



**CMA Submission to the Senate Community Affairs Legislation  
Committee**

**Therapeutic Goods Amendment (2017 Measures  
No. 1) Bill 2017**

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January 2018



## Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA members represent greater than 80% of all product sales within Australia. Membership includes the entire value chain, including sponsors, retailers, manufacturers, raw material suppliers, distributors, consultants, allied health professionals and educators. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality. CMA is the principal reference point for members, the Government, the media and consumers to communicate about issues relating to the complementary medicines industry.

CMA welcomes the opportunity to provide input to the Senate Community Affairs Legislation Committee on the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* (the Bill).

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## Executive Summary

- CMA is proud to represent an industry that supports individuals and communities to better care for their health. A vibrant industry contributes to illness prevention and health enhancement, reducing burden upon the healthcare system and increasing productivity.
- Australia's global reputation for quality and safety, backed by the strongest regulatory system for complementary medicines in the world, makes Australian products a sought-after choice.
- The sector significantly contributes to high-skilled local manufacturing, employment, innovation, investment, and opportunities for research institutions. Global demand is high, but Australian exporters are increasingly competing with companies from around the world.
- CMA is widely supportive of the Bill as it implements a range of Expert Panel recommendations. The Bill introduces a new category offering a unique, world-class opportunity to expand the therapeutic range of evidence-based complementary medicines.
- The Bill also replaces an excessively cumbersome advertising system with a streamlined and centralised mechanism that includes tougher sanctions, but reduces red-tape and improves fairness of complaint-handling.
- CMA is highly concerned that two new legislative instruments being introduced by the Bill will provide the political mechanism for vocal opponents of complementary medicine to cause immediate and ongoing harm. Disallowance of the first instrument by opponents will cause a \$4.7billion industry be unable to operate. Negative media attention would spread damaging misinformation about the industry and the Government's capacity to regulate. These efforts are a misplaced ideological bid to throttle the use of complementary medicines in contrast to the worldwide boom in demand. Australia's reputation could be unjustifiably put at risk at the key moment Australia is proudly securing its place as a world leading exporter of high-quality goods. As the introduced risk outweighs the benefit, and as the items in question are suitable as guidance documents, the two legislative instruments should be removed from the Bill.
- CMA is aware that other stakeholders have raised the non-Bill-related issue of a negative disclaimer for traditional medicines. The World Health Organisation recognises the validity of traditional medicines and actively encourages nations to promote their use. Introduction of a disclaimer by Australia would be in contradiction of global trends and medicines policy.
- CMA asks that the Senate Committee considers the following recommendations:
  - ✚ Schedules 1 and 3 - 9 – Retain all Bill provisions.
  - ✚ **Schedule 2, Item 15 – Remove the legislative instrument mandating a list of permitted indications.**
    - *Retain proposed list as guidance.*
    - *Retain new & improved criteria.*
  - ✚ **Schedule 2, Item 5 – Remove the legislative instrument for evidence.**
    - *Retain existing guidance.*



## Introduction

Complementary medicines are an important and culturally acceptable part of healthcare around the world. They are an accessible and affordable way for many people to proactively contribute to their health.<sup>i</sup> The use of complementary medicines is based upon an ever-growing scientific research base, use within traditional medicine systems, or a combination of these disciplines.

Use of complementary medicines is not only increasing rapidly in Australia, but in Europe, North America, and Asia, and the sector is of growing importance to national economies.<sup>ii</sup> The global market is expected to reach US\$115 billion by 2020.<sup>iii</sup> The 2017 Australian complementary medicine industry audit showed that the industry sales in Australia alone have almost doubled in just two years, generating annual revenues of AU\$4.7 billion.

Australia's export business has doubled in size in just three years – largely due to the growing popularity in Asia of our clean, high-quality, and exceptionally-regulated products. International demand for Australian products has boosted skilled jobs in the complementary medicines sector across a range of areas, including manufacturing, scientific evaluation and research.

The Australian Trade and Investment Commission (Austrade) reports that the complementary medicines market in China is booming, and that the Australian industry is in a prime position to capitalise on the growing demand for high-quality complementary medicines. With a current value of US\$30 billion, the Chinese market has the potential for 10 per cent year-on-year growth to reach a potential of US\$150 billion by 2025.<sup>iv</sup>

The regulatory regime for complementary medicines in Australia is viewed by most countries as the consumer protection benchmark. In comparable countries, such as the UK, USA and NZ, the standards for similar products are considerably lower, with many treated as supplemented food, and manufactured and regulated accordingly.

