Review of Complementary Medicines Regulation

Complementary Medicines Australia (CMA) welcomes the opportunity to provide feedback to the expert panel review of medicines and medical devices regulation in Australia, in particular to Chapter Nine: Regulation of Complementary Medicines. Please find our response attached.

In general, the current regulatory regime for complementary medicines is appropriate, but there are a number of aspects of the current system in Australia that are not commensurate with the low risk posed by complementary medicines. CMA believes that the Therapeutic Goods Administration (TGA) is the correct regulator for complementary medicines, and that the challenge lies not in finding another regulatory paradigm or regulator, but in finding the correct balance in therapeutic goods regulation for low risk products.

The regulatory requirements for complementary medicines currently create a substantial burden and cause significant financial impact, particularly on small and medium-sized businesses. Many of the recent criticisms with the current system arise because complementary medicines do not fit seamlessly within a regulatory model designed primarily to accommodate over-the-counter and prescription medicines. However, industry is of the firm belief that the current regulatory burden of compliance can be reduced without risking the safety and quality of complementary medicines available to Australian consumers.

It should be noted that complementary medicines produced in Australia are highly regarded, especially within Asian countries, because they are recognised as meeting the highest global standards of quality, safety and efficacy. The Complementary Medicines Industry Survey 2014 highlighted that over 60 per cent of complementary medicines companies (excluding retailers) are engaged in exporting, but that one of the largest barriers to remaining competitive was the burden of government regulation. Survey results indicated that the complementary medicines manufacturing sector is not exempt from feeling the pressures of excessive red tape, with 83 per cent of complementary medicines manufacturers claiming excessive regulatory burden as the biggest challenge affecting their business.
Removal of over-regulation will help the Australian complementary medicines industry to gain its position as an innovative and competitive market that is able to meet growing consumer demands.

Thank you for the opportunity to submit our feedback to the Review. We would be pleased to provide evidence or discuss any points of this submission further as required.

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Executive Summary

CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality. The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the risk profile of these products.

Please find below a summary of CMA’s recommendations to the Review.

- The current regulatory framework for complementary medicines should be retained, but certain aspects of the current system need to be simplified as they are not commensurate with the low risk posed by these products.

- Mutual recognition of overseas regulatory decisions with regard to new ingredients should be more broadly adopted by the TGA, providing that the overseas regulator is established and reputable and has either completed a review of the safety, or the material has been on the market with some history of use.

- CMA supports the preservation of a Complementary Medicines Branch (Office of Complementary Medicines Authorisation) within the TGA, with sufficient resources and complementary medicine specific expertise.

- CMA recommends implementation of a modified registration pathway for complementary medicines containing ingredients permitted for use in listed products seeking to make higher level indications and health claims.

- A revision of the guidelines for the evidence required to support indications for listed medicines is required, in addition to the current review of the associated checklists.

- CMA recommends a review of the amount of detail that is required to be captured on the Australian Register of Therapeutic Goods (ARTG) for listed medicines, and proposes the detail could be minimised with no additional risk to consumers or limitation of their access to pertinent product information.

- Manufacturing standards for complementary medicines should be aligned with the principles of the Pharmaceutical Inspection and Cooperation Scheme (PIC/S) Code of GMP. The TGA’s adoption of revisions of the PIC/S Code should occur on an opt-in basis after broad industry consultation, rather than automatic adoption and subsequent development of the necessary exemptions and/or interpretations.
• Development and implementation of regulatory protection mechanisms would incentivise innovation in listed medicine ingredients in the place of standard IP protection.

• CMA recommends maintenance of the existing exemption under the advertising requirements for responsible marketing and the education of bona fide practitioners.

• The current system of advertising pre-approvals should be abolished.

It must be highlighted that the following recommendations would need to be implemented as a package of measures, strengthening the complaints system, and allowing the abolition of advertising pre-approvals.

• CMA supports strengthening of industry associations’ ability to enforce sanctions against non-compliant companies, via sponsors signing to an industry Code of Practice as a condition of listing on the ARTG.

• The Complaints Resolution Panel (CRP) should be abolished and be replaced with a co-regulatory complaints handling model, potentially using mechanisms already in place to handle such matters across other advertised goods.

• CMA supports the implementation of an accreditation/licensing scheme for sponsors, as a cost-effective solution to ensuring that before a sponsor is able to list products on the ARTG they have undertaken a reasonable level of compliance training.
About Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing members throughout the value chain: manufacturers, raw material suppliers, distributors, retailers, practitioners and consultants. CMA promotes industry viability and growth, and a marketplace where consumers can enjoy the positive health benefits of high quality complementary medicines. We are the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

Complementary medicines include vitamins, mineral and nutritional supplements, homoeopathic, aromatherapy products and herbal medicines (unless specifically exempt). The term ‘complementary medicines’ also comprises traditional medicines, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Traditional and long-term use is taken into account in establishing safety as a medicine.

Over the last few decades, the complementary medicine sector has evolved into a major industry which requires complex supply chains, clinical trials, global marketing and export acumen. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health\(^1\). Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care.\(^2\)

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**Chapter Nine: Regulation of Complementary Medicines**

**Theme 1: Duplication of Regulatory Processes**

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

**CMA Initial Submission:** Many ingredients commonly used in overseas jurisdictions are unavailable in Australia due to a mandated, costly and needless duplication of assessment. This is seen to be the primary factor inhibiting the innovation of the Australian complementary medicines industry. Where ingredients have been approved as safe by competent overseas regulators, these decisions should allow for a pathway to expedited adoption.

