



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Therapeutic Goods Advertising Compliance Education Strategy 2021

Encouraging compliance through high quality,  
relevant and timely education

Version 1.0, July 2021

**TGA** Health Safety  
Regulation

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## Overview

The regulation of therapeutic goods advertising is an important role of the Therapeutic Goods Administration (TGA), part of the Australian Government Department of Health. The advertising of therapeutic goods is regulated to ensure it is socially responsible, and to protect Australians from advertising that does not support informed product choice. Therapeutic goods advertising that is accurate, balanced and does not mislead or take advantage of the vulnerability of consumers supports informed consumer choices about their health care.

An effective education strategy and function can prevent and address minor non-compliance, ensuring advertisers are supported in their understanding and application of the rules, and consumers can rely on the advertising they see to make informed and appropriate choices.

The **Advertising Compliance Education Strategy** is intended to benefit all parties involved in the advertising of therapeutic goods. The strategy outlines the approach the TGA will use to identify, engage with, and educate stakeholders about advertising requirements.

## Background

In October 2014, the Australian Government announced the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR). The objective of the review was to make [recommendations](#) to assist Government enhance the regulatory framework for medicines and medical devices, including their advertising. Recommendation 58 proposed the development of a formal education program to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with the advertising requirements.

During implementation of the MMDR recommendations, the Government made a further commitment to review the effectiveness of the reforms to the therapeutic goods advertising framework within two years. This review was led by Ms Rosemary Sinclair AM.

This strategy responds to two of the recommendations made by Ms Sinclair:

- **Recommendation 11:** the TGA should develop an Advertising Framework Education Strategy with clearly defined priorities that are aligned to Compliance Priorities and consumer outcomes, and
- **Recommendation 12:** the TGA should develop Education Priorities to more effectively target educational activities. In setting these priorities, the TGA should develop factors to be considered, consult with stakeholders, and focus on consumer and industry benefit. The education priorities should be publicised and clearly communicated to stakeholders. The priorities should be reviewed annually.

# Public statement on education as a compliance strategy

The TGA's approach to managing advertising compliance, as described on the [TGA website](#), includes the following:

*We educate advertisers, consumers, health professionals and industry to promote voluntary compliance with the advertising requirements. We invest in these activities because they are beneficial for advertisers and consumers, and are an effective way to achieve overall compliance.*

*Education activities assist advertisers to apply the advertising requirements by providing information that:*

- *raises awareness of their legal obligations*
- *helps advertisers understand how to comply and meet their obligations, and*
- *keeps advertisers updated on changes to the requirements.*

*Education activities empower consumers by:*

- *helping them to recognise non-compliant advertising, and*
- *ensuring that consumers know how to report suspected non-compliance.*

*We distribute news and information about therapeutic goods advertising through a range of channels including:*

- *the Advertising Hub and the Compliance and Enforcement Hub on the TGA website, both of which contain educational material and other information, such as media releases and web statements*
- *social media such as Facebook, Instagram, Twitter, YouTube and LinkedIn*
- *face-to-face engagements such as workshops, roadshows and focused SME Assist seminars*
- *webinars*
- *printed and electronic fact sheets, and information for industry publications*
- *public consultations, and*
- *engagement with key stakeholders including through the Therapeutic Goods Advertising Consultative Committee (TGACC) and a range of other industry fora.*

Education is an essential and effective compliance strategy.

## Strategy

Our education strategy is to maximise compliance, and minimise inadvertent non-compliance with the advertising rules, for the benefit of Australians, by:

- providing fit for purpose information and educational resources
- leading and participating in education and training opportunities
- generating targeted compliance and enforcement-based communications, and
- providing an efficient enquiry management function.

Using a range of means and channels to reach our intended audiences, our education activities will be based on:

- the advertising compliance priorities
- stakeholder input and needs, and
- emerging trends and issues.

Our strategy is driven by:

- advertising policy and legislation in Australia
- the TGA's [regulatory compliance framework](#) and [approach to managing advertising compliance](#)
- the advertising compliance priorities (listed on the TGA website), and
- emerging information on stakeholder needs and areas of non-compliance.

## Education priorities

Our education strategy will be implemented through a series of education priorities, which are underpinned by an **Advertising Compliance Education Plan**.

