



# Review of Medicines and Medical Devices Regulation

## Chapter Nine: Regulation of Complementary Medicines

Emeritus Professor Lloyd Sansom AO  
Mr Will Delaat AM  
Professor John Horvath AO





## Purpose of this chapter

This chapter on complementary medicines is being released as an addendum to the Panel's Discussion Paper on Medicines and Medical Devices, which was released in November 2014. You are encouraged to read this chapter together with the Discussion Paper as that document provides further context to the Review of Medicines and Medical Devices Regulation (the Review). The discussion paper is available on the Department of Health's website at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation>

Chapter nine on the regulation of complementary medicines summarises concerns that have been expressed by stakeholders in the past about the regulation of complementary medicines and some of the options put forward by stakeholders to address these concerns. These have been drawn from previous reports, from a summary of stakeholder views and options for change provided to the Panel by the Therapeutic Goods Administration (TGA), and from a review of stakeholder submissions to a range of fora, including the Australian Government National Commission of Audit and consultations on Regulatory Impact Statements conducted by the TGA from time to time. As such, the issues, concerns, and possible options for the future outlined in the chapter do not necessarily represent the views of the Panel.

The chapter is being released to promote discussion and to assist the Panel to form a view about whether there is a shared understanding amongst stakeholders of the issues and options for the future in respect of the regulation of complementary medicines in Australia. The Panel has made best efforts to ensure that the chapter reflects current regulatory practice and issues. However the chapter draws on historic documents and stakeholder submissions on particular issues and this may impact the currency of some of the content. The Panel welcomes corrections of fact as well as input on issues and options. This chapter, along with your responses, will form important input to the Panel's report.

## Have your say

The Panel is seeking feedback from stakeholders to inform its thinking. Written submissions are invited on the *questions for consideration* raised in this chapter plus any other relevant feedback. Stakeholders are also welcome to bring to the attention of the Panel other issues related to complementary medicines that fall within the Review's Terms of Reference.

All submissions received by the due date will be analysed and considered by the Panel in formulating its recommendations to government. The Panel has no capacity to respond to individual submissions, but may seek further information or clarification of issues as necessary.

It is the intention of the Panel to publish submissions that it receives on the Review's webpage (follow the link at [www.health.gov.au](http://www.health.gov.au)). Please complete the Review of Medicines and Medical Devices Submission Cover Sheet (Review Cover Sheet) indicating your permission (or otherwise) for this to occur. The Review Cover Sheet is at Appendix 1 or may be downloaded from the Review's [webpage](#).

## **Lodging your submission**

Completed submissions, in Word 2010 format and PDF format, accompanied by a Review Cover Sheet, can be lodged via email to [medicines.review@health.gov.au](mailto:medicines.review@health.gov.au) or posted to:

Review of Medicines and Medical Devices Regulation Secretariat  
Department of Health  
MDP 67  
GPO Box 9848  
CANBERRA ACT 2601

Submissions are due by COB **Wednesday 8 April 2015.**

Submissions received after this date may not be considered by the Panel.

Please email the Review Secretariat should you have any questions on the process:  
[medicines.review@health.gov.au](mailto:medicines.review@health.gov.au).

## Table of Contents

Purpose of this chapter.....	i
Have your say.....	i
Lodging your submission.....	ii
Table of Contents.....	iii
ACRONYMS .....	iv
BACKGROUND TO THE REVIEW .....	1
Review Terms of Reference .....	1
Background .....	1
Scope of the Review.....	1
Additional requirements.....	2
Timeframe for the Review .....	3
Expert Panel .....	3
CHAPTER NINE: REGULATION OF COMPLEMENTARY MEDICINES.....	5
How does the complementary medicines regulatory framework work?.....	6
Post-market monitoring.....	7
Regulation of complementary medicines in Australia – identified issues.....	7
Theme 1: Duplication of regulatory processes .....	8
Theme 2: Regulatory requirements are not commensurate with risk .....	12
Theme 3: Complex regulatory framework.....	21
Theme 4: Inadequate deterrents.....	23
APPENDIX 1: REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET .....	27

## ACRONYMS

ACCC	Australian Competition and Consumer Commission
ACCM	Advisory Committee on Complementary Medicines
ANAO	Australian National Audit Office
ANZTPA	Australia New Zealand Therapeutic Products Agency
ARGCM	Australian Regulatory Guidelines for Complementary Medicines
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self Medication Industry
CMA	Complementary Medicines Australia
CRP	Complaints Resolution Panel
DSHEA	Dietary Supplements Health and Education Act 1994 (US)
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration (US)
FTC	Federal Trade Commission (US)
GMP	Good Manufacturing Practice
HSA	Health Sciences Authority (Singapore)
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
NHP	Natural Health Product
NNHPD	Natural and Non-prescription Health Products Directorate (Canada)
OTC	Over-the-counter Medicines
PAGB	Proprietary Association of Great Britain
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council

## BACKGROUND TO THE REVIEW

On 24 October 2014 the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash announced the establishment of an expert panel to undertake an independent Review of Medicines and Medical Devices Regulation (the Review). The Review will examine the Therapeutic Goods Administration's regulatory framework and processes in respect of prescription, over-the-counter, and complementary medicines and medical devices with a view to identifying:

- Areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

### Review Terms of Reference

The Panel has been asked to undertake the Review in accordance with the following Terms of Reference.

#### Background

1. Australia has, by a number of different measures (life expectancy, survival with cardiovascular disease, survival with a range of cancers), amongst the best health outcomes of the OECD countries.
2. The regulatory framework of the Therapeutic Goods Administration (TGA) provides an important protection to the Australian community ensuring only safe and effective medicines and medical devices are granted authority to be marketed and/or exported.
3. The TGA also performs crucial post-market roles including the regulation of advertising for therapeutic products and the monitoring of adverse events to ensure the ongoing safety of therapeutic products.
4. A safe and effective regulatory framework for medicines and medical devices should balance safety and market access priorities to the benefit of patients and industry and align with the government's commitment to increase productivity and competitiveness.
5. It is timely to review the regulatory framework and processes under which the TGA operates, to identify opportunities to improve its operations. This will ensure the TGA is able to operate effectively and efficiently in comparison with high quality international regulators, in respect of regulatory imposts such as timeframes and costs to industry, while also maintaining appropriate public health and safety protections.

