Complementary Medicines Australia submission to the Therapeutic Goods Administration Consultation:

The Therapeutic Goods Advertising Code: Proposed improvements including proposed framework for Schedule 3 medicine advertising

October 2017

To:
Advertising Consultation
Regulatory Practice, Education and Compliance Branch Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
advertising.consultation@tga.gov.au

From:
Complementary Medicines Australia
PO Box 450
Mawson ACT 2606

[redacted]

Contents

1. Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment with regard to the TGA's consultation on the proposed improvements to the Therapeutic Goods Advertising Code.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals.

The increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, both economically and as an employer. Over the last few decades the Australian complementary medicines sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports.

Advertising is a central pillar of the capability to businesses to promote any types of products that are available for self-selection by consumers, including therapeutic goods in the lower spectrum of risk. CMA recognises that an update to the existing Advertising Code is required to encompass the broadening range of therapeutic goods being advertised and promoted to consumers, and to better capture expanded methods of promotion.

Development of advertising requirements must achieve a delicate balance between *permitting* goods to be effectively and reasonably advertised, including where there are promotional constraints such as limited time and space; *limiting* what is inappropriate to promote to consumers; and *determining* what is critical to advise consumers including those situations of constrained limits. The review of the Code offers a unique opportunity to achieve this balance for the benefit of all.

As the Code is primarily a document that is weighted towards outlining the limitations on advertising rather than permissions, it is important to recognise that consumers want to know adequate information about the medicines within an advertisement. Limitations should be carefully set so that they are suitable and objective but not preventing advertisements from reasonably conveying appropriate information about the goods that consumers seek.

2. Minimising Subjectivity; Increasing Objectivity

Q: Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

In principle, CMA is in support of increasing the objectivity of the Code. Support is subject to consultation on the actual provisions contained in the new Code. CMA's reservations in this area are based on introduction of strict liability offences and penalties in the enhanced enforcements and sanctions regime. The application of offences and penalties has impacts upon businesses that are can be very significant. It is imperative that the principles are closely considered for real world application.

CMA supports a clearer and less ambiguous redrafting of the Code requirements, but is concerned that objectives proposed in this Consultation document contains content that could be considered an expansion of the relatively subjective principles already within the existing Advertising Code. While many of the principles are valid, CMA believes that they need to be closely examined to determine for each provision whether objectivity and clarity is being enhanced.

CMA also has some concern about the regular use of the words, 'imply' and 'implication', in relation to a number of proposed advertising provisions, as this has been a large barrier to objectivity in delegate decision making under current arrangements. Whilst the purpose of referring to implications is understood and supported as a concept, CMA believes in some circumstances it has been applied in a subtle manner and therefore has captured items that reasonably could or should have been able to be advertised. CMA is concerned that there is likely to be continued difficulties unless the wording is rephrased or more definitively interpreted, so it cannot be used to capture items that generally would be considered reasonable.

CMA also seeks interpretation of the term 'reasonable consumer' within the Code. It is a relevant consideration to determining whether there has been a subtler or more subjective breach of the Code, another item that has been subject to debate in the history of determining the compliance of advertisements.

The Code is a document that is not only used by individuals within organisations with a biomedical or regulatory background, but also by individuals with a marketing background in the development of advertising campaigns. The Code is a document that should continue to be readily accessible to all.

With the above considerations in mind, CMA believes that the Advertising Code requirements must:

- Be appropriate in scope.
- Be minimally subjective.
- Have clarity of interpretation.
- Be able to be applied fairly, reliably and consistently.

If sponsors are to have confidence that they are operating within the parameters of the new Code (and avoid penalties), the document and any supporting guidance materials, education program and tools, must contain clear criteria, as well as numerous examples, demonstrating a variety of scenarios including those that approach ambiguous gray areas.

3. An Objective Advertising Code: Proposed Objectives

In section 4.2 of the Consultation, the TGA has outlined a number of core objectives. CMA supports in principle many of the objectives outlined, but does not support some or believes that some require re-examination for subjectivity, clarity, and application. Where the Consultation has provided new requirements, reasons for including these new provisions haven't been provided. Without such information it can be difficult to gauge why current provisions where not meeting requirements and whether the addition of these items are entirely relevant and necessary.

CMA's response to specific objectives contained in the consultation document are as follows.

