

AUSTRALIAN  
SELF MEDICATION  
INDUSTRY



# **ASMI Response to the Review of Medicines and Medical Devices Regulation**

## **Chapter Nine: Regulation of Complementary medicines**

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## About ASMI

ASMI is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. A full list of ASMI members is available on the ASMI website.

## Introduction

In ASMI's view, complementary medicines should continue to be regulated as therapeutic goods by the Therapeutic Goods Administration.

ASMI is broadly supportive of the current Australian regulatory system for complementary medicines. The current system does not need dismantling, but should be improved in the ways suggested in this response.

## Quality Use of Medicines

ASMI is committed to expanding and promoting Quality Use of Medicines (QUM), which is central to the National Medicines Policy. The goal of QUM is to make the best possible use of medicines by:

- Selecting management options wisely
- Choosing suitable medicines if a medicine is considered necessary
- Using medicines safely and effectively.

Mechanisms and initiatives that are supported by ASMI that contribute to QUM include:

- Development of criteria for consumer-focussed labelling,
- Provision of information and education, in partnership with other key stakeholders
- Setting standards for promotional activities via the ASMI Code of Practice and participation in the co-regulatory arrangements for promotion of complementary medicines.

QUM requires a partnership approach, a close collaboration between consumers, healthcare professionals and other relevant stakeholders in a consultative manner.

## National Medicines Policy

ASMI is a supporter of the National Medicines Policy (the “NMP”), and affirms the description in the Discussion Paper of the NMP as “an important policy framework for medicines nationally”. ASMI notes that the four central objectives of the NMP are:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry.

On the objective of maintaining a responsible and viable medicines industry in Australia, the NMP document states that:

*It is clear that the first three objectives of the National Medicines Policy require the continued existence of a responsible and viable medicines industry in Australia. It is essential that industry policy and health policy be coordinated, providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.*

*International competitiveness will only be achieved if Australian industry can operate in a global environment.*

*Thus regulatory partners should be committed to early achievement of harmonisation of standards and/or mutual recognition, and to the promotion of a strong export culture consistent with standards and ethics endorsed by the World Health Organization. Industry is likewise committed to these objectives, and recognises the need to be forward-looking and proactive. Intellectual property protection should be in line with international standards, and medical research and innovation supported.*

*To the extent possible, partners must recognise the primary position of the consumer. Industry must therefore be able to communicate directly and clearly with health practitioners and provide information to potential consumers about the nature and benefits of their products. They should be able to do so by means of educational materials, Consumer Medicine Information, and responsible advertising, where to do so will enhance the health outcomes of the Australian people.*

In relation to making the partnership work, the NMP document states that:

*All partners need to enact their part of progressing the National Medicines Policy in a manner which is both cognisant and respectful of the interrelationships and expertise of other partners.*

*Different partners, or groups of partners, bear responsibility for the various outcomes, and to various degrees.*

## COAG Principles of Best Practice Regulation

ASMI is a supporter of the COAG *Principles of Best Practice Regulation* and notes that COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. *Establishing a case for action before addressing a problem;*
2. *A range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;*
3. *Adopting the option that generates the greatest net benefit for the community;*
4. *In accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:-*
  - a) *The benefits of the restrictions to the community as a whole outweigh the costs, and*
  - b) *The objectives of the regulation can only be achieved by restricting competition;*
5. *Providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;*
6. *Ensuring that regulation remains relevant and effective over time;*
7. *Consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and*
8. *Government action should be effective and proportional to the issue being addressed*

## ASMI Approach

ASMI appreciates the opportunity to provide comment on Chapter Nine of the Discussion Paper entitled *Review of Medicines and Medical Devices Regulation* (the “Discussion Paper”).

ASMI suggests that the processes underpinning this Review as well as any subsequent reforms to come out of the Review must be consistent with both the National Medicines Policy and the COAG Principles of Best Practice Regulation.

ASMI has been able to undertake consultation with members but in the limited time available, we have not been able to fully explore the details or the impact of all the proposals put forward and we offer this response on that basis. ASMI anticipates that any proposed regulatory changes coming out of this Review will be subject to a full consultation and it will be at that point that all the implications can be assessed.

ASMI has compiled this response with a view to putting forward suggestions for a best-practice regulatory system. The ideal should be an effective, efficient and transparent system. Our proposed solutions have not simply been confined to eliminating regulation, but are intended to make sure that the system works well. We are seeking *better* regulation and not necessarily *less* regulation.

ASMI remains available to the Expert Panel to answer any questions that may arise.

## Executive Summary

ASMI would be disappointed if this Review should simply be an exercise in reducing/removing regulation. The review ought to have a best-practice regulatory system as its goal. Having said that, ASMI is broadly supportive of the current Australian regulatory system for complementary medicines. The current system does not need dismantling, but should be improved in the ways suggested herein.

Consistent with the COAG *Principles of Best Practice Regulation* an appropriate mix of regulatory, co-regulatory and self-regulatory mechanisms is the best way of ensuring that the system is effective, efficient and transparent.

ASMI re-iterates its position that Principle 2 of the Discussion Paper should be appended as follows:

*The level of regulation should be commensurate with the risk posed by the regulated products, with the aim being to establish the minimum effective regulation.*

Disproportionate rigour ultimately impacts the costs of products or reduces access to overseas innovation in this market and disadvantages Australian manufactured products in the global market place with products that can't compete on price.

The ASMI responses in relation to each of the Themes can be summarised as follows:

### Theme 1 – Duplication of regulatory processes

#### **(Issue 1) – TGA assessment of ingredients approved overseas?**

- In principle, there should be little need for the TGA to re-evaluate data where a comparable overseas evaluator has already done so (or where another Australian agency has done so).
- Defining (and subsequently identifying) “trusted” regulators will be a complex process and will require consultation with all affected stakeholders.
- In order to develop a best-practice, risk-based regulatory system we should draw on overseas examples and experiences. However, it is not simply a matter of looking at what other regulators currently do, we need to take into account how they are developing their regulatory systems.
- There is no need for the TGA to *initiate* the adoption of overseas decisions. Any move to refer to an overseas decision should be at the request of the applicant. The level of assessment undertaken by the overseas body will be relevant as will any history of safe use in the overseas market.
- The approval of new ingredients should either be fee-free, or should incorporate data protection or market exclusivity mechanisms to incentivise research into complementary medicines.

#### **(Issue 2) – Interface between advertising and listing evidence requirements**

- Listing is a process concerned with product *indications*. Advertising is a process concerned with product *claims*. The two processes (i.e. listing and advertising) are separate and have separate requirements.

## Theme 2 – Regulatory requirements are not commensurate with risk

### **(Issue 1) – Interface between complementary medicines and pharmaceuticals**

### **(Issue 2) – Threshold for therapeutic goods**

### **(Issue 3) – Interface between complementary medicines and foods**

### **(Issue 4) – Evidence requirements**

### **(Issue 5) – Compliance with GMP**

- Many other markets contain aspects of complementary medicines regulation which are closely aligned with the current Australian system.
- The Review Panel should be cautious about simply recommending the adoption of the current practices in other comparable markets. Rather, the Panel should consider where those markets are heading, especially since the observed trends are towards increased regulatory oversight of complementary medicines.
- A lowering of the regulatory burden ought to be considered for all complementary medicines.
- The regulation of complementary medicines should remain with the TGA.
- The range of product changes that can be made without communicating with the TGA should be examined and the ability for sponsors to make changes by way of notification should be re-introduced.
- The processes for approving new ingredients, naming new ingredients, ensuring GMP compliance, applying Compositional Guidelines and registering complementary medicines should all be reformed to make them transparent, predictable, certain and capable of review.
- Modified pathways for all registered complementary medicines should be introduced.
- The current evidence requirements for listed medicines are onerous and should be revised.
- A simplified claims system could be introduced which would remove the need for sponsors to independently verify claims established by the TGA.
- The PIC/S standard of GMP should be maintained for complementary medicines but additional flexibility and clearer interpretive guidance materials should be developed.
- Substantial reforms are necessary in relation to the advertising of all therapeutic goods.

### **(Issue 6) – Pre-publication approval for advertising**

- Advertising to healthcare professionals should be compliant with industry codes of practice (with all sponsors having to nominate a code to which they would comply – even those sponsors who do not belong to an association)
- The pre-approval of consumer advertising should be expanded to include all media (from all sponsors) directed to consumers. This expansion of the pre-approvals system would be conditional upon the implementation of a self-regulatory pre-approvals system along the lines of the New Zealand Therapeutic Advertising Pre-vetting System (TAPS).
- The “asymmetric delegation” between ASMI and CHC should be removed so as to allow advertisers to choose a single point of contact for multi-media campaigns.
- For certain lower risk activities, such as minor revisions to previously approved advertisements and re-approvals of existing advertisements, a self-regulatory pre-approvals system should be considered along the lines of the New Zealand TAPS system. Under such a system trained and qualified internal company delegates would complement the pre-approvals currently provided by ASMI and CHC.

- The jurisdiction of the CRP should be expanded to include all media and all advertisers.
- The CRP's membership should be expanded and its processes refined.
- The CRP should be able to impose sanctions which are meaningful and effective.
- There should be a formal appeal mechanism in relation to CRP determinations.
- TGA imposed sanctions need to be meaningful, but the TGA already has a range of enforcement powers available and it is simplistic to assume that the problems with the current system can be fixed by merely increasing the size of the penalties.
- ASMI is opposed to the introduction of any US-style "disclaimer" on the labels of complementary medicines.

