



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic goods import, advertising and supply compliance education strategy

Encouraging compliance through high quality,
relevant and timely education

Version 2.0, July 2023

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Overview

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and is responsible for administering the *Therapeutic Goods Act 1989*.

In support of this purpose, the TGA is responsible for regulating the import, export, manufacture, supply and advertising of products defined as therapeutic goods. This includes undertaking compliance activities and enforcement action in relation to the unlawful import, advertising and supply of therapeutic goods, including unapproved goods¹.

The TGA's monitoring and compliance activities for therapeutic goods are in place to protect Australians from exposure to potentially poor quality, unsafe, or ineffective therapeutic goods, and to ensure that the marketing and advertising of therapeutic goods to the public is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive the public.

An effective education strategy and function can prevent and address minor non-compliance by supporting regulated entities to understand and follow the rules.

This compliance education strategy:

- is intended to benefit all parties involved in the import, advertising and supply of therapeutic goods
- outlines the approach the TGA will use to identify, engage with, and educate stakeholders about the regulatory requirements and our compliance outcomes
- aligns with our [Import, advertising and supply compliance priorities](#), which are updated annually.

Public statement on education as a compliance strategy