#### Scope of the Review

6. The Review will benchmark TGA regulatory arrangements against trusted international authorities.

7. The Review will make recommendations and related implementation information to:
  - a. Ensure there is an appropriate balance between risk and benefit in the regulation of prescription, over-the-counter, complementary medicines and medical devices, as well as access for individuals to unapproved medicines and medical devices;
  - b. Simplify and streamline the approval processes undertaken by TGA. This will include recommendations on:
    - i. fast tracking approvals processes for medicines and medical devices;
    - ii. opportunities for working together with trusted regulators in other jurisdictions, including the potential for work-sharing assessments for products marketed in multiple countries; and
    - iii. exploring how risk assessments, standards and determinations of trusted regulators can be used more extensively by Australian regulators when approving the supply of medicines and medical devices.
  - c. Ensure regulatory arrangements are sufficiently flexible to accommodate developments in medicines and medical devices, including exploring opportunities to streamline approvals that cross regulatory categories;
  - d. Improve the processes that assist industry, researchers and consumers to navigate the regulatory system for medicines and medical devices;
  - e. Support work underway on medical device reforms and clinical trial approval arrangements in Australia; and
  - f. Any other matters that the review committee regards as important and relevant to the safe and efficient supply of effective medicines and medical devices to the Australian people.
8. The Review will not make recommendations in relation to:
  - a. Any aspect of the Pharmaceutical Benefits Scheme;
  - b. Work by the Department of Health on the reimbursement systems, including reimbursement and or subsidy of medicine and medical devices;
  - c. National Health and Medical Research Council arrangements relating to research and development; or
  - d. Work currently underway by the Department of Health and the Department of Industry on ethics processes for clinical trials.
9. The Review report will be provided to the Minister for Health, copied to the Prime Minister, the Assistant Minister for Health, and the Parliamentary Secretary to the Prime Minister responsible for deregulation, by 31 March 2015.

### **Additional requirements**

In addition to the Terms of Reference the Panel has been asked to identify:

- Opportunities for reducing red tape burden in the short and long term.

- Strategies for ensuring red tape reduction can be sustained.
- Issues threatening the achievement of reductions in regulatory burden.

## Timeframe for the Review

The Panel will undertake the Review in two stages:

**Stage one** – The first stage of the Review will focus on the regulation of prescription medicines, over-the-counter medicines and medical devices. The Panel will make recommendations to government on the regulatory framework for these therapeutic goods by 31 March 2015.

**Stage two** – The second stage of the Review will focus on the regulatory framework for complementary medicines. The Panel will have a particular focus on this area of regulation during the second quarter of 2015 with a view to making recommendations to government on the regulatory framework for complementary medicines by mid-2015.

## Expert Panel



### **Emeritus Professor Lloyd Sansom AO (Chair)**

Professor Sansom is a distinguished educator, researcher and policy adviser. He has sat on numerous government and industry advisory groups. He played a major role in the development of Australia's National Medicines Policy and was Chair of the Pharmaceutical Benefits Advisory Committee between 2001 and 2011.



### **Mr Will Delaat AM**

Mr Delaat has over 40 years of experience in the pharmaceuticals industry in a range of roles. He was Managing Director of Merck, Sharp & Dohme (Australia/NZ) for 11 years to 2008 and the Independent Chairman of Medicines Australia until December 2011. Mr Delaat is currently on the Boards of a number of pharmaceutical companies including Pharmaxis Pty Ltd and EnGeneIC Ltd.



### **Professor John Horvath AO**

Professor Horvath was the Australian Government's Chief Medical Officer from 2003 to 2009. He continues to advise the Department of Health as principal medical consultant and is on numerous health related Boards and Committees, including the Prostheses List Advisory Committee, which he chairs.

Page left intentionally blank

## CHAPTER NINE: REGULATION OF COMPLEMENTARY MEDICINES

In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations are referred to as 'complementary medicines'. A complementary medicine is defined in the *Therapeutic Goods Regulations 1990* (the Regulations) as a 'therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.' Designated active ingredients for a complementary medicine are outlined in Schedule 14 of the Regulations:

1. an amino acid;
2. charcoal;
3. a choline salt;
4. an essential oil;
5. plant or herbal material (or a synthetically produced substitute), including plant fibre, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll;
6. a homeopathic preparation;
7. a microorganism, whole or extracted, except a vaccine;
8. a mineral including a mineral salt and a naturally occurring mineral;
9. a mucopolysaccharide;
10. non-human animal material (or a synthetically produced substitute) including dried material, bone and cartilage, fats and oils and other extracts or concentrates;
11. a lipid, including an essential fatty acid or phospholipid;
12. a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis;
13. a sugar, polysaccharide or carbohydrate; and
14. a vitamin or provitamin.

Complementary medicines are regulated as medicines under the *Therapeutic Goods Act 1989* (the Act), which outlines the basic characteristics, such as safety, quality, efficacy or performance that therapeutic goods must demonstrate before they can be lawfully imported, manufactured, supplied or exported in Australia. The Act provides for a two-tiered system for the regulation of medicines that is based upon the assessed risk level of the medicine. Higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves an evaluation of the quality, safety and efficacy of the product. Lower risk medicines are only required to be listed on the ARTG and are not individually evaluated by the TGA prior to being entered on to the Register. The Act also creates various penalties that can be imposed by the TGA or the courts for any breaches of these regulatory requirements.

Australia's regulation of complementary medicines under the same legislative framework as higher risk prescription medicines is unusual. Other comparable international regulators (e.g. Canada, the United Kingdom, the United States and New Zealand) regulate these products differently than

prescription medicines, in recognition of their different risk profile. To illustrate, Canada regulates complementary medicines as Natural Health Products and applies a separate legislative framework to that applied to medicines.<sup>1</sup>

Complementing the therapeutic goods legislation, the TGA issued document, the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM), provides detail on the regulation of complementary medicines to assist sponsors to meet their legislative obligations. Supporting this document is a suite of European Union guidelines adopted in Australia which outline the quality requirements for complementary medicines, including the *Note for Guidance on Quality of Herbal Medicinal Products* and the *Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products*.

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

The Australian community expects medicines on the Australian market to be safe, of good quality, effective and available promptly. There are close to 12,000 complementary medicines available on the Australian market, with approximately two thirds of all Australians using complementary medicines.<sup>2</sup> The vast majority of these medicines are listed on the ARTG, with fewer than 200 products registered on the ARTG.<sup>3</sup>

Registered complementary medicines are considered to be of relatively higher risk than listed medicines, based on their ingredients or indications. Applicants seeking registration of a complementary medicine are required to submit a detailed dossier of information to the TGA, for full evaluation for quality, safety and efficacy prior to being accepted on the ARTG. Medicines registered on the ARTG are assigned a unique AUST R number, which must be displayed on the medicine label.

Listed complementary medicines:

- can only contain certain low risk ingredients in acceptable amounts and for particular roles (eg. active, excipient and/or component) ;
- must be manufactured in accordance with the principles of Good Manufacturing Practice (GMP); and
- can only make indications (claims for therapeutic use) for health maintenance and health enhancement or certain indications for non-serious, self-limiting, conditions.<sup>4</sup>

When listing a medicine on the ARTG, the sponsor must make certifications about quality; compliance with labelling, packaging and GMP standards; and use of approved ingredients. The sponsor must also certify that they hold evidence to support any therapeutic claims. As outlined above, the TGA does not individually evaluate listed medicines before they are entered on the ARTG and, as a result, sponsors of listed medicines can generally supply their product in Australia within 48 hours of submitting an electronic application. Medicines listed on the ARTG are assigned a unique AUST L number, which must be displayed on the medicine label.

## Post-market monitoring

The Office of Complementary Medicines, a division within the TGA, regulates complementary medicines based on an assessment of risks against benefits. In assessing the level of risk, factors such as side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used are all taken into account. A framework of compliance reviews for listed complementary medicines has been developed based on this risk management approach.<sup>5</sup> Medicines can be removed from the ARTG (and therefore the market) if they are found to be non-compliant with the regulatory requirements or if any of the required certifications are incorrect.