## Theme 3 – Complex regulatory framework

### **(Issue 1) – Lack of understanding of requirements for listing**

### **(Issue 2) – Poor consumer understanding**

- The regulation of therapeutic goods is unavoidably complex. While it is the responsibility of all sponsors to understand and comply with the requirements, the TGA has an obligation to make the regulatory requirements consistent with the legal underpinning, proportionate to risk and as clear as possible.
- ASMI questions if consumers are interested in the details of the Australian regulatory system. ASMI understands that consumers assume that there is government oversight to make sure that products are safe and effective, but beyond that, there is little apparent interest in the regulatory system itself.

## Theme 4 – Inadequate deterrents

- The TGA already has a range of enforcement powers available.
- ASMI supports enhanced investigative and enforcement powers only on the condition that the enhanced powers are consistent with the Attorney General's Department publication "*A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*".
- ASMI rejects the assumption that the problems with the current system can be fixed by simply increasing the size of the penalties.

## Chapter 9 – Regulation of complementary medicines

### How does the complementary medicines regulatory framework work?

Under this section there is a significant misrepresentation of the time it takes to supply a product. The Discussion Paper states that:

*“...sponsors of listed medicines can generally supply their product in Australia within 48 hours of submitting an electronic application”*

This is not strictly true. Within 48 hours of listing, the sponsor will usually have received an AUST L number for the product. This number then needs to be incorporated into the labelling artwork, labels need to be printed, product manufactured and then labelled. While it might be technically possible to meet this timeframe it would require the product to have been made and the labels to have been printed at risk. It would also require the technology to print AUST L numbers on the labels at the time of packing. Typically there is a 4 to 6 month delay between listing and supply. This misrepresentation has the potential to reinforce the negative stereotypes of complementary medicine sponsors by suggesting that they operate slap-dash, fly-by-night operations, listing and supplying products without proper controls.

### Post-market monitoring

Under this section, the Discussion Paper makes reference to a 2010 report that supposedly indicated that 90% of complementary medicines were found to be non-compliant. This report and the figures attributed to it have been subject to criticism. Importantly, the 2011-2012 ANAO Report *Therapeutic Goods Regulation: Complementary Medicines*<sup>1</sup> at page 110 stated that:

*Targeted reviews are likely to reveal a higher number of compliance failures than random reviews. Therefore no statistically valid, general conclusion can be drawn about the state of compliance among newly-listed medicines at that time from the results of the 110 reviews as a whole. The random reviews alone can provide some general insight, though the small sample size (31) limits the confidence with which conclusions can be drawn.*

Also, more recent materials published by the TGA<sup>2</sup> showed that 27% of random reviews identified compliance breaches. ASMI notes the small sample size of this recent review (41 random reviews finalised). ASMI also notes the absence of details as to the nature of those non-compliances. It is therefore impossible to draw conclusions as to the significance of these figures.

As with the “48 hour” statement above, this glib reference to an industry with “90% non-compliance” only serves to reinforce the negative stereotypes of the complementary medicines industry. It does not set the scene for a meaningful dialogue. It does not reflect the many responsible members of the industry.

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<sup>1</sup> <http://www.anao.gov.au/Publications/Audit-Reports/2011-2012/Therapeutic-Goods-Regulation-Complementary-Medicines>

<sup>2</sup> <https://www.tga.gov.au/complementary-medicines-compliance-reviews-outcomes-2014>

# Theme 1 – Duplication of Regulatory Processes

## Overview

In principle, there should be little need for the TGA to re-evaluate data where a comparable overseas evaluator has already done so (or where another Australian agency has done so).

Defining (and subsequently identifying) “trusted” regulators will be a complex process and will require consultation with all affected stakeholders.

In order to develop a best-practice, risk-based regulatory system we should draw on overseas examples and experiences. However, it is not simply a matter of looking at what other regulators currently do, we need to take into account how they are developing their regulatory systems.

There is no need for the TGA to *initiate* the adoption of overseas decisions. Any move to refer to an overseas decision should be at the request of the applicant. This activity should take place in the context of streamlining processes and data requirements with the aim of removing uniquely Australian requirements. The level of assessment undertaken by the overseas body will, of course, be relevant in determining how much weight can be given to the overseas decision by the TGA. The level of assessment undertaken by the overseas body will also determine the level of assessment (if any) required by the TGA to satisfy the Australian requirements. The extent to which there is a history of safe use in the overseas market ought also to be taken into account.

The approval of new ingredients should either be fee-free, or should incorporate data protection or market exclusivity mechanisms to incentivise research into complementary medicines.

## Theme 1 (Issue 1) – TGA assessment of ingredients approved overseas?

### Ingredient Approval

The issues with regard to ingredient approval by the TGA are discussed in detail below (under the heading of “Exclusivity” and under Theme 2 (Issue 1)).

In summary the current TGA processes should be revised to make them simpler, more efficient, more transparent and more effective. The reforms should:

- Apply to both active ingredients and excipients.
- Not involve the TGA duplicating the work of others.
- Recognise both Australian and international agencies.
- Develop processes that are either fee-free or where fees are charged there should be exclusivity mechanisms in place to encourage innovation.

## Product Approval

The discussion under this point touches upon (but does not examine) the Australian regulatory concepts of “separate and distinct” goods and “groupings” of different goods under the one AUST L (or AUST R) number.

These concepts mean that certain product changes will result in a new ARTG entry for the revised product (and a new AUST L/R number being generated) – unless the changes are of a particular type.

The new entry and new number create an extra level of regulatory complexity that is not present in other markets (for example New Zealand). Changes to the label become necessary (to reflect the new number) and the old entry and the old number continue to represent the older product in the market-place and so must be separately maintained.

While the need for such an approach ought to be investigated, ASMI has suggested some mechanisms through which the impact of these concepts could be reduced, by way of reduced level of detail in the ARTG entry (refer to the table included under Theme 2 (Issue 1)).

### How might a trusted overseas regulator be defined?

From a practical point of view this issue (identifying a trusted international standard) is less pressing for complementary medicines than it is for prescription medicines since many of the complementary medicines contain established substances with Australian-specific branding, labelling or claims.

Any adoption of international decisions should be at the request of the sponsor and should be seen as complementing rather than replacing the Australian decision making process.

In relation to CM applications for new ingredients and new products, the TGA is likely to evaluate the following types of data in relation to substances and products:

- Clinical data
- Safety data
- Toxicological data

ASMI would support the TGA in forming partnerships and work-sharing arrangements with other comparable regulators in the context of streamlining processes and data requirements with the aim of removing uniquely Australian requirements. However it is important to maintain the TGA’s local decision making ability.

There should be little need for the TGA to re-evaluate data where a comparable overseas evaluator has already done so, even if the TGA needed to evaluate a product’s claims and labelling in the context of the Australian market.

Defining (and subsequently identifying) “trusted” regulators will be a complex process and will require consultation with all affected stakeholders. Even if a “trusted” regulator can be identified, the trust may only extend to certain activities, certain products, certain ingredients. For example, if a “trusted” overseas regulator approved an ingredient for use in foods, would the TGA accept that ingredient as approved for use in Australian therapeutic goods? As an excipient? As an active?

## Comparison of the TGA and Other Regulators

Before any process can be commenced by which an overseas regulator might be identified as “trusted” by the TGA, the Australian regulatory system needs to be placed in the global context.

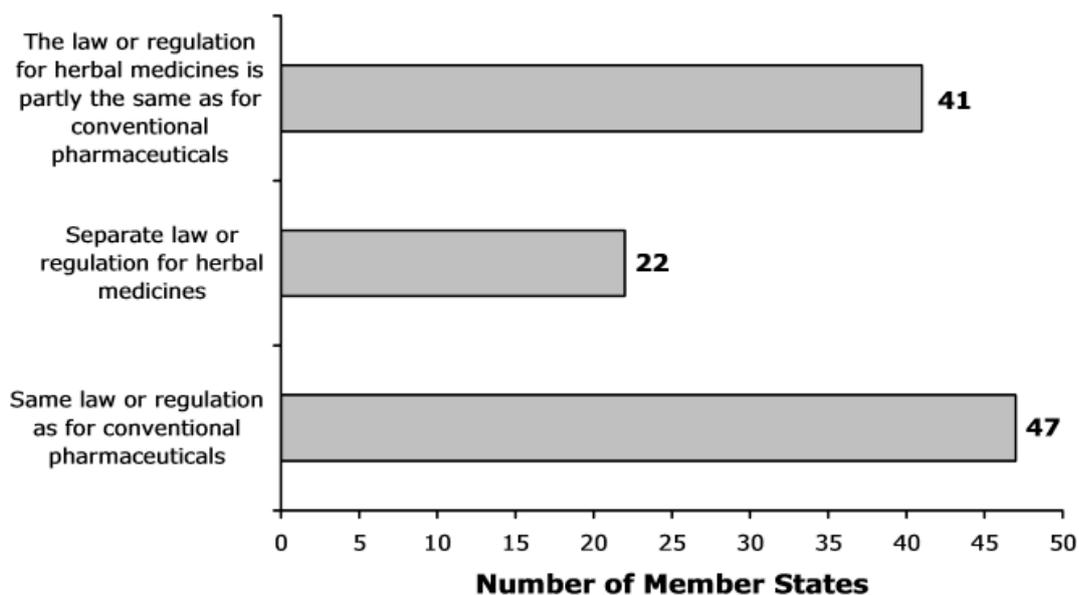
Currently, there is a wide range of approaches that have been adopted by overseas regulators. While there are some similarities in approach there is no global system. Most regulators adopt a tiered approach to regulation based on risk, and many employ regulatory elements that are closely aligned with the current Australian system (for example, lists of approved ingredients, controls on manufacturing sites, product databases and labelling and advertising controls).

A summarised comparison of the major overseas regulators has been included as Attachment 1.

