Submission to Therapeutic Goods Administration consultation: The regulatory framework for advertising therapeutic goods

October 2017

Introduction

Our previous submissions to the Therapeutic Goods Administration (TGA) have provided an overview of the structure and history of the National Registration and Accreditation Scheme (eg our November 2016 submission on advertising reforms) and the restrictions on advertising a regulated health service under the Health Practitioner Regulation National Law, as in force in each state and territory. We have not repeated this content here but would be happy to provide further information if it would assist.

Relationship with the Therapeutic Goods Administration (TGA)

Anyone who advertises a regulated health service must comply with the National Law's advertising provisions and other applicable Australian legislation, including the Australian Consumer Law (ACL), the Therapeutic Goods Act and regulations.

If an advertising complaint is relevant to another regulator such as the TGA, AHPRA will refer the matter for consideration. The *Guidelines for advertising regulated health services* further explains how the National Law relates to other laws that apply to advertising.

Response to Consultation: Therapeutic Goods Advertising Code

We note that the consultation paper references government decisions and reform directions made following previous consultations to which we contributed, and outlines the implications and proposed changes for the Therapeutic Goods Advertising Code.

The consultation paper outlines how the types of therapeutic goods being promoted and sold directly to the public have broadened and the ways in which the advertising of therapeutic goods has changed. We have also been aware of these changes and the potential implications for regulation of the professions in the National Registration and Accreditation Scheme. Like the TGA, we recognise the need for advertising regulation to remain effective and relevant in a highly dynamic environment.

We support the proposed updating of the Code to address aspects that have become outdated. We also support the proposed work to minimise subjectivity in the interpretation of the Code. We also note and support the proposal for a formal advertising compliance education program to facilitate compliance and are interested in more information about this aspect of the reforms.

We support the core objectives for the new Code, including the objective that all claims made in advertising therapeutic goods must be substantiated. We support the explanatory material about this objective and in particular, that advertising must reflect the body of scientific evidence. The National Boards have also taken action to clarify the evidence needed to support therapeutic claims made in advertising a regulated health service. Boards have advised that to avoid the potential to be misleading and deceptive, advertisers must have acceptable evidence for any therapeutic claims made.

We note the consultation paper position on testimonials that they must be authentic, genuine, current and typical and acknowledge any valuable consideration provided for the testimonial. The person providing the testimonial must be accurately identified and must not be an employee or related to the sponsor or the advertiser. The National Law prohibits using testimonials to advertise a regulated health service. We have adopted a risk-based approach to enforcing this prohibition in the context of health practitioner regulation, and only pursue

advertising which involves testimonials about the clinical care aspects of regulated health services. We are at the early stages of reviewing the Guidelines for Advertising a Regulated Health Services and expect advertising involving testimonials to be a key focus.
We agree that a public interest perspective must inform advertising regulation. We agree that advertisements must not discourage consumers from taking medicines prescribed by a health care professional, particularly those regulated under the National Scheme. We also agree that advertisements should not offer personal incentives to sales personnel employed by health practitioners.

In relation to the specific question of whether further guidelines should be developed for advertisers, we would support this approach if it provides additional clarity and facilitates compliance.

We note that previous consultation feedback on the proposal to revise the Code expressed support for publishing examples of compliant and non-compliant advertising. Stakeholders have expressed similar views to National Boards and AHPRA and Boards have recently published a range of examples.

In relation to the canvassed option for an Advertising Framework for Schedule 3 (pharmacist only) medicines, we reiterate our previous support for maintaining Appendix H of the Poisons Standard which enables pharmacists to meet their legal and professional obligations in relation to the supply of Schedule 3 medicines including when it is appropriate to supply such medicines.

We note the proposal to allow direct to consumer advertising of a wider range of Schedule 3 substances which was supported by a significant majority of stakeholders in the recent *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)*. We also note the additional safeguards proposed including the additional specific labeling requirements for medicines included in Appendix H, and the list of categories of medicines which may not be appropriate for direct-to-consumer advertising. We agree with the proposed limitations, and note that these may need to be reviewed from time to time in order to ensure public safety is not compromised.