Consideration

- **Streamed Approach**: CMs should be managed as a separate medicine stream, based on medicine-type as well as risk, as outlined in Figure 1 below.

Figure 1: Medicines Risk Model

Medicine Type	Risk	Description	Availability	Purpose
Prescription (Rx)	High	Have high-risk active ingredients listed on the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).	A patient requires a prescription from a medical practitioner.	Medical intervention
Over-the-counter (OTC)	Medium and Low	Over-the-counter medicines (OTC) are medicines that are not prescription medicines and are not Complementary Medicines.[iii] Most OTC medicines have active ingredients listed on the SUSMP. However, the approved pack size and intended use represent a lower risk than prescription medicines.	Generally sold in pharmacies, although some are available in supermarkets.	Medical intervention
Complementary* (CM)	High, Medium and Low	Approved active ingredients with a traditional or prescribed use. Therapeutic claims for these medicines are generally along the lines that their use provides: health maintenance, including nutritional support; vitamin and mineral support; or relief of symptoms..	Available through health food stores, pharmacies, direct sales, practitioners and supermarkets.	Short and long term health benefits Maintain and enhance health and wellbeing Maintenance of specific health conditions

*** Those Complementary Medicines that may fit into a higher risk streams should be regulated as Complementary Medicines, not Over-the-Counter Products.**

- **Expert Advisory and Standard Setting Committees**: the ANZTPA should adopt a co-regulatory model and include continuation of expert committees on CMs with agreement on membership and terms of reference between the Government, Regulator and Industry. These committees include: the Office of Complementary Medicines / Industry Advisory Group, the Informal Working Group on Complementary Medicines and the Advisory Committee on Complementary Medicines. Their membership should be CM-specific, comprising industry leaders, academics, consumers, industry association representatives, regulatory agency representative and other stakeholders as applicable.

- **Interface Issues**: the interface between CMs and OTCs is clear, concise and well-defined. The interface between CMs and Foods is not well-defined and this has been exacerbated in recent times by the Food Standards Australia New Zealand (FSANZ) Nutrition Health and Related Claims Standard. This Standard allows foods to make high-level 'health claims' that are 'therapeutic claims', but not permitted for Listed CMs. In many instances, the health claims for foods are consistent with and unable to be differentiated from therapeutic claims allowed for Listed CMs under the *Therapeutic Goods Act 1989*.[5]

[5] Examples extracted from the Australia New Zealand Food Standards Code - Standard 1.2.7 - Nutrition, Health and Related Claims: "Reduces blood cholesterol", "Reduces risk of coronary heart disease", "Reduces risk of Osteoporotic fracture", "Reduces blood pressure", Necessary for normal nerve and muscle function", "Necessary for normal blood coagulation", "Contributes to normal energy metabolism", "Contributes to normal cell division", "Contributes to cell protection from free radical damage" and "contributes to weight loss or weight maintenance".

- **Advertising**: the CHC advocates a co-regulatory approach to advertising and a distinct separation between the various medicine industries.
    - The CHC strongly advocates that ANZTPA advertising provisions for CMs be administered under a co-regulatory approach. The CHC considers that this model is the most appropriate based on a risk management and cost effectiveness approach.
    - The CHC supports a streamed risk management approach to administering the ANZTPA advertising provisions and supports a Therapeutic Product Adverting Code.[iv] However, advertising should be managed in the specific stream of risk management with each industry sector responsible for all advertising specific to the sector.
    - Advertising Clearance: Each industry should be solely responsible for approving all relevant consumer advertisements specific to the sector. Advertising Service Managers (ASMs) should be industry specific with an in-depth knowledge of industry issues. The CHC ASMs have this knowledge and experience in relation to CMs. Having specialised clearance officers will improve the consistency in decision making and the appropriateness of decisions. Sponsors would also benefit by only having a single review of advertising material. For Complementary Medicines, the CHC is the appropriate industry representative body.[v]
    - Complaints Mechanisms: The CHC supports a co-regulatory approach to advertising complaints similar to the current system, but with industry specific committees hearing all complaints relating to CMs. The CHC recommends that peak industry representative bodies receive a delegation under the ANZTPA regulations to undertake the administration of the advertising code, including complaints mechanisms. Such a system could expect to be supported by the anticipated TGA-sanctions and enforcement for serious advertising breaches. For Complementary Medicines, the CHC is the appropriate industry representative body.[vi]

3.2 CHC Position on the Separate Regulation of certain, low-risk "Natural Health and Supplementary Products" in New Zealand

The Complementary Healthcare Council of Australia is supportive of the New Zealand initiative to develop specific legislation for its Complementary Medicine industry, which will provide appropriate, light-touch regulatory oversight of Complementary Medicine production and supply. In light of this initiative, Australia should develop specific legislation for its Complementary Medicine industry that will also provide appropriate, light-touch regulatory oversight of Complementary Medicine production and supply.