3.1 Principles/Objectives

a. '*Must be truthful, balanced, valid and consistent with the indications on the ARTG*'. In some circumstances, whether something is truthful, balanced and valid can be assessed from the presentation of the advertisement and commonly available information. In other circumstances, a review of the evidence held by a sponsor is relevant to determining whether an advertisement

is true. CMA does not support the review of a sponsor's evidence by the Advertising area as this would entail a separate process from the evidence review conducted by the regulatory area for complementary medicines, and one that is outside the scope of advertising assessments. An advertisement already has to be consistent with the ARTG, and that the evidence for theses indications must be evaluated or held by the sponsor. If evidence for indications is called into serious question by Advertising, it should be subject to a single review by the regulatory area so that different decisions are not being made by different areas.

Further guidance should be provided around what is considered balanced and valid, including reference to subtler non-compliance scenarios.

Regarding consistency with the indications on the ARTG, there has been a number of concerns regarding how such intentions are applied. Under current arrangements, this requirement in legislation has resulted in sponsors only being able to advertise the indication as it is exactly worded on the ARTG, a situation that has been out of step with the existing policy and future intention to allow statements that have the same or similar meaning or effect. In relation to the Permitted Indications Determination, the complementary medicine regulator has provided that 'words to the effect' will be acceptable, e.g. (TGA Presentation April 2017), '*indications will not have to be 'word for word' on the label or advertising material*'. Whilst more specific guidance from the Complementary Medicines Branch is to be released, it is imperative that the advertising area recognise this policy when interpreting whether an advertisement is consistent with the ARTG indications. CMA requests that it is, at a minimum, reflected in associated advertising guidance.

b. "Exploit the lack of knowledge.. of consumers.' This provision in the existing Code has been used to state the advertisements that are providing appropriate information to the consumer, but that the consumer might not already know, are exploiting the lack of knowledge of the consumer. CMA would suggest that due to this confusion, and the fact that the concept of not exploiting consumers or providing incorrect information is more than covered by other provisions (such as truthful, balanced, valid, not misleading, not deceiving, and not abusing the trust), that removing this likely unnecessary phrase reduces subjectivity.

c. '*Must not mislead or deceive or be likely to deceive…. or exploit the superstitious…or without justifiable reason, play on fear or cause distress'*. To increase the Code objectivity, it should be clarified that providing accurate information in a balanced and meaningful way, where it may cause minor interest or concern, which is quite distinct from playing on fear or causing distress. CMA therefore supports addition of the new phrase 'without justifiable reason' and also believes thinks that further clarification of the distinction between these types of scenarios will be needed.

CMA is not sure why the phrase 'exploit the superstitious' has been added.

CMA queries the relevance of whether a consumer is considered to be superstitious or not with respect to the regulation of medicine advertising. This also implies that the advertiser is expected to anticipate whether an audience is superstitious or not. CMA is also concerned that such a provision could be used unfairly against complementary medicines that are based upon a tradition of use rather than scientific evidence. The use of traditional medicines is not superstitious; the World Health Organisation[1] recognises the valid use of traditional medicines:

> Traditional medicine has a long history. It is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary / alternative / non-conventional medicine are used interchangeably with traditional medicine in some countries.

CMA requests that reference to superstition is not included in the new Code as it believes the inclusion of is likely unnecessary, and may open the door to creating unfounded problems for sponsors of traditional medicines.

d. *'Cannot lead a person to believe that they are suffering from a serious ailment or that harmful consequences may results from the goods not being used*.' This is a provision that has provided interpretative difficulty in practice. CMA recommends that this provision could be re-examined for additional clarity, and that there are included examples or acceptable and unacceptable statements.

[1] http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/

e. '*The advertisement must not contain any claim or statement or implication that it is effective for specific demographic groups of patients (particularly where this may be a vulnerable group) without detailing the supporting evidence*'. This is a newly proposed provision. CMA seeks clarity about what is meant by the statement 'effective for specific demographic groups (particularly where this may be a vulnerable group)'. If a medicine is indicated for or advertised in relation to a demographic group, is that sufficient to suggest it is effective for that group and therefore this clause applies? Or are there situations where demographic groups can be referred to and this doesn't apply, is it only applicable in some circumstances? Importantly, what is meant by 'detailing the supporting evidence'? In what manner must it be detailed, and how much information is expected to be included? CMA is concerned that there hasn't been enough consideration of exactly what circumstances this applies to and whether it is practicable to include in advertisements. At a minimum, the Code explicitly describe what is meant by 'vulnerable groups' or specify them.