**Questions:**

1. How might a ‘trusted international standard or risk assessment’ be defined in the context of complementary medicines? 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?

2. 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?

CMA supports mutual recognition of overseas regulatory decisions with regard to new ingredients, providing that the overseas regulator is established and reputable and has either completed a review of the safety or the material has been on the market with some history of use. Regardless of differences in regulatory classification/listing requirements, established and reputable regulators, with appropriate processes for assessing new ingredients (such as Swiss Medic, Singapore’s HSA, CA-NNHPD and others) should be trusted, thus allowing for a reduced TGA assessment. The TGA requires assessment of quality and safety for complementary medicine ingredients. Canadian assessment in the Natural Healthcare Products (NHP) category covers quality, safety and efficacy of ingredients before products can be licensed for use; therefore, NHP ingredients should be readily accepted by the TGA.

The TGA has provided a recent example of an expedited evaluation, utilising cost recovered resources³, with the approval of *Garcinia Gummi-Gutta* (*Garcinia cambogia*), which was based on data from Health Canada and TGA internal information. While CMA supports this process of permitting a new ingredient via an expedited process, utilising cost recovery, we would like to see a system in which any further assessment by the TGA is considered unnecessary. There is currently minimal investment in applications for new ingredients due to the inability for an

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³ Cost recovery involves the Australian Government charging the non-government sector some or all of the efficient costs of a specific government activity. That activity may include the provision of goods, services or regulation, or a combination of these. Australian Government Cost Recovery Guidelines, July 2014, 3rd edition.
applicant to achieve a level of market exclusivity/protection. It should be noted that the priority for resource allocation remains with sponsors’ paid applications.

Where reviews remain required, uncertainty over timelines for approval of an application for a new ingredient is a barrier to bringing innovative products to market. CMA recommends the setting of predictable timelines, and believes this to be an important aspect of pre-submission meetings with the TGA. The setting of target timelines via determination of a well-defined set of data requirements and proposed timeframes, based on each individual application, would achieve the benefits of greater transparency and predictability. This would allow sponsors to forward plan their business operations and would help expedite the process of bringing a new ingredient to market.

3. **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?**

Yes, in general, an ingredient should be considered to have been ‘approved’ by an overseas regulator if it has been subjected to some form of assessment. However, it should be noted that the vast majority of ingredients have not been assessed by overseas regulators for efficacy; they have been assessed for quality and safety. In order to achieve international alignment, and reduce rather than increase the regulatory burden on the Australian industry, CMA does not support assessment of efficacy of ingredients by the TGA.

4. **Should evidence standards be comparable with, or superior to, those currently applying in Australia?**

Evidence standards for listed complementary medicines are currently overly onerous. Please see comments to Theme 2 Issue 4.

5. **Is there good reason why Australia should ‘impose additional requirements’ in respect of the approval of an ingredient for use in listed medicines?**

6. **If Australia were to adopt approvals by ‘trusted’ overseas regulators, what additional assessment, if any, should be conducted by the Australian regulator?**

7. **What value do you believe assessment by the TGA adds in cases where such an assessment has already been undertaken?**

8. **Are there aspects of safety or quality that need to be considered in the Australian context?**

Additional assessment may be required and will depend on the approach and level of assessment performed by the ‘trusted’ overseas regulator. For example, Natural Health Products (NHPs) are evaluated for safety and efficacy before being approved for use in Canada. Therefore, NHP ingredients should be accepted without further assessment by the TGA. In relation to other regulatory frameworks that do not cover all aspects of assessment as required by the TGA, the aspects that are covered should be trusted, thus allowing for a reduced TGA assessment.
To maintain the high standard of complementary medicines in Australia, CMA supports the current legislative provisions (under section 28 of the Act) that allow the Secretary to impose, vary or remove an additional condition of listing on therapeutic goods at the time of listing or anytime thereafter. Where quality aspects may need to be further underpinned, there are conditions of listing that may be imposed on a medicine in relation to a specific ingredient in that medicine. For example, a condition of listing, to conduct an additional identification test on the material, was imposed on listed complementary medicines that contain preparations of the herbal material *Gingko biloba* leaf extract.

**Issue 2 - Interface between advertising and listing evidence requirements.**

**CMA Initial Submission:** At the time of listing on the ARTG, sponsors must certify that they hold evidence to support indications and claims. Sponsors must submit their advertisements for pre-approval, and in doing so, must demonstrate they meet advertising standards and do not mislead. These are slightly different requirements, but the TGA has indicated that there is some overlap that might be eliminated through harmonising the listing and pre-approval requirements.

9. **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?**

The TGA’s permitted indications project is being completed and is intended to limit indications to those that are appropriate for listed medicines, thus providing consistency to consumers about the health benefits of listed medicines. Corresponding alignment of advertising claims will mean that the likelihood of unsubstantiated claims will be extremely low.
Theme 2: Regulatory requirements are not commensurate with risk

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

*CMA Initial Submission:* Complementary medicines have increasingly been expected to meet regulatory standards more suited to high-risk prescription medications. CMA believes that many of the complexities currently contributing to the regulatory burden upon this industry would be eased through complementary medicine relevant regulation.