- The New Zealand Government is introducing a separate scheme to regulate natural health and supplement products. On 31 October 2012 the New Zealand Parliament voted on the Natural Health and Supplement Products Bill and recommended by majority that the Bill be passed with amendments.[vii] Two important distinctions apply: New Zealand has adopted, and appropriately adapted the Bill's title, to reflect an internationally consistent definition of CMs; and is not trying to manipulate pharmaceutical regulation (appropriate for high-risk pharmaceuticals) to fit CMs (low-risk non-pharmaceuticals).
- The CHC recognises that Australia is some 20 years ahead of New Zealand in terms of the regulation of CMs. However, the approach taken by Australia has been to take regulation appropriate for high-risk pharmaceutical ingredients and modify it for a stream of low-risk medicines. Several reports – Australian National Audit Office Performance Reports (2003 and 2011), the Expert Committee on Complementary Medicines in the Health System Report (2003)[viii] and the Phase 1 ANZTPA project

(2007) provide evidence to show that this model is flawed. Continuing to manipulate such a framework can only recreate the same "confusion, and differing interpretations, by industry…".[ix] In addition to the potential ANZTPA implications, the Therapeutic Goods Administration (TGA) expects to implement some 48 Blueprint recommendations with no less than 36 that will directly affect the CM industry.[x]

Streamed Approach – Listed and Registered CMs

- Complementary Medicines are generally low risk health solutions that do not have the same level of serious adverse reactions associated with other higher risk medicines. Some CM products have been required to be registered, due to high-level indications for use. The management of risk should be based on the recognition of risk status and a streamed risk management approach should to be implemented for all medicines regulated by ANZTPA.
- ANZTPA should develop a sound risk management policy that removes the potential for risk aversion and risk elimination and that supports consistency and predictability in decision making processes.

3.3 CHC Position on the Effect of ANZTPA on an already Un-Level Playing Field

The Complementary Healthcare Council is concerned that the proposed Australia New Zealand Therapeutic Products Agency will exacerbate an already un-level playing field for many Australian Complementary Medicine companies.

- Permitted Ingredients List (PILs): The CHC supports the implementation of the PILs List from the Phase 1 ANZTPA Project that included ingredients currently permitted in Listable medicines in Australia, *plus* those added as a result of Permitted Ingredients List project.[xi] This would remove the necessity of Australian consumers importing products containing low-risk, but 'illegal' substances into Australia from New Zealand and other markets.

  Additionally, the CHC strongly advocates that the additional substances be added to the list of substances that may be used in Listed medicines in Australia, as was originally proposed under ANZTPA, at no cost to Australian industry. The CHC notes, that since the Phase 1 ANZTPA proposals were shelved, Australian manufacturers and sponsors have continued to be charged high fees to have ingredients included on the list of substances that may be used in Listed medicines in Australia, even if such ingredients were on the PILs List and already permitted in New Zealand.
- Differences between the Australian and New Zealand systems and the potential impact on Australian exports, particularly to Asia (our largest export market) are unknown at this stage, but could be heavily impacted by the commencement of ANZTPA. At the time of implementation, there could be three separate systems available to New Zealand companies exporting their CM products.
  - ANZTPA Product;
  - New Zealand Product - these products may be exported from New Zealand using the New Zealand regulations to enter other markets. The NHSP Bill requires New Zealand residency, which should prevent companies using this route to market without being manufactured by a New Zealand company (unless ANZTPA resolves the special exemption for therapeutic products under the Trans Tasman Mutual Recognition Arrangement, these products will continue to enter Australia); or
  - Non-New Zealand-Regulated Export Product - adherence to destination country regulations required.