Whilst considered by the vast majority of stakeholders that it is proper and even advantageous for complementary medicines to be regulated by the Therapeutic Goods Administration (TGA) in Australia – ensuring strict quality and safety standards for this category of low-risk health products – over-regulation, without evidence of any genuine risk, is the biggest challenge to the ongoing success of the Australian sector.



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## Low-risk Listed Medicines

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The *Therapeutic Goods Regulations 1990* define a complementary medicine as:

‘a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a tradition of use.’ Examples of such ingredients are vitamins, minerals, amino acids, herbal plant materials, homeopathic preparations, natural fatty acids, biological substances such as glucosamine, and probiotic microorganisms.

The vast majority of complementary medicines are *listed* in the Australian Register of Therapeutic Goods (ARTG), which means they:

- only contain approved low-risk ingredients approved by the TGA;
- only carry low level indications for therapeutic use for health maintenance and enhancement or self-limiting, self-manageable conditions; and
- are required to hold scientific or traditional evidence to verify all indications and claims.

Listed complementary medicines have an excellent safety record. Product sponsors must:

- manufacture their product in accordance with strict principles of Good Manufacturing Practice in TGA licensed facilities;
- report any serious adverse events to the TGA so that emerging trends can be identified and action taken quickly;
- have all active ingredient raw materials tested prior to manufacture;
- comply with established methodology to verify label content;
- hold stability data to demonstrate the product remains potent for the entire shelf life; and
- conduct annual product reviews to continually monitor and assure quality.

Unless included on the ARTG, the majority of complementary medicines cannot legally be imported, exported, manufactured, or supplied to consumers. Listed medicines on the ARTG have an AUST L number displayed on the pack.



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## Expert Panel Review of Medicines & Medical Devices Regulation

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The Bill supports the implementation of key recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR), the main objectives of which were to improve the timely and safe access to quality therapeutic goods for consumers, and to minimise the regulatory and administration burden for business, whilst ensuring that any legislative framework is commensurate with the risk of such goods. The MMDR review was consistent with the Australian Government's *Industry Innovation and Competitiveness Agenda*, recognising that Australia must remain competitive on the global stage.

CMA is, in the main, supportive of the Bill, which implements a range of important MMDR recommendations for all therapeutic goods, whilst including a ground-breaking new assessment pathway for complementary medicines and a significantly improved advertising system.

However, significant concern has arisen across the complementary medicines industry about the risks associated with the introduction of two legislative instruments within Schedule 2 of the Bill. It is possible for these items to be removed with minimal impact upon the operation of the regulatory framework, which is discussed in more detail below.

We would like to acknowledge the significant efforts that have been undertaken to date by the Government, the Minister for Health, the Hon. Greg Hunt MP, and the Therapeutic Goods Administration in progressing the MMDR reform package and the readiness to engage with industry. We particularly acknowledge and appreciate the TGA's willingness to work closely with industry in resolving matters of policy and process as they arise.



## Schedule 3: New Category for Complementary Medicines

The Bill provides a new category to include a medicine upon the Australian Register of Therapeutic Goods (ARTG). Currently, the vast majority of complementary medicines sit within the low-risk listed 'AUST L' category, with a tiny percentage in the higher-risk registered 'AUST R' category.

Figure 1. Complementary Medicine categories in Australia.



The intention of the new category is that a business may voluntarily elect a product with low-risk ingredients to undergo pre-market evaluation of the efficacy of its indications (health claims). The medicines will be called 'AUST L(A)' to reflect the pre-assessed status and will be permitted to include a positive claimer of efficacy. An AUST L(A) medicine must include at least one intermediate-level claim, which is not as low-risk as AUST L medicines but not as high-risk as AUST R over-the-counter or prescription medicines.

If implemented successfully, this represents a ground-breaking and unique opportunity for complementary medicine products to gain recognition for undergoing rigorous scientific assessment. By incentivising expansion of the clinical research base for non-patentable naturally occurring substances, it will encourage increased investment by industry into Australian research bodies. Consumers, both locally and globally, would be able to access complementary medicines for an increasing range of health benefits.

CMA has strongly supported the introduction of the new category on the basis it is opt-in only, and the understanding that there would be no substantive change to the existing listed category. However, opponents of complementary medicines have petitioned to reduce the existing listed category by way of permitted indications, which would result in the forcing of currently acceptable, low-risk medicines into the pre-assessed category and lead to a loss of products, jobs and small businesses.