**Questions:**

1. Is the current regulatory regime for complementary medicines in Australia appropriate and commensurate with the risk posed by these products? If not, why not?
2. Should complementary medicines in Australia be regulated in Australia under a separate legislative framework? If yes, key features of this framework?

The overall regulatory regime for complementary medicines is appropriate, but certain aspects of the current system in Australia are not commensurate with the low risk posed by these products. As an example, complementary medicines are currently manufactured under PIC/S GMP, which is designed for pharmaceuticals. Many of the requirements for PIC/S are inappropriate for complementary medicines, and as such a complex web of guidelines must be developed with each version of the PIC/S Code, to modify the requirements to ensure they are more appropriate for lower risk products.

Complementary medicines in Australia should not be regulated under a separate legislative framework. CMA strongly supports the preservation of a Complementary Medicines Branch (Office of Complementary Medicines Authorisation) within the TGA, with sufficient resources and complementary medicine specific expertise. This, along with a flexible, pragmatic approach, will assist in continuing to minimise some of the complexities raised through the application of a pharmaceutical paradigm to low risk listed products.

**Issue 2 – Threshold for therapeutic goods**

**Questions:**

3. 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?
4. What criteria should be used to determine whether a complementary medicine should be regulated as a therapeutic good?

Low risk complementary medicines should not be regulated as general consumer goods. Whilst complementary medicines are low risk products, they are generally concentrated in dosage forms at levels that can be up to several hundred times the level that would be found in the respective food consumed at recommended levels. It is rare to see an adverse reaction or medicine interaction when used as directed, however the potential remains.
The overall system of how goods are regulated in Australia (and the existing factors that determine whether a product is a therapeutic good) is effective and appropriate, but could benefit from greater flexibility and simplification. Our industry is proud of the high quality standard of Australian complementary medicines, is supportive of retaining high standards, and believes the current regulatory paradigm should be retained. Modifications can be made without lowering standards, and indeed, can improve consumer access to the timely availability of safe and high quality complementary medicines. Areas identified as benefiting from amendment include the listing, evidence and GMP requirements, all of which need to be commensurate with the low risk nature of complementary medicines.

Many of the current listing, evidence, and PIC/S GMP requirements offer minimal consumer benefit above that which alternate solutions could offer. For example, the amount of information that is required to be captured on the ARTG entry is very detailed and the maintenance of this information is onerous. The detail that is required to be included on the ARTG entry should be reviewed to minimise the regulatory burden on industry, whilst still maintaining a high standard of consumer safety. For example, the ARTG database could be modified to only capture the following detail:

- Product name
- Sponsor’s name
- Name and quantity of active ingredient(s) per dose
- Proposed indications
- Dosage form
- Maximum recommended daily dose (MRDD)
- Image of the product label (submitted after launch to market)

This level of detail would still allow the consumer to uniquely identify a therapeutic good and would allow the medicine sponsor to make a range of product changes without the associated regulatory burden associated with the listing system and with product record maintenance. For example, allowing variations to the information on the ARTG entry by way of notification and reducing the range of changes that would result in a ‘separate and distinct good’ (new AUST L) would substantially reduce regulatory burden.

One current challenge for industry is that ARTG listings of product formulations require the inclusion of all excipients, some with quantification (export listings require the inclusion of all excipient quantities). Even minor changes to the formulation or an ingredient can result in relisting, relabelling, and revising of specifications. Such minor changes are frequently required based on raw material availability and/or product improvement initiatives. A simple solution would be to enable an update to an ARTG record, keeping the original AUST L number, which would eliminate the need for a completely new ARTG listing and a new AUST L number. For

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4 Proposed indications to be based off list of permitted indications.
5 Notification provided to the TGA linking dosage form, licensed manufacture and approved manufacturing steps
additional information, outlining a simple policy change, please see Additional Considerations – Incidental Minor Excipients.

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

5. *Should certain dietary supplements, such as water soluble vitamins, be regulated as foods or as general consumer goods rather than as therapeutic goods? If no, 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?*

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

CMA does not support regulation of complementary medicines, or a sub-category such as water soluble vitamins, being transferred to a separate regulator. A separate dedicated regulator for complementary medicines is likely to be very costly and only achieve a duplication of the regulatory system currently in place, with very limited benefit. An unintended consequence of this proposal is that businesses would then require regulatory expertise across a broader range of regulatory requirements – including knowledge of food standards and dealing with the various State and Territory Food Authorities. A number of products exist as complex combinations of herbs and vitamins, which would likely add to the regulatory burden.

7. *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?*

CMA strongly supports a modified registration pathway for complementary medicines (entirely formulated using ingredients permitted for use in listed products) seeking to make higher level indications and health claims. The modified registration application would not require consideration of safety and quality aspects of the medicine as this would have been considered as part of the ingredient(s) already being permitted as safe for use in listed medicines.