- The question remains around how companies will elect (or be required to select) one system over another, and whether these companies will be able to switch between environments in which they want to operate.
- Part 2 of the 'New Zealand Natural Health and Supplementary Products Bill' will establish a code of manufacturing practice, however at this time, it is unknown whether the standards implemented will be equivalent to current Australian GMP requirements, or whether it will be a specialised CM-specific standard.
- Currently in Australia, CM manufacturers must comply with PIC/S requirements as Australia has adopted many of these into its Code of GMP. However, as previously stated, several exemptions are required as PIC/S requirements are only appropriate for high-risk drug products of low complexity, and are therefore, not suitable for CM products.
- The impact of ANZTPA on other manufacturing costs is unknown:
    - Increasing global competition and pace of change: the expansion of China and India (and other emerging nations) as manufacturing powers will continue to have a direct impact on Australian manufacturing that is already having to cope with accelerating changes in technology and globalisation.
    - Input costs: Australian manufacturers are at times paying more for raw materials than some international competitors. Some overseas governments intervene directly in key markets. This is problematic for local manufacturers competing globally and is also increasingly impacting on local markets.
- A potential solution could be to review Australian Export Rules to permit adherence to destination country regulations, for export-only products, without requiring ANZTPA compliance.
- Regardless, Australian CMs should be able to be marketed without any changes (ie: to labels) in New Zealand. However, this is not explicitly clear in the discussion paper. It would go some way to alleviate these issues by not having to modify packaging or formulation to comply with separate New Zealand Regulations.

3.4 CHC Position on Cost Implications for Australian Companies

The Complementary Healthcare Council of Australia strongly advocates a fee for service cost recovery policy, set to a maximum percentage of operating costs and capped for industry contributions. The ongoing reviews of cost recovery policy should occur as industry sector specific discussion.

- Financial management committees within ANZTPA should have independent chairs and the process of financial management should be fully open, transparent and industry sector specific.
- The CHC's long-standing position is that the current Australian 100% cost recovery policy is not sustainable in the long term and does not support the objectives of the National Medicines Policy (NMP). The Productivity Commission – Cost Recovery by Government Agencies inquiry report 2001 highlighted that cost recovery should not be implemented where it would be inconsistent with policy objectives.[xii] Two of the primary objectives of the NMP are to ensure that the community has timely access to affordable medicines and maintaining a responsible and viable medicines industry. The CHC strongly believes that the current cost recovery model is in conflict with the objectives of the NMP and increases in regulatory cost are ultimately passed on to the consumers in the form of increased product pricing or the reduction of industry innovation and production.
- Regulatory agencies cost recovery mechanisms cannot be considered in isolation to regulatory compliance costs. The CHC is concerned that the current full cost recovery policy, in combination with

increasing regulatory compliance costs, is not sustainable in the long term. The establishment of ANZTPA will mean further increases to cost burdens on both industry and on the consumers of CMs. The CM industry in Australia is already paying an increase of 3.6 per cent based on the indexation model agreed with industry, plus a further increase of 2 per cent in order to fund the implementing of reforms set out in the document *TGA Blueprint Reforms*, and to improve the TGA's post market surveillance capacity.[xiii] Note that this cost is in addition to compliance costs.

- Increasing costs have forced many sponsors to seek cost savings by manufacturing in lower cost offshore facilities. The Australian CM manufacturing industry is finding it increasingly difficult to compete with these international suppliers or compete in the international markets. Coupled with the high Australian dollar, this has substantially impacted Australia's export opportunities.
- No evidence has been presented that will allow cost-comparisons to be undertaken for the Australian CM Industry, and this is especially important as it is the only industry that will participate in ANZTPA in an Australian-only capacity.

3.5 CHC Position on the Impact of ANZTPA on Consumers

There is no evidence that the Australia New Zealand Therapeutic Products Agency will provide any benefit to consumers of Complementary Medicines. The Australia New Zealand Therapeutic Products Agency should establish an appropriate risk model for Complementary Medicines, one which measures the cost of compliance against community benefit.