In general, CMA opposes the concept of broadly detailing supportive evidence for a medicine, as a collection of evidence is proprietary evidence held by a sponsor that can be reproduced in the development of competitor's products. Consumers are highly unlikely to cross-reference it and read it. Evidence requirements are different across all the medicine and device classes, and is provided for by the existing legislation, and assessed by the relevant TGA division. This provides the necessary consumer protection. As per the previous feedback related to item 3.1.a above, for consistency, evidence should be scrutinised by the regulator of those medicines. The requirement to detail supporting evidence in the advertisement provides an inappropriate mechanism for external parties to target and conduct their own efficacy reviews of complementary medicines with their own motivations, biases and agendas. This causes ongoing and unfair problems for industry. It opens the regulator up to inappropriate criticisms.

f. '*Must contain all mandatory and applicable information to provide consumers relevant information that encourages responsible use and promotes safe use Mandatory information, (e.g. requirements to include contraindications and warning statements) will be listed in the new Code'*. The consultation document suggests that advertisements must contain all mandatory and applicable information to provide consumers relevant information that encourages responsible use and promotes safe use of the therapeutic good. This is a very broadly worded provision and

it is not abundantly clear in the consultation as to the specific manner in which it will be applied. CMA supports the use of critically important advisory statements on advertisements, such as 'if symptoms persist consult your healthcare professional'. Other advisory statements, contraindications and information for medicines are already mandated under the updated Labelling Order. An advertisement is not an appropriate place to include a wide-ranging amount of applicable and cautionary information. The label is the appropriate place for such items, and CMA supports continued use of the advertising statement 'Always read the label'.

Inclusion of full statements in every advertisement is unnecessary and cumbersome. If a product does carry a risk, this is already matched by appropriate product/label information, access issues and point of sale care. We would also request that the TGA consider the added burden to industry to maintain up-to-date contraindication information on marketing materials which can be valid for 2 years. Each time an update to contraindication, or safety message occurs marketing material would need to be pulled from market and replaced, causing significant regulatory impacts on businesses. Where information is already on labels and is not critical for advertisements, it could be an unnecessary duplication of regulation that is unlikely to be supported by the deregulation principles outlined in the *Australian Government Guide to Regulation*.

In relation to specific warning information for vitamins, CMA supports the continued use of vitamin specific provision in the existing Code for example, 'vitamins must not replace a balanced diet', but does not support the addition of new vitamin warning information or other vitamin statements required by other legislation to be included on the label.

g. All claims used in advertisements for therapeutic goods must be substantiated

The consultation document claims that any scientific information presented in an advertisement must be 'educationally appropriate…and readily understood by the audience to whom it is directed'. The term 'educationally appropriate' is subjective, open to interpretation and likely to create confusion. CMA suggests that this term is probably not necessary, but if it were to be included it must be quite definitively interpreted and explained within the Code itself.

h. Regarding presentation of scientific information mentioned in Section 3 page 11, and repeated under restricted representations (section 4.3 page 13) requiring that an advertisement must identify the sponsor of the scientific study, and must also must declare vested interests in the therapeutic good OR the ingredients. Scientific information identifies the funding source, commissioning body for the study and relationship to the sponsor or advertiser.

CMA provides the following feedback about these proposed new requirements:

i) It is not clear what is meant by 'details of the scientific information'. Will full studies or citations, need to be made available? Due to copyright restrictions the publication of papers on a sponsor website may be prohibited. The provision of lengthy citations of a sponsor's dossier of evidence is also proprietary information that is the intellectual property of the sponsor and should not available in the public domain. Also refer to item (e) above in this section.

ii) **CMA does not support the publication of evidence summaries held by sponsors**. The relevant MMDR recommendation was rejected by the Government and this must be honoured by the advertising provisions. The publication of evidence by sponsors is commercially prohibitive and will allow for competitors to simply emulate the work of others, rather than investing resources into developing and holding their own evidence. This has the potential to suppress innovation which is inconsistent with parallel reforms, such as the 3-tier complementary medicine assessment pathway system, which is designed to encourage sponsor innovation by safe-guarding intellectual property.