A new food standard to regulate nutrition content claims and health claims on food labels and in advertisements became law on 18 January 2013 – *Standard 1.2.7 Nutrition, Health and Related Claims*. Under this standard, foods are able to make stronger health claims (such as lowering high cholesterol), while having both lower manufacturing and evidence requirements, than complementary medicines listed on the ARTG. At this stage, the pathway for a complementary medicine to be able to make stronger health claims is via the registration process; a process that requires a substantial data package, similar to that required for the registration of a new pharmaceutical, which is inappropriate for low risk products. Registration also requires safety and toxicology data, despite in some instances the ingredient(s) already being approved for use in listed complementary medicines sold on the Australian market (and therefore already deemed safe to be consumed in accordance with the products dosage instructions).

A modified registration pathway for products containing listable ingredients would remove the prohibitive additional cost of redundant product safety evaluation and be an incentive to
expand the clinical research base on existing products. There is currently little or no incentive for industry to invest in clinical trials to expand the evidence base for complementary medicines.

An application would be proposing only a new indication and would therefore not require the provision of a comprehensive evaluation report. Rather, an evaluation would be conducted on the evidence to support the proposed indication. Quality and safety risks would be low, given GMP requirements and ingredient safety assessments.

CMA proposes a distinct administrative category for a modified AUST R (comprising of already approved listed ingredients), to ensure the system remains streamlined and eliminating the possibility of two requests for information from the regulator in relation to an application.

CMA is supportive of the current TGA complementary medicines business process review, which is developing expedited application pathways for evaluation of complementary medicines. Once again, the setting of target timelines via determination of a well-defined set of data requirements and proposed timeframes, based on each individual application, would achieve the benefits of greater transparency and predictability. This would allow sponsors to forward plan their business operations and would help expedite the process of bringing a new product to market.

**Issue 4 – Evidence Requirements**

**Questions:**

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

9. 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?

The TGA has recently updated the guidelines for the evidence required to support indications for listed medicines. Unfortunately, the new guidelines and associated checklists have introduced a significant regulatory burden for companies to remain compliant with evidence substantiation for their products. The TGA has been working with industry to review the checklists as these were found to be unwieldy, and to add a prohibitive and duplicated administrative burden, rather than achieve their intended purpose of assisting users with compilation of evidence substantiation.

The requirements for evidence substantiation, coupled with revised pharmacovigilance expectations for listed medicines, means that the administrative burden of compiling, monitoring and maintaining records is substantially increasing costs and slowing innovation and efficiency. CMA strongly supports a revision of the guidelines (in addition to the checklists) to ensure they are relevant, user-friendly and consistently interpreted by users.
A deregulatory approach to evidence requirements should apply to products with low level, health maintenance and structure function type indications, removing some of the regulatory burden for this category of lowest risk medicines. Australian Consumer Law remains as a strident backdrop ensuring consumer goods are promoted in a way that is truthful and not misleading.

A number of issues with the evidence guidelines have been raised by CMA members, with a few outlined below as examples. This list is not exhaustive and additional detail can be provided if required.

- Currently, the evidence guidelines specify that studies used to justify scientific indications in complementary medicines should be conducted in populations that are representative of, or can reasonably be extrapolated to, the general Australian population. Sponsors should be able to utilise studies on substances used in populations that are not strictly representative (or reasonably extrapolated) if a particular substance is approved by an internationally recognised monograph and/or has been discussed in systematic reviews and shown to be beneficial in humans.

- Currently, evidence used to support indications relating to biomarkers (e.g. blood pressure, blood glucose and cholesterol) must be based on study populations with baseline biomarker levels that lie inside the ‘normal healthy range’. Much of the research in this area is, however, conducted on study populations that lie outside the normal healthy range. For example, to make the indication “may assist in the maintenance of normal cholesterol levels in healthy individuals” one must provide evidence that the ingredient can lower cholesterol in healthy individuals with normal cholesterol levels. Given that cholesterol claims can be made in the food environment and in the context of preventative health, CMA supports the extrapolation of biomarker data from ‘diseased’ populations to be applicable to the general population.

- With regard to weight loss indications for complementary medicines, the evidence guidance document should not specifically detail the need to substantiate with a 6 month trial; rather a trial should be of sufficient length to show a health benefit that is of clinical significance.

- A specific scientific indication should be acceptable if it has been approved as such by an internationally recognised monograph, such as by Health Canada or the European Medicines Agency. Currently, the evidence guidelines only allow use of internationally recognised monographs to support general non-specific scientific indications or as additional evidence to support a specific scientific indication.

- No differentiation should be made between tablet and capsule dosage forms in relation to finding relevant high quality studies to support scientific or traditional indications; only the dose equivalent should be relevant due to an unlikely significant difference in dissolution of these two forms. Notably, this differentiation is not observed in internationally recognised
monographs or systematic reviews, considered by the TGA as high quality sources of scientific evidence.

**Issue 5 – Compliance with GMP**

**CMA Initial Submission:** The adoption of the Pharmaceutical Inspection and Co-operation Schemes (PIC/S) guide to Good Manufacturing Practice (GMP) has meant that Australia consults on revised manufacturing requirements after PIC/S has already adopted them (Australia is obliged, through both PIC/S and MRA/MoU arrangements, to maintain equivalence). The TGA’s manufacturing guidelines should be revised to ensure an appropriate level of regulatory oversight is applied to these lower risk medicines, in particular revising the rigour around Product Quality Reviews, whilst still upholding the basic tenets of GMP.

Another common issue raised is the lack of a level playing field with respect to approval and audit of overseas manufacturing facilities. An alignment of TGA clearance frequencies with that of overseas agency’s audits is desirable.

