



Aboriginal and Torres Strait
Islander Health Practice
Chinese Medicine
Chiropractic
Dental
Medical
Medical Radiation Practice
Nursing and Midwifery
Occupational Therapy
Optometry
Osteopathy
Pharmacy
Physiotherapy
Podiatry
Psychology

Australian Health Practitioner Regulation Agency

1 June 2018

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

Consultation: Complaints handling – Advertising therapeutic goods to the public

Dear Advertising Compliance Unit

Re: Submission from National Boards and AHPRA about the proposed complaints handling model for advertising therapeutic goods

The National Boards and the Australian Health Practitioner Regulation Agency (AHPRA) are pleased to provide the following joint response to the Therapeutic Goods Administration's (TGA) proposed advertising complaints handling model.

Given National Boards and AHPRA are responsible for regulating the conduct of health practitioners and advertising of regulated health services there are clear links between how we each manage complaints about advertising. We support the risk-based, proportional approach and the priority framework proposed for complaints handling and are pleased to contribute to the consultation process and share our experience in implementing a risk-based approach to the regulation of advertised health services.

The attached joint response provides the collective views of National Boards and AHPRA. We are keen to work with you and other regulators to identify relevant intersections and opportunities for collaboration to improve how we regulate and more effectively protect the public from harm.

If you wish to discuss this matter, please contact Chris Robertson, Executive Director Strategy and Policy Directorate on 03 8708 9037.

Thank you again for the opportunity to comment.

Yours sincerely

Martin Fletcher

Chief Executive Officer
Australian Health Practitioner Regulation Agency

Submission to Therapeutic Goods Administration consultation: Advertising complaints handling model

June 2018

Introduction

Our previous submissions to the Therapeutic Goods Administration (TGA) 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. Please contact us if you seek more information about this.

In May 2017, we launched the Advertising and Compliance Strategy for the National Scheme (the strategy). The strategy explains:

- how our risk-based approach is applied to advertising compliance and enforcement
- how we encourage voluntary compliance and deal with non-compliant advertising, and
- how we plan to evaluate and refine this strategy.

The proposed complaints handling model for advertisements of therapeutic goods directed to the Australian public aligns closely with the approach AHPRA and the Boards have taken to ensure advertising about regulated health services is done responsibly. As a risk-based regulator we too have applied a risk –based approach to regulating advertising enforcement and compliance. This means we take different actions depending on the level of risk identified and what is likely to have the most impact. We focus our resources on the highest risk matters and those with the most benefit to the public.

Our submission provides an overview of our Advertising compliance and enforcement strategy for the National Scheme, our experience implementing the strategy and identifies opportunities for collaboration to enable more effective regulation to keep the public safe.

Priority based complaints handling model

The proposed complaints process and model for complaints handling for advertised therapeutic goods aligns closely with the approach we have taken for managing complaints about advertised regulated health services. We take a differentiated approach to managing advertising complaints, according to the level of assessed risk. We allocate more resources to managing high risk matters and take action that is proportionate to the assessed risk.

We have found that the initial notice to advertisers in low or medium risk matters has been effective in changing behaviour as the majority of advertisers who receive an initial notice review their advertising and attempt to make changes to achieve compliance.

Education and capacity building

We support the intent to provide education and guidance as a key strategy in support of therapeutic goods advertising compliance.

Our approach is based on supporting voluntary compliance to build community confidence in regulation with a key element of this model is acknowledging that most people are willing or try to do the right thing. Our aim is therefore to make compliance as easy as possible. We recognise some people need more help to comply, so we have targeted activities to help this group achieve greater compliance.

We provide education for practitioners to support compliance with advertising obligations and have increased focus on information for consumers, so they know what to expect from providers advertising health services.

We have found this approach to be useful in increasing capacity in the sector and building understanding to assist practitioners and other advertisers to advertise responsibly. While there are some resources and guides that are useful to all professions and services, feedback from the sector suggests that profession specific guides have also been very helpful by providing relevant and contextualised advice about how to advertise lawfully. In addition to providing examples of advertising claims common to all regulated professions, we have developed some profession-specific guides. These resources, together with other tools and guides are available on our [Check, Correct Comply webpage](#).

Claims in advertising

Section 133 (1)(a) of the National Law states that a person must not advertise a regulated health service, or a business that provides a regulated health service, in a way that is false, misleading or deceptive or is likely to be misleading or deceptive. To assist advertisers to comply with this provision we publish resources to explain the evidence requirements necessary to support claims made in advertising a regulated health service, so to avoid breaches of the National Law.

Boards have advised that when advertising a regulated health service, the evidence needed for making claims about services (therapeutic, diagnostic, screening or aetiological) in advertising and the evidence needed for decision-making in the clinical context differs. 'Acceptable' evidence is required to support claims made when advertising regulated health services. This is because in advertising, a statement may be easily misinterpreted or taken out of context, or applied incorrectly and then become misleading.

We note and support the proposal to further develop evidence requirements to support advertising therapeutic goods and would welcome a joint and collaborative approach in this respect where possible, to facilitate and simplify the requirements for compliance across both sectors (advertising regulated health services and therapeutic goods).

Referrals to other entities

We note that the proposed model includes referring a complaint to another agency for action where the TGA cannot action a complaint within the advertising framework.

While we understand the reason for referral in this situation, we note that some complaints or breaches may also fall under the jurisdiction or may be of interest to other entities. For example, a potential breach of the TGA's advertising code may also be relevant to a health complaints entity if the lead (complainant) is also seeking a resolution or conciliation outcome. Breaches of the TGA's Advertising Code may also represent a professional practice or conduct issue if the advertiser is a registered health practitioner, under the National Law.

We would therefore welcome further discussion and collaboration to consider circumstances or criteria for where referrals, concurrent handling or information sharing might be relevant. This also applies to how we manage notifications about practitioner's conduct that might also be of interest to the TGA.