iii) It is CMA's view that the only specific circumstance where it is appropriate to reference the source of scientific information is where the indication or claim has quantified the effect, for example "Colds get better on average 2 days faster".

iv) Many journal articles are through paid portals, and cannot be re-distributed for copyright reasons. 'Publicly accessible' therefore cannot require that the sponsor has to provide that full papers for the public can access. A citation or other appropriately trackable reference should be sufficient.

v) Identifying the sponsor of the study. CMA believes that this clause is unnecessary -

sponsors of various studies can be wide-ranging. If it is intended to capture where the sponsor has paid for a study, it is not new information that sponsors can financially support studies for their own products. In classes of medicines and devices, including prescription medicines, sponsors are involved in sponsoring studies and research institutions conducting studies. Sometimes the sponsorship passes through multiple hands so this provision doesn't add to the transparency for the consumer and potentially creates an unlevel playing field between sponsors.

If the study is sponsored by Government or funded by NHMRC research grant, would inclusion of such a statement then contravene the clause of prohibiting implied endorsement by a government body?

vi) Some of the supporting information a company holds for a product may be commercial-in-confidence and inappropriate for companies to release. The information may belong to them or to a completely separate entity such as a raw material supplier or other, and cannot be provided publicly. The emphasis of advertising requirements should be on whether claims are truthful, an evidentiary requirement examined by the relevant regulatory division within the TGA.

vii) Certain scientific information available that is suitable for use is not published or is proprietary.

viii) The reference to ingredients is irrelevant, given that the regulatory environment is concerned with the presentation of the final, formulated therapeutic good, not individual ingredients. Multi-ingredient products would face a highly cumbersome requirement.

ix) Many studies publish outcomes that go beyond that which is permitted for use as indications in listed medicines, potentially misleading consumers and leading to the use of medicines that isn't safe or responsible, and possible implicating the sponsor in trying to make claims beyond those published on the ARTG, which breaches other legislation.

x) Regarding vested interests, is this confined to the interests of the advertiser, or does the TGA expect advertisers to publish the conflicts declared in the paper of the researchers?

CMA suggest that disclosure of a conflict of interest e.g. where authors of a study are employed by the sponsoring company, is more in line with current 'Guidelines on the evidence required to support indications for listed complementary medicines' and consistent with how research papers are written and published. We recommend any disclosure of financial interests be limited to these circumstances.

xi) Collectively the consultation document is suggesting a number of publication requirements to be included in an advertisement. This could make advertisements cluttered and full of footnotes of warnings, declarations of interest, study citation, etc., in addition to the advertising copy. This is cumbersome, mostly unnecessary, and has the potential to confuse or mislead consumers about the intent of the goods: an impact the Code is designed to minimize.

i. **Testimonials (page 11)** must be "authenticated…and accurately identified". This statement is broad and subjective. CMA suggests the code stipulate how the TGA would like a testimonial to be authenticated and accurately identified. Furthermore, in light of the privacy rights of the person providing the testimonial, CMA suggests that accurate identification consist of name and State only.

j. **Endorsements (page 11)** must not be misleading. In this spirit of minimising subjectivity, CMA suggests that criteria to be applied to determine if an endorsement is misleading or be specified in the Code. In addition, there must be an exemption for the positive claimers" introduced by the introduction of the new 'listed assessed' pathway for listed medicines.

k. The consultation document suggests that the promotion of therapeutic goods "must be **consistent with current social expectations for public media**". This statement is in similar vein to "reasonable consumer" and "be reasonably understood", that is, very widely subjective and not consistent with the move toward a more objective code. CMA requests that the Code move away from broad, principle-based statements, and toward specific requirements and examples.

l. Regarding "and presentation of claims and content in advertisements must also be consistent with **any relevant public health or safety campaigns of the Commonwealth, State or Territory governments** (page 11)**"**. CMA maintains that this is an unrealistic expectation of any company to be abreast of *all* public health campaigns across *all* jurisdictions. Furthermore, it is often not

clear exactly what kind of information constitutes an official campaign, and to distinguish this from all other available public health information, past and present. Given the nature of the strict liability penalties being imposed, inclusion of such criteria could make a sponsor uncompliant easily and unknowingly. There must be much more consideration of what and how this should be applied in an reasonable manner, or it should be withdrawn.

m. There are concerns about the subjectivity of the statement: "An advertisement must also not unduly glamourise products or prey on the vulnerability of particular consumers". Is it in reference to celebrity endorsements? Further qualification and specification is needed of what is meant by "unduly glamourise" in the new Code.