**Questions:**

10. **Should Australia remove the requirement for manufacturers of low risk products or ingredients to comply with medicinal 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?

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

The complementary medicines industry currently manufactures to some of the highest international standards and while the industry is supportive that the standards applied to medicines are beyond that of what is required for food, there are improvements that can be made that recognise a risk benefit approach.

The current manufacturing standards are aligned to the Pharmaceutical Inspection and Cooperation Scheme (PIC/S) Code of GMP, which is essentially designed for pharmaceutical manufacturing. The manufacturing of a low risk product should not need to meet the same requirements as for high-risk products, such as high level HVAC systems or atmospheric variations to prevent particle migration.

As the PIC/S standard evolves and is updated, the new additions and changes become increasingly burdensome for low risk complementary medicine product manufacturers. There have been a number of exceptions and specific interpretations by way of guidance documents to fit complementary medicines manufacturing to the PIC/S Code. This can make certain requirements overly complex and difficult to be consistently audited against. Developing and implementing further Australian specific complementary medicines concessions with each review of the PIC/S Code is generally required, is resource intensive for both the TGA and industry, and is unsustainable in the long term.
As an example, the latest version of the PIC/S Code specifies (in Annex 16) for an Approved Person (AP) to hold responsibility for batch release. For complementary medicine products, many of which incorporate 30 or more ingredients, this requirement is not able to be met due to the sheer volume of documentation needing review prior to release of a batch. In addition, a number of different products may be released for supply on a given day.

The TGA-Industry Working Group on GMP (TIWGG) has agreed that the TIWGG would provide a forum for real-time consultation with industry to ensure the TGA is able to reflect Australian market considerations in its comments to PIC/S on revisions of PIC/S guidelines. The intention is for the TGA to be in a position to adopt new versions of PIC/S in line with international regulators utilising the PIC/S Code. It has been proposed by the TIWGG that the process allows for the development of Australian specific guidelines where there may be product, industry or Australian market related issues that make implementation of PIC/S difficult. As the manufacture of complementary medicines does not fit well under PIC/S this TIWGG process allows for appropriate complementary medicines specific guidelines.

Manufacturing standards for complementary medicines should be aligned with the PIC/S Code of GMP, but adoption of revisions of the PIC/S Code should occur on an opt-in basis, rather than automatic adoption and subsequent development of the necessary exemptions and/or interpretations.

Specific areas suggested for exemption or simplification from PIC/S requirements:

- **Product Quality Reviews**
  There are currently multiple controls on product quality, safety and efficacy via testing, validation and release reviews. The additional burden in requiring yet another review may be desirable for high-risk prescription medications but is excessive for low risk complementary medicines. It adds little additional value in increasing the quality, safety or efficacy commensurate with the burden of this requirement. As a comparison, Health Canada GMP for Natural Health Products does not require product reviews (product quality reviews or annual product reviews).

- **Ongoing Product Stability**
  The current requirement is for a stability program that is ongoing or monitored continuously. At least one batch per year of every strength and every primary packaging type of each product (unless none produced that year) must be tested for stability. Equipment (stability chambers) used for the stability program need to be qualified. As a comparison, Health Canada allows similar product formulations to be used to make an initial determination of the expiry date.

  The requirement to run an on-going stability program for finished products should be amended to ensure there is an appropriate stability standard that is suited to complementary medicines and that formally recognises product grouping.
• Validation and Revalidation
Similarly to high-risk products, the current TGA requirement for manufacture of complementary medicines is that validation is required for critical processes and revalidation necessary if changes are made which impact the validated process. The TGA recommends periodic critical revalidation of processes. As a comparison, Health Canada does not require validation for natural health products unless the product meets the definition and/or is classified as a sterile product. No other validation requirements are mentioned for equipment, utilities or cleaning.

Currently, the TGA allows manufacturers to ‘group’ similar products from a validation perspective so as to allow the validation results of one product to represent all products in that group. PIC/S requires any new manufacturing formula or method of preparation to be validated.

CMA recommends the implementation of an appropriate validation standard which is applicable for complementary medicines, with a risk based threshold similar to Health Canada.

• Release for Supply
CMA recommends a simplified release for supply process which does not include a review of PQR and on-going stability data. This type of information should be assessed as part of these systems and should only be relevant by exception, by deviation or by risk assessment.

Whilst it is difficult to exactly quantify the total compliance costs to industry of meeting medicinal GMP standards as opposed to GMP standards more applicable to lower risk products, an estimated value is A$5 million per annum.

Issue 6 – Pre-publication approval for advertising

CMA Initial Submission: Currently, advertising of complementary medicines is regulated via a complex and inefficient process. Advertisements for low risk complementary medicines should not require pre-approval as they must comply with best practice under the Australian Consumer Law, similarly to foods and beverages that can now also make health claims but don’t require advertising pre-approval.

Questions:

12. 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?

Australia should not continue to require compulsory pre-vetting of advertising of complementary medicines under the current model as it is costly, inflexible and inefficient.
Approval for advertising is delegated by the TGA to two bodies, which often requires advertisers to seek two sets of approvals across a media campaign. The system is already limited as only a sub-set of advertising media are included; most notably the rapidly growing area of internet advertising is not covered.