In late 2010, the Department of Health reported that, based on 2009-10 data, as many as 90 per cent of listed products reviewed were found to be non-compliant with regulatory requirements, despite the system of self-assessment by sponsors. A significant number of products subsequently required removal from the ARTG.<sup>6</sup>

Following these findings an Advisory Committee on Complementary Medicines (ACCM) was established to provide advice and recommendations to the Office of Complementary Medicines on the inclusion, variation, or retention of a complementary medicine on the ARTG. The ACCM provides scientific and policy advice relating to controls on the supply and use of complementary medicines in Australia, with particular reference to the safety and quality of products and, where appropriate, efficacy relating to the claims made for products. The ACCM currently consists of 10 members with expertise across complementary medical practice, manufacturing of medicines, consumer issues, general medical practice, herbal medicine, naturopathy, nutrition and nutritional medicine, pharmacology, pharmacognosy, toxicology and epidemiology.

In August 2011, the Australian National Audit Office (ANAO) undertook a review of therapeutic goods regulation focussing on complementary medicines (Audit Report No.3 2011-12). This Review made a number of recommendations, including:

- improve the integrity of pre-market listing;
- develop a risk-based approach to targeted post-market reviews; and
- improve transparency of information available to consumers, health professionals and industry.

In December 2011, the TGA released *TGA reforms: A blueprint for TGA's future*, which identified reforms to address the recommendations from the ANAO Report. Since the release of this document, the TGA has undertaken a series of reforms to improve community confidence in the safety and quality of complementary medicines, while balancing the regulatory burden on industry. This included reforms to evidence required to support indications for listed medicines, revising the ARGCM and developing a new framework for post-market reviews which included publishing outcomes of reviews on the TGA website.

## Regulation of complementary medicines in Australia – identified issues

The regulation of complementary medicines in Australia has drawn criticism from both consumers and industry, with concern expressed about the safety and efficacy of listed complementary medicines on the one hand and about over regulation on the other. A range of previous reviews,

inquiries and/or stakeholder consultations have examined aspects of the regulation of complementary medicines in Australia and have identified a number of issues. These issues primarily relate to listed complementary medicines and can be grouped into the following themes:

1. There is duplication of regulatory processes, which creates an unnecessary burden on industry.
2. Some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products.
3. The regulatory framework is overly complex and poorly understood by many of those who have to interact with it.
4. In some areas, the Act provides inadequate enforcement powers and penalty regimes, resulting in a poor deterrent effect and in the TGA not responding to some breaches in a timely manner.

An overview of the issues raised in respect of each of these areas of concern is provided below. The issues, concerns and possible options for the future outlined in each section do not necessarily represent the views of the Review Panel. Rather they have been drawn from: previous reports; a summary of stakeholder views and options for change provided to the Panel by the TGA; and a review of stakeholder submissions to a range of fora, including the Australian Government Commission of Audit Inquiry and consultations on Regulatory Impact Statements conducted by the TGA from time to time. They are documented here in order to promote discussion and to assist the Panel to form a view about whether there is a shared understanding amongst stakeholders of the issues and of options for the future.

### **Theme 1: Duplication of regulatory processes**

In respect of duplication of regulatory processes, stakeholders have identified two key areas that relate to listed complementary medicines:

1. Requirement for TGA assessment of ingredients that have already been assessed and approved by another country.
2. Interface between evidence requirements to list complementary medicines and for advertising pre-approval.

#### ***Issue 1 – Requirement of TGA assessment of ingredients approved overseas***

Listed complementary medicines may only contain low risk ingredients permitted for use in listed medicines. Schedule 4 to the Regulations and Therapeutic Goods Listing Notices provide the types of ingredients eligible for inclusion in medicines listed on the ARTG. The majority of ingredients that can be included in listed medicines are those that were included in therapeutic goods supplied in Australia before the Act came into operation in 1991. Since then, all new active and excipient ingredients must have undergone a safety assessment by the TGA.

If a sponsor wishes to market a complementary medicine that contains an active or excipient ingredient that is not currently approved for use in listed medicines, an application for a new complementary medicine substance must be made to the TGA.<sup>7</sup> The TGA then reviews the data to determine if the substance is of sufficiently low risk to be used in listed medicines. The review involves an assessment of quality (for example: chemical identity, manufacturing process, process

controls and stability) and safety. The efficacy of the substance is not assessed, but the evaluation process includes consideration of the proposed therapeutic indication/s for medicines containing the ingredient to determine if the proposed ingredient is safe at the dose, route of administration, and duration of exposure required for therapeutic effect. There is currently no statutory timeframe for the evaluation of complementary medicine substances, but stakeholders claim that an evaluation can take one to two years to complete.<sup>8</sup> The cost is dependent on the size of the data dossier to be examined. As at 1 July 2014 the applicable fee ranged from: \$9665 for 1-50 pages to \$67,600 for >3000 pages.

According to the Complementary Healthcare Council of Australia, many ingredients that are commonly used in complementary medicines in overseas jurisdictions are not available for use in listed medicines in Australia as the cost and time involved in getting such ingredients approved in Australia are viewed as prohibitive. As a result, the Council claims that 'product savvy (consumers) are increasingly turning to complementary medicines bought online from overseas in order to access innovative products that contain ingredients currently not available in Australia. This, in effect, exports jobs offshore...'<sup>9</sup> It also, depending on the source country, potentially exposes Australian consumers to complementary medicines containing ingredients that have not been assessed for quality and safety. To facilitate more timely access by Australian consumers to innovative complementary medicines, the Complementary Healthcare Council has called for a fast tracked approval process for ingredients that have already been assessed and approved by countries with a comparable regulatory system.<sup>10</sup>

As outlined in the *Industry Innovation and Competitiveness Agenda, An action plan for a stronger Australia*, the Australian Government has adopted the principle that:

*...if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so. All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle.<sup>11</sup>*

In the context of complementary medicines, this principle means that where an ingredient has been approved under a trusted overseas risk assessment, the TGA should not impose any additional requirements, unless there is good reason to do so. This raises a number of issues for consideration:

1. How might a 'trusted international standard or risk assessment' be defined in the context of complementary medicines?
2. Is there good reason why Australia should 'impose additional requirements' in respect of the approval of an ingredient for use in listed medicines?

### ***How might a trusted international standard or risk assessment be defined?***

There is significant commonality in the way major international regulators, such as the European Medicines Agency and the US Food and Drug Administration (FDA), assess new chemical entities that in Australia are required to be registered on the ARTG. They have adopted a Common Technical Document for the submission of data dossiers and undertake a thorough assessment of the medicine for quality, safety and efficacy. In respect of the regulation of complementary medicines there is a much greater degree of variability.

