

## Introduction

I welcome the opportunity to provide comment with regard to the TGA's consultation on the proposed improvements to the 'Therapeutic Goods Advertising Code'.

I acknowledge the TGA's efforts in reducing red tape by removing the preapproval process, and assisting industry in self-assessment. I also acknowledge the TGA's acceptance of the review panels recommendation that consumer advertising of all medicine types should be consistent. Given the large difference in risk profile between listed complementary medicines and registered OTC products, I do not agree that such an approach is appropriate, especially given the number of proposed updates in the Code requiring a heavier burden of contraindication and safety messaging, as well as detailing evidence within advertisements.

I provide the following comments for consideration.

## Proposed changes

### Changes to support effective sanctions and enforcement of advertising.

I agree in principle but await a draft Code for specific comment.

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

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I agree with minimising subjectivity in interpretation of the Code and would like to see this achieved through the development of a comprehensive guidance document. Rather than creating numerous, lengthy, and highly specific provisions in the Code, a guidance document would maintain flexibility and achieve the desired outcome in reducing subjectivity. This guidance document would be helpful if made available to sponsors on the TGA website.

I also agree in principle to an education program for industry, however it remains unclear if this would be a mandatory, or voluntary program. I recommend that the education program would be voluntary except in cases where non-compliance may see the education program being used as part of the sanction process.

### Core objectives of the new Code

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The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described in section 4.2, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

#### **1. Advertisements must comply with the *Therapeutics Goods Act 1989*, regulations made under this Act, and the *Therapeutic Goods Advertising Code***

I agree with this core principle.

## **2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of goods on the ARTG**

Regarding the proposed provision, ‘...advertisements must not directly, or indirectly or by implication, omission, ambiguity, exaggerated claim or comparison mislead or deceive, or be likely to mislead or deceive, or abuse the trust or exploit the lack of knowledge, or exploit the superstitious or, without justifiable reason, play on fear, or cause distress’, I request that there be clarity around what would constitute ‘a justifiable reason’ for causing distress or playing on fear, e.g. a ‘justifiable reason’ may be where there is a public health benefit in the statement or message within the advertisement that is of higher value than any distress or fear that may be caused by such a message.

Regarding the proposed provision, ‘an advertisement (including a product label) must not contain any claim, statement or implication that: - it is effective for specific demographic groups of patient (particularly where this may be a vulnerable group) without detailing the supportive evidence’, I request further clarity on what would be sufficient in detailing the supporting evidence for claims of efficacy for certain populations. For example, in advertising of a multivitamin which has been developed for a particular population such as men, women or for pregnancy, there are a multitude of studies that support the use of ingredients included in the product for such populations, which would make it very difficult to detail the supportive evidence in advertising. Therefore, I oppose provisions that would require detailing supporting evidence where there has been an implication of efficacy for a specific population, including vulnerable groups.

Additionally, any new terms introduced in the new Code should be accompanied by clear definitions (e.g. ‘Vulnerable population/group/persons’, ‘the superstitious’), and multiple examples which are relevant for each class or type of medicine, and/or device. These definitions could be in the Code itself, or as part of the guidance document.

## **3. All claims used in advertisements must be substantiated**

I oppose provisions where ‘the advertisement must **identify the sponsor of the scientific study** and must also detail if the sponsor of that study has, or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement’.

If necessary, it would be more relevant to disclose a conflict of interest where authors of a study are employed by the sponsoring company and is more in line with current ‘**Guidelines on the evidence required to support indications for listed complementary medicines**’ and how research papers are written and published. I recommend any disclosure of financial interests be limited to these circumstances.

## **4. Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help.**

I oppose contraindications being added to advertising, except in certain circumstances, such as scheduling requirements. An advertisement is not an appropriate place to educate a consumer on concomitant medicine use, or side effects.

I insist that the mandatory statement ‘always read the label and use only as directed’ is sufficient. The label and product information provides safety information on contraindications, where required to do so, and given that the labelling orders have been updated to increase clarity of safety

messaging on pack, and that the information is available at the point of purchase, provides sufficient and appropriate protection to consumers.

With the proposed update to include contraindication information in advertising there is considerable increased risk to consumers. Updates to contraindication information on product packaging and advertising may differ from one another due to inherent constraints in time-to-market of these materials. Consumers will not know which source of information is correct and it is impossible to guarantee that the updated information would appear in packaging and advertising in market at the same time. One source of product specific contraindication information, e.g. the product packaging, would reduce this risk. Often an advertisement contains multiple therapeutic goods, thus having to provide contraindication information for each of these medicines would further obfuscate the message, and contradict the objective of the Code to have clear messaging.

I also request that the TGA consider the added burden to industry to maintain up-to-date contraindication information considering that some marketing materials have a market shelf life of 2 years upwards. Each time an update to contraindication, or safety message occurs marketing material would need to be pulled from market and replaced.

If the TGA persists with this inclusion in the new Code then I would request that it be applied to appropriate classes of medicine only, e.g. OTC medicines, and exclude the lower risk listed medicines.

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

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I agree with development of comprehensive guidelines which should be made available on the TGA website.

### The Council recommendations

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

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As mentioned previously, I oppose requirements pertaining to declarations of sponsors of research in advertising.

### Consultation comments

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*Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?*

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I agree in principle but await a draft Code for specific comment.

## Price information Code of Practice (PICOP)

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*Do you consider that the PICOP should: remain in the new Code, or; be established as a separate legislative instrument under the Therapeutic Goods Act 1989, or; are there other mechanisms for managing compliance with the PICOP?*

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I consider that the PICOP should remain in the Advertising Code, and non-compliance be managed by mechanisms proposed for general therapeutic goods advertising.

## An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines.

I agree in principle on this section however I do work with any schedule 3 products currently and will not add detailed comments on the proposed framework within this consultation.

## Next steps

I welcome further consultations on the draft Code and any other proposed changes to the advertising framework.