Among established markets there is a trend towards the regulation of traditional herbal products as medicines, while dietary supplements have more typically been regulated under food standards for quality control. More recently there has been a shift towards the development of national registers for all natural health products, such as the Canadian Natural Health Products Directive and the New Zealand Natural Health and Supplementary Products Bill. In other jurisdictions, while dietary supplements are regulated under food legislation and levels of quality control, there are moves towards systems of notification prior to a product being placed on the market, such as in Germany.

Although there are some differences in scope, Australia is consistent with most markets in regulating herbal products as medicines. A WHO global survey on herbal medicine regulation from 2005, identified that of the 92 countries who responded to the survey, the majority regulated herbal medicines at least partially or entirely the same as conventional pharmaceuticals, as demonstrated in the below table.

Figure 1 Type of law or regulation on herbal medicines<sup>3</sup>



<sup>3</sup> <http://apps.who.int/medicinedocs/en/d/Js7916e/7.html>

Currently one of the likely “trusted” international regulators is Health Canada, however the Canadian system includes pre-market evaluation for efficacy, in addition to safety and quality (which is the current standard for TGA evaluation of listed medicines). The Natural Health Products Directorate also incorporates a monograph system as a fast-track to market approach, which helps simplify the application and pre-approval process for common goods.

In order to develop a best-practice, risk-based regulatory system we should draw on overseas examples and experiences. However, it is not simply a matter of looking at what other regulators currently do, we need to take into account how they are developing their regulatory systems.

### Exclusivity

Wherever the TGA processes cannot be made quick and fee-free, or where there has been substantial investment by the applicant, there should be appropriate data protection or market exclusivity to incentivise research into complementary medicines.

A period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment and costs associated with approvals of new substances, new products and new claims. This would act as an incentive to research new therapeutic claims and products.

Getting an over-the-counter or complementary medicine (or ingredient) onto the market in Australia requires a significant initial capital investment, and investment in research. Currently, the lack of investment protection available deters investment in research to support product innovation.

Unlike innovator prescription products, non-prescription medicines generally lack standard patent protection. This affects both over-the-counter and complementary medicines. This lack of intellectual property protection means that sponsors of these products need to find other ways to protect their investment. Typically, this has meant keeping the information out of the public arena. Another option (which is not currently available in Australia) would be to take advantage of some sort of data protection.

Currently there is no provision for data protection in relation to non-prescription medicines and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage. Data protection is a means by which a sponsor's data (new R&D) is protected for a period of time from competitors, and this includes from a subsequent sponsor seeking similar approval for an equivalent therapeutic good. In this context, “data” refers to the information that a sponsor provides in relation to a therapeutic good when seeking some form of approval for that good under the *Therapeutic Goods Act*.

Other jurisdictions, particularly the European Union and the United States, have data protection regimes that are quite favourable to sponsors and make Australia's look rather restrictive by comparison.

Through some form of data protection, albeit brief, sponsors will be encouraged to invest in innovation if they have the opportunity to gain a return on their investment before competing products enter the market. Industry believes that appropriate data protection provisions in the Therapeutic Goods legislation will create an environment conducive to investment in R&D for this important range of medicines.

In ASMI's view there are four broad options for protecting a sponsor's investment in research into non-prescription medicines:

- Keeping the information out of the public arena (which is getting harder to do),
- Data protection (which is not currently available for non-prescription medicines), and
- Patent protection (which non-prescription medicines generally lack)
- Innovation patent protection

ASMI notes that both the industry and the community desire increased access to evidence based complementary medicines and that greater investment in scientific research and development will expand the range of well-evidenced non-prescription medicines available for self-care.

ASMI believes that a period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment costs and, importantly, act as an incentive to research new therapeutic claims and products.

In ASMI's view, there are two methods of implementing data protection, as follows:

- Data exclusivity. Which means a defined period during which subsequent sponsors of equivalent therapeutic goods may not, during the period of data exclusivity, benefit from data provided by the first sponsor. This data exclusivity may take different forms, all ultimately having the same effect, i.e. a prohibition on relevant regulatory bodies from granting approval to subsequent sponsors of equivalent therapeutic goods if the application in question is dependent upon referral to data provided or generated by the first sponsor. This is the form of data exclusivity currently in the Therapeutic Goods Act in so far as concerns new active ingredients (new chemical entities, as opposed to well-established entities). Section 25A of the *Therapeutic Goods Act* provides for a five-year period of data exclusivity, but only in respect of information about new active ingredients (i.e. active ingredients not contained in any already approved therapeutic good) which are not publicly available. This form of data exclusivity prevents the TGA from using data provided by the first sponsor in considering an application put forward by a subsequent sponsor. Emphasis is placed on not relying, as opposed to not disclosing, since generally most of the regulatory bodies under the Act already treat information supplied to them by sponsors as commercial-in-confidence. However, this provision does not apply to new complementary medicine ingredients. Put simply, data exclusivity prevents Person B from using Person A's data package (as submitted to the TGA) to register the same medicine. Unlike a patent, data exclusivity: generally does not require lengthy, complex litigation to enforce; does not prevent Person B, or anyone else, from doing any research; and does not prevent person B from lodging their own data package, if they have one, to register and bring to market a competitor medicine.
- Market exclusivity. Which means a defined, enforced period during which a sponsor that is successful in obtaining some form of approval for a therapeutic good is granted an exclusive market status that prevents subsequent sponsors from obtaining similar approval for equivalent goods during the period of market exclusivity, even if new data is provided. This is analogous to patent protection, which grants the patent holder a monopoly in relation to their innovation for the life of the patent, preventing others from making use of that innovation, even if it is arrived at independently. Currently there is no provision for market exclusivity and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage

There are regulatory impediments to innovation in the non-prescription and complementary medicines industry in Australia and measures need to be implemented to address this market failure and to create an environment more conducive to investment in the generation of regulatory data to support innovative products.

In ASMI's view, *data* exclusivity would be appropriate for:

- New indications, claims and/or dosage regimes for products or ingredients.
- New Listable ingredients.
- New formulations.
- New combinations.

Whereas *market* exclusivity would be appropriate for:

- Rescheduling.

The above forms of data protection will encourage investment in innovation, because they will give sponsors an opportunity to gain a return on their investment before competing products enter the market.

In ASMI's view, data protection and confidentiality can both be used collectively to incentivise and protect research into innovative consumer healthcare products.

Expansion of the existing data protection provisions in the above ways would not require any budgetary outlay by the Commonwealth but would, in fact, be revenue positive for its encouragement of additional investment and employment.

Non-prescription medicines (both over-the-counter and complementary) do not benefit from the same level of intellectual property protection as do prescription medicines and so, measures designed to encourage investment in innovation need to be tailored to suit these differences between the different types of therapeutic goods.

For a full discussion, refer to Attachment 2.

#### Questions for Consideration:

**Given the apparent differences in the definition of complementary medicines internationally and the level of pre-market assessment that they undergo, how might Australia determine "trusted" regulators for the purpose of undertaking assessments of ingredients for use in listed products in Australia?**

See above discussion as to the role of Australian and overseas decisions, the identification of trusted regulators and the differences between the TGA and other regulators.

**If a criteria based approach were to be adopted, what criteria should apply in determining whether an overseas regulator is "trusted" for the purpose of undertaking assessments of ingredients for listed products in Australia?**

Defining (and subsequently identifying) "trusted" regulators will be a complex process and will require consultation with all affected stakeholders. Even if a "trusted" regulator can be identified, the trust may only extend to certain activities, certain products, certain ingredients. For example, if a "trusted" overseas regulator approved an ingredient for use in foods, would the TGA accept that ingredient as approved for use in Australian therapeutic goods? As an excipient? As an active? Furthermore, the TGA would need to be transparent about which regulators were "trusted" and which ones were not.

#### Questions for Consideration:

**Should an ingredient only be considered to have been “approved” by an overseas regulator if it has been subjected to some form of assessment? If yes:**

- **Should this assessment include quality, safety and efficacy?**
- **Should evidence standards be comparable with, or superior to, those currently applying in Australia?**

As per the discussion above, there is no need for the TGA to initiate the adoption of overseas decisions. Any move to refer to an overseas decision should be at the request of the applicant. This activity should take place in the context of streamlining processes and data requirements with the aim of removing uniquely Australian requirements. The level of assessment undertaken by the overseas body will, of course, be relevant in determining how much weight can be given to the overseas decision by the TGA. The level of assessment undertaken by the overseas body will also determine the level of assessment (if any) required by the TGA to satisfy the Australian requirements. The extent to which there is a history of safe use in the overseas market ought to be taken into account as well.

Note that for some ingredients, there may already be a decision from another Australian regulator (e.g. NICNAS, FSANZ) that the TGA may be asked to consider. So this issue is not confined only to overseas regulators.

#### Questions for Consideration:

**If Australia were to adopt approvals of ingredients provided by “trusted” overseas regulators, what additional assessment, if any, should be conducted by the Australian regulator?**

As per the discussion above, there is no need for the TGA to initiate the adoption of overseas decisions. Any move to refer to an overseas decision should be at the request of the applicant. This activity should take place in the context of streamlining processes and data requirements with the aim of removing uniquely Australian requirements. The level of assessment undertaken by the overseas body will, of course, be relevant in determining how much weight can be given to the overseas decision by the TGA. The level of assessment undertaken by the overseas body will also determine the level of assessment (if any) required by the TGA to satisfy the Australian requirements. The extent to which there is a history of safe use in the overseas market ought to be taken into account as well.

Note that for some ingredients, there may already be a decision from another Australian regulator (e.g. NICNAS, FSANZ) that the TGA may be asked to consider. So this issue is not confined only to overseas regulators.