For example, products that are defined in Australia as complementary medicines may be defined in the United States (US) as a food (including a dietary supplement) or a drug (a botanical drug). The determination that something is a dietary supplement or another botanical product depends on the ingredients, claims, and marketing of the product. If a product meets the definition of a 'dietary supplement' under the *Dietary Supplement Health and Education Act 1994* (DSHEA) then it will be regulated as a special category of food. Generally speaking, firms do not need to notify/list or register a dietary supplement with the FDA. A firm does not need to receive any approval before marketing a dietary supplement, nor provide the FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products. However, if the firm wishes to use a new dietary ingredient, notification is required and the FDA will undertake a review of safety data. It is not clear to the Panel the extent to which such a review equates with the review of quality and safety that would be undertaken by the TGA.

Similarly, in Singapore the Complementary Health Products Branch of the Health Sciences Authority (HSA) regulates complementary medicines. The groups of medicines regulated by the HSA can be categorised as Chinese proprietary medicines, other traditional medicines and health supplements. Unlike medicines, health supplements are not subject to approvals, licensing or registration before being sold in the Singaporean market. This is similar to the US regulatory system.

In Canada the Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada regulates complementary medicines under the Natural Health Products Regulations, which came into force in 2004 and fall under Canada's Food and Drugs Act. In the Natural Health Products Regulations, natural health products (NHPs) are defined as:

- Vitamins and minerals.
- Herbal remedies.
- Homeopathic medicines.
- Traditional medicines such as traditional Chinese medicines.
- Probiotics.
- Other products like amino acids and essential fatty acids.

NHPs must be safe to use as over-the-counter products and not need a prescription to be sold. NHPs are evaluated for safety and efficacy before being approved for use in Canada. Once Health Canada has assessed a product and decided it is safe, effective and of high quality, it issues a product licence along with an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM), which must appear on the label.

Given the disparity in how complementary medicines are defined and regulated internationally, how is the Australian public to be reassured that an ingredient 'approved' by an overseas regulator has been assessed with a degree of rigour that is comparable to an assessment by the TGA? One option may be to develop a set of transparent criteria against which overseas regulators would be assessed in order to designate them 'trusted' for the purpose of approving ingredients for use in listed medicines in Australia.

**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?**

**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 use in listed products in Australia?**

As outlined above, there is little commonality between overseas regulators in terms of whether or not ingredients used in listed complementary medicines are required to undergo an assessment for safety, quality or efficacy prior to being available. For example, Canada undertakes a pre-market evaluation of ingredients for quality, safety and efficacy, whereas the FDA only requires notification of a new ingredient, in which case the manufacturer (and distributor) must demonstrate to the FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement.<sup>12</sup> As such, 'approval' of a new ingredient in Canada means something quite different than 'approval' of a new ingredient in the US. In Australia, the TGA assesses quality and safety of a new ingredient, but does not undertake an assessment of efficacy.

**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?**

***Is there good reason why Australia should impose additional requirements?***

The proposal by industry bodies is for a fast track assessment mechanism to be established that will allow speedier consideration by the TGA of applications for inclusion of a new ingredient on the list of permissible substances for use in listed medicines. If it is possible to define a 'trusted regulator' for the purpose of undertaking assessments of such ingredients, and that regulator has approved an ingredient, it could be argued that, unless there are aspects of quality and safety that need to be considered in the Australian context, further assessment by the TGA represents unnecessary duplication which acts as a barrier to timely access by consumers to safe new complementary medicines.

**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?**

**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?**

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

**Issue 2 – Interface between advertising and listing evidence requirements**

At the time of listing complementary medicines on the ARTG, sponsors must certify that they hold information and evidence to support indications and claims. This evidence must be held for the entire time the product is listed on the ARTG.

For complementary medicines, sponsors must submit their advertisements to the relevant delegated authority (Australian Self Medication Industry and/or Complementary Medicines Australia) for pre-publication approval. In doing so, sponsors must demonstrate that their advertisement satisfies the advertising standards, including the requirement not to mislead.

Evidence requirements associated with listing differ from those associated with pre-publication approval. For listing, evidence must support the indications at the time the medicine was included on the ARTG and will be in the form of available open literature, or in some instances clinical trials. For advertising pre-publication approval, the sponsor is not required to demonstrate evidence behind indications but instead satisfy that the claims are not false and misleading.

The TGA has indicated that, to a certain extent, the requirement to comply with the advertising rules and the requirement to hold evidence are overlapping requirements. Harmonising the listing requirements and the advertising requirements could simplify the regulatory regime for sponsors.

**Question 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?**

**Theme 2: Regulatory requirements are not commensurate with risk**

In respect of complementary medicines, stakeholders have identified a number of areas where they believe Australian regulatory requirements are excessive and out of step with requirements internationally. These relate to:

1. Failure to recognise the inherent difference in nature between complementary medicines and higher risk pharmaceuticals.
2. The threshold at which a product is classified as a therapeutic good, which is considered to be too low.

3. Uncertainty surrounding the interface between complementary medicines and food, with implications for the regulation of products such as vitamins and mineral supplements.
4. Evidence requirements, which are considered by some to not be commensurate with the low level claims of listed complementary medicines.
5. The requirement to comply with medicinal GMP for low risk products/ingredients.
6. The requirement to seek pre-publication approval for advertising low-risk complementary medicines.

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

In Australia, complementary medicines are regulated as ‘medicines’ under the Act in the same way as higher risk pharmaceuticals. Stakeholders have expressed concern that, as a result, ‘regulation of the complementary medicines industry is becoming increasingly focused on evaluating complementary medicines against medical criteria – in much the same way that the pharmaceutical industry is evaluated.’<sup>13</sup> They argue that this ‘one-size-fits-all’ approach fails to recognise the inherent differences between complementary medicines and pharmaceutical medicines and has resulted in the Australian complementary medicines industry being regarded as one of the most tightly regulated in the world.<sup>14</sup>

Australia’s regulatory framework for complementary medicines is largely out of step with other international jurisdictions, which regulate complementary medicines under a different (though related) legislative framework to that which applies to higher risk medicines. In many instances, such as the US and Singapore, the regulatory frameworks appear to be less stringent than those applicable in Australia. For example, in the US, the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed.

*There are no provisions in the law for the FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer. Under DSHEA, once the product is marketed, FDA has the responsibility for showing that a dietary supplement is "unsafe," before it can take action to restrict the product's use or removal from the marketplace. However, manufacturers and distributors of dietary supplements must record, investigate and forward to FDA any reports they receive of serious adverse events associated with the use of their products that are reported to them directly.*<sup>15</sup>

Similarly, in Singapore, there is no requirement for health supplements to register or notify prior to entering the market. There is also no list of permitted ingredients, so long as products do not contain substances listed under the *Poisons Act*.

