



Complementary Medicines Australia submission to the Therapeutic Goods Administration Consultation:

The 2018 Therapeutic Goods Advertising Code & associated guidance

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To:

Advertising Consultation
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Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the TGA's consultation on the draft Therapeutic Goods Advertising Code and associated guidance material.

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 consumer demand for complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare. Over the last few decades the Australian complementary medicines sector has evolved into a world class industry supporting domestic skilled jobs, research, manufacturing and exports.

Advertising is a central pillar of the capability of the lower risk complementary medicine industry to communicate information about products that are available for self-selection by consumers. CMA supports the introduction of the new Code in response to the advertising recommendations of the Review of the Medicines and Medical Devices Regulation. We support the further alignment of the Code with World Health Organization policy objectives and the Australian Government's Quality Use of Medicines framework.

In our response to the Advertising consultation in October 2017, CMA expressed support for Advertising Code requirements that were appropriate in scope, minimally subjective, have clarity of interpretation, and that are able to be applied fairly, reliably and consistently. The draft Code presented, as a whole, presents a balanced advertising environment which allows the ability to appropriately advertise a product to the public while maintaining proper consumer protection. *However*, there are areas of regulatory overlap and refinements that are required on technical issues to make the Code practical in application and that will prevent implementation difficulties.

Our assessment primarily considers the effect upon the advertising of complementary medicines and has raised some items that would assist in harmonizing the advertising requirement with those of the complementary medicines regulatory branch. We have also raised areas we believe would create significant red-tape for little benefit to ensure that best practice regulation is in effect.

We acknowledge the vast amount of work and careful consideration that has gone into producing these documents, and appreciate our views being heard through consultation.

General Considerations

Guidance

Much of the guidance that affecting the practical implementation of the Guide is under development. We appreciate ongoing dialogue for those part of the guidance that are currently undeveloped or being re-developed.

Transition Arrangements

The new Code contains a number changes from the 2015 Code including many new or changed mandatory requirements. In this respect, we acknowledge the TGA's commitment for any pre-approved advertisement under the 2015 Code to be used for the full 2 year approval period.

There must also be a specified transition period provided for those advertisements produced under the 2015 Code that are not required to be pre-approved. This period should also be 2 years to allow any coordinated advertising campaigns to be finalised in unison.

Implementation

The draft Code is significantly different to the existing. While recognising the new advertising framework requires change to meet modern considerations, there are many concerns about the implementation challenges of new and changed requirements. In particular – how additional mandatory information will fit into various advertising mediums that are fundamentally limited by time and financial resources, particularly for complementary medicines that are lower volume turnover than other consumer medicines.

The many changes to mandatory statements and other new requirements that are as yet untested. The Code will require flexibility in application and a method for industry and TGA to record the areas that are not able to function reasonably for further assessment.

CMA support the proposed education mechanisms for sponsors and advertisers, in particular the online training portal.

The vast majority of sponsors are well aware of advertising obligations, however there are many other advertisers who are not aware that they are or will be bound by an Advertising Code. There will need to be education and awareness raised around this for these advertisers.

Finally, we strongly advocate that all mechanisms through legislation, guidance, and compliance officer training are explored to ensure that application of the Code is objective, fair, and creates a level playing field for industry.

Response to individual requirements

Sections 1 to 9

- CMA supports Sections 1 to 9 of the Code in the proposed form.
- Technical issues relating to guidance is included in Attachment 1.

Section 10 – Effect

- CMA supports the intent of Section 10.
- Section 10 requires minor amendment for clarification to reduce confusion in application. Technical discussion is included in Attachment 1.

Section 11 – What must advertisements contain

- CMA supports the intent of Section 11.
- Section 11 requires minor amendment for correct application to listed medicines. Technical discussion is included in Attachment 1.

Section 12 – What must advertisements contain – direct marketing and internet marketing

- CMA supports the required availability of the information within Section 12, for digital and other direct marketing sources where the consumer is able to directly purchase within that advertisement. As per the guidance, it appears that this is the intention.
- The terms ‘direct marketing’ and ‘internet marketing’ need definition within Section 4 of the Code, rather than the guidance. Technical discussion is included in Attachment 1.

Section 13 – Required Statements

- CMA supports the intent of Section 13.
- There are several areas that require minor amendment and clarification. Technical discussion is included in Attachment 1.

Section 14 – required statement for pharmacist only medicines

- CMA supports the proposed statement.

Section 15 – Required statements

- CMA supports the intent of Section 15.
- Section 15 requires minor amendment for clarification to reduce confusion in application. Technical information is included in Attachment 1.

Section 16 – Endorsements

- CMA supports the intent of Section 16 and the currently drafted guidance.
- We request consideration of the additional guidance under development.

Section 17 – Testimonials

- CMA supports the intent of this Section.
- We recognise that this area is particularly challenging to manage. We support the TGA in developing ways to sensibly and appropriately manage testimonials.
- We are unable to fully respond to this part without the full meaning and effect of the guidance that is under development. We appreciate an ongoing conversation in relation to this part.
- We note and support the exclusion provided in the guidance for testimonials and recommendations that are freely made on social media and which are outside the control of the advertiser.
- To capture the intent but avoid difficulties in implementation, we propose a minor amendment for clarification. Technical discussion is included in Attachment 1.

Section 18 – Incentives

- CMA supports Section 18 and the associated guidance.

Section 19 – Advertising to children

- CMA supports that advertisements should not be directed at children. Discussion on requirement for clarification is included in Attachment 1.

Section 20 of the Code – Allergens

- CMA supports appropriate regulatory mechanisms to protect consumers from inadvertently consuming products that represent a risk of allergy.
- Section 20 needs attention and amendment to harmonise with recent changes to allergy disclosure by other regulatory requirements. Technical discussion in Attachment 1.

Section 21 – Consistency with public health campaigns

- CMA supports the intent of this Section. Technical discussion is included in Attachment 1.

Sections 22, 24

- CMA supports these Sections.

Section 23 – Complementary Medicines

- CMA supports Section 23. We do not support any expansion of this Section. We note Australia’s commitment to the World Health’s Organisation’s strategy on traditional medicines. Technical discussion is included in Attachment 1.

Section 26 – Weight Management

- CMA supports Section 26 and the intent of managing weight loss claim advertisements responsibly. Technical discussion is included in Attachment 1.

Section 28 – Restricted representations

- In the main, CMA supports the proposed wording of the restricted representations.
- CMA proposes an amendment to allow **alignment with permitted indications**. Technical discussion is included in Attachment 1.

Section 29 – Prohibited representations

- CMA supports Section 29.