



Ad Standards

PO Box 5110, Braddon ACT 2612
P (02) 6173 1500 | F (02) 6262 9833

AdStandards.com.au

Advertising Standards Bureau Limited
ACN 084 452 666

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

By email: advertising.consultation@health.gov.au

5 June 2018

Dear TGA

Submission re Complaints handling – Advertising of therapeutic goods to the public

Ad Standards appreciates the opportunity to provide comment on the TGA’s Consultation Paper regarding its proposed new complaints handling model as it relates to advertisements for therapeutic goods directed to the Australian public¹.

As set out in our submission to the TGA’s consultation on the *Regulatory Framework for Advertising* in December 2016, Ad Standards have developed and maintained a robust and effective advertising complaint management process for over 20 years, which meets international best practice standards and provides confidence to consumers, industry and government.

Although the TGA have decided not to outsource its complaints handling function, given Ad Standards’ long history in effectively managing advertising complaints and our common interest in encouraging a greater understanding of and compliance with advertising rules, we are keen to support the TGA in addressing the issues identified in the *Expert Review of Medicines and Medical Devices Regulation* (the Review) regarding the existing complaints handling mechanisms.

General comments on approach

Given that the TGA Consultation Paper only sets out the complaints handling process at a high level, we have only sought to provide general comments in this submission. We would however be pleased to discuss with the TGA the proposed model in greater detail.

To ensure greater certainty for consumers and advertisers under the TGA regulatory scheme, we suggest that further clarity be provided on the following matters.

¹ TGA “*Consultation: Complaints handling – Advertising of therapeutic goods to the public*”, Version 1.0, May 2018



- 1.1. **Definition of “responsible entity”²**: It would assist consumers and advertisers if guidance was providing regarding how a “responsible entity” will be determined. For example, will there need to be evidence that they have some degree of control over the advertising material i.e. who will be the responsible entity if a third party uses material associated with a therapeutic good or service and includes their own statement or representation about the health benefits of the product or service.
- 1.2. **Approach to complaints handling**: We support the TGA’s proposal to take a risk-based and graduated response approach to complaints handling. In our experience, an assistance and educative approach is an effective way to raise awareness and reduce infringements. It would therefore be helpful if further guidance or practice notes are provided regarding elements of the process, including:
 - (i) the factors taken into consideration by the TGA when deciding to investigate a complaint or take action;
 - (ii) on what basis a complaint may be rejected;
 - (iii) how many breaches will escalate the priority of a complaint;
 - (iv) by what measures will a breach be considered serious; and
 - (v) how will the TGA assess actual or likely harm or injury to consumers.
- 1.3. **Acceptance of complaints**: The TGA Consultation Paper indicates that the TGA will accept anonymous complaints. In our experience, this may give rise to vexatious or frivolous complaints, or complaints between competitors.

Under the process administered by Ad Standards anonymous complaints are not sufficient to initiate a formal complaint. However we keep the details of complainants confidential throughout the complaints handling process. We also have a separate Ad Standards Industry Jury (user-pays) process to manage competitor complaints.

Governance

We note that a new non-statutory committee, the Therapeutic Goods Advertising Committee (TGAC) will be formed. It is proposed that the TGAC will have wide representation across a range of stakeholders, including representation from “advertising and other parts of the media industry”³.

Given that we are already the central authority for receiving complaints about advertising across all forms of media in all areas of Australia and in relation to advertising of any products, Ad Standards would be a valuable a member of the TGAC. Specifically we can provide experience and advice on advertising issues, advertising complaints, compliance, advice and education.

We would therefore be pleased to discuss further with the TGA our nomination as member of the TGAC.

² Section 8.1 of the TGA Consultation Paper

³ TGA Consultation Paper p.16



Education and guidance

Ad Standards supports the introduction of education programs for advertisers of therapeutic products to support compliance.

Ad Standards already works closely with other industry associations to support education of advertisers about the complaint resolution process, covering trends in complaint decisions and advertisers' obligations under the self-regulatory system.

Given that advertisers have obligations to comply with both the TGA regulatory scheme and Ad Standards administered AANA advertiser codes, we would appreciate the opportunity of consulting with or co-delivering with the TGA education and training initiatives to advertisers, specifically SMEs, on their obligations under the AANA advertiser codes, decision trends, and our complaint process. Working collaboratively in this way will assist to provide clarity for advertisers and consumers.

Through sharing our expertise and insights into complaints handling, we look forward to assisting the TGA in developing a complaints handling model in line with best practice principles, which meets the key goals of delivering a timely and effective complaint resolution process.

Kind regards

Fiona Jolly
Chief Executive Officer