In contrast, the regulation of Natural Health Products (NHPs) in Canada appears to be more stringent than that applicable in Australia. To be legally sold in Canada, all natural health products must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licences. In order to obtain product and site licences, specific labelling and packaging requirements must be met, good manufacturing practice must be followed, and proper safety and efficacy evidence must be provided.<sup>16</sup> NHPs are evaluated for safety, quality and efficacy before being approved for use in Canada. The type and level of evidence required, and the level of

assessment that products are required to undergo is determined based on the risk classification of the NHP.<sup>17</sup>

**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?**

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

***Issue 2 – Threshold for therapeutic goods***

At present, the therapeutic goods legislation requires low-risk complementary medicines, including non-oral aromatherapy products and some homeopathic products, to be listed on the ARTG. Regulation of these products by the TGA causes delays to market and considerable regulatory burden related to the imposition of Pharmaceutical Inspection Cooperation Scheme (PIC/S) GMP requirements and other regulatory compliance requirements such as random audits. In 2013-14 the cost of compliance and monitoring of complementary medicines to government was \$8.9 million.<sup>18</sup>

It could be argued that the risk profile of these products is so low that they would be better regulated as consumer goods. Regulating low-risk complementary medicines outside of therapeutic goods regulation would remove the need for sponsors to comply with evidence and other listing requirements. Further, as these products would no longer be listed on the ARTG they would not receive an AUST L number (which some argue provides a level of credibility with the public, who wrongly assume that the product has been assessed as safe and efficacious by a government authority). If such products were removed from the auspices of the Therapeutic Goods Act they would still be subject to requirements under relevant consumer legislation, including requirements not to make false and misleading claims.

**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?**

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

***Issue 3 – Interface between complementary medicines and foods***

In Australia, most dietary supplements, such as vitamins and minerals, fall within the definition of a therapeutic good and are therefore regulated at the federal level by the TGA while other dietary supplements are regulated as foods by State and Territory food regulatory bodies under the *Food Standards Australia New Zealand Act 1991*. This can create regulatory uncertainty and inconsistency – where similar products with only limited differences in their claims can be regulated under different regimes by different regulators.

Given that dietary supplements are intended to supplement the diet, they tend to have a risk profile and health benefits that are comparable to many food goods rather than therapeutic goods - this is in contrast to other complementary medicines, such as some herbal products, that are recognised as

higher risk. Overseas regulators such as the FDA and Singapore's Health Science Authority classify supplements as a type of food and do not require registration or listing of these products nor do they require medicinal manufacturing standards, although they are still subject to manufacturing standards and inspections. In contrast, Health Canada regulates these supplements as medicines and requires individual pre-market approval prior to supply.

Consideration could be given to the possibility of regulating these products as foods in Australia. In relation to appropriate health claims, this proposition has become more viable since the introduction of *Standard 1.2.7 – Nutrition, Health and Related Claims in 2013*, which provides for both general level claims, as well as high level claims for food goods, including high level claims that refer to osteoporosis and neural tube defects. An alternative approach would be to exclude the unscheduled low risk (e.g. water-soluble) vitamins and low dose minerals from the therapeutic goods framework altogether – they are already sold in supermarkets and convenience stores – and regulate them as general consumer goods. Under this approach, products such as herbally-derived products could still be regulated as low-risk medicines.

**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?**

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

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

In respect to the 2013 food standard, *Standard 1.2.7 Nutrition, Health and Related Claims*, some industry peaks have expressed concern that under this standard, foods are able to make stronger health claims, while having lower manufacturing and evidence requirements, than complementary medicines listed on the ARTG. Further, for complementary medicines to be able to make stronger health claims the sponsor is required to register the medicine on the ARTG, a process that requires a substantial data package similar to that required for the registration of a new pharmaceutical drug.<sup>19</sup> The Complementary Healthcare Council of Australia has called for a modified registration pathway that requires substantiation of evidence for higher level health claims 'without the prohibitive additional cost of redundant product safety testing' relating to an assessment of safety and toxicology data in respect of compounds that have already been approved for use in listed medicines.<sup>20</sup>

**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?**

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

**If not, why not?**

#### **Issue 4 – Evidence requirements**

In listing a medicine on the ARTG, sponsors are required to certify that the medicine complies with all applicable regulatory requirements, including that they hold evidence to support any therapeutic claims in respect to the product. Under Section 26A of the Act, sponsors must:

- hold evidence to support indications at the time the medicine was included on the ARTG;
- retain that evidence at all times while the medicine remains listed; and
- provide that evidence to the TGA if requested to do so.<sup>21</sup>

This evidence must have the same meaning and intent as the proposed indication, be related to the same medicine or active ingredient/s, and have the same therapeutic action and the same context.<sup>22</sup>

The type and level of evidence required varies depending on the type of indication – traditional or scientific – and the sub-category of indication – non-specific/general indications and specific indications. For example, TGA *Guidelines on the evidence required to support indications for listed complementary medicines* provides the following advice in respect of evidence requirements for scientific use:

*Scientific indications are usually supported with data from relevant controlled human clinical trials or studies which may be supplemented by other sources of evidence. The sponsor may also choose to conduct clinical trials on their ingredient/s or medicine.*

*A high quality evidence base for scientific indications should include peer-reviewed original clinical research, systematic review of clinical research, unpublished studies or ‘propriety research’ and secondary sources or non-clinical studies. When using clinical studies, sponsors are required to evaluate and assess each piece of evidence to ensure that it is relevant and of high quality, with some clinical studies more reputable than others. For example, sponsors should assess whether the target group in the study is consistent with the target population of the indication.*

*Additional evidence is also required depending on the sub-type of scientific indication. Sponsors should hold evidence in the form of descriptive studies and evidence-based reference texts to support non-specific scientific indications. To support specific indications sponsors must hold evidence obtained from well-designed controlled trials with randomisation, well-designed analytical studies preferable from more than one centre or research group, or multiple time series with or without intervention.<sup>23</sup>*

While the regulatory system for listed complementary medicines in Australia was designed to have a ‘light touch’, some industry organisations have described the evidence requirements as overly burdensome and out of step with the low risk nature of these medicines. In contrast, health consumers and clinical stakeholders have called for stricter application of evidence requirements in respect of these products.

**Questions for consideration:**

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

**How could the 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?**

**Issue 5 – Compliance with GMP**

To be a listed or registered medicine on the ARTG, complementary medicines must be manufactured in compliance with medicinal GMP standards according to an international standard known as the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Although the approach used for inspections of complementary medicines manufacturers is less stringent than, for example, that used for manufacturers of injectable prescription medicines the PIC/S code is nonetheless designed for medicinal products. As a result, several exemptions are required as PIC/S is not directly applicable to complementary medicine substances/products.

For overseas manufacturers of complementary medicines supplied in Australia, the onus is on the sponsor to ensure that the manufacturer has the required level of GMP clearance. An overseas GMP clearance can be granted by the TGA to a sponsor on the basis of GMP compliance evidenced by any one of the following:

- A GMP Certificate issued by a country with which Australia has a Mutual Recognition Agreement in relation to the relevant overseas manufacturing site.
- A Compliance Verification assessment of a recent GMP inspection report of the relevant overseas manufacturing site prepared by a competent overseas regulatory agency acceptable to the TGA, together with supporting manufacturing documentation supplied by the sponsor or manufacturer.
- A GMP Certificate issued by the TGA following an on-site audit of the relevant overseas manufacturing site.<sup>24</sup>

Internationally, there is no common approach to GMP requirements for low risk medicines. Canada, like Australia, applies medicinal GMP standards. But other regulators such as the FDA, New Zealand and Singapore do not. For example, in Singapore manufacturing standards for food will generally apply, while in the US the FDA has developed a 'Current Good Manufacturing Practice' for Dietary Supplements.<sup>25</sup>

Industry bodies have described the manufacturing requirements for low-risk complementary medicines as overly burdensome and out of step with the risks posed by these products. They argue that Australian complementary medicine manufacturers are suffering, with manufacturing for products supplied in Australia increasingly being carried out overseas as compliance with Australian regulations becomes too difficult and costly on-shore.

