

9 October 2017

Advertising Compliance Unit  
Regulatory Practice, Education and Compliance Branch  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

To whom it may concern,

**Re: Consultation: Therapeutic Goods Advertising Code — Proposed improvements including proposed framework for Schedule 3 medicine advertising**

NPS MedicineWise would like to thank the Therapeutic Goods Administration (TGA) for providing the opportunity to offer feedback on the proposed improvements for Schedule 3 medicine advertising.

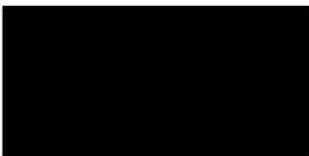
NPS MedicineWise is an independent, not-for-profit and evidence-based organisation that supports the quality use of medicines and medical tests. Therefore, our work is aligned with the object of the Code, which is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

After reviewing the consultation document, we are supportive of the proposed improvements to the Code. We agree with proposed changes to provide more objective tests to determine breaches of the Code; address the inconsistencies between medicines and medical devices (where appropriate); and develop a framework to underpin advertising of S3 medicines to the public.

Specific comments are provided below in response to the questions posed in the consultation document.

Thank you again for the opportunity to provide feedback. We are very happy to provide further clarification or guidance as needed and look forward to our continued collaboration with the TGA in the future.

Yours sincerely,



Bronwyn Walker  
External Relations and Policy Manager

## Specific comments

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

We support this change and agree it would be of mutual benefit to advertisers and regulatory decision makers to have clearer and more detailed objective requirements applying to advertisements about therapeutic goods directed to the public at large. The changes are of particular importance given the Government's acceptance of the recommendation that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

In addition, more objectivity would enable greater clarity in monitoring compliance with changes and may be helpful in supporting research on the impact of changes in consumer behaviour.

***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 [4.2], and any other details or requirements that stakeholders believe should be clearly specified under the new Code.***

We strongly endorse the 4 core objectives that are specified the code should satisfy:

1. Advertisements must comply with the Therapeutic Goods Act 1989, regulations made under this Act, and the Therapeutic Goods Advertising Code
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
3. All claims used in advertisements for therapeutic goods must be substantiated
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.

***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?***

We agree guidelines should be developed and made available. The guidelines should be made available via TGA website. The guidelines could be presented in online learning modules and illustrated using case studies.

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

We are supportive of the including recommendations in 4.3 in the code, ie:

- ▷ New definitions of prohibited and restricted representation
- ▷ New restricted representations
- ▷ Testimonials and free samples.

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

We support Code changes proposed in 4.4:

1. To remove subjectivity by revising the interpretative provisions.
2. To clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising, and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis.
3. To develop guidelines to assist with understanding of the requirements to enable compliance to the Code.

**Do you consider that the Price Information Code of Practice (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?**

We are uncertain of the implications of establishing a separate legislative instrument for PICOP. However, we are certain that understanding of price of products is an important determinant in consumer decisions to buy products and in how they use products. In addition, often it is not straightforward for consumers or health professionals to determine the price implication of medicines. Therefore we are supportive of better underpinning of the PICOP in developing the new Code.

**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.**

**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**

Specific requirements for advertisements

We support the proposed additional requirements for advertisements for medicines containing Schedule 3 substances, ie:

- ▷ “Your pharmacist *must decide* if this product is suitable for you.”
- ▷ “Ask your pharmacist about side effects relevant to you”.

Factors to be considered by the delegate

We support the existing factors that are considered by the delegate in the current Scheduling Policy Framework for making a decision on whether or not a substance should be included in Schedule 3 of the Poisons Standard, namely:

- ▷ The potential public health benefit;
- ▷ The likelihood of advertising of the substance leading to inappropriate patterns of medication use;
- ▷ The provisions of the Code and any prohibited and restricted representations relevant to the substance;

- ▷ Whether the application may result in advertising of goods for an indication other than those included in the Australian Register of Therapeutic Goods;
- ▷ The responsibility of pharmacists to be actively involved in the supply of [these] substance(s);
- ▷ Available Consumer Medicine Information;
- ▷ Available Risk Management Plan and application to the substance in an S3 environment;
- ▷ The level of patient education necessary to ensure safe and effective use;
- ▷ The desire of consumers to manage their own medication;
- ▷ Any other information that is relevant to the decision making.

#### Restrictions on inclusion in Appendix H

We generally agree with the proposed categories that may not be appropriate for DTC advertising however we are unclear of the rationale why the category 'Substance for use in emergency situations' may be inappropriate.

#### The proposed process

We are supportive of the proposed process.