   It is also subjective and unclear as to what prey on the vulnerability of particular consumers means in practical application. Which kind of consumers and in what manner are they considered vunerable? CMA requests that any reference to vulnerable/vulnerability be qualified with examples of what would constitute a breach of this part.

n. 'The advertisement is not likely to create a **false expectation** in its likely audience **that the product will deliver health benefits or improvements to their quality of life**'. Complementary medicines are designed to deliver health benefits and improvements to quality of life. Complementary Medicines are primarily designed to deliver health benefits or improvements to quality of life. Furthermore, this proposed clause is in contradiction with the proposed permitted indication determination where the following claims and indication types will be listed for selection:
   - health enhancement
   - health maintenance
   - prevention or alleviation of dietary deficiency; and/or
   - a health benefit for a non-serious forms of a disease, ailment, defect or injury.

   CMA is particularly concerned about this clause. This part has the capacity to capture almost any advertisement, is inconsistent with permitted indications, and should be removed.

4. Guidance to the Code

Q: Do you agree with guidelines to the new Code being developed? How should the guidance be made available to stakeholders?

The proposed changes are a significant change to the advertising regulatory framework including the repeal of pre-approvals and the introduction of strict liability penalties. In this environment of heightened responsibility and heightened penalties, CMA agrees that a guidance document would provide additional clarity and certainty to sponsors in how to interpret and apply the Code.

In relation to the content of guidance, CMA suggests that:

- Definitions and interpretations of key terms should be included as much as possible in the legislated Code.
- Guidance should be accompanied by examples, and that the examples should be vetted beforehand to ensure there is general agreement.
- Examples should be provided for the majority of provisions, including acceptable as well as unacceptable statements. Examples should approach the subtle and ambiguous interpretations of the Code, which have been the most difficult areas for industry to navigate.
- Guidance documents should be accessible from the same TGA website as the Code.

CMA agree in principle to an education program for industry, but it is not clear as to what kind of program is proposed. For example, if it will take the style of a presentation that sponsors would voluntarily attend, in which case repeat sessions would need to offered in each major location in the initial stage, and semi-regular sessions should be offered on an ongoing basis. Other kinds could be considered in addition to face-to-face sessions, such as voluntary online modules for sponsors. This would be particularly helpful for the ongoing training of staff who are new to an organisation. CMA is open to discussing other forms of educational programs.

CMA also recommends that the TGA provides additional support for sponsors in determining compliance of proposed advertisements during the initial transition phase.

5. Council recommendations

Q: Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?

5.1 New PROHIBITED representation

CMA recognises it may be necessary to expand the definition of a prohibited representation from the existing one that refers to 'treatment, cure and prevention' of neoplasia, STDs, HIV or mental illness. If it is broadened in such a way to preclude any reference then it should be in respect of named serious conditions relating to those illnesses. This is important so that it does not inadvertently capture acceptable permitted indications for listed medicines, such as the maintenance or enhancement of healthy mood.

5.2 New RESTRICTED representations

a. Reference to 'any procedure (or product requiring such a procedure for its intended purpose), that can only be performed by a suitably qualified healthcare professional to become a restricted representation'. CMA has concerns that this new restricted representation, particularly 'product requiring such a procedure for its intended purpose' may capture reference to the measurement of ubiquitous biological substrates that – in and of themselves are not diseases, conditions and ailments – and when expressed according to the permitted indications list are not serious in nature. The inclusion of this has the potential to make a vast number of permitted indications into restricted representations, which is not consistent with the goal that 'the Code will also be required to be consistent with the proposed complementary medicine reforms that may impact on advertising such as the permitted indications list'. **Therefore, CMA does not support the proposed restricted representation in this form.** There could be continued discussions on how to best capture the intention of the regulator without inadvertently including permitted indications.