It could be argued that the manufacture of low risk products or low-risk ingredients in facilities that only manufacture other low-risk ingredients or products does not have the same risk profile as the manufacture of high-risk products or ingredients. As such, Complementary Medicines Australia (CMA) has proposed the development and adoption of complementary medicine-specific GMP

guidelines, with specific changes to things such as ongoing stability testing and validation testing. Formally amending the standards (or the approach to their application) for low-risk manufacturing facilities could have considerable regulatory cost savings for industry without increasing risks to consumers.

**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? What risks do you believe this would create and what evidence is there for this?**

**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?**

***Issue 6 – Pre-publication approval for advertising***

Advertising of most over-the-counter (OTC) medicines (Schedule 2 and unscheduled) and complementary medicines direct-to-consumers is allowed, but is subject to pre-publication approval if the advertisements are to appear in free-to-air broadcast transmissions; mainstream print media; cinema advertising; and billboards/posters on public transport or in places such as shopping malls.

These regulatory requirements are administered via a co-regulatory scheme whereby requirements are set out in legislation, such as the Act; the Regulations; and the *Therapeutic Goods Advertising Code 2007* (the Code), and the TGA has ultimate responsibility for ensuring compliance, but administration of the pre-approval requirement has been delegated to industry peak bodies, namely the Australian Self Medication Industry (ASMI) and CMA. Under this delegation:

- ASMI is responsible for the pre-approval of all non-prescription medicines (OTC and complementary) advertising appearing in broadcast media; and for advertisements for OTC medicines appearing outdoors or in print media; and
- CMA is responsible for the pre-approval of complementary medicines advertising appearing outdoors or in print media.

The compulsory requirement for advertising and marketing campaigns aimed at the general public to be pre-approved is regarded by some stakeholders as unnecessary and out of step with international practice. For example, in New Zealand and Canada pre-vetting<sup>i</sup> by peak industry bodies, while strongly encouraged, is not mandated by government. Rather, industry self-regulates by

---

<sup>i</sup> These organisations vet advertisements against requirements but do not ‘approve’ the advertisement. Responsibility for ensuring compliance with the requirements remains with the sponsor/advertiser.

making pre-vetting of advertisements a requirement of organisational membership of industry associations.

The efficacy and efficiency of Australia's pre-publication approval process has been questioned by many stakeholders. Issues identified include:

- The efficacy of the scheme, particularly the fact that some pre-approved advertisements are still deemed to have breached the Code (although the proportion is low); and the lack of effective enforcement powers and penalties, with many stakeholders viewing the TGA as a 'toothless tiger.'
- The complexity of the current scheme, including the need for some advertisements to be approved by multiple bodies, depending on the product and the type of media in which the advertisement will occur; and multiple bodies dealing with complaints, leading to confusion for those who may wish to avail themselves of the complaints mechanism.
- Whether advertising requirements are commensurate with the risk posed by the regulated products. In particular, stakeholders question the pre-publication approval of advertisements for listed medicines. These have not been assessed for efficacy prior to listing on the ARTG and, as such, the application of Section 22(5) of the Act, which establishes an offence where therapeutic goods are advertised with indications other than for which they have been accepted in the ARTG, is viewed as a bit of a nonsense. It also creates a situation whereby therapeutic claims for these products may be first assessed through the advertising complaints process, but the process is not designed for such purposes. Stakeholders also question why pre-approval only applies to advertisements in some forms of media and not others.

Internationally, authorities still seek to protect consumers from false and misleading advertising of medicines, but some do so with a lighter touch on industry. This is generally achieved through either:

- Self-regulatory schemes, whereby pre-vetting of advertisements direct-to-consumers is strongly encouraged but not required by government. However, the peak industry associations require it as a condition of membership; or
- Through more risk based pre-vetting requirements, combined with self-regulation (as in the UK).

In Canada health product advertisements directed to consumers are self-regulated. Advertisements are reviewed and pre-cleared by independent agencies that have notified Health Canada that they have publicly attested to meeting Health Canada's *Recommended criteria for the preclearance of advertising material of non-prescription drugs and natural health products directed to consumers*. These criteria include: written policies, procedures, and standards to ensure consistent, accurate and complete assessments of advertising materials consistent with the Canadian Food and Drugs Act and its Regulations, policies and guidelines; an objective and timely complaints mechanism; and meaningful self-regulatory sanctions that are proportional to the level and frequency of infraction. Such agencies are also required to have a process in place to refer to Health Canada complaints or issues where:

- health and safety risks are identified;
- it relates to advertising of unauthorized health products;
- it relates to cases of wilful non-compliance; or
- it relates to advertising of other health products such as prescription drugs to consumers.

Health Canada adopts a risk based approach in its compliance and enforcement activities and reserves the right to enforce the advertising provisions contained in federal legislation.

In the United Kingdom, traditional herbal medicines and homeopathic medicines are subject to the general rules on misleading advertising administered by the Advertising Standards Authority. In addition, the advertising of medicines is controlled by a combination of statutory measures enforced by the Medicines and Healthcare Products Regulatory Agency (MHRA), and self-regulation through Codes of Practice for the pharmaceutical industry, administered by trade associations. All of the general rules about medicine advertising apply to the advertising of traditional herbal medicines and homeopathic medicines.<sup>26</sup>

The self-regulatory system includes industry Codes of Practice and advice and vetting services for consumer advertising prior to publication. For over-the-counter medicines and traditional herbal medicines these services are provided by the British Herbal Medicine Association; Health Food Manufacturers' Association; and Proprietary Association of Great Britain. These organisations require their members to submit all advertising aimed at consumers for vetting prior to issue. As with other medicines, where complaints about advertising are upheld, the MHRA may consider vetting of future advertising to ensure compliance.<sup>27</sup>

In addition to the general rules about medicine advertising, specific rules apply in respect to the advertising of traditional herbal medicines and homeopathic medicines. In particular, registered traditional herbal medicines are required to include in all advertising directed at the public or healthcare professionals the following statement:

*Traditional herbal medicinal product for use in [specify one or more indications for the product consistent with the terms of the registration] exclusively based upon long-standing use as a traditional remedy.*<sup>28</sup>

This requirement is in recognition of the fact that products captured under the UK traditional herbal medicine registration scheme do not fulfil the requirement to demonstrate efficacy for marketing authorisation that applies to other medicines, such as prescription medicines.

