

13 October 2017

Comments to the Consultation: Therapeutic Goods Advertising Code

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

The Company supports minimising subjectivity in the interpretation of provisions in the new Code. The current Code has not kept up with the rapid development in digital technology and platforms. Unless a device includes a S4 substance, the Act allows advertisement of medical devices to the public; however some of the current provisions of the Code cannot be applied to advertisements of these therapeutic goods. These have allowed varying interpretations, both by the advertiser and by those who administer the Code. Ultimately, the casualty is the consumer who is exposed to contents that are decided 'on the spot' by those who interpret the Code, in spite of their best intentions. A thoughtful and thorough review and update of the Code, provision of guidelines and formal sponsor education will go a long way in ensuring a more objective interpretation of the provisions of the new Code, and will help enable a more self-regulatory regime.

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods. The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code. Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below). Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

The Company supports the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods. Regarding the requirement to satisfy four core objectives

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

The Company agrees that advertisements must satisfy this core objective

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

The Company agrees that advertisements must satisfy this core objective. However, we question the specific requirement to include all mandatory and applicable information (e.g., contraindications and warning statements) in the advertisement. Firstly, it may not be possible to include these pieces of information due to space and time constraints. Secondly, there's a risk the safety information will cause consumers undue concern about drug safety and may cause noncompliance. It may also lead to increased GP visits by consumers needing assurance about the safety of their medicine or requesting the GP to prescribe a medicine for an ailment that is amenable to management by a non-prescription medicine.

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

The Company agrees that advertisements must satisfy this core objective. However, guidance must be given on the level of details that must be provided in case where Data on File is used to substantiate a claim.

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*

The Company agrees that advertisements must satisfy this core objective.

Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code? Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?

The Company offers the following comments to Section 4.3 Council Recommendations

New definitions of prohibited and restricted representations

The Company supports this change. Additionally, the requirement against prohibited and restricted representations must include product names, which themselves can mislead consumers into believing that the therapeutic good is a treatment for the condition that is contained in the product name, for example, IBS Support, Macula Support, Bio-Arthritis.

New restricted representations

- Reference in an advertisement for a therapeutic good 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.

The Company does not support this recommendation because in cases where the approved indication for the product is for use in a treatment that requires a procedure, it will contradict the requirement to include a reference to the approved use of the product, and this can result in misinformation and confusion. Additionally, the AHPRA Guidelines for Advertising Regulated Health Services provides adequate regulation of such services, such as the requirement to include specific mandatory warning statements.

- Reference to “obesity” either directly or indirectly to become a restricted representation within the meaning of the Therapeutic Goods Act 1989 (the Act).

The Company supports this recommendation. With overweight and obesity reaching epidemic proportions in Australia, too many products, both food and therapeutic goods purport to offer treatment for obesity without adequate scientific substantiation. Obesity is recognised by the WHO as a chronic disease that requires defined intervention. Including obesity as a restricted representation may help deter opportunistic advertiser from preying on the desperation of people suffering from this condition, by imposing specific conditions in any approval for exemption.

4.4. Consultation comments

The Company agrees with these comments.

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?

The Company offers no comments.

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

The Company supports advertising Schedule 3 (S3) medicines directly to the general public. When a medicine is placed in Schedule 3 in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), the Advisory Committee on Medicines Scheduling (ACMS) would have assessed the safety of the medicine, the potential risks it poses to consumers, and has determined that the medicine can be supplied to the consumer after consultation with the pharmacist, without a doctor prescription, to enable speedy access to effective treatment. Therefore, we believe that consumers have a right to know what treatments are available.

Advertising of S3 medicines directly to the general public will significantly increase consumer awareness of availability of treatments for a wide variety of ailments. This will have many beneficial flow-on effects. For example, consumers have easier access to community pharmacists compared to general practitioners (GPs), enabling timely access to medical advice and treatment. This in turn will likely reduce the number of GP visits due to delayed treatment and worsening of disease, leading to Medicare cost savings and the freeing up of GPs for more serious ailments.

In light of the above, rather than retaining a “positive” list, we propose to have a “negative” list in Appendix H to enable as many S3 medicines to be advertised as appropriate.