b. CMA supports that direct reference to obesity is included as a restricted representation. Caution must be exercised in what is considered an 'indirect' reference to obesity. The wording of the new Code must ensure that appropriate references to weight loss and overweight are not inadvertently excluded.

c. 'Clarifying that the representation "prevention of skin cancer" in respect of certain sunscreens is permitted as a restricted representation.' CMA notes that prevention of skin cancer is a prohibited representation as such should be permitted as a prohibited representation, not a restricted representation.

d. Regarding reference to scientific information: given the proposed changes to scientific information in section 4.2 of the consultation document, appearance of these remarks under restricted representation is somewhat contradictory and suggests that reference to scientific information constitutes a restricted representation. CMA does not believe that it is appropriate to capture any provisions around scientific information in the restricted representation part. CMA requests clarification on this matter and also refers to the previous feedback provided earlier in this document in relation to scientific information proposed requirements.

5.3 RESTRICTED representations and the definition of 'serious forms' of conditions

The consultation does not include a revised definition of 'serious form'. Definition of a 'serious form' has long been considered ambiguous and difficult to apply in practice, and is unquestionably a part of the Code that needs further clarity and objectivity. The Administrative Appeals Tribunal has noted that the definition is not practical when attempting to practically apply as a statutory test:

> There is only one relevant difference of substance between the two limbs of the definition of serious. The first limb speaks of the appropriateness of self-diagnosis and treatment, the second speaks of the ability of the average consumer to do so. It seems to us to be inconceivable that it could be generally <u>appropriate</u> for patients to self-diagnose and treat yet beyond their <u>ability</u> to evaluate accurately (which cannot mean other than self-diagnose), and to treat the condition.[i]

CMA has considered the difficulties with the definition of 'serious form' at length and has considered a number of solutions, and would like to work with the TGA to develop a definition and extended guidance

that suits the requirements of the regulator, is consistent with policy and medical considerations, and provides adequate clarity for industry.

5.4 Testimonials and free samples

Regarding testimonials, please see CMA's comments under part 3 where testimonials are also referred to in the consultation document.

Regarding samples, Council's proposal does not appear to be distinct from the existing clause in the Code, section 4(8). CMA seeks clarification about any proposed changes to this section.

Summary

In summary, CMA believes the majority of the proposed changes to prohibited and restricted representations require thorough re-examination for practical and appropriate applicability, particularly, in regard to permitted indications. Further, the definition of 'serious form' must be revisited.

Advertising Framework for S3 medicines

CMA supports, in principle, the proposed processes for managing the advertising of S3 medicines.

Summary

In light of the over-arching reforms to the advertising framework, CMA provides in principle support for a more objective Advertising Code, subject to the detail and provisions in the proposed draft of the new Code. In response to the proposed content, there are a number of general and specific considerations provided by CMA throughout this submission that we believe need further examination.

In response to the consultation, the CMA:

- Requests that the new Code be supported by detailed guidance with an array of examples across varying scenarios and media modes.
- Supports the notion of an educational program for sponsors alongside additional support during transition.
- Does not support the broadening of vague or ambiguous language or unqualified definitions

within existing or proposed Code principles.

- Provides that any terminology and phrases such as 'vulnerable populations', 'reasonable consumer', 'reasonably understood', and 'educationally appropriate' must either be reconsidered or clearly interpreted within the new Code.
- Regular use of the term 'imply' or 'implication' should be revisited to determine if it affects objectivity. It should be considered if there is a better way to phrase this intent or whether an interpretation could be provided to the effect that subtle and unreasonable interpretations of 'imply' are not being captured.
- Supports the ongoing use of mandatory advertising information that is included in the existing Code, but does not support the need for additional mandatory information to be included in advertisements where this is sufficiently provided for in other legislation and labelling.
- Has many concerns regarding the additional requirements regarding scientific information and the appropriateness of making many references and sources available in advertisements.
- Has a number of concerns regarding the new proposed definitions of prohibited and restricted representations that should be carefully examined.
- Propose that a new definition of 'serious form' is needed within the Code.
- Has concerns about new proposed specific phrases and provisions.
- Supports in principle the proposed processes for S3 advertising.

CMA is willing to work with the regulator on specific considerations, with the intention of moving forward with a very practical, sensible, balanced and enforceable Code.

[i] http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/AATA/2013/388 html?context=1;query=Health%20world