RACGP

Royal Australian College *of* General Practitioners

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# *RACGP submission*

# *Therapeutic Advertising Code*

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## 1. Introduction

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) on options to improve the Therapeutic Goods Advertising Code (No.2) 2018 (the Code).

The RACGP is Australia's largest professional general practice organisation, representing over 41,000 members working in or toward a career in general practice. The RACGP is responsible for:

- defining the nature and scope of the discipline
- setting the standards and curricula for training
- maintaining the standards for quality general practice
- supporting specialist general practitioners (GPs) in their pursuit of excellence in patient and community service.

## 2. General comments

The RACGP strongly supports the regulatory role of the TGA and takes a keen interest in the regulation of advertising of therapeutic goods. Consumer choice based on unregulated mass advertising, claims, testimonials, and free samples can result in increased costs to the patient and reductions in the quality of decision-making. The Code plays a critical role in prescribing the minimum requirements for the advertising of therapeutic goods to the public in Australia.

GPs are responsible for most medical prescriptions in Australia and are regularly involved in discussions with patients around over-the-counter medications where advertising and promotion may have influenced the patient's purchasing decision. As such, the RACGP provides the below feedback regarding the proposed options to improve the Code.

## 3. Recommendations

The RACGP recommends the TGA address the below feedback in its review of the Code.

## 4. Feedback on the specific TGA proposals for reform

**Section 4: Additional definitions**

The RACGP supports the proposed clarifications of the terms: 'claim', 'indication' and 'intended purpose' in the Code. It is expected these clarifications will help advertisers understand how relevant Code requirements should be applied in relation to an advertisement.

The RACGP notes greater guidance is needed in this section about the accuracy of advertising claims for therapeutic goods. Although scientific articles are peer reviewed, they can be subject to bias, withdrawals, quality issues, narrow definitions of participants, and misleading use of certain terms, including different types of risk in academic studies. Claims should be backed by recently conducted high-quality systematic reviews where these exist to prevent 'cherry-picking' of convenient peer reviewed single-trial articles.

**Section 10: Prohibition on causing fear or distress**

The RACGP strongly supports amendments to the Code to ensure it adequately prevents an advertisement from causing 'fear and distress'. We support the introduction of a clause like that in the 2015 version of the Code, as per the following:

> *Advertising for therapeutic goods must not exploit consumers' lack of knowledge or contain language that could bring about fear or distress.*

The RACGP also supports further amendment to Section 10 to restrict suggestions that entire demographics should be consuming a particular therapeutic good. Marketing based on 'fear of missing out' should not be acceptable. This amendment could include an exception if future national guidelines made a clear recommendation for use of a particular therapeutic good in a specific population or group.

**Section 11: Introduction of a mandatory statement for therapeutic goods that cannot be purchased by the public**

The RACGP supports the inclusion of a new statement for advertisements of goods that cannot be purchased by the public. The following statement is preferred:

> *This product / these products can only be purchased by health professionals and healthcare facilities. Talk to your health professional about whether this product would be right for you.*

The RACGP considers that, in general, advertisers should hide advertisements directed at health professionals from the public if they can do so. Ideally, advertisements for products directed towards health professionals should be restricted from certain communication channels if there is a 'reasonable expectation' that the audience will include the public. Examples include television, radio, mainstream print media and associated internet sites, social media and publicly displayed posters and flyers.

**Section 12: Streamlining requirements for mandatory statements in advertisements for the purchase of therapeutic goods without prior physical examination**

For advertisements that facilitate the purchase of a therapeutic good without prior examination, the RACGP is supportive of the Code requiring advertisers to reproduce relevant health warnings in the advertisement wherever possible.

Where there is limited physical space or character counts, providing the option for consumers to click a hyperlink to access health warnings may be appropriate. This should only be allowable in exceptional circumstances where the TGA has confirmed space is a clearly proven issue prior to the advertisement's distribution.

For advertisements that facilitate the purchase of a medicine without prior examination, the RACGP does not support conveying the necessary warnings and contraindications through a reproduction of parts of a medicine label. This option could be confusing for consumers, open to significant interpretation by advertisers and result in the advertisement not fully representing all the relevant information about a medicine.

In addition, more visible and explicit warnings are needed when the therapeutic claims or use-indications relate to potentially serious medical conditions and/or the product could have significant adverse effects.

**Section 13: Requirements for mandatory statements in other types of advertisements**

The RACGP supports the requirements under Section 13 regarding the general information that all advertisements for medicines, medical devices and other therapeutic goods must contain.

Our view is that the list of current exceptions provided under subsection 13(5) should not be expanded.

It is suggested that if a platform does not allow for the thorough provision of all relevant information, that platform should potentially be considered unsuitable for advertising therapeutic goods.

**Sections 12 and 13: Wording of mandatory statement**

The RACGP supports the retention of the current wording of the mandatory statements. The provision of as much information as possible in the mandatory statements is supported.

**Schedule 1: Option to amend the approach to the identification of health warnings**

The RACGP supports the approach in the consultation paper for determining the relevant health warnings included in an advertisement. The procedure could be made clearer by including defined guidance on what is mandatory to include, what is desirable and what does not need to be included.

The reliance on the label of the medicine available to the advertisers is considered appropriate.

**Section 16 Endorsements and Section 17 Testimonials**

The RACGP supports Option 1 outlined in the consultation paper. This option is flexible and will most appropriately support the ongoing application of Sections 16 and 17 of the Code.

The RACGP notes that product safety certification should not be used in advertising to endorse therapeutic products. Statements such as 'TGA approved' are liable to be misinterpreted by the public.

Further, we caution that testimonials highlight experiences of a single individual at a single point in time and can be misleading. As such, testimonials do not necessarily assist the public in making an informed choice.

**Section 20 and Schedule 3: Clarification of samples requirements and additional eligible goods**

The RACGP supports amending subsection 20(1) to make it clear that both the offer of a free sample of therapeutic goods, and the provision of the therapeutic good sample itself, in advertising are prohibited.

The RACGP does not support permitting applications for therapeutic goods to be considered for inclusion in Schedule 3.

**Sections 28 Restricted representations – serious form of disease, condition, ailment or defect; and 29 Restricted representations – public interest criteria: clarifications**

The RACGP supports the proposed language for Sections 28 and 29 of the Code.

**Section 30 Prohibited representations: clarifications**

The RACGP supports the proposal not to change the operation of Section 30 of the Code.

## 5. Conclusion

The RACGP encourages the TGA to consider the above feedback throughout the process of revising the Code. Further, we encourage the TGA to undertake targeted engagement with GPs in their next relevant consultation and ensure the consultation materials are as clear and concise as possible.

We welcome the opportunity to contribute to further discussions about the Code on behalf of our members and look forward to continuing to support effective regulation of advertising of therapeutic goods.

Please contact Leonie Scott, National Manager – Policy and Advocacy, on (03) 8699 0031 or via leonie.scott@racgp.org.au if you have any questions or comments regarding our feedback.