 **CMA asks the Senate Committee recommend retention of Schedule 3 of the Amendment Bill that provides for the new assessment pathway.**



## Schedule 2, Item 15 (Amend): Permitted Indications

### Risks Arising from Legislative Instrument for Permitted Indications

The Government accepted the Recommendation for the introduction of a list of 'Permitted Indications' (health claims) that low-risk complementary medicines must exclusively use. CMA has consistently supported this concept and worked closely with the TGA to develop this list for over seven years. However, recent developments during the last several months have demonstrated that the list in the form of a legislative instrument will introduce serious risks that far outweigh the benefit for the majority of stakeholders – industry, consumers, and the Government.

- **CMA proposes removal from the Bill of the legislative instrument for a list of permitted indications.**

The proposed benefit was to create a definitive list, increasing transparency and reducing inadvertent non-compliance. Retaining the benefit without introducing the risk is possible by introducing the list as a guidance document. The risks of retaining the legislative instrument in the Bill are outlined below.

#### **1. Proposed Disallowance of the instrument by opponents of complementary medicines will leave an AU\$4.7 Billion dollar industry unable to operate.**

Inclusion of listed medicines on the ARTG will be reliant upon the availability of Permitted Indications. Planned disallowance of the initial legislative instrument by complementary medicine opponents means that the new Therapeutic Goods Act will legally prevent industry from creating and maintaining products on the ARTG. The \$4.7 billion dollar sector would grind to a halt, with severe implications for consumer access to medicines, manufacturing and jobs. The media attention of this scenario will cause significant loss of confidence in the sector by Australian and overseas consumers. With the boom in complementary medicines overseas there could be irreversible and long-term effects on Australia's international reputation for medicine regulation and export markets, affecting not only this sector but other medicine sectors.



## 2. Negative Media Attention & Political Scrutiny on a Regular Political Cycle.

The TGA plans to introduce a new (disallowable) legislative instrument every 3 months. The list is becoming used as an avenue for public opinion groups to pressure the Government and the TGA to remove indications. Introduction of the list is shaping up to be a constant battle over precisely what industry may and may not refer to during the parliamentary introduction of the legislative instrument, which will occur on a regular cycle, resulting in continuing negative media attention and political difficulty for both industry and the Government.

## 3. Reduction of Indications due to Opponent Submissions.

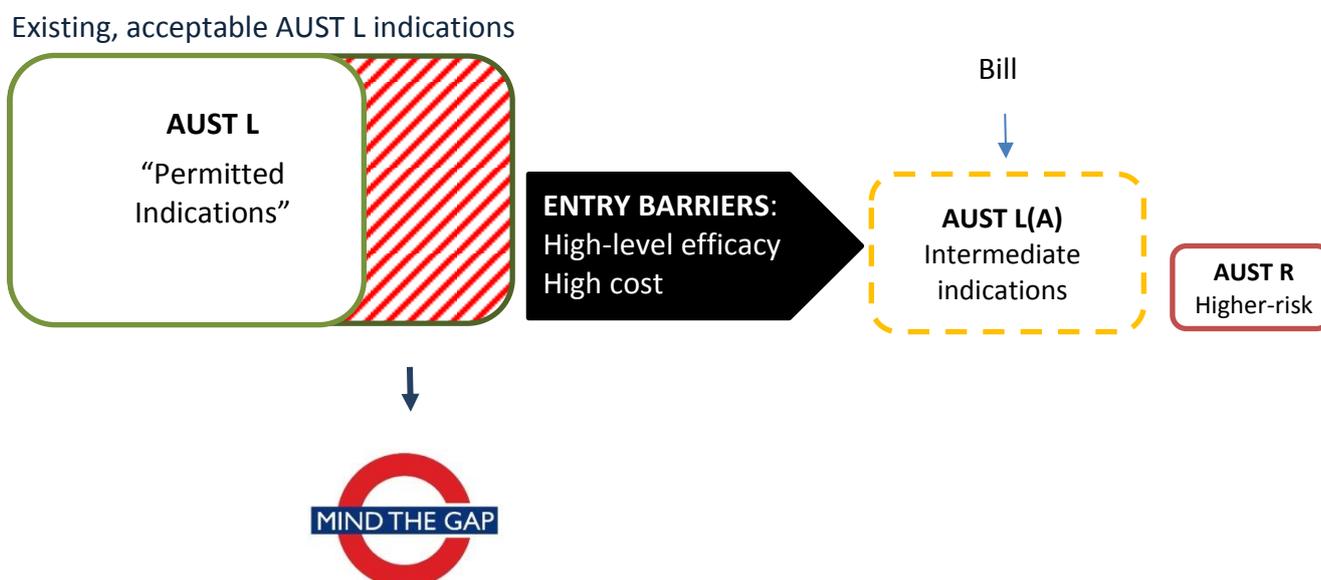
The legislative instrument provides a political mechanism for the continued push by anti-complementary opponents to remove indications from the list. The effect upon the recent consultation process demonstrated a reduction in the:

- *Number* of indications that have been safely used for over 30 years;
- *Strength* of indications; and
- *Specificity* of indications.

The influence of such groups has led the Government away from ‘light touch’ regulation. The pressure on the TGA to reduce indications will continue with the introduction of the list every 3 months.

Reduced indications and the entry barrier to the new category create a ‘gap’ that many existing complementary medicines may fall into. Immediate and ongoing loss of indications heralds a loss of product, Australian jobs and small businesses, consumer confidence, and export value.

Figure 2. Complementary Medicine Indications in Australia.





The following disadvantages for the TGA and industry to be exposed to continual political pressure to reduce the list of indications are further outlined below:

**a. Over-Regulation**

Over the last 30 or more years of use, there has not been evidence of occurrences of inappropriate use of complementary medicines based on commonly used indications, scientific or traditional, let alone risk of any magnitude posed to the Australian population. Reduction of indications in these circumstances represents over-regulation, which damages industry, disadvantages consumers and is against best practice principles outlined in *The Australian Government Guide to Regulation – Cutting Red Tape*<sup>v</sup>.

**b. Reduced Consumer Information**

Increasingly vague indications raise the risk of medicine misuse and leads consumers to have less information about the specific purpose of the product. Reduced information will cause Australian consumers to increasingly seek and purchase medicines from overseas, putting consumers at risk of importing illegal, unregulated, unsafe, low-quality products.

**c. Loss of Consumer Confidence**

Reduced indications that are currently used on existing complementary medicine products for commonly self-treated conditions will confuse consumers and cause a loss of confidence in the industry and the regulator.

**d. Export impediment**

Consumers in China pay particular attention to labelling changes (due to higher awareness of counterfeiting), and a removal and change to indications on labels is likely to reduce confidence in Australian products. The push by complementary medicine opponents to make indications increasingly limited and vague will remove Australia as a serious competitor in the growing global market.



**e. Widening Gap between Foods and Complementary Medicines**

Removal of indications from the list further widens the gap between claims for therapeutic goods regulated by the TGA under Good Manufacturing Practice, and those permitted for foods regulated by FSANZ and the ACCC without the same strict manufacturing quality controls for medicinally active ingredients.

**CASE EXAMPLE: CHOLESTEROL PRODUCTS**



Launched in 2017, the Weetbix product is an example of the burgeoning health claims in relation to cholesterol products and foods. Foods such milk, margarine and cereals currently make claims such as **“Clinically proven to reduce cholesterol levels by an average of 10% in 4 weeks...”** (regulated by Food Standards Australia New Zealand) combined with **“...which may reduce the risk of heart disease”** (by default, regulated by the Australian Consumer and Competition Commission.)

Due to external pressure from opponents of complementary medicines, the claim for listed complementary medicines from permitted indications: **“Helps maintain healthy cholesterol levels”** has been removed, despite information to demonstrate compliance with the criteria. To allay concerns, industry concurrently proposed the warning statement/s: **“Not for use in high cholesterol levels”** or **“If concerned about your cholesterol levels please see your healthcare professional”**. As the complementary medicine’s ingredients have an effect upon cholesterol levels, informing consumers about the actions of the medicine, along with a responsible advisory statement, represents the lower-risk position. Removing information to consumers introduces safety risks.

Unlike foods, complementary medicines are subject to strict GMP quality manufacturing standards. Despite superior quality control, there is an increasing gap between the health claims available for foods and complementary medicines. It creates an increasingly confusing regulatory landscape between foods and complementary medicines for consumers, and pushes more products to be presented as foods with lower manufacturing regulatory requirements.