The advertising education priorities are:

1. Plan for and develop communication and education products as part of the Compliance Plans for the agreed advertising compliance priorities<sup>1</sup>.
  - The Compliance Plans are intended to address non-compliance in particular market segments, having an effective communications approach is a key part of the plans to achieve enhanced compliance in those areas.
  - Identifying the target audience, the most effective message, content and channel, is key to success in this priority.
2. Timely communications on regulatory changes and emerging issues.
  - This priority includes customised information on the advertising requirements as they relate to an issue of public or industry importance, as well as customised information to

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<sup>1</sup> The 2021-22 priorities are published on the TGA website ([www.tga.gov.au/how-we-manage-advertising-compliance](http://www.tga.gov.au/how-we-manage-advertising-compliance)) and include, for example, goods associated with COVID-19, medicinal cannabis, performance and image enhancing drugs (PIED), and weight loss products.

accompany regulatory changes. Regulatory changes that introduce new product sponsors to therapeutic goods regulation are particularly important.

- Examples include fact sheets, targeted information particularly for new sponsors entering the therapeutic goods market, and specific guidance on key issues from time to time.
3. Publish information on compliance and enforcement actions for transparency of compliance activities and as a deterrent to non-compliance.
    - This includes the use of media releases associated with compliance and enforcement actions.
  4. Maintain and enhance fit for purpose educational resources, and participate in training and education opportunities.
    - This priority is underpinned by the **Advertising Compliance Education Plan**, which outlines the suite of education activities and materials to be developed for the upcoming year, with a focus on consumer and industry benefit.
  5. Engage with key stakeholders, including members of the TGACC, as partners in education and communication activities.
  6. Maintain and enhance an advertising enquiry management function as a key educational tool.

## Key products and channels

A range of different product types and channels will be used to educate and engage with stakeholders. It is important that the most appropriate channel for each target audience is used. This may require creative thinking or new ways of communicating.

For example, there are differences in advertiser obligations for consumer advertising versus advertising directed exclusively to health care professionals. Different advertisers may advertise predominantly to one audience over the other, or have different staff responsible for preparing advertising for each audience and whose affiliations with professional or peak bodies may differ. Our approach to communications needs to be informed but flexible to maximise the reach of our messaging and convey the messaging appropriately for the audiences involved.

The following channels are examples only, the list is not exhaustive.

**Structured, targeted education activities aligning to compliance and education priorities.**

**These activities are intended to provide information and guidance on the advertising requirements.**

Channel	Purpose
Guidance materials	<ul style="list-style-type: none"> <li>• Detailed guidance on the rules/legislation, Advertising Code, and relevant procedures</li> <li>• Long term, enduring content</li> </ul> <p>Often published as a 'document' on the TGA website</p>
Fact sheets	<ul style="list-style-type: none"> <li>• Succinct summary information on the rules and how to apply them or important changes, pointing to where to find more detailed guidance</li> <li>• Published on the TGA website. Can also be printed for use by advertisers, at conferences, and for face-to-face training               <ul style="list-style-type: none"> <li>– Also intended as a longer term information resource</li> </ul> </li> </ul>
Web statements	<ul style="list-style-type: none"> <li>• Information for stakeholders related to a new topic or emerging issue               <ul style="list-style-type: none"> <li>– Not as detailed as guidance, and with a longer intended life than a media release</li> </ul> </li> </ul>
Media Releases	<ul style="list-style-type: none"> <li>• Provide succinct information and advice on compliance actions and sanctions in a format suitable for dissemination to and by media outlets</li> <li>• Alert advertisers to important information that may impact on how they advertise               <ul style="list-style-type: none"> <li>– Alert consumers and health professionals to the TGA's work</li> </ul> </li> </ul>
Education sessions, conferences, forums, presentations	<ul style="list-style-type: none"> <li>• Face-to-face education and information sharing—legislation, policy, practices               <ul style="list-style-type: none"> <li>– Education through problem based scenarios or case studies</li> </ul> </li> </ul>
Webinars (live and pre-recorded)	<ul style="list-style-type: none"> <li>• Advertising basics presentations for those new to therapeutic goods advertising               <ul style="list-style-type: none"> <li>– Small topic- specific education sessions for advertisers</li> </ul> </li> </ul>
Medical newsletters and journals content	<ul style="list-style-type: none"> <li>• Raise awareness of the advertising requirements, generally or in relation to specific compliance issues               <ul style="list-style-type: none"> <li>– Highlighting the benefits of compliant advertising</li> </ul> </li> </ul>