Among other things, advertising of traditional herbal medicines must also:

- encourage the rational use of the product by presenting it objectively and without exaggerating its properties;
- not give the impression that a medical consultation or surgical operation is unnecessary;
- not suggest that the effects of taking the medicinal product are guaranteed, are not accompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product;

- not suggest that health can be enhanced by taking the medicinal product or that health could be affected by not taking the medicinal product; and
- not suggest that the safety or efficacy of the product is due to the fact that it is natural.<sup>29</sup>

In the US the Federal Trade Commission (FTC) and the FDA work together to regulate the advertising of health supplements. The FDA has primary responsibility for claims on product labelling, including packaging, inserts, and other promotional material distributed at the point of sale. The FTC, which enforces laws of 'unfair or deceptive acts or practices', has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogues, and similar direct marketing materials. The FTC approaches advertising of dietary supplements like any other products – advertising must be truthful, not misleading, and substantiated. The FTC applies the principles of its general enforcement policies regarding food to health supplements and gives deference to FDA determinations as to whether there is adequate support for a health claim. If a manufacturer of a health supplement makes a structure or function claim (that is that the nutrient or dietary ingredient is intended to affect the structure or function of the body, such as 'curb appetite' or 'support immunity') then it is required to include the following disclaimer:

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.*<sup>30</sup>

This disclaimer is required in recognition of the fact that the manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not independently assessed or approved by the FDA.<sup>31</sup>

#### 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?**

**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?**

**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?**

### Theme 3: Complex regulatory framework

In respect of complementary medicines, stakeholders have indicated that there is poor understanding of regulatory requirements by industry, practitioners and consumers. These relate to:

1. Poor understanding of requirements/obligations prior to listing a medicine on the ARTG.
2. Poor consumer understanding of the extent to which listed medicines are subject to independent scrutiny.

***Issue 1 – Lack of understanding of requirements for listing***

When listing medicines on the ARTG, sponsors are required to certify that they hold evidence to illustrate that their medicine complies with applicable regulatory requirements, including evidence to support indications to be included on the ARTG. There is, however, no process to establish that a sponsor understands the regulatory requirements with which they are certifying compliance, and audits of listed complementary medicines continue to show high levels of non-compliance with regulatory requirements. For example, from September 2012 to December 2013, a total of 249 reviews of listed complementary medicines were undertaken by the TGA. Of these reviews (both targeted and random) only 31 per cent had no breaches of regulatory requirements. Compliance issues identified included: incomplete or inappropriate information included on the ARTG; issues with formulation, manufacturing or quality; labelling and advertising; and inadequate evidence to substantiate claims.<sup>32</sup>

Industry bodies argue that the majority of sponsors seek to do the right thing, with non-compliance largely related to a lack of understanding of regulatory requirements rather than through intent. As a result they call for enhanced education and information for sponsors prior to them listing a product on the ARTG. For example, the CMA has called for the introduction of an accreditation and licensing scheme, with sponsors having to undertake compliance training and be issued with a certificate before listing a medicine on the ARTG. It proposes that the scheme be administered collaboratively with industry groups and the TGA on a cost recovery basis.<sup>33</sup> Another proposed option is that the TGA conduct education campaigns directed at manufacturers and sponsors.

**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?**

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

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

***Issue 2 – Poor consumer understanding***

When a complementary medicine is listed on the ARTG it receives an AUST L number which must be printed on the label of the medicine. A number of previous submissions and reviews have reported consumer confusion surrounding the AUST L number and the evidentiary requirements associated with these medicines, with the presence of an AUST L number often incorrectly interpreted to mean the product has been assessed by the TGA for safety, quality, and effectiveness.<sup>34</sup> To overcome this confusion, consumer groups have called for the development of consumer friendly resources to explain the regulatory environment, including the difference between AUST R and AUST L.<sup>35</sup>

The TGA has been progressing work under its *TGA reforms: A blueprint for TGA's future*, to address this issue, including providing more consumer friendly resources on its website. This includes video presentations on key topics, such as the role of the TGA, the risk versus benefit approach to

regulating therapeutic goods, and information about higher and lower risk medicines (AUST R and AUST L).<sup>36</sup>

It has also been suggested that a simplified regulatory framework for complementary medicines would provide greater clarity and confidence to consumers regarding the quality, safety and efficacy of products, and the extent to which these have been independently assessed. This would provide consumers with increased opportunities to make informed choices regarding their healthcare options.<sup>37</sup>

**Question 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?**

#### **Theme 4: Inadequate deterrents**

As noted previously, complementary medicines listed on the ARTG are not evaluated by the TGA prior to their entry on the ARTG. However, a proportion of listed complementary medicines are reviewed by the TGA for compliance with regulatory requirements. These reviews may be:

- random reviews: a proportion of newly listed medicines are randomly selected by computer; or
- targeted reviews of listed medicines identified with potential non-compliance issues.<sup>38</sup>

Compliance reviews involve assessing information about the product against relevant legislative requirements, including the certifications given by the sponsor at the time the product was listed, and taking appropriate actions when a breach of legislative requirements is identified. The TGA focuses compliance reviews on the evidence the sponsor holds to support the indications, the presentation of the medicine and the advertising of the medicine. Upon completion of the review, the product is given a compliance status. The TGA publishes information on compliance activities and review outcomes on its website.

During any stage of the compliance review the sponsor of the product undergoing review can request that the product listing on the ARTG be cancelled. In this situation the review will not be completed. That is, the review will be terminated when the product is cancelled from the ARTG.<sup>39</sup> However there is nothing stopping the sponsor from re-listing the complementary medicine on the ARTG at a later date. The TGA includes re-listing of products as one of the risk factors that it takes into account when determining which products should be subject to targeted review, but not all such re-listings will be reviewed. This creates an opportunity for sponsors to 'game' the system. That is, sponsors perceive little risk in listing products that are non-compliant, as they can simply request the product be removed from the ARTG should it become subject to review.

**Questions for consideration:**

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

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

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

---

<sup>1</sup> Health Canada, *Natural Health Products Program Quarterly Snapshot* webpage. Accessed 6 November 2014 at <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/qs-at-eng.php>.

<sup>2</sup> Australian National Audit Office (2011), *Audit Report No.3 2011-12 Therapeutic Goods Regulation: Complementary Medicines*, 2011, Commonwealth of Australia, p. 13.

<sup>3</sup> Therapeutic Goods Administration, *Half-yearly performance reports July to December 2013*, May 2014, Commonwealth of Australia, p. 7. Downloaded from: <https://www.tga.gov.au/publication/half-yearly-performance-reports-july-december-2013>

<sup>4</sup> Therapeutic Goods Administration, *Listed complementary medicines* webpage. Accessed 21 January 2015 at [www.tga.gov.au/listed-complementary-medicines](http://www.tga.gov.au/listed-complementary-medicines)

<sup>5</sup> Therapeutic Goods Administration, *Listed complementary medicine compliance review* webpage. Accessed 21 January 2015 at <https://www.tga.gov.au/listed-complementary-medicine-compliance-reviews>

<sup>6</sup> Australian National Audit Office (2011), *Audit Report No.3 2011-12 Therapeutic Goods Regulation: Complementary Medicines*, 2011, Commonwealth of Australia, p. 15.

<sup>7</sup> Therapeutic Goods Administration (2014), *Australian Regulatory Guidelines for Complementary Medicines*, Version 5.1, August 2014, p. 49

<sup>8</sup> Complementary Healthcare Council of Australia, (2014), *Submission to the Competition Policy Review*, Complementary Healthcare Council of Australia, Mawson ACT, p 2.

