



**MTAA Submission to TGA Consultation:
Complaints handling –
Advertising of therapeutic goods
June 2018**



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1. Executive Summary

On 2nd May 2018, the TGA opened the consultation: *Complaints handling - Advertising therapeutic goods to the public 2018* which proposes a new complaints handling model as it relates to direct-to-consumers advertising for therapeutic goods.

The proposed complaints handling model is intended to be implemented along with broadened TGA enforcement powers and a tiered system of regulatory actions proportionate with the risk associated with the advertising of therapeutic goods.

The body that has been responsible for the revision and maintenance of the Therapeutic Goods Advertising Code - the Therapeutic Goods Advertising Code Council (TGACC)¹ - will be replaced by the TGA Advertising Committee (TGAC) on July 1st, 2018. This will make the TGA the single body responsible for the handling of complaints about the advertising of therapeutic goods to the public.

MTAA supports the proposed changes. In the next sections we provide detailed feedback to the TGA consultation document.

2. Proposed complaints handling model

2.1 TGA approach

MTAA is supportive of TGA's graduated approach to compliance:

- 1) providing help and support by making compliance easy;
- 2) inform and advise advertisers to help them become and stay compliant;
- 3) correct behaviours and deter by detection;
- 4) enforce administrative, civil or criminal action.

Furthermore, the five principles underpinning the complaints process – ethical, consistent, transparent, risk-based and timely - are in our opinion appropriate and necessary.

2.2 The complaints process

We agree with the proposed complaint process as represented and explained in the consultation document. We would like to suggest setting up an electronic complaints system that allows reporters to check the status of their complaints online, for example by using a simple workflow diagram that indicates the complaint status – see Figure 1.



Figure 1: Complaints process workflow indicating complaint status being “Complaint being investigated”

¹ TGACC website: <http://www.tgacc.com.au/history.cfm>

2.3 Priority based complaints handling model

Triaging and prioritizing complaints is in our view a sensible and well-accepted way to manage complaints. The proposed criteria for classifying complaints into one of four priority categories – low, medium, high and critical - are in our opinion appropriate:

- Likelihood of claims made in advertisement to cause public harm
- Ability of consumers to safely and appropriately use the goods for their intended purpose
- Frequency and potential impact of non-compliant advertising
- Advertisers’ awareness of their obligations

MTAA supports the proposed model that assigns specific regulatory actions to each risk category of advertising breach, in direct proportion with the level of risk (*Overview of proposed complaints handling model once a breach is established*, p. 11 of the consultation document).

In the consultation document it is mentioned that information on complaint trends will be published in bi-annual reports. We are seeking clarification on what specific information will be included in the published bi-annual reports.

2.4 Reporting outcomes and measuring performance

MTAA supports the proposed reporting of complaints outcomes, summarized in the table below.

Priority level - outcomes	Identity of responsible entity	Case ID #	Date received	Date complete	Therapeutic goods involved	Compliance action/s taken	Outcome
Low	-	•	•	•	-	-	•
Medium	•	•	•	•	•	•	•
High	•	•	•	•	•	•	•
Critical	•	•	•	•	•	•	•

We would like to seek clarification on whether the reported outcomes will be made available on an ongoing basis by updating a publicly accessible database, or whether they will only be made available in the bi-annual reports.

The proposed KPIs, summarized in the table below, are in our opinion appropriate.

Priority level of accepted complaint	Time to action	Time to close
Low	95% in 14 days	90% in 20 days
Medium	95% in 40 days	90% in 90 days
High	95% in 20 days	90% in 90 days
Critical	100% in 10 days	90% in 60 days

We acknowledge and accept that there will be exceptions to the metrics as explained in section 9.2 of the consultation document.

2.5 Governance

MTAA agrees with the proposed governance model. MTAA has been a member of the TGACC and we expect to be a member of the TGAC after July 1st, 2018.

2.6 Education and guidance

MTAA strongly agrees with TGA's proposed education and guidance goals outlined in section 11 of the consultation document.

2.7 The TGA website advertising hub

MTAA strongly agrees with setting up a TGA website advertising hub, as outlined in section 12 of the consultation document.

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