**f. Access to Natural Justice**

To keep the list manageable, the number of indications has been reduced but “words to the same effect” will be allowable. Words to the same effect are something that have always been permitted, but in recent years Delegates within the advertising administrative area have required verbatim use of ARTG indications. There are some concerns that there will be dispute over whether similar words will be acceptable, and some sponsors prefer to create business surety by including indications on the ARTG that match their product label.

**g. Legal Risk to the Government**

The push by complementary medicine opponents has led, and may continue to lead, to the removal of some indications that in industry’s view conform to the legislated, low-risk criteria. The legality of removing access to indications that comply with eligibility criteria, for an entire industry, creates a risk for the Government. In 2013, the Administrative Appeals Tribunal overturned an administrative law decision by the regulator, determining that ‘cystitis’ was an acceptable health claim for a low-risk complementary medicine.<sup>vi</sup>

Reduction of indications may pose a legal risk to the Government if there were to be lawsuits where the courts determines that incorrect administrative decisions have occurred, inducing costly commercial impacts for an entire industry.



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## The Regulatory Landscape without Permitted Indications

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Concerns and responses to removing Permitted Indications as a Legislative Instrument are included below.

### 1. Managing Free-Text Claims

Industry support for the permitted indication list included the reason that due to a very small minority of sponsors using misleading claims, media attention was creating a negative perception of the industry. The TGA has gone to significant efforts in creating a draft list of indications, which if implemented as guidance provides a mechanism to create a manageable solution for listed products in ways outlined below.

#### a. Significantly reduced free-text usage and adoption of TGA suggested indications.

A great number of sponsors will choose from the TGA available list of indications. With few products using free-text indications, identifying problematic products will be significantly easier for the TGA than current arrangements where almost all products use free text.

#### b. Refusing to list or targeting new products with problem claims.

In the few products that include a problematic claim at the time of the listing, the TGA could either refuse to list the product, as per Expert Panel Recommendation Thirty-Four, or could immediately target the product for a compliance review.

#### c. Auto-screening of serious conditions.

Both the existing and proposed low-risk criteria quite rightly prevent indications for “serious conditions”, such as heart disease, depression, etc for listed complementary medicines. The electronic listing system is capable of detecting and preventing the use of named, serious conditions.

#### d. Free-text character limit.

With the large number of TGA available indications, the free-text could be subject to a reasonable character limit so that the regulator is not presented with excessive information.

#### e. Increased post-market monitoring

The TGA is already in the process of implementing a more comprehensive post-market monitoring scheme for listed complementary medicines by the recommendation of the Expert Panel Report. The number of post-market reviews has increased from 99 in 2014/15, to 551 in 2016/17.



#### **f. Penalties and Sanctions**

In response to Expert Panel recommendations, the TGA is considering financial penalties and other sanctions for compliance concerns in post-market reviews. Such sanctions and penalties will further increase the deterrence of unacceptable claims.

### **2. Managing Advertising**

The existing regulatory scheme has tight controls over health claims and advertisements. Controls are tightened by the Bill's regulatory reform by way of clarified advertising requirements and increased sanctions and penalties, which are a significant deterrent to inappropriate advertising. These measures are described in detail in 'Schedule 6' below, and are particularly effective when combined with the increased post market measures described above.

### **3. The Bill - Drawing the line between categories**

The Bill currently uses permitted indications to demarcate the difference between listed 'AUST L' and listed assessed 'AUST L(A)' medicines. As part of reforms, new and clearer eligibility criteria for listed medicines are introduced in the Amendment Bill. The vast majority of stakeholders, including the TGA, industry, and public opinion groups are satisfied with the new criteria. As the TGA has already determined eligibility criteria for each category (low and intermediate), the line between categories can be drawn by the relevant criteria.

In summary, CMA submits that due to the harmful measures being undertaken by complementary medicine opponents, the risks to industry and the Government of introducing the list of indications as a legislative instrument is too high; in particular, the threat to the ability of the industry to operate. Due to the immense amount of work conducted by the TGA in developing a final list of permitted indications, and other vastly improved controls and compliance measures including sanctions and penalties, the benefits may be maintained via a guidance document.