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In particular, we would appreciate feedback on

- ***the specific requirements for advertisements containing Schedule 3 substances***
- ***factors to be considered by the delegate***
- ***restrictions on inclusion in Appendix H***
- ***the proposed process***

The Company’s comment:

the specific requirements for advertisements containing Schedule 3 substances

- Statement A - “Your pharmacist’s advice is required”
- Proposed statement B - “Your pharmacist must decide if this product is suitable for you”
- Proposed statement C - “Ask your pharmacist about side effects relevant to you”

Currently, Therapeutic Goods Advertising Code 2015 (the Code) already has provisions in place for the advertising of S3 medicines to the public (for example, S3 advertising must include the

mandatory statement “Your pharmacist’s advice is required” – Statement A). Therefore, we disagree with the TGA’s proposal to include additional mandatory statements (“Your pharmacist must decide if this product is suitable for you” “Ask your pharmacist about side effects relevant to you” – statements B & C). Mandatory statements are important to inform the consumer where they can access a medicine and also to ensure the product is used correctly. However, too many mandatory statements can detract from the main message or put consumers off from reading them at all. Hence, we believe the two additional statements are unnecessary, as they are already encapsulated in statement A.

However, currently the Code causes confusion regarding exactly what the requirements are in S3 advertising, particularly section 6, paragraph (3)(e). The paragraph starts with “or”, but it is unclear what it is an alternative to. Thus, clarifications are needed on exactly what mandatory statements are needed in S3 advertising.

If the TGA’s proposed mandatory statements are to replace statement A, we believe only proposed statement B is relevant and necessary, as the message in proposed statement C is already encapsulated in proposed statement B. During a pharmacist consultation, the pharmacist will have assessed if there are any contraindications, drug interactions and will have advised the consumer on dosage as well as expected side effects as part of the pharmacist’s professional service. Thus, it is unnecessary to single out side effects as in proposed statement C.

A general comment on the positioning of mandatory statements; statements are mandatory because they deliver important messages to the public. They should be presented in the easiest and most logical way possible for an audience to receive and retain that information. Therefore, separating them, e.g. one mandatory statement at the top and another at the bottom of a printed advertisement, would not be the best way of delivering the information because the audience would have to look at several places on the ad as the messages are dispersed. Similarly, in broadcast media, having one mandatory statement as a leading statement without any context of what the advertisement is about is not the best way to deliver the message, as the audience would not remember it by the end of the ad. We believe mandatory statements should be placed together in one location. Hence, if the TGA were to replace statement A with proposed statement B, we believe it should not appear at the top of a printed advertisement, or be the leading statement in broadcast media.

- factors to be considered by the delegate

The delegate needs to consider realistically what the risks are in permitting the advertising of S3 medicines to the general public and if they are based on sound assessment of real world data rather than theoretical conjectures. They need to be weighed against the benefits of increased public awareness of common ailments and the available treatments, timely access to medication and reduced incidents of complications.

- restrictions on inclusion in Appendix H

An S3 medicine is not an over-the-counter product, consumers cannot self-select and a pharmacist must be involved in its supply. Therefore, we believe that as many S3 medicines should be permitted to be advertised to the general public as appropriate. Thus, we support turning Appendix H into a “negative” list of S3 medicines that cannot be advertised.

We disagree that all substances for use in emergency situations should be excluded from DTC advertising, for example, salbutamol in an acute asthmatic attack, or injectable adrenaline in anaphylactic shock. These are life-saving substances and increasing public awareness of their availability will have significant public health benefits.

- the proposed process

When a new S3 product is submitted to be registered on the Australian Register of Therapeutic Goods (ARTG), the submission should have a justification of why it should be allowed to be advertised directly to the public. If the justification is sound, then the “negative” list in Appendix H can remain the same, which can potentially reduce the administrative burden of having to regularly update the SUSMP.

The current process for DTC advertising of S3 medicines is working. That is, external approval is required for all S3 advertising in broadcast media. A mandatory statement to consult a pharmacist should be included.

OTHER MATTERS

Section 2 – Definitions: Therapeutic Goods Advertising Code 2007 had the full definition of each term displayed, however, the 2015 edition only displays the relevant sections in the Therapeutic Goods Act or Regulation. For easier usability of the Code, full definitions should be brought back.

Section 3, paragraph (3) – the updated wording in Therapeutic Goods Advertising Code 2015 is much harder to comprehend compared to the wording in Therapeutic Goods Advertising Code 2007. For easier usability of the Code, improvement on the wording is needed.

Section 6, paragraph (3)(i) – a definition for direct marketing is needed. Currently there is no clear definition of what is considered direct marketing.