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From the President

12 October 2017

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

Via Email: advertising.consultation@tga.gov.au

Dear Sir/Madam

Re: TGA consultation on Therapeutic Goods Advertising Code (the Code)

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to contribute to the Therapeutic Goods Administration (TGA)'s consultation on proposed changes to Therapeutic Goods Advertising Code and Schedule 3 medicine advertising framework.

The Therapeutic Goods Advertising Code (the Code) is a crucial instrument of the therapeutic goods advertising regulatory framework that protects consumers in Australia against misleading, unproven claims and promotions of medicinal products, especially those products for serious conditions or with no pre-market assessment and post-marketing surveillance. The RACP strongly supports many of the proposed reforms. However, it is vital that the TGA has sufficient resources and enforcement capabilities to impose timely and effective sanctions for any advertising breaches and deter repeated offences. This is central to any reforms having the impact they have been designed to achieve.

The RACP supports the Code being less subjective and the proposal for associated guidelines to be developed. The provisions in the new Code and the associated guidelines need to be clear, concise and sufficiently detailed such that both the user and the regulator understand what is and what isn't compliant within the Code. We specifically recommend that the associated guidelines be developed by people who have considerable expertise in medicine advertising but who no longer have a direct connection with pharmaceutical companies, to ensure that they reflect and appropriately deal with the complex context. In terms of the price information code of practice, it should be included in the new Code.

On the issue of misleading and unproved advertisement claims, the Code must be sufficient to ensure there can be no repeat of the incidence of false claims, exemplified by the case where Nurofen claimed specific pain relief, despite each product containing identical active ingredients. As well as the issue of inflating prices of consumer medicines, such claims can easily mislead consumers and result in medication overdose.

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The new Code must not permit:

- The use of strong adjectives or adverbs to describe the efficacy of medicines, for example: 'rapid relief' ', ' strong action', or 'works quickly;
- The use of visual content that contains positive emotional appeals or that potentially can generate unrealistic expectations of, or beliefs about product efficacy, for example, employing the image of an active young woman to promote a product for which the majority of its users are over 60 years old; and
- Any reference to any successful clinical trials which had minority participation.

The RACP is concerned about the impacts of direct to consumer adverting (DTC) of S3 medicines on consumers. DTC advertising can potentially encourage consumers to self-medicate and to request an S3 medicine that is not the best treatment for them; less experienced pharmacists may feel pressured to allow its purchase despite knowing it's not the most appropriate treatment. Moreover, it is undeniable that pharmacy is not only a health profession, but also a retail business, which needs to build good customer relations and satisfaction levels in order to maintain their loyalty and repeat purchasing.

Furthermore, S3 medicines encompass an extremely wide range of medicine categories; from asthma (e.g.Ventolin inhaler) and weight loss medications (e.g. Xenical) to cold and flu medications (e.g. Pseudoephidrine combination products). Some of these S3 medicines carry potentially serious adverse side effects or risk of abuse.

Therefore, the RACP strongly supports the status quo, whereby the default is that Schedule 3 substances are not able to be advertised directly to consumers, and that they are specifically considered for this on a case by case basis and only included in Appendix H if deemed appropriate.

The RACP appreciates the opportunity to provide input into such an important issue and would like to remain informed of and be involved in future consultations and developments on this matter. Should you require any further information regarding this response, please contact [redacted]

Yours faithfully

[redacted]

Dr Catherine Yelland PSM