- In 2007, Australian consumers had a reported choice of over 17,000 CM products containing around 2,200 active ingredients.[xiv] Five years later, this choice is now reported at approximately 11,200.[xv]
- CMs are generally low risk[xvi] medicines that do not have the same level of serious adverse reactions associated with higher risk medicines. CMs under ANZTPA should be managed according to this commensurate risk. Even where CMs may fit into a higher-risk stream, they should appropriately be regulated as CM products, *not* OTC products. The low-risk status of CMs can be managed with appropriate safety and quality standards that recognise unique properties and intrinsic compliance difficulties with the current system and allow for standards that are appropriate, achievable and practical in application.
- The CHC believes that Australia's regulatory system for CMs has an intrinsically reasonable basis but one that requires appropriate and considered reform if it is to provide consumers with access to safe, effective and cost effective medicines.
- Under the current regulatory scheme, the increasing cost of compliance is impacting on the predominantly small and medium businesses of our members, by restricting business growth, limiting innovation and reducing consumer access to CMs. A broad brush approach (ie: one size fits all) places an unnecessarily heavy burden on those who produce and sell CMs.
- There is low consumer understanding of the current regulatory system and under a more complex regime, consumer understanding would likely be lower. The Consumer benefits of a more simple CM regulatory framework would be benefited by greater:
    - Clarity
    - Quality, safety and efficacy
    - Informed consumer choice in healthcare

4. Recommendations

No investigation has been conducted on the impact of the Australia New Zealand Therapeutic Products Agency on the Australian Complementary Medicine Industry, in light of the introduction of the Natural Health and Supplement Products Bill in New Zealand.

4.1 The Impact of the Australia New Zealand Therapeutic Products Agency on the Australian Complementary Medicines Industry should be investigated and consulted

- Framework options for investigation must include:
  - Australian CM Products regulated by ANZTPA
  - Australian CM Products regulated by NHSP Bill – Joint CM/NHSP Regulatory Agency
  - Australian CM Products regulated by Independent Australian Agency
- Investigation should include industry input and Risk Impact Statements.
- Irrespective of the framework selected, the framework should include an Office of Complementary Medicines Authorisation and Complementary Medicine relevant Regulations.

4.2 Australia should implement an appropriate Regulatory Framework for Complementary Medicines. The framework should include an Office of Complementary Medicines Authorisation and Complementary Medicine-relevant Legislation

- The framework should be administered by an 'Office of Complementary Medicines Authorisation'.
- Such a framework should be either legislated (*Complementary Medicines Act*) or at the very least, include CM specific-regulation (*Therapeutic Goods (Complementary Medicines) Regulations*);
- This framework should include appropriate *Code of Good Manufacturing Practice for Complementary Medicines*.
- The ANZTPA should establish an appropriate risk model for CMs, one which measures the cost of compliance against community benefit.
- This framework should adopt the principles of minimum effective regulation as opposed to risk elimination or risk aversion, a strategy based on co-regulatory and self-regulatory options that offer the most cost effective regulatory governance and administration.
- A framework that manipulates pharmaceutical regulations is not suitable or appropriate for CMs.

About the CHC

The Complementary Healthcare Council of Australia (CHC) is the peak industry body for the Complementary Medicine industry and presents the views of the entire supply chain, including manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. These entities range in size from multinationals through to smaller regional-based business (typically SMEs).

The CHC promotes appropriate industry regulation and advancement to ensure consumers have access to Complementary Medicines of the highest quality. The global market has been estimated at $US 83 billion annually.[xvii] 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.[xviii]

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.[xix]

The CHC develops and manages a series of codes of conduct to which its members are required to comply, and to which the 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.

The Australian National Audit Office estimates that Complementary Medicine market growth has been around 3-12 per cent per year. There are more than 250 individual Complementary Medicine companies in Australia, with 59 Therapeutic Goods Administration (TGA) approved manufacturing facilities around the country. Combined, these companies generate approximately $2 billion in annual revenues.[xx]

Australian consumers understand that Complementary Medicines are not a replacement for prescription medications; rather they use Complementary Medicines to enhance overall wellbeing and to maintain a healthy balance in their lives. Research has indicated that half the adult population of Australia will purchase a Complementary Medicine product at least every quarter and that the majority (75%) of consumers can name the exact Complementary Medicine product they purchase and why.[xxi]

The Complementary Medicine industry today directly employs around 5000 highly skilled workers and generates approximately $200 million in GST revenue each year.[xxii]

Over the past few decades the Complementary Medicines sector has evolved into a major world class industry, supporting domestic jobs, research, manufacturing and exports.

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