**CMA asks that the Senate Committee recommends:**

- + Removal of the legislative instrument mandating a list of permitted indications.**
  - *Retain proposed list as guidance.*
  - *Retain new & improved criteria.*



## Schedule 2, Item 5 (Amend): Evidence Requirements

### Legislative Instrument for Evidence Requirements

The Bill introduces Item 5 of Schedule 2, that the Minister may make a legislative instrument specifying evidence requirements for listed medicines. The Expert Panel Review of Medicines and Medical Devices did not make a Recommendation for evidence guidelines to be made into a legislative instrument. Recommendation Thirty-Nine of the Expert Panel’s Stage Two Report provided that complementary medicines should be ‘listed’ onto the ARTG “*in circumstances where ... F) the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the NRA from time to time.*”<sup>vii</sup>

There is concern that problems may arise in the evaluation of evidence, which is a complex consideration of many variable factors that cannot be captured to the definitive extent that is required by a legislative instrument. It could lead to the cancellation of products based upon minor items that may not bear relevance to the overall consideration of whether a dossier of evidence is applicable to support a therapeutic indication. This would reduce natural justice for complementary medicine sponsors and may result in increased challenges to administrative decisions, incurring legal costs for the Government.

Evidence requirements are currently served by industry guidance material, and the legal requirement to hold evidence has been included in the *Therapeutic Goods Act 1989* since its inception.

- **Without the Expert Panel’s recommendation, industry consultation, or a Regulatory Impact Statement, the impacts have not been assessed accordingly, and the proposed legislative instrument should be removed from the Bill.**

 **CMA asks the Senate Committee to recommend removal of the legislative instrument for evidence.**

- *Retain existing guidance.*



## Schedule 6: Advertising of Therapeutic Goods

The Expert Panel recommended simplifying the framework by which advertising of therapeutic products to the public is regulated, via the removal of the costly pre-approval mechanism and by strengthening the regulator's compliance powers to deter misleading advertising. The Bill implements both these recommendations.

Advertising is a central pillar of the capability of businesses to promote any type of product that is available for self-selection by consumers, including therapeutic goods in the lower spectrum of risk. The advertising framework is designed to ideally find the balance between providing information to consumers to support their selection of product and ensuring that low-risk medicines are used safely.

All advertising for over-the-counter and complementary medicines must comply with the *Therapeutic Goods Advertising Code*, which has the objectives of ensuring that advertising is to be conducted in a way that promotes the quality use of therapeutic products, is socially responsible and does not mislead or deceive consumers.

The vast majority of the complementary medicines industry appreciates the importance of responsible advertising of therapeutic products. Our industry strongly supported the retention of an advertising code, the ability for the TGA to take swift action against blatant non-compliance and repeat offenders, and a strong educational component within the advertising framework.

Simplifying the advertising framework will help reduce complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary red-tape and regulatory burden. Removal of the pre-approvals mechanism is a vital element of improving the advertising framework as it has become costly for industry, inefficient, complex, and in 2018 is now a very dated system. A number of issues were identified with the pre-approval system, contributing to the Panel recommendation for its removal.

These include:

- Advertisers must often seek approvals from two separate delegates for a multi-media campaign. Approval for advertising is delegated by the TGA to two bodies (Complementary Healthcare Council of Australia and Australian Self Medication Industry), which often requires advertisers wishing to advertise in broadcast and print media to seek two sets of 4-8 approvals via two separate delegates for the same advertisement.
- The use of different delegated authorities for different media for advertisements of the same product creates an environment conducive to inconsistency in decision making.
- There is no provision of pre-evaluation assistance to advertisers or industry.



- The system is inflexible; changes to approved advertisements can be very costly.
- Currently, pre-approvals are not required for any advertising on the internet, social media, subscription television, or in materials such as leaflets, flyers, brochures. To require pre-approvals across all advertising channels would be extremely prohibitive. With the rapid pace of technological development, it is highly likely that firms will be communicating with consumers via a range of channels, some of which we may not be even be aware of yet.

Ideally, any advertising framework needs to be simple, rational and effective. In 2018, the pre-approval system is none of those things and no longer meets the needs of consumers, the regulator or industry. A delay in implementing the new, more modern and effective advertising framework would cause ongoing difficulty for industry and the TGA.

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### More Effective Complaints System

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The Bill allows the TGA to implement new arrangements to simplify and improve the handling of complaints about the advertising of medicines and medical devices to the public.

The majority of stakeholders support that the current convoluted system for managing complaints be disbanded and a single agency be responsible for receiving and managing complaints regarding the advertising of therapeutic goods to the public.