<sup>9</sup> *Ibid.*, p. 2.

<sup>10</sup> Complementary Healthcare Council of Australia (2014), *Complementary Healthcare Council of Australia's 2014/15 Federal Budget Submission*, Complementary Healthcare Council of Australia, Mawson ACT, p 4.

<sup>11</sup> Australian Government, *Industry Innovation and Competitiveness Agenda. An action plan for a stronger Australia*, released 14 October 2014, p. ix.

<sup>12</sup> United States Food and Drug Administration, *Q&A on Dietary Supplements* webpage. Accessed 6 November 2014 at <http://www.fda.gov/Food/DietarySupplements/ucm191930.htm>

<sup>13</sup> Complementary Medicines Australia (2014), *2014-15 Pre-Budget Submission*, Complementary Medicines Australia, January 2014, p. 2. Downloaded from: <http://www.cmaustralia.org.au/resources/Documents/Submissions/Complementary%20Healthcare%20Council%20of%20Australia%20Pre-budget%20Submission%202014-15.pdf>.

<sup>14</sup> *Ibid.*, p.2.

<sup>15</sup> United States Food and Drug Administration, *Q&A on Dietary Supplements* webpage. Accessed 6 November 2014 at <http://www.fda.gov/Food/DietarySupplements/ucm191930.htm>

<sup>16</sup> Health Canada, *About Natural Health Product Regulation in Canada* webpage. Accessed 2 February 2015 at <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php>

---

<sup>17</sup> Health Canada, *Natural Health Products Program Quarterly Snapshot* webpage. Accessed 6 November 2014 at <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/qs-at-eng.php>.

<sup>18</sup> Therapeutic Goods Administration, (2014), *Cost Recovery Impact Statement, Complementary Medicines 1 July 14-30 June 2015*, Commonwealth of Australia, June 2014, p. 15. Downloaded from: <https://www.tga.gov.au/cost-recovery-impact-statement-complementary-medicines-1-july-2014-30-june-2015>.

<sup>19</sup> Complementary Medicines Australia (2014), *Submission to the Competition Policy Review*, Complementary Medicines Australia, p.3. Downloaded from: <http://competitionpolicyreview.gov.au/files/2014/06/CHCA.pdf>.

<sup>20</sup> *Ibid.*, p. 3.

<sup>21</sup> Therapeutic Goods Administration (2014), *Guidelines on the evidence required to support indications for listed complementary medicines*, Version 2.1, July 2014, Commonwealth of Australia, p. 7. Downloaded from <https://www.tga.gov.au/book/guidelines-evidence-required-support-indications-listed-complementary-medicines>.

<sup>22</sup> *Ibid.*, p. 15.

<sup>23</sup> *Ibid.*, pp. 27-37.

<sup>24</sup> Therapeutic Goods Administration (2011), *GMP Clearance for Overseas Manufacturers*, 17th Edition, Version 1.0, May 2011, p.7.

<sup>25</sup> United States Food and Drug Administration (2007), *Dietary Supplement Current Good Manufacturing Practices (CGMPs) and Interim Final Rule (IFR) Facts* webpage, Accessed on 3 February 2015 at: <http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110858.htm>

<sup>26</sup> Medicines and Healthcare Products Regulatory Agency (2014), *The Blue Guide – Advertising and Promotion of Medicines in the UK*, Third Edition, First Revision, September 2014, Appendix 1.

<sup>27</sup> *Ibid.*, p. 78.

<sup>28</sup> *Ibid.*, p. 75.

<sup>29</sup> *Ibid.*, pp. 80-81.

<sup>30</sup> United States Department of Health and Human Services, Office of Inspector General (2012), *Dietary Supplements: Structure/Function claims fail to meet Federal Requirements*, October 2012, OEI-O1-11-00210

<sup>31</sup> United States Food and Drug Administration, *Q&A on Dietary Supplements* webpage. Accessed on 4 February 2015 from: [http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm191930.htm#what\\_info](http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm191930.htm#what_info)

<sup>32</sup> Therapeutic Goods Administration, *Complementary medicines - compliance reviews 2013* webpage. Accessed on 4 February 2014 from: <https://www.tga.gov.au/behind-news/complementary-medicines-compliance-reviews-2013>

<sup>33</sup> Complementary Healthcare Council of Australia, (2014), *2014/15 Federal Pre-Budget Submission*, January 2014, Complementary Healthcare Council of Australia, Mawson ACT.

<sup>34</sup> Consumers Health Forum (2012), *Submission to the Consultation on Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)*, Consumers Health Forum, May 2012, p. 2. Downloaded from: <https://www.chf.org.au/pdfs/sub/sub-873-evidence-requirements-for-listed-Medicines-May2012.pdf>.

<sup>35</sup> *Ibid.*, p. 4

<sup>36</sup> Therapeutic Goods Administration (2014), *TGA Reforms: A blueprint for TGA's future Progress Report as at 30 June 2014*, Commonwealth of Australia, August 2014, p. 13.

<sup>37</sup> Complementary Medicines Australia (2013), *Response to the ANZTPA Discussion Paper "Description of a possible joint regulatory scheme for therapeutic products under ANZTPA, January 2013*, Complementary

Medicines Australia, February 2013, p. 12. Downloaded from:

<http://www.cmaustralia.org.au/Resources/Documents/Submissions/CHC%20Response%20to%20the%20ANZT%20Discussion%20Paper%20Final.pdf>.

<sup>38</sup> Therapeutic Goods Administration (2014), *Australian regulatory guidelines for complementary medicines*, version 5.1, August 2014, p. 45.

<sup>39</sup> Therapeutic Goods Administration, *Listed complementary medicine compliance reviews* webpage. Accessed on 4 February 2014 from: <https://www.tga.gov.au/listed-complementary-medicine-compliance-reviews#review>

## APPENDIX 1: REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET

Please complete all parts of this document, sign it, and attach it to your submission.

### 1. Contact information

<b>Name and work title</b>	
<b>Organisation</b>	
<b>Contact email address</b>	
<b>Contact phone number</b>	

### 2. Consent to publish on the internet

It is the intention of the Panel to publish submissions that it receives, along with the name of the individual or organisation that made the submission, on the Review's webpage, located on the Department of Health website. Please indicate your willingness for your details to be published on the website by checking the appropriate box below.

- I CONSENT to the attached submission being published in its entirety on the Department of Health website.
- I CONSENT to a redacted version of my submission being published on the Department of Health website. If you check this box please provide a copy of your submission with the information you do not want to be published redacted and clearly mark the submission *Redacted for Publication*.
- I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Department of Health website. \*

Signature \_\_\_\_\_ Date \_\_\_\_\_

**\*NOTE:** The Panel will consider submissions in formulating its report to Government and may cite particular submissions. If your submission contains confidential information that cannot be cited, please clearly mark these parts of your submission as 'in-confidence'.

### **3. Abstract**

Please provide a brief abstract (no more than one page) of your submission, highlighting the key points that you would like the Panel to consider.