Advertisements for therapeutic goods in Australia are subject to the requirements of the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990, the Competition and Consumer Act 2010 and other relevant laws. Advertisements for therapeutic goods must also comply with the Therapeutic Goods Advertising Code 2007. CMA proposes that the current advertising regulatory standards are maintained, such as compliance with the Therapeutic Goods Advertising Code 2007, but to remove the onerous regulatory burden by abolishing the existing pre-approvals and complaints system.

The requirement for pre-approval of advertisements was introduced into therapeutic goods legislation in 1997 (Therapeutic Goods Regulations (Amendment) 1997 No. 400). The explanatory statement to the above amendment makes it clear that the intent of the amendment was:

‘to establish a pre-clearance scheme for advertisements, about mainly non-prescription drugs, herbal remedies and like products, that are intended to be published or inserted in mainstream print media. The scheme is designed to ensure that advertisements published in mainstream media about these drugs will not include any claims that they can prevent, treat or cure major or serious medical conditions that usually require the intervention of a medical practitioner.’

Unless prior approval for the use of a restricted representation has been granted, advertisements for therapeutic goods must not include a ‘restricted representation’, which in an advertisement about therapeutic goods refers to a form of disease, condition, ailment or defect identified in the Therapeutic Goods Advertising Code 2007 as a serious form of a disease, condition, ailment or defect.

If a sponsor wishes to make reference to a ‘higher level’ claim, such as a restricted representation, there is an existing mechanism for seeking approval to use a restricted representation in advertising (referred to in section 42DE and 42DF(1) of the Therapeutic Goods Act 1989).

Currently, the advertising of complementary medicines to consumers and to healthcare professionals is managed by a combination of statutory measures administered by the TGA and the ACCC, and self-regulation through an industry Code of Practice.

The CRP considers complaints about advertisements directed to consumers for complementary medicines that appear in mainstream print media (newspapers and magazines), broadcast media (radio and TV), cinema films, outdoor billboards, posters and internet. CMA’s Complaints Resolution & Monitoring Committee (CRMC), established by CMA’s Code of Practice for the Marketing of Complementary Medicines & Health Food Products (the Code) considers complaints received about breaches of the Code including those clauses in relation to the Therapeutic Goods Act 1989 and the Therapeutic Goods Advertising Code 2007 in ‘below the line..."
material’. Included in ‘below the line material’ are brochures, leaflets, flyers, shelf talkers, newsletters, point of sale material, videos, audio tapes, catalogues and websites, and any magazine or journals that are not considered mainstream media.

Advertising complaints are currently heard by separate bodies, which make rulings that are often inconsistent with the approval provided for the advertisements previously. In effect, this means that an advertiser has to go through a preapproval process to ensure compliance, but then has no certainty that their advertisement will not be the subject of complaint and subsequent sanctions from the Complaints Resolution Panel (CRP) and TGA.

Criticism has often been levelled at the CRP due to its lack of transparency and timeliness, limited penalties and lack of appeals process. CMA recommends the CRP is abolished and replaced with the following co-regulatory complaints model, which allows an escalation of complaints’ consideration:

- In the first instance, complaints would be considered by the relevant industry association (e.g. CMA’s Complaints Resolution & Monitoring Committee for complaints relating to all advertising of complementary medicines across all media);
- Unsatisfactory conclusion of a complaint (non-compliance) would mean that a complaint could be referred to a Complementary Medicines Branch—Industry Complaints Committee, administered by the TGA and constituted with appropriate stakeholders to ensure transparency. This committee would also be the appropriate forum for determining the suitability of evidence to support efficacy or performance claims.
- The above model is supported by the deterrent of appropriate sanctions and penalties under Australian Consumer Law. However, for this to be implemented successfully, and to strengthen the complaints system sufficiently to enable removal of advertising pre-approvals, the following measures would be essential:
  - Industry associations’ ability to enforce sanctions against non-compliant companies would need to be strengthened, via sponsors signing to an industry Code of Practice as a condition of listing on the ARTG;
  - The implementation of an accreditation/licensing scheme for sponsors, which allows the TGA to rescind the sponsors licence in rare, extreme cases of non-compliance.

This model would remove the difficulties raised by the existing arrangements, whereby a complaint about the same advertisement in a newspaper and in a flyer must be directed to two different places, even if the substance of the advertisement and the complaint is the same.

13. 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?
If Australia was to adopt a self-regulatory model, industry associations such as CMA would need the power to be able to enforce sanctions against non-compliant companies, including both association members and non-members. As such, CMA supports the concept of strengthening industry associations’ ability to enforce sanctions against non-compliant companies via sponsors signing to an industry Code of Practice as a condition of listing on the ARTG. This concept was proposed by the Working Group for the Promotion of Therapeutic Products in 2011, as a recommendation to strengthen and standardise industry self-regulation and to provide a mechanism to ensure compliance by both members and non-members of industry associations. This had a very high level of support across multiple stakeholders at the time, and would help to provide the ability for an effective sanctions and penalties framework to deter non-compliance.