This new mechanism is expected to be consistent with best practice principles for complaint handling, such as those set out in the Commonwealth Ombudsman's: Better Practice Guide to Complaints Handling. The decision to provide, through the TGA, a single body to manage all complaints is also expected to address many of the criticisms made about the current arrangements and help to deliver consistency in decision-making, compliance and enforcement.<sup>viii</sup>

Criticisms that have been levelled at the existing arrangements include:

- The current complaints handling system is inefficient, costly, and confusing for consumers and businesses to navigate.
- Complaint handling for complementary medicines involves a number of different delegated authorities (CRMC, CRP, ASMICP) which has created inconsistency in decision making.

Criticism has often been levelled at the Complaints Resolution Panel (CRP) due to its lack of transparency and timeliness, limited penalties and lack of appeals process.

- The CRP does not deliver timely or consistent decisions and often makes rulings that are inconsistent with the approval from the delegate(s).
- There is a lack of an appropriate appeal mechanism in order to have decisions of the CRP reviewed.



- The panel lacks expertise in the complementary medicines sector, yet invests time in consideration of issues of efficacy, which not only slows the process but can be more appropriately dealt with by the regulator.

The first quarter of the 2017/18 financial year provides an accurate reflection of the work of the Complaints Resolution Panel. Out of over 12,000 products on the market, the Complaints Resolution Panel received only 45 complaints, of which:

- 11 were treated as withdrawn
- 1 withdrawn because it had already been dealt with
- 7 were not within the jurisdiction of the Panel
- and 10 were forwarded to the TGA.

The average number of days from receipt of a complaint to determination is currently 126 days<sup>ix</sup>.

According to Piper Alderman Lawyers, as written in their Stakeholder Submission to the Consultation on the regulatory framework for advertising therapeutic goods:<sup>x</sup>

It is apparent, based on our extensive involvement in the management of numerous complaints, that the current processes which regulate the advertising of therapeutic goods are procedurally deficient. The time, costs and other resources expended by our clients in respect of almost every complaint handling process have been excessive and consistently attributable to poor communication between the various decision makers, inconsistency of decisions and lack of transparency regarding the reasons for decisions by particular bodies. Some of our clients have exited the industry entirely as a result of ongoing frustration with the haphazard and inconsistent treatment of advertising complaints.

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## Increased Sanctions and Penalties

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The Expert Panel recommended that related reforms also be implemented to support the *Therapeutic Goods Advertising Code* and the responsible advertising of low-risk products. These reforms include an increase in post-market surveillance, increased penalties and sanctions for regulatory violations and an industry education program.

The Bill will allow the TGA to impose significant penalties, ranging from 5000 penalty units for an individual to 50 000 penalty units for a body corporate. The vast majority of industry seeks to comply with the regulations and supports that the regulator has the ability to swiftly and effectively deal with those who severely flout the rules or repeatedly fail to comply. The increased penalties and sanctions, coupled with the increase in post-market monitoring activities, sets the stage for an effective deterrent regime.



**CMA asks that the Senate Committee recommend the retention of Schedule 6 of the Amendment Bill in its existing form that provides for an improved advertising system.**

## **CMA Response to Stakeholder Issues that do not refer to the Bill**

CMA is aware that a small group of stakeholders has brought issues to the attention of the Senate which are not topics of discussion applicable to the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*. CMA responds to these issues below.

### **Negative Advisory Statement and Restriction of Traditional Medicine Claims**

CMA consistently supports the use of necessary and important advisory statements on advertisements and product labels, such as ‘if symptoms persist consult your healthcare professional’. The statements are not included within the *Therapeutic Goods Act 1989* but within subordinate legislation.

CMA understands that some stakeholders are supportive of the concept of including a negative disclaimer on the labels and promotional materials of products making claims based upon traditional medicinal use, to the effect that they are not supported by Western scientific evidence and that the products ‘do not work’. Indeed, it appears that these stakeholders desire the complete elimination of traditional indications, to be achieved by the extreme restriction of the list of permitted indications for medicines in the listed category.

Not surprisingly, the stakeholders supportive of the negative statement, and a very limited permitted indications list, are spear-headed by groups such as Friends of Science in Medicine who contend that “...the whole idea here is that we should abandon all alternative and complementary medicines.”<sup>xi</sup>

Research has shown that a negatively-worded statement about the regulatory status of a product has the unsurprising result of decreasing market share for that product. Spinks & Mortimer (2015) found that consumers prefer positively worded statements to negative ones and that “if the intention of including negatively-worded statements is to decrease the likelihood of making poor quality decisions (as opposed to simply decreasing utilisation), it is not clear how such an effect would act in isolation and not ‘spill-over’ to decrease potentially good consumer choices.”



It should be noted that the desire to “abandon all alternative and complementary medicines” is not shared by the majority of healthcare professionals. Along with the burgeoning popularity of complementary medicines among consumers, general practitioners across the industrialised world are increasingly incorporating complementary medicines into their practice, as recognition of their safety profile and therapeutic effects, both scientific and traditional, is growing.

The World Health Organisation (WHO) recognises the long history of traditional medicine and encourages its valid and modern-day use in self-care. The WHO describes traditional medicine as the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of illness.<sup>xii</sup> Complementary medicines that are supported by evidence from a traditional medicine paradigm are Traditional Chinese Medicine, Western herbal medicine, Ayurvedic medicine, and many other systems and paradigms of traditional medicine.

The WHO’s 2008 Congress on Traditional Medicine that included Australia, adopted the ‘Beijing Declaration’. The Declaration includes the following articles:

- The knowledge of traditional medicines, treatments and practices should be respected, preserved, promoted and communicated widely and appropriately based on the circumstances in each country;
- Governments have a responsibility for the health of their people and should formulate national policies, regulations and standards, as part of comprehensive national health systems to ensure appropriate, safe and effective use of traditional medicine;
- Recognizing the progress of many governments to date in integrating traditional medicine into their national health system, we call on those who have not yet done so to take action;
- Traditional medicine should be further developed based on research and innovation in line with the “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property” adopted at the 61st World Health Assembly in 2008.<sup>xiii</sup>

Traditional medicine terminology is currently being standardised by the WHO to provide international equivalency and establish global norms, which will also allow these terms to be used as outcomes in research projects. It must also be noted that traditional evidence claims have been upheld in Australian and international law, verified as coming from a legitimate tradition of use and being compliant with that tradition of use.

Products that make a traditional use claim are already the most heavily regulated in Australia versus elsewhere around the world. In Australia, complementary medicines based on a tradition of use are already required to state this on the product label and in advertisements. For example, “This [medicine]/[herb] is traditionally used in Western herbal medicine to soothe dry cough”. This statement provides abundant transparency to consumers when making purchasing decisions that the basis of the product or claim is a tradition of use.



Adding a negative statement for Australian products, in direct contrast to national and international legal determinations, global health policy and global health research, would be illogical. It would only succeed in damaging the competitiveness and reputation of the Australian complementary medicines industry and our burgeoning exports. Chinese consumers' demand for Australian manufactured products has been well-publicised in recent years, and the Asia-Pacific region is the largest market for complementary medicines in the world, and growing rapidly. The Australian complementary medicines industry is only well-placed to capitalise on this growing demand, supporting jobs across manufacturing, scientific evaluation and research, if allowed and supported to do so.

In summary, CMA notes that the Senate Standing Committee on Community Affairs does not need to make a specific recommendation regarding the Bill. We would respectfully ask for Senate Committee comment that the TGA should not include a negative disclaimer, which would greatly assist in resting an issue that is aggressively targeted by complementary medicine opponents despite it being starkly out of step with the current global trend, the goals set out by the WHO, consumer interests, and Australia's export interests.

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### Advertised Health Claims for Foods

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CMA is aware that some stakeholders have requested the broadening of the *Therapeutic Goods Advertising Code* and TGA advertising complaint system to include foods. As the regulation of food falls under an entirely separate legislative framework, we recognise that it is not a topic of discussion applicable to the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*.

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### Final Word

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CMA looks forward to continued collaboration to develop and implement a regulatory framework that best reflects the current and future interests of the industry, Australian consumers and the Government.

We appreciate the opportunity to make this submission. Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

**Carl Gibson**  
**Chief Executive Officer**  
**Complementary Medicines Australia**



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- <sup>v</sup> The Australian Government Guide to Regulation – Cutting Red Tape (2014), accessed electronically at [https://cuttingredtape.gov.au/sites/default/files/documents/australian\\_government\\_guide\\_regulation.pdf](https://cuttingredtape.gov.au/sites/default/files/documents/australian_government_guide_regulation.pdf)
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- <sup>xiii</sup> World Health Organisation Beijing Declaration. <http://www.who.int/traditional-complementary-integrative-medicine/about/beijing-congress/en/index4.html>