

Thank you for the opportunity to comment on the proposed **improvements to the Therapeutic Goods Advertising Code** that is being developed by the Therapeutic Goods Administration (TGA). To quote from the consultation paper, *“The object of the Code 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.”*

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

We support this suggestion. In particular, we support the proposal to develop education programs and to provide sample advertisements that are acceptable marketing items. However **we do not support the proposal to change the advertising to a self-regulatory regime**. Therapeutic goods are a special product and inappropriate use can lead to considerable harm. Inappropriate use of medicines can lead to delayed access to correct treatment and adverse side effects.<sup>1</sup> Some non-prescription medicines are later found to have significant safety concerns, and are removed from sale or returned to prescription-only status.<sup>2</sup>

Even among commonly-used medicines considered safe enough to maintain over-the-counter status, such as paracetamol, preventable adverse events are a frequent cause of emergency department visits, hospitalisations and deaths.<sup>3</sup> A study of Australian parents found that children are often provided over-the-counter medications for reasons other than medical need, raising concerns about medication misuse among a vulnerable population group.<sup>4</sup> By providing unrealistic expectations of the outcomes of medicine use, advertising messages can contribute to inappropriate use.

Self-regulation with post-advertisement recall after consumer complaints is an insufficiently powerful system for public protection. There has been little systematic evaluation of the quality of advertising for non-prescription medicines governed under self-regulatory systems. However, a systematic review on the quality of information of pharmaceutical advertising in medical journals - mainly governed through self-regulation - found widespread low information quality, unlikely to support rational medicine use.<sup>5</sup> Consumers are a more vulnerable target audience.

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

We agree that guidelines for the new Code would be useful. We applaud many elements within the suggested core objectives for the new Code, in particular we commend the TGA for highlighting the importance of reporting the sponsor of scientific studies referred to in advertisements (4.2, point 3). We note that clinical research can be biased at many points in the research cycle, and that over all, industry funded research is more likely to deliver results that are favourable to the sponsor.<sup>6</sup>

Further to the text on substantiation of claims (also 4.2, point 3), we strongly recommend additional guidance regarding the form of research evidence that may be

used to substantiate claims of treatment benefits, specifically that these claims must include quantitative information on the likelihood of treatment success and that such claims must be based on systematic reviews of randomised controlled trials or randomised controlled trial evidence.

We applaud the requirement for mandatory information on harm as well as benefits in advertising including contraindications and warning statements, serious adverse events and the most common adverse events. (4.2, point 4), Attention is needed to ensuring that such information is presented with as much prominence and similar font size as information on benefits.

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

We recommend **prohibiting the use of testimonials** in the advertisement of medicines because these could encourage inappropriate use of medicines by consumers. We would encourage the TGA to adopt the same stance on prohibition that is used in the United Kingdom: *“Advertisements to the general public should not contain material which refers to recommendations by scientists or healthcare professionals, or which refers to recommendations by celebrities who, because of their celebrity, could encourage consumption of products”*.<sup>7</sup>

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

We agree with these proposals, which build on the suggestions above about developing a new Code that is less subjective, includes examples of compliant and non-compliant advertising, and has accompanying guidelines.

#### 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?

No comment

#### 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
- the proposed process

We recommend **retaining the existing system whereby prohibition of advertising is the default position for Schedule 3 drugs**, and permission of advertising is

considered on a case by case basis, with the decision to allow advertising based on reliable, high quality evidence of an added benefit to public health from such advertising for the specific product in question. Advertising of S3 medicines is likely to lead to inappropriate use. This is partly because advertising limits the effectiveness of pharmacists to perform their important gatekeeping function for S3 medicines. Consumer requests for specific products interrupts the desired process whereby consumers discuss their needs with pharmacists, who then provide advice about appropriate medication to consumers.<sup>1,8</sup> Consumers who demand particular products are likely to be able to obtain them even if that product is unsuitable for their needs, by targeting, for example, busy pharmacies where supervision by a pharmacist is 'perfunctory' or from unregulated sources via the internet.<sup>9</sup>

We look forward to the forthcoming public consultation on the new draft Code in late 2017 / early 2018.

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## References

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