14. 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. A large number of claims are general public knowledge, such as folate and neural tube defects, B-vitamins and energy, fish oil and heart health, claims that are also readily made on foods. Any disclaimer is likely to create confusion amongst consumers, especially in relation to claims that are well accepted as general knowledge. This also creates a much greater regulatory burden for industry and adds to the uneven requirements between low risk complementary medicines and foods.
Theme 3: Complex regulatory framework

Issue 1 – Lack of understanding of requirements for listing

**CMA Initial Submission**: A licensing scheme for sponsors, administered by a body such as CMA, is a cost-effective solution to ensuring adequate education about regulatory obligations. This would further engage industry and assist in the removal of regulatory burden arising from lack of understanding, whilst providing an additional level of assurance for the protection of consumers.

**Questions:**

1. **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 be 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?

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

Complementary medicine sponsors should undergo an appropriate level of compliance training. As with any business decision, the individuals behind a product should be aware of the regulatory requirements and the need to either undergo the necessary training or to employ a professional regulatory consultant. This is especially the case given the complexity of the regulatory environment within which complementary medicine sponsors operate and the varied guidance documents that need to be understood.

Listed complementary medicines are included in the ARTG via an electronic application process that is designed to allow simple and fast access to market for low risk complementary medicines. At the time of listing, the product sponsor must certify that they hold the evidence to support indications included in the ARTG for their products, and that the indications are true, valid and not misleading. However, to become a sponsor one does not necessarily require any knowledge about one’s legal, regulatory and ethical responsibilities.

CMA is of the view that the majority of industry participants are conducting their marketing in an ethical and responsible manner, but it must be acknowledged that a small number of industry participants are operating outside the established rules and regulations, either unwittingly due to a lack of knowledge or by design.

CMA contends that creating an accreditation/licensing scheme for sponsors is a cost-effective solution, ensuring that before a sponsor is able to list products on the ARTG they must undertake a level of compliance training and be issued with a certificate or licence by a recognised training facility or organisation, which would also require that currency of knowledge be maintained. The scheme could be administered by a body such as CMA, in collaboration with the TGA and on a cost-recovery basis.
A Licencing of Sponsors scheme offers a method of ensuring that sponsors have a level of understanding of the industry and their ongoing regulatory obligations, allows further ability for enforcement, and provides an additional level of assurance for the protection of consumers.

It is envisioned that a training course would cover and assess a learner’s ability to, for example:

- Submit product listings on the ARTG;
- Source correct evidence to support indications and prepare it in a manner suitable for TGA submission;
- Determine appropriate claims for a product;
- Prepare and review advertising/marketing for a product;
- Provide required label information for a product.

An individual would need to complete the associated assessments to receive a statement of attainment or certificate.

Once training was completed, an individual would be given an ‘Authority ID’ which could be issued by a body such as CMA, an ID number that would be required in order to list a therapeutic product on the ARTG. This requirement for an ‘Authority ID’ allows the ability for the TGA to rescind the licence of repeat non-compliance offenders and also goes some way to replacing the need for the costly mandatory pre-approvals system for advertising.

**Issue 2 – Poor consumer understanding**

3. *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?*

The TGA has been progressing work to raise consumer understanding under *its TGA reforms: A blueprint for TGA’s future* in response to the ANAO recommendations. As noted in the discussion paper (p. 22) this includes providing more consumer friendly resources on the TGA website, including video presentations on key topics such as the role of the TGA and information about higher and lower risk medicines (AUST R and AUST L). CMA believes that this has begun to improve transparency of the regulatory environment.
Theme 4: Inadequate deterrents

Questions:

1. 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?
2. Should complementary medicines that are withdrawn from the ARTG require some form of assessment before being able to be re-listed?
3. How effective are the current post-market compliance reviews of complementary medicines in minimising exposure of consumers to non-compliant complementary medicines?

CMA supports stronger deterrents, especially for blatant and repeat offenders. A licencing scheme would provide the TGA with the ability to withdraw a sponsor’s licence for a blatant lack of compliance.

If a product is withdrawn or cancelled from the ARTG because of an identified major compliance issue, and the sponsor subsequently chooses to re-list the product, then the product should be flagged for priority/targeted review. The TGA could use its existing risk profiling framework to determine where to focus its resources. It should be noted that there will be situations where sponsors will be updating their ARTG listings to comply with the new permitted indications project and new evidence guidelines.

A past statistic that is often quoted indicated that 90% of the listed complementary medicines reviewed against the regulations as part of an audit were found to be non-compliant. This statistic is misleading, as the audit was looking at a very small number of products and these figures included products that were targeted for review of listing compliance. The higher rate of non-compliance in targeted reviews reflects that these reviews were initiated by the TGA due to a potential issue of non-compliance being identified. The 90% statistic encompassed various minor issues including missing full stops and wrong font size in labelling, and subsequently 97% of the instances of non-compliance were corrected.
Lack of flexibility required to facilitate early access to innovative products

There is no intellectual property protection for a large proportion of complementary medicine products regulated by the TGA, which creates a disincentive to innovate or bring new products to market. One solution is to develop regulatory protection to incentivise innovation in listed medicines and ingredients in the place of standard IP protection.

In 2003, in a report to the Parliamentary Secretary to the Minister for Health and Ageing, the Expert Committee on Complementary Medicines in the Health System recommended that, “the TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.”