Channel	Purpose
Stakeholder engagement, meetings and correspondence	<ul style="list-style-type: none"> <li>• Targeted, detailed discussions and workshops</li> <li>• Correspondence in support of a compliance priority or as part of a Compliance Plan               <ul style="list-style-type: none"> <li>– May be conducted with TGACC members, groups of TGACC members or individual stakeholders as needed</li> </ul> </li> </ul>
Case studies	<p>Analytical educational tool to demonstrate the application of the requirements in practice. They provide valuable insights into how the TGA interprets and applies the rules.</p> <ul style="list-style-type: none"> <li>– Published in the Advertising Hub or used in educational activities.</li> </ul>
Scenarios and examples	<ul style="list-style-type: none"> <li>• Hypothetical advertising scenarios that demonstrate non-compliance and how to comply with the requirements.               <ul style="list-style-type: none"> <li>– Published in the Advertising Hub or used in educational activities.</li> </ul> </li> </ul>
Decision Trees	<ul style="list-style-type: none"> <li>• To assist with the application of the advertising requirements in particular circumstances, particularly where more complex concepts are involved</li> </ul>
Checklists	<ul style="list-style-type: none"> <li>• To assist advertisers in ensuring they have met all relevant requirements</li> </ul>
Social media (e.g. Facebook, Twitter)	<ul style="list-style-type: none"> <li>• Alerts and advice distributed through the TGA's social media channels</li> <li>• Promotion of a call to action to read more about the advertising rules               <ul style="list-style-type: none"> <li>– Choice of social media channel(s) will be informed by intended target audience</li> </ul> </li> </ul>
TGA corporate publications including the Therapeutic Goods Advertising Compliance Annual Report	<ul style="list-style-type: none"> <li>• Information and awareness of advertising compliance activities and outcomes               <ul style="list-style-type: none"> <li>– Use of case studies to explain application of the advertising rules, as well as our approaches to compliance and enforcement</li> </ul> </li> </ul>

**Further channels suitable for general correspondence, consultation, feedback.**

Channel	Purpose
TGACC	<ul style="list-style-type: none"> <li>• Engagement on a range of issues pertinent to advertisers, health professionals and consumers</li> <li>• Assistance with development of priorities for education content</li> <li>• Assistance with development and distribution of content as a conduit to their stakeholders</li> </ul> <p>Providing ongoing feedback to the TGA on a range of matters, including performance of, or need for educational materials and activities</p>
Email – targeted and/or bulk	<ul style="list-style-type: none"> <li>• Providing information</li> <li>• Awareness raising about advertising requirements</li> </ul> <p>Alerting to educational activities or events</p>
Meetings – virtual or face to face	<ul style="list-style-type: none"> <li>• Interactive, consultative and participatory engagement to explore more complex issues</li> </ul>
Phone or face to face conversations	<ul style="list-style-type: none"> <li>• Coordination <ul style="list-style-type: none"> <li>– Consultation and advice</li> </ul> </li> </ul>
Surveys	<ul style="list-style-type: none"> <li>• Feedback, consultation and research</li> </ul>

## Evaluation

The strategy will be reviewed annually to ensure alignment with the TGA's advertising compliance and advertising education priorities. We will evaluate the effectiveness of the strategy to ensure that our activities and products remain contemporary, fit for purpose, and distributed widely through the appropriate channels.

In addition to the measures contained in individual compliance plans, the following indicators will be used to evaluate effectiveness:

## Reach

- Website analytics embedded in media releases and web statements, and selected guidance materials, will assist us to track the reach of educational products.
- Direct engagement with TGACC member organisations to ensure wide dissemination of education products.

## Impact

- Number of reports of advertising non-compliance received by the TGA
- Number of advertising enquiries received by the TGA
- Compliance data and observed changes in advertiser behaviour
- Observed trends in advertising enquiries and reports submitted
- Outcomes from relevant questions in the annual TGA Stakeholder Survey

For further information on the key performance indicators in relation to advertising compliance, see [how we manage advertising compliance](#).

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Regulatory Compliance Branch	July 2021

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