**What value do you believe an assessment by the TGA adds in cases where such an assessment has already been undertaken by a “trusted” overseas regulator?**

See the discussion above.

#### Questions for Consideration:

**Are there aspects of safety or quality that need to be considered in the Australian context? If so, what aspects?**

See the discussion above.

## Theme 1 (Issue 2) – Interface between advertising and listing evidence requirements

#### Questions for Consideration:

**How might evidence requirements for listing on the ARTG and for advertising pre-approval of complementary medicines be harmonised? What changes to evidence requirements would be required?**

It is not simply a matter of harmonising the requirements. At the point of listing the sponsor assesses the evidence in terms of the product *indications*. At the point of advertising the sponsor assesses the evidence in relation to the *claims* made about the product. The claims may well refer to aspects of the product other than the indications (e.g. the comparative benefits of the product versus another product). The advertisement which contains the claims must also comply with the Therapeutic Goods Advertising Code. What is required is a clearer understanding that the two processes (i.e. listing and advertising) are separate and have separate requirements.

## Theme 2 – Regulatory requirements not commensurate with risk

### Overview

- Many other markets contain aspects of complementary medicines regulation which are closely aligned with the current Australian system.
- The Review Panel should be cautious about simply recommending the adoption of the current practices in other comparable markets. Rather, the Panel should consider where those markets are heading, especially since the observed trends are towards increased regulatory oversight of complementary medicines.
- A lowering of the regulatory burden ought to be considered for all complementary medicines.
- The regulation of complementary medicines should remain with the TGA.
- The range of product changes that can be made without communicating with the TGA should be examined and the ability for sponsors to make changes by way of notification should be re-introduced.
- The processes for approving new ingredients, naming new ingredients, ensuring GMP compliance, applying Compositional Guidelines and registering complementary medicines should all be reformed to make them transparent, predictable, certain and capable of review.
- Modified pathways for all registered complementary medicines should be introduced.

- The current evidence requirements for listed medicines are onerous and should be revised.
- A simplified claims system could be introduced which would remove the need for sponsors to independently verify claims established by the TGA.
- The PIC/S standard of GMP should be maintained for complementary medicines but additional flexibility and clearer interpretive guidance materials should be developed.
- Substantial reforms are necessary in relation to the advertising of all therapeutic goods.

## Theme 2 (Issue 1) – Interface between comp. medicines and pharmaceuticals

### Comparison with other markets

The Discussion Paper states that *“Australia’s regulatory framework for complementary medicines is largely out of step with other international jurisdictions”*. This is not true.

As discussed above (under Theme 1 (Issue 1)) and as described in Attachment 1, while there are similarities between the various jurisdictions, there is no one consistent approach. In fact, many other markets contain aspects of complementary medicines regulation which are closely aligned with the current Australian system.

While we should certainly draw on overseas examples and experiences, we should be looking at where those other regulators are heading rather than simply where they are now. For example:

- New Zealand currently has lower levels of regulatory intervention than Australia, however, an entire government apparatus (the Natural Health and Supplementary Products Bill) is being proposed.
- ASEAN member states are moving to implement uniform controls on Traditional Medicines and Health Supplements.
- In the US, there is a new Dietary Ingredient Notification guidance which provides a framework for new ingredients and there is increased enforcement of the updated manufacturing standards.

The Review Panel should therefore be cautious about simply recommending the adoption of the current practices in other comparable markets. Rather, the Panel should consider where those markets are heading, especially since the observed trends are towards increased regulatory oversight of complementary medicines.

### Impact of Regulatory Burden

Sponsors of therapeutic goods are subject to the following burdens:

- Regulatory fees and charges.
- Costs of building and maintaining compliant manufacturing sites.
- Costs of acquiring compliant raw materials, packaging and uniquely Australian labelling.
- Costs associated with maintaining regulatory compliance.
- Delays awaiting regulatory approvals.

These burdens are intended to protect consumers and the costs are inevitably passed on to them.

Disproportionate rigour further impacts the costs of products or reduces access to overseas innovation in this market and disadvantages Australian manufactured products in the global market place with products that can't compete on price.

There is also a tension in establishing the right level of regulatory burden. Where products are subject to different regulatory requirements in different markets, then products from these different markets may find it hard to compete. This issue is most apparent in relation to products at the cosmetic/therapeutic and food/therapeutic interfaces. For example:

- The Australian marketplace may initially appear attractive for importing a product made overseas to a lower standard, on the basis of a lower cost of goods. However the regulatory costs required to enter the Australian marketplace in terms of the burdens listed above may represent a significant barrier. (Hence the appeal for consumers of online purchase of overseas complementary medicines.)
- On the other hand there is a certain premium (in terms of quality and cost of goods) that attaches to Australian made products as a result of the higher regulatory standard imposed here. This can either translate into a marketing advantage or a price point disadvantage in those markets into which the Australian made products are exported.

It is therefore essential that the regulatory burden appropriately reflects the risks to consumers.

ASMI suggests that complementary medicines currently regulated by the TGA could be subjected to a lower level of regulatory intervention, on the basis that those products represent the lowest risk to consumers. The reduction of regulatory intervention will reduce the burden on industry and result in more products becoming available at a lower price to consumers. Care only needs to be taken not to reduce the regulatory requirements to such an extent that consumer safety is jeopardised. For example, while a daily multivitamin product poses a low risk to users (by virtue of its indications and low risk ingredients) an ineffective, poor quality or adulterated product exposes the user to a substantial risk of harm (given the daily use of the product).

## Relevant Agency

ASMI suggests that all complementary medicines should remain within the jurisdiction of the TGA for the following reasons:

- Classification as a therapeutic good allows products to make therapeutic claims and allows products such as calcium and vitamin D to make restricted representations (e.g. in relation to osteoporosis). Retention of these claims is of benefit to consumers.
- The TGA is a national body, and so can impose standards throughout the entire market (without the difficulties inherent in a system managed by the States).
- The national regulation of these products is essential for consumer protection.
- The TGA has expertise regulating a wide range of therapeutic products (expertise not necessarily shared by other agencies).
- Even if products are removed from the TGA's oversight they would still need to be regulated to some extent by some other body (the ACCC has been suggested by some stakeholders) and so this would simply be shifting responsibility as opposed to improving regulation.
- The TGA's focus on therapeutic goods means that regulatory oversight is not diluted by oversight of other product categories (for example, if the ACCC were to regulate these products then the

compliance activities in relation to therapeutic goods would need to be prioritised against activities in relation to banking, retail, telecommunications etc.).

### Regulation of the lowest-risk products

ASMI suggests that the following criteria should be used to determine whether a particular product poses the lowest-risk to consumers:

- The safety of the ingredients themselves.
- The route of administration.
- The risks associated with the claims.
- The nature of the conditions being addressed.
- The nature of the population using the product.
- The impact of poor quality, adulterated or contaminated products.

### Summary of Reforms

The reforms that ASMI has in mind would subject all listed complementary medicines to a decreased regulatory burden. The key elements of the scheme are summarised in the following table:

Aspect	Proposal	Comments
ARTG entry	Retain the ARTG database but only record the following minimum data: <ul style="list-style-type: none"> <li>• Product Name</li> <li>• Sponsor's name</li> <li>• Name and concentration of active(s)</li> <li>• Descriptive formulation framework</li> <li>• Picture of the product label (submitted post-launch)</li> </ul> Only allow ingredients from a pre-approved list. Only allow indications from a pre-approved list.	This level of detail would allow stakeholders to uniquely identify a product, but would allow sponsors to make a range of product changes without triggering a regulatory impact. Sponsors would retain the credibility associated with a TGA listed good. Consumers would retain the protection of a national register. The AUST L number would still appear on the label. A reduced level of detail reduces the regulatory burden associated with the initial listing and with product maintenance.
Variations	# Allow product changes to be made by notification.	Where a product change does impact on the ARTG entry then that change should be done by way of notification only. Noting that, the reduced database contents will allow a range of changes to be made which will not impact the ARTG entry.

Aspect	Proposal	Comments
Grouping	<p># Minimise impact of product changes on the AUST L or AUST R number.</p> <p># Update the Therapeutic Goods regulations to reduce the list of changes that lead to a “separate and distinct” good.</p>	<p>Any change to the AUST L or AUST R number results in a costly change to the labelling.</p> <p>Reducing the range of changes which necessarily result in a new AUST L or AUST R will reduce costs and regulatory burden.</p>
Approval of new ingredients (actives and excipients)	<p># The TGA should not be duplicating the work of others, but should recognise the decisions of both Australian and international agencies when requested by an applicant.</p> <p># The approval processes should either be fee-free or where fees are charged there should be exclusivity mechanisms in place to encourage innovation.</p> <p># Where an ingredient has already been evaluated by another agency in Australia or overseas, the process for including the material in the Register should simply be an administrative activity.</p> <p># Where an ingredient has not been approved in a comparable market, the processes should be streamlined, with one of two potential approaches. Firstly, the process for including the material in the Register could be fee-free (covered out of the combined revenue from annual fees). Secondly, the TGA could provide some form of exclusivity to the initial applicant.</p>	<p>Endorsing the decision of a comparable regulator should simply be an administrative exercise by the TGA.</p> <p>Charging the applicant to approve a material which then becomes available to all sponsors disadvantages the applicant, enables “free-riders” and is a disincentive to innovation.</p> <p>The TGA has recently used their general revenue to fund the approval of <i>Garcinia cambogia</i>.</p>
Raw material standards	<p>Permit food grade ingredients to be used as alternatives to pharmacopoeial grades (for oral products).</p> <p>Permit cosmetic grade ingredients to be used as alternatives to pharmacopoeial grades (for topical products)</p>	<p>Reduced costs of ingredients.</p> <p>Greater flexibility for sponsors.</p> <p>No appreciable increase in consumer risk.</p> <p>Allows for greater parity of cost of goods in export markets.</p>
Manufacturing standards	<p>Maintain PIC/S standard but adopt additional flexibility and clearer interpretive guidance materials for complementary medicines (e.g. providing interpretive guidance for an appropriate risk based approach to the application of PQR and Ongoing Stability) (e.g. providing clearer guidance on release for supply by third party contactors)</p>	<p>Sponsors would retain the credibility associated with PIC/S standard, but would be allowed some flexibility for lowest risk products.</p> <p>Consumers would retain the protection of the PIC/S standard.</p>

Aspect	Proposal	Comments
	TGA to align clearance frequency with overseas agency audits (i.e. If the overseas agency audits every 3 years then the TGA clearance should be for 3 years)	
Other product standards	# Revise TGO 77 to allow alternative Preservative Efficacy Testing.  # Revise TGO 78 to appropriately distinguish between registered complementary medicines and other registered medicines (e.g. the dissolution requirements imposed on multi-vitamin and multi-mineral preparations) (e.g. the active ingredient limits for content applied to complementary medicine preparations).	More appropriate requirements will result in a reduced need for section 14 exemptions.
Simplified claims system	Implement a system whereby the TGA establishes sets of claims for specific types of products so that if sponsors market those products with those claims then they would not have to hold evidence to substantiate the claims. The most likely types of products would be: <ul style="list-style-type: none"> <li>• Vitamins and minerals for supplementing inadequate dietary intake.</li> <li>• Herbal and other products for health maintenance purposes.</li> <li>• Products making structure/function claims.</li> </ul>	Sponsors are provided with an easier regulatory pathway for routine products.  Reduced regulatory costs.  Reduced timelines.  Consumers are protected through the use of permitted claims.  There would also need to be a mechanism for adding claims to the system.
<i>Proposals marked “#” could be applied to all complementary medicines and not just listed complementary medicines.</i>		

## Approval of new ingredients

The approval of a new ingredient can be a costly and time consuming exercise and at the end of that process, the new ingredient will be available for all sponsors to use (not just the sponsor who invested in the application).

In broad terms there are two ways to approach this issue;

- Firstly the TGA could make the process fairer and less burdensome to the initial applicant by not charging a fee for the application.
- Secondly, the TGA could provide some form of exclusivity to the initial applicant to incentivise applications.

The current system of including new excipient ingredients in listed medicines is overly onerous and can delay product launches for reasons other than quality or safety. In order to include a new ingredient in a

listed medicine one must first apply for inclusion of the ingredient in the Register by submitting an application for an approved name and a safety/toxicological assessment.

An important limitation of the current process for approving new ingredients is the absence of an appeal or review mechanism should the new substance application be rejected. ASMI suggests that a formal appeal mechanism should be included, given the significant impact that such a decision could have on the applicant.

The following specific concerns have been raised by ASMI members about the evaluation process:

- There is currently no transparency regarding the progress or status of a new complementary medicine substance submission.
- There are no well-defined timelines for each stage of the evaluation process.
- There are undocumented processes (for example, final review and sign off by the TGA executive) that have not been publicly articulated by the TGA.

In support of these comments, ASMI provides the following case studies:

In relation to a concentrated omega-3 ingredient, which cost the applicant \$8,680 and took 508 calendar days to approve, an ASMI member has stated:

*“The substance was a non compendial substance and the TGA forced compliance with a compendial monograph. This necessitated the production of a unique product for the Australian market, delaying launch and increasing production costs by around 20% making the substance uncompetitive in the marketplace. This has caused ongoing problems as it has proven difficult to always meet the TGA stipulated specification. The outcome of the TGA action was a failed product launch.”*

In relation to a freshwater algae extract, which cost the applicant \$20,300 and took 639 calendar days to approve, an ASMI member has stated that:

*“It became apparent that there was another applicant for an almost identical substance. Finalisation of our application seemed to be delayed as the TGA tried to manage two submissions for essentially the same substance”*

In relation to an extract of a succulent herb, which cost the applicant \$15,200 and took 585 calendar days to reject, an ASMI member has stated that:

*“The application was almost through the evaluation process and we were working through the remaining quality related questions to enable the drafting of a mutually acceptable compositional guideline. Then the TGA went quiet and we received notification that the application had been rejected at the TGA executive level ... it was truly very strange and highlighted the lack of transparency of process and decision making.”*

In relation to animal cartilage material, which has cost the applicant \$16,600 and so far taken 406 calendar days, an ASMI member has stated that:

*“10 months after the application was submitted, the TGA requested a meeting to discuss the application. An agenda was requested for the meeting so we could be suitably prepared. At the meeting the main issue discussed was not even included on the agenda.*

*It is an issue that potentially jeopardises the chances of success of the application. Subsequently we have provided TGA with information that shows that the substance has been approved by Health Canada for use in natural health products ... in an effort to “conclude this application as soon as possible”, the TGA then imposed an unreasonably short timeframe for us to provide additional information, otherwise a decision would be made by the TGA on the information already available to them. This was despite the TGA refusing to commit to, or agree to, any timeframe to review the additional information that was going to be submitted.”*

In relation to a marine extract, which has cost the applicant \$9,665 and so far taken 101 calendar days, an ASMI member has stated that:

*“The application was submitted in December 2014. The TGA had some internal issue within the finance area that resulted in them not being able to issue an invoice until February 2015 (a delay of 54 calendar days). We have been advised that there will be no effort made to make up the time lost. In addition the invoice that was issued did not even specifically reference the application.”*

The ASMI position can be summarised as follows:

- Where an ingredient has already been evaluated by another “trusted” agency either in Australia or overseas, the process for including the material in the Register should simply be an administrative activity and should not attract an application fee (but should be covered out of the combined revenue from annual fees).
- Where an ingredient has not been approved in a comparable market, the processes should be streamlined, but there are two potential approaches to reform:
  - Firstly, the process for including the material in the Register would not attract an application fee (but would be covered out of the combined revenue from annual fees). This would make the process fairer and less burdensome to the initial applicant.
  - Secondly, the TGA could provide some form of exclusivity to the initial applicant. This would incentivise applications.
- In any event, the processes need to be clearly documented, transparent and have published timelines.
- There should be a formal appeal or review mechanism if the new substance application is rejected.

### Uniquely Australian names for ingredients

As a further reform to the processes for approving new ingredients, the TGA should avoid developing uniquely Australian ingredient names.

Also, the TGA should begin a process of revoking existing Australian-specific ingredient names and replacing them with internationally harmonised names. However, this would need to be very carefully managed so as to avoid further unnecessary costs and to minimise consumer confusion.

In a 2013 consultation on International Harmonisation of Ingredient Names (IHIN), the TGA identified 472 ingredients which had uniquely Australian names (and this total excluded herbal ingredient names). This additional regulatory burden does not protect or assist consumers and only serves to make the regulation more complex and products more expensive.

The ASMI response to the IHIN consultation has been included as Attachment 3.

In summary, ASMI believed that while the IHIN project allowed the TGA an opportunity to establish an effective naming policy the TGA's proposals provided limited consideration of complementary medicines, listed OTC medicines and excipients.

## GMP processes

The TGA is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and adopts the PIC/S Guide for Good Manufacturing Practice for Medicinal Products. This underpins existing Mutual Recognition Agreements (MRAs) and Memoranda of Understanding (MOUs) currently in place between the TGA and other Governments.

While the adoption of the PIC/S guide and the agreements with other governments provide consumers with an assurance of quality products and provides Australian made products for export with high quality credentials valued in other markets, there are a number of improvements that can be made to the TGA's processes which would not adversely impact product quality.

ASMI suggests that the following proposals be considered:

- The TGA should align the Clearance review periods with other agency review periods (i.e. If the overseas agency audits every 3 years then the TGA clearance should be for 3 years). Extensions to the TGA clearance are an inefficiency to be avoided.
- The TGA should cease conducting multiple desk top audits for the same site on behalf of numerous sponsors. There should be one audit per site. Where the costs cannot be easily distributed amongst sponsors, the TGA should consider covering the costs out of the combined revenue from annual fees. This represents unnecessary duplication.
- The TGA should re-consider its policy of only recognising audits from comparable regulators that take place within that other auditor's geographical boundaries (e.g. if the TGA can accept an MHRA audit conducted on a site within the UK, why can't the TGA accept an MHRA audit conducted on a site in India?).
- ASMI commends the TGA's OMQ for its initiatives to work more closely with other agencies to develop an understanding the other agencies processes, approaches and standards. We encourage further development of trust with other PIC/S member agencies, beyond API inspections to also include finished product inspections. This ought to increase the TGA's ability to rely on overseas documentation and reduce the number of TGA requests for additional information where, in the TGA's view, the overseas documentation is insufficient. This is of particular importance where products are regulated differently in other markets. For example, where sunscreens are regulated as cosmetics and complementary medicines are regulated as dietary supplements. The benefits of MRAs and MOUs in recognising comparable authority's audits and the broadening base of PIC/S member countries therefore may not extend to these products, even when manufactured in a pharmaceutical grade plants. The relevant comparable authority has no cause to routinely audit the site for what they consider to be "non-medicinal" products. The impact is the ongoing (high) cost of mandatory TGA site inspections for what are the lowest risk products.

## Compositional Guidelines

When a new complementary medicine substance is evaluated and approved it results in the requirement for the substance to comply with an existing monograph of a default standard (such as BP, USP or Ph. Eur.) or if there is no relevant monograph a compositional guideline is generated to define the minimum quality standard for the substance that has been evaluated. This draft compositional guideline is then published on the TGA website and undergoes a public call for comment period.

Compositional Guidelines currently have no legislative underpinning and therefore compliance cannot be enforced.

ASMI understands that the TGA conducts the public consultation as an exercise in transparency and to provide industry with clarity around specifications and test methods. However, there is no legislative basis for this public consultation.

ASMI does not support the public consultation on draft compositional guidelines.

Instead, where the compositional guideline is the result of a paid application, it should be published in final form without a comment period.

Taking this approach would result in a reduction of administrative burden on the TGA. This includes having to manage a public comment period, respond formally to every submission, undertake further assessment/evaluation if necessary, actively manage the comment period, formally close out and publish the compositional guideline in final form. On this point, ASMI notes that there have been recent instances where compositional guidelines have remained in draft form long after the comment period has closed, leading to industry confusion regarding the validity of the draft compositional guideline, but more importantly concerns around TGA processes. ASMI notes that there are currently compositional guidelines remaining in draft form that date back to earlier than May 2011.

As the TGA is fully cost recovered, removal of non-fee paying work enables the focus to remain on paid applications and more importantly enable more accurate workflow planning.

If a potential applicant wishes to have a similar substance approved/enabled by TGA then they can utilise the same process as the original applicant, which is prepare a formal submission, pay the appropriate application and evaluation fees (based on page count) and join the queue. This is a fundamental premise of a fair and equitable, transparent process.

The publication of the compositional guideline in final form will mean that the substance that has been evaluated for safety and quality is clearly defined.

If the TGA processes for substance evaluation were revised in this way, they would align with those of other paid applications to the TGA. For example, as part of the registration of a new medicine, the quality standard (if the medicine is not the subject of an existing monograph) is agreed upon between the applicant and the TGA. This quality standard is not then published for broad public comment.

**Questions for Consideration:**

**Is the current regulatory regime for complementary medicines in Australia appropriate and commensurate with the risk posed by these products? If not, why not?**

The current Australian regulatory regime is risk-based, but reforms should be made in the ways suggested above. This would take advantage of the opportunities to reduce regulatory burden, to create an efficient regulator and to reduce costs.

**Should complementary medicines in Australia be regulated under a separate legislative framework? If yes, what should be the key features of the framework?**

Complementary medicines should continue to be regulated by the TGA to provide a nationally consistent and centralised authority. Reforms should be undertaken by the TGA to adopt regulations and processes which are commensurate with the risks posed by the product with the aim being to establish the minimum effective regulation.

## Theme 2 (Issue 2) – Threshold for therapeutic goods

**Questions for Consideration:**

**Should low-risk complementary medicines be regulated as general consumer goods, removing the requirement for listing on the ARTG? If yes, why? If not, why not?**

No. For the reasons outlined above (under Theme 2 (Issue 1)) there are numerous advantages to the TGA providing a focussed, national, oversight of products which make therapeutic claims. The threshold should be based on the claims made rather than the risk profile of the product.

**What criteria should be used to determine whether a complementary medicine should be regulated as a therapeutic good?**

Regulation as a therapeutic good should be on the basis of the claims made in relation to the product. For example, despite a product being low risk because of the safety of the ingredients themselves, the risks to the consumer may be increased if the product is ineffective, of poor quality, adulterated, or used to treat a serious condition in preference to an orthodox medicine.

## Theme 2 (Issue 3) – Interface between complementary medicines and foods

### Questions for Consideration:

**Should certain dietary supplements, such as water soluble vitamins, be regulated as foods or as general consumer goods rather than as therapeutic goods? If not, why not? What is the rationale for continuing to regulate these products as therapeutic goods?**

No. Refer to the discussion above (under Theme 2 (Issue 1)). All complementary medicines should be regulated by the TGA but with a level of regulatory intervention commensurate with risk.

**If yes, should such goods be regulated as foods or consumer goods?**

N/A

**What criteria should be applied to determine whether a product should continue to be regulated as a therapeutic good?**

As discussed above, regulation as a therapeutic good should be on the basis of the claims made in relation to the product.

### Registered Complementary Medicines

There are a number of reasons why a particular complementary medicine would be *registered* rather than *listed*. For example:

- The use of higher level claims in relation to the product.
- The inclusion of a listable ingredient above a scheduling threshold.

Various regulatory pathways may therefore be appropriate.

ASMI is currently participating on a Business Process Reform Project with the TGA looking at this very issue. In ASMI's view, modified registration pathways will need to balance the requirements (if any) for additional quality, safety or efficacy data with the practicalities of generating such data.

### Questions for Consideration:

**Should the TGA introduce a modified registration pathway for complementary medicines seeking to make higher level health claims that would allow it to only assess the evidence to support the higher level claims?**

Yes. The TGA should also introduce modified pathways for all registered complementary medicines and not just one specific type.

**Questions for Consideration:**

**If yes, what would be the risks and benefits of this approach? How might any risks be mitigated?**

The risks and benefits for each registered complementary medicine will depend on the reason why the product is registered instead of listed. The details are expected to be fleshed out as part of the ongoing Business Process Reform Project with the TGA.

**If not, why not?**

Not applicable.

## Theme 2 (Issue 4) – Evidence requirements

The current evidence requirements for listed medicines are onerous. For example, in relation to the listing of a new product, an ASMI member has stated:

*“We were trying to list a product but in terms of our primary evidence we had a controlled, multi centric, simple blind unpublished study, in addition we had a number of published review articles which would be considered secondary evidence, and a US monograph also secondary evidence. We were advised that unpublished studies should be reviewed by 2 independent reviewers, with appropriate expertise to undertake the review. This was particularly highlighted if we were relying on this evidence as our primary source of evidence to support a specific scientific indication.”*

*“In the end, we were unable to get our evidence over the line in terms of “primary evidence” when we felt that if a US monograph exists along with published review articles, it should be sufficient enough to support a low risk medicine. We were unable to list the medicine ...”*

**Questions for Consideration:**

**Are the current evidence requirements for listed medicines overly onerous? If so in what way?**

The current evidence requirements for listed medicines are onerous. Especially for ingredients with a long established use and scientific evidence to support the indications. A comprehensive literature search and assessment of data is still required for ingredients that are included in authoritative texts or when recent meta-analysis of clinical trials is available. Sponsors still have to review evidence from all sources even when a clear authoritative text is available.

#### Questions for Consideration:

**How could current evidence requirements for listed medicines be altered to reduce the burden on sponsors without reducing consumer confidence that complementary medicines are safe, efficacious and comply with quality standards?**

The original evidence guidance consultation proposed the option of using Sources of Established Evidence (SEE) for well-established ingredients, thereby making the full literature search unnecessary. The evidence requirements should be proportionate to risk (for example, health maintenance claims consistent with a published text should not require a literature review). As discussed above (refer to the table included under Theme 2 (Issue 1)) a simplified claims system could be introduced which would remove the need for sponsors to independently verify claims established by the TGA.

## Theme 2 (Issue 5) – Compliance with GMP

Issues in relation to GMP are identified and discussed above (under Theme 2 (Issue 1)).

#### Questions for Consideration:

**Should Australia remove the requirement for manufacturers of low risk products or ingredients to comply with medicinal Good Manufacturing Practice (GMP) standards?**

**If not, why not?**

**If yes:**

- **What are the risks of removing PIC/S requirements**
- **How could these risks be mitigated?**
- **What would a complementary medicine-specific GMP scheme look like?**

**What is the compliance cost of meeting medicinal GMP standards as opposed to GMP standards applying to other products such as foods?**

As discussed above (under Theme 2 (Issue 1)), the PIC/S standard should be maintained for complementary medicines but additional flexibility and clearer interpretive guidance materials should be developed.

## Theme 2 (Issue 6) – Pre-publication approval for advertising

ASMI's position in relation to advertising of therapeutic goods was discussed in our previous submission to the Review Panel in January 2015. The following discussion is consistent with our previous response.

### Overview

The ASMI position in relation to advertising of therapeutic goods is discussed in detail below, but our proposals can be summarised as follows:

- Advertising to healthcare professionals should be compliant with industry codes of practice (with all sponsors having to nominate a code to which they would comply – even those sponsors who do not belong to an association)
- The pre-approval of consumer advertising should be expanded to include all media (from all sponsors) directed to consumers. This expansion of the pre-approvals system would be conditional upon the implementation of a self-regulatory pre-approvals system along the lines of the New Zealand Therapeutic Advertising Pre-vetting System (TAPS).
- The “asymmetric delegation” between ASMI and CHC should be removed so as to allow advertisers to choose a single point of contact for multi-media campaigns.
- For certain lower risk activities, such as minor revisions to previously approved advertisements and re-approvals of existing advertisements, a self-regulatory pre-approvals system should be considered along the lines of the New Zealand TAPS system. Under such a system trained and qualified internal company delegates would complement the pre-approvals currently provided by ASMI and CHC.
- The jurisdiction of the CRP should be expanded to include all media and all advertisers.
- The CRP's membership should be expanded and its processes refined.
- The CRP should be able to impose sanctions which are meaningful and effective.
- There should be a formal appeal mechanism in relation to CRP determinations.
- TGA imposed sanctions need to be meaningful, but the TGA already has a range of enforcement powers available and it is simplistic to assume that the problems with the current system can be fixed by merely increasing the size of the penalties.
- ASMI is opposed to the introduction of any US-style “disclaimer” on the labels of complementary medicines.

## Advertising Therapeutic Goods to Health Professionals

ASMI was a member of both the Working Group on Promotion of Therapeutic Products and the Code of Conduct Implementation Advisory Group. ASMI endorsed the Working Group's Report<sup>4</sup> and updated our Code of Practice accordingly. Like the other members of the Working Group, ASMI also supported the recommendation to require all sponsors (regardless of association membership) to subscribe to a nominated industry code of practice as a condition of registration or listing.

Unfortunately, the Government in response to the Working Group's Report did not support this recommendation. We now have what is effectively a two-tiered system where members of the industry associations are held accountable to their codes of Practice and non-members are free to promote their products without oversight or sanction.

This situation could be easily rectified by adoption of recommendation 5 from the Working Group's Report which stated that:

*The working group recommends that TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe as a condition of registration/listing on the ARTG.*

Adoption of such a recommendation would allow control through the self-regulatory codes of practice but backed by the force of the *Therapeutic Goods Act* and the *Therapeutic Goods Regulations*.

## Advertising of Therapeutic Goods Direct-to-Consumers

There exists a labyrinth of complex interlocking statutory, regulatory, co-regulatory and customary practice processes, all designed to control the advertising of therapeutic products. There have been efforts over quite some time to improve and simplify these arrangements and ASMI has been in the forefront of these efforts. Most recently, the TGA put out a consultation paper in 2013 examining a range of advertising proposals. While the TGA consultation document had many shortcomings, the following items are of particular relevance here:

- There had been no significant progress since the previous 2010 consultation.
- The consultation document was disparaging of industry (citing potential conflicts of interest and bias as a result of industry involvement in co-regulatory processes – despite there being no evidence to support such views).
- Many of the proposed options did not streamline, clarify or simplify the rules and processes. Indeed a number of the proposed reforms simply re-allocated responsibilities.
- The TGA ignored the ANAO report from 2011-2012 which was critical of the TGA's own complaints handling processes.
- The TGA proposals sought to minimise industry involvement.

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<sup>4</sup> Working Group on Promotion of Therapeutic Products, *Report to Parliamentary Secretary Catherine King* 18 March 2011, pp. 29-30. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/96C6072A13E95EDCCA257BF0001A8E01/\\$File/Report%20of%20the%20Working%20Group%20on%20Promotion%20of%20Therapeutic%20Products.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/96C6072A13E95EDCCA257BF0001A8E01/$File/Report%20of%20the%20Working%20Group%20on%20Promotion%20of%20Therapeutic%20Products.pdf)

- The TGA proposals sought to remedy fundamental problems with the system simply by increasing the size of the penalties available.
- The TGA proposals failed to recognise that the risks posed by a device itself may be different to the risks posed by the advertising of that device.

In relation to the specific issues and proposals, the ASMI response of 19 July 2013 remains relevant and reflects current ASMI policy. A copy of the ASMI response has been included as Attachment 4.

The TGA has yet to respond to the submissions.

In terms of a high-level overview, the following are the most pressing concerns:

- Pre-approvals only applies to certain therapeutic goods (e.g. medicines but not devices)
- Pre-approvals only applies to certain media (e.g. free-to-air TV but not Pay TV).
- For complementary medicines a multi-media campaign requires pre-approval from ASMI and from CHC (e.g. ASMI for the TV component and CHC for the print component)
- The complaints processes are complex and do not effectively cover all media or all advertisers. While the industry association complaints panels have jurisdiction over all media used by members, the CRP does not have jurisdiction over all media (e.g. TV and internet are covered but point of sale materials are not). Complaints about a non-member advertising in a medium that is outside the CRP's jurisdiction cannot be made through any formal process (the TGA claims to have an informal process for such complaints, but no details have been published of the process or the outcomes). So, for example there is no formal complaints process for point of sale materials used by an advertiser unless that advertiser is a member of an industry association. This complex arrangement thereby discriminates against industry association members by subjecting them to complaints and sanction mechanisms which cannot be applied to non-members.
- The CRP cannot impose sanctions.
- There is no formal appeal mechanism in relation to CRP determinations.
- Sanctions need to be enforceable, effective and business impacting.
- The Therapeutic Goods Advertising Code is outdated.

## Co-regulation and the Pre-approval Process

The current co-regulatory arrangement for advertising pre-approvals works well by blending the pragmatism and efficiency of industry with the universal application of the regulations.

Therapeutic goods are not ordinary items of commerce and the advertising controls need to reflect this. For example, misleading or improper advertising of therapeutic goods could lead to consumers using the wrong product for their condition, using an ineffective product, delaying treatment, or failing to seek professional advice. In each of these situations, the preferred outcome would be to prevent the advertising in the first place rather than seeking redress afterwards.

Pre-approval of advertising has worked in Australia to protect consumers. Evidence from both ASMI and CHC shows that of the thousands of advertisements approved each year less than 0.5% are subsequently found in breach.

It is also worth noting that a substantial proportion of the complaints received by the CRP (and the CRP's workload) are in relation to internet advertising (a medium which is not subject to pre-approval). The following table presents the results from the last three TGACC report periods:

Period	Proportion of complaints received by the CRP in relation to the internet
2011/2012	73.5%
2012/2013	69.7%
2013/2014	71.8%

Pre-approval of advertising works in the UK to protect consumers.

ASMI suggests that the UK complaint statistics provided on page 95 of the initial Discussion Paper have been incorrectly interpreted to inappropriately suggest that pre-approval does not work. ASMI disputes this. In support, a copy of the most recent MHRA annual report by their Advertising Standards Unit has been included as Attachment 5.

Importantly, the MHRA make the following statement in relation to the *industry* pre-approval of OTC advertising:

*Since the Proprietary Association of Great Britain (PAGB) reviews all proposed advertising to the public by its members, the number of upheld cases each year in the OTC sector is very small. One of five cases was upheld in the year. It concerned a traditional herbal medicine where the advertising failed to make it clear that product was a traditional herbal remedy registered on the basis of traditional use rather than demonstration of efficacy. [Page 7]*

The MHRA make the following statement in relation to *their own* (targeted) vetting activities:

*The overall result of the survey was that 70% of the products vetted in the survey period had promotional material containing at least one significant issue that had the potential to mislead prescribers. This clearly indicates the need for pre-vetting, that it is indeed adding value and that the current targeting is achieving the aim of raising standards for advertising and promotion of medicines. [Pages 14 to 15]*

Further to this, ASMI has been advised by the PAGB that the PAGB approves approximately 6,000 pieces of advertising per year and that in relation to complaints they receive around a dozen preliminary enquiries per year and of those 2-3 end up with the MHRA.

It is clear that a pre-approvals system protects consumers and can be practically applied to all media.

ASMI therefore advocates for retaining the current pre-approvals system with the following modifications:

- Expand the process to include all media (from all sponsors) directed to consumers (as in the UK). This expansion of the pre-approvals system would be conditional upon the implementation of a self-regulatory pre-approvals system along the lines of the New Zealand Therapeutic Advertising Pre-vetting System (TAPS).
- Remove the “asymmetric delegation” between ASMI and CHC so that ASMI is responsible for approval of all OTC and all complementary medicines advertising and CHC is responsible for approval of all complementary medicines advertising (this would allow a single point of contact

for multi-media campaigns, with sponsors being able to choose which office to submit the materials to).

- For certain lower risk activities, such as minor revisions to previously approved advertisements and re-approvals of existing advertisements, consider a self-regulatory pre-approvals system along the lines of the New Zealand Therapeutic Advertising Pre-vetting System (TAPS)<sup>5</sup>. This system would complement the revised pre-approvals delegation described in the preceding point and would provide effective, flexible and responsive approvals of lower risk activities.
- So as to minimise the impact of the expanded pre-approvals scheme, the TAPS style delegates would be trained and qualified to complement the pre-approvals currently provided by ASMI and CHC. This would allow routine approvals to be done “in-house” quickly and without an associated fee. Efforts would also be made to minimise the cost and time impacts of such a system so that the advantages of the reforms are not outweighed by the increased burden.
- While broadening the scope of the pre-approvals scheme increases costs for all advertisers, the benefits of responsible advertising should outweigh this increase. Further, the deployment of TAPS style delegates would offset the extent of the increase in costs.

## Management of Complaints and Enforcement Powers

### Relevant Agency

While there have been suggestions that other agencies (e.g. the ACCC) assume the compliance role for therapeutic goods, ASMI believes that the TGA remains the appropriate and relevant agency, for the following reasons:

- Classification as a therapeutic good allows products to make therapeutic claims.
- The TGA is a national body, and so can impose standards throughout the entire market (without the difficulties inherent in a system managed by the States).
- The TGA has expertise regulating a wide range of therapeutic products (expertise not necessarily shared by other agencies).
- Even if products are removed from the TGA’s oversight they would still need to be regulated to some extent by some other body (so this would simply be shifting responsibility as opposed to improving regulation).
- The TGA’s focus on therapeutic goods means that regulatory oversight would not be diluted by oversight of other product categories (for example, if the ACCC were to regulate these products then the compliance activities in relation to therapeutic goods would need to be prioritised against activities in relation to banking, retail, telecommunications etc.)

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<sup>5</sup> [http://www.anza.co.nz/Category?Action=View&Category\\_id=262](http://www.anza.co.nz/Category?Action=View&Category_id=262)

## The CRP

To address the issues listed above, and consistent with the ASMI position outlined in Attachment 4, ASMI suggests that the jurisdiction of the CRP should be expanded to include all media and all advertisers.

In addition, the following changes should be made to the CRP to add efficiency, to improve the determinations, to provide effective penalties with appropriate review:

- The beneficial multi-stakeholder membership should be expanded to include a member with communications expertise.
- A triaging step should be included to identify obvious non-compliance.
- The CRP should be able to impose sanctions which are meaningful and effective.
- There should be a formal appeal mechanism in relation to CRP determinations.

## Other Models

ASMI is aware of the following successful approaches which could provide alternative solutions:

- The role of the media organisations in New Zealand in preventing the broadcast of unapproved advertising and in removing non-compliant advertising.
- The role of the Advertising Standards Board in Australia in managing complaints about advertising.
- The roles of the Council for Responsible Nutrition (CRN), the Council for Better Business Bureau and the National Advertising Divisions (NAD) in a US self-regulatory complaints system<sup>6</sup>. Under this system, the NAD is the advertising industry's self-regulatory body which looks at advertising complaints. Advertisers do not have to comply with an NAD determination, but if they do not then the matter is referred to the Federal Trade Commission (FTC) which then gives it a priority review. The practical outcome is that advertisers either comply with the determination or risk the substantial penalties that the FTC can impose.

## Sanctions

ASMI's position in relation to sanctions is described in Attachment 4, and can be summarised thus:

- The TGA already has a range of enforcement powers available.
- ASMI supports enhanced investigative and enforcement powers only on the condition that the enhanced powers are consistent with the Attorney General's Department publication "*A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*"<sup>7</sup>.
- ASMI rejects the assumption that the problems with the current system can be fixed by simply increasing the size of the penalties.

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<sup>6</sup> More information is available here: <http://www.crnusa.org/NAD/>

<sup>7</sup> <http://www.ag.gov.au/Publications/Pages/GuidetoFramingCommonwealthOffencesInfringementNoticesandEnforcementPowers.aspx>

## Label Disclaimer

ASMI is opposed to the introduction of any US-style “disclaimer” on the labels of complementary medicines for the following reasons:

- The true purpose of the label is to explain what the product does, what it contains, how to store it, when to use it, how to use it, when not to use it and when/where to seek further information.
- The label is not for the purposes of educating consumers about the Australian regulatory system.
- There is no evidence that consumers need or want this sort of information.
- There is no evidence that a disclaimer would address any compliance issues.
- There is no evidence that such disclaimers benefit consumers, and in fact, recent evidence from the US<sup>8</sup> reveals that many consumers are unaware of the disclaimer or report that it did not affect their perceptions of a product.
- There is already limited space on the labels of complementary medicines.
- It will be impossible to draft a disclaimer which accurately describes the Australian regulatory system in a few words that apply to all complementary medicines. Even if such a disclaimer could be crafted it will be misleading as soon as the product successfully passes a post-marketing review by the TGA.
- The disclaimer would not be included on the labels of overseas products purchased over the internet. The presence of the disclaimer on product in the Australian market would thereby serve to denigrate the Australian regulatory system.

### Questions for Consideration:

**Should Australia continue to require compulsory pre-vetting of complementary medicines advertised direct-to-consumers or should it move towards a self-regulatory model or combined statutory and self-regulatory models such as that operating in the UK?**

For the reasons outlined above, compulsory pre-vetting should be retained and refined. The current co-regulatory model should be extended to cover all media. Refer to the discussion above.

**If Australia was to adopt a self-regulatory model or a model which combined risk based regulation with self-regulation (such as the UK) what key elements would need to be in place to ensure that public health and safety was protected, while minimising regulatory burden?**

Any self-regulatory model would need some form of regulatory backing in order to have application to those advertisers who did not belong to an industry association. Refer to the discussion above.

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<sup>8</sup> <http://content.healthaffairs.org/content/34/3/438.abstract#xref-corresp-1-1>

**Questions for Consideration:**

**Should listed complementary medicines be required to include a disclaimer in all advertising materials and on product labels advising consumers that statements / claims have not been independently assessed by the TGA?**

No. See the discussion above.

## Theme 3 – Complex regulatory framework

### Theme 3 (Issue 1) – Lack of understanding of requirements for listing

The regulation of therapeutic goods is unavoidably complex. It is the responsibility of all sponsors to understand and comply with the requirements. Having said that the TGA has an obligation to make the regulatory requirements consistent with the legal underpinning, proportionate to risk and as clear as possible.

ASMI continues to work with the TGA to draft clear regulatory guidelines.

**Questions for Consideration:**

**Should sponsors of complementary medicines have to undergo compliance training before being able to list a product on the ARTG? If yes:**

- **What evidence is there that such a scheme would increase compliance?**
- **What would the impact of this be on sponsors in terms of additional costs and time to market? Would it delay consumer access to new products?**

See the discussion below on the licensing of sponsors (under Theme 4)

**If not, what other strategies might be put in place to increase sponsors' understanding of regulatory requirements and / or increase compliance with regulatory requirements?**

See the discussion below on other potential strategies (under Theme 4)

**Is current material user friendly and easily understood by sponsors?**

ASMI continues to work with the TGA to draft clear regulatory guidelines.

## Theme 3 (Issue 2) – Poor consumer understanding

### Questions for Consideration:

**Is the regulation of complementary medicines transparent enough in terms of informing health consumers about the level of scrutiny that the medicine has undergone? If not, how could it be improved?**

ASMI acknowledges that the TGA has made substantial recent progress improving its website and its communications generally. There is now information aimed at consumers explaining the regulation of therapeutic goods in Australia and the role of the TGA.

Having said that, ASMI questions if the majority of consumers are interested in the details of the Australian regulatory system. There is nothing in the discussion paper to demonstrate that consumers are interested and ASMI has seen no evidence that this is the case. Anecdotal evidence suggests that, in general, consumers assume that there is government oversight to make sure that products are safe and effective. Beyond that general assumption, there is little apparent interest in the regulatory system itself.

## Theme 4 – Inadequate deterrents

### Overview

ASMI's position in relation to sanctions is described in Attachment 4, and can be summarised thus:

- The TGA already has a range of enforcement powers available.
- ASMI supports enhanced investigative and enforcement powers only on the condition that the enhanced powers are consistent with the Attorney General's Department publication "*A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*"<sup>9</sup>.
- ASMI rejects the assumption that the problems with the current system can be fixed by simply increasing the size of the penalties.

ASMI notes that the following potential areas of reform may offer solutions:

- Introducing some sort of "flag" or alert to prevent unacceptable products being listed afresh (with slight changes).
- Licensing of sponsors.
- Licensing of raw material suppliers and raw material manufacturers.
- Licensing of wholesalers.

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<sup>9</sup> <http://www.ag.gov.au/Publications/Pages/GuidetoFramingCommonwealthOffencesInfringementNoticesandEnforcementPowers.aspx>

ASMI also notes that the ease with which a listable product can be marketed needs to be matched with a corresponding increase in the level of monitoring (i.e. the easier it is to list a product the greater the need for effective post-marketing surveillance and enforcement).

### Licensing of Sponsors

ASMI notes that unlike Europe there is currently no routine mechanism available to the TGA to assess the suitability of the Quality Management System of sponsors who are not licensed manufacturers.

Many in the industry are now of the opinion that too much responsibility is being placed on the Manufacturer's Authorised Person (AP), responsible for release for supply and that alternative approaches, need to be considered to restore the appropriate balance of responsibility.

Addressing the balance of responsibility between Sponsors and Manufacturers in the Australian Regulatory Framework in the absence of licensing of Sponsors has been a growing concern of ASMI members particularly in Listed Medicines area, where it is quite easy and inexpensive to become a sponsor of products with little understanding of the responsibilities within the regulatory framework.

The issue was highlighted during the implementation of the PIC/S Guide 009-08, where the changes had implications to both sponsors and manufacturers. For the "entrepreneurial" sponsor the only source of communication of the changes would be their manufacturer wanting to renegotiate the GMP Agreement/Supply Agreement to reflect the necessary changes. There is no other method of formal communication from the TGA to the sponsor and ultimately there is no comeback to the sponsor. It will be the manufacturer who will receive the deficiency at the licensing inspection, even though they may demonstrate efforts to make the sponsor comply. The sponsor will not receive a Section 31 letter in relation to the deficiency.

ASMI suggests that licensing sponsors and providing educational seminars would allow small sponsors to gain an understanding of the full extent of their responsibilities and the systems and qualified personnel they need within their businesses to discharge them effectively.

### Licensing of wholesalers

Currently, wholesalers are licensed by the States. Such licensing only applies to the handling of S2, S3, S4 and S8 substances and products. The wholesaling of unscheduled medicines (and unscheduled substances) is not controlled. A system of national controls (under the TGA) would apply to all medicinal substances and products. This incomplete coverage between the Commonwealth medicines regulations and the State & Territory poisons regulations should be remedied by way of Commonwealth oversight of the warehousing, supply, wholesaling and distribution of medicines within Australia.

#### Questions for Consideration:

**Does the current legislative framework provide sufficient deterrents to prevent sponsors from knowingly listing non-compliant medicines on the ARTG? If not, what additional measures should be considered?**

See the discussion above.

**Questions for Consideration:**

**Should complementary medicines that are withdrawn from the ARTG require some form of assessment before being able to be re-listed?**

Yes. There should be a mechanism in place to prevent unacceptable products being listed afresh (with slight changes).

**How effective are the current post-market compliance reviews of complementary medicines in minimising exposure of consumers to non-compliant complementary medicines?**

The post-marketing compliance reviews by the TGA are a necessary element of the regulatory system. The reviews need to be coupled with advertising reforms and with effective sanctions. See the discussion above (under Theme 2 (Issue 6))

## List of Attachments

- 1 ASMI tabulated comparison of the regulation of complementary medicines by the major overseas regulators
- 2 ASMI submission to the Senate Inquiry into Australia's Innovation System(2014)
- 3 ASMI response to the International Harmonisation of Ingredient Names (IHIN) consultation (2013)
- 4 ASMI response to the Regulating Advertising of Therapeutic Goods to the General Public consultation (2013)
- 5 *Delivering High Standards in Medicines Advertising Regulation*, MHRA's Advertising Standards Unit's Annual Report (Jan – Dec 2013)