Data protection is a well-established methodology in the regulatory systems of most developed countries, including Australia, to provide adequate incentive for product innovation, recognising that significant investment is required to generate and provide data to gain regulatory approval. However, for the complementary medicines industry, the commercial reality of ‘difficult-to-obtain patent protection’ to recoup clinical trial costs has limited the amount of clinical trials being conducted to provide scientific evidence for complementary medicines. In this area, complementary medicines are always at a disadvantage when compared to pharmaceuticals.

A possible solution is to develop Regulatory Protection as an alternate to IP protection to stimulate investment and innovation. This would help to recoup the enormous costs involved in generating data to gain regulatory approval before a competitor is permitted to rely on those data for the approval of a copying product.

Example method for achieving a level of protection for applicants with innovative ingredients

When a sponsor applies to the TGA for evaluation of a new complementary medicine substance a compositional guideline is generated, which defines the substance that has been evaluated and approved for use in Australia.

The compositional guideline, being generated from a paid application should, once approved, be published on the TGA website as a final compositional guideline. Public consultation on the draft version, as is current practice, would no longer occur. This proposal does not, strictly speaking, change transparency of either the process or information, with Complementary Medicines Australia supporting that all compositional guidelines be published to enable industry to refer to the approved specifications as necessary. However this process could build in a window of exclusive use, prior to compositional guideline publication, which would be an incentive for industry to apply for the listing of a new substance.

Should another company wish to amend the final compositional guideline they can still do so by applying to the TGA. The amendment would need to provide justification and would be evaluated by the TGA. This process would incur a specified evaluation fee. If the amendment is considered to be appropriate, the final compositional guideline would be updated to reflect the change and re-published on the TGA website.

This process and the publication of compositional guidelines on the TGA website would not prevent another sponsor from submitting a closely related yet distinct substance with its own specific compositional guideline for separate assessment. A compositional guideline for a pre-existing complementary medicine substance would not be affected by this proposal.

The decision as to whether to amend the original compositional guideline or to create a second compositional guideline for a different substance should remain with TGA and compositional guidelines and monographs may be modified as the test methods change.
Additional Considerations

TGA Consultation Draft TGO 79 Standards for the Labelling of Medicines

CMA provided a comprehensive response to the TGA’s ‘Consultation Draft TGO 79 Standards for the Labelling of Medicines’, highlighting that overall the proposed changes to the labelling of medicines was largely based on the risk profile associated with prescription and registered over the counter medicines. The extra regulatory requirements proposed for labelling and packaging of complementary medicines is considered to be out of proportion to the risk classifications of these medicines.

CMA supports that the current mechanisms in place for the labelling and packaging of complementary medicines are sufficient to promote the quality use of these medicines by consumers.

Incidental Minor Excipients

Incidental minor excipients (IMEs) have been described as substances added at low concentrations to a raw material during manufacture of that raw material, and are added for the purpose of stability/extension of shelf life. Generally they are present in the final dosage form at a level of less than 1%, very often less than 0.1%. Currently, there are only two instances where the TGA formally recognises changes to incidental minor excipients in the raw material of complementary medicines, meaning that no changes are required to the ARTG listing. These include the type of anti-oxidants used in the manufacture of some oil-based materials (e.g. fish oils) and the possible presence of silicone dioxide when used as an anti-caking agent in certain ingredients. Based upon minimal risk, the list of formally approved incidental minor excipients should be expanded to include additional listable substances that do not require declaration in the ARTG. It should be noted that the non-disclosure of IMEs does not reduce the TGA’s ability to enforce all relevant regulatory obligations on applicants or sponsors.

Education exemptions for Health Professionals

In alignment with the principles of the Quality Use of Medicines framework, industry needs to be able to provide information to health professionals about the nature and benefits of therapeutic products. Product sponsors currently share pertinent information with health professionals through responsible advertising in order to enhance the health outcomes for Australians.

In the TGA’s discussion paper regarding the regulatory framework surrounding advertising of therapeutic goods, ‘Advertising regulatory framework: Options for Reform’, May 2012, the TGA recommended that the legislation be amended to remove the use of Schedule 1 of the Regulations, which identifies those organisations whose members are recognised as healthcare professionals for the purposes of receiving advertising. The proposal was that Schedule 1 should
be phased out and replaced with references to healthcare professionals accredited through the National Registration and Accreditation Scheme (NRAS).

Under this recommendation, health professionals not registered under the NRAS, such as naturopaths, herbalists and nutritionists would be at risk of being considered lay persons and only able to receive educational and marketing materials directed to the general public. However, these practitioners are regarded by the public as primary care health professionals. They have a higher level of knowledge and an ethical duty of care to be as informed as possible about the products they prescribe, especially in relation to herb/nutrient/drug interactions and understanding the realistic expectations of natural medicines.

In this age of Dr Google and internet self-prescribing, there is mounting pressure on naturopaths, herbalists and nutritionists to evaluate products with particular regard to safety and efficacy. The public is increasingly importing supplements from over the internet and via the personal importation scheme, which means the potential for taking high dose, non-TGA approved ingredients is very high. Conversely, the majority of companies supplying practitioner products hold much greater evidence and knowledge of their products beyond what is allowable to be included on the ARTG.

CMA supports a continuation of advertising exemption under the section 42AA of the Act for the responsible marketing and the education of bona fide practitioners. This would continue to see these health professionals on an equal footing as those registered under the NRAS in terms of receiving more detailed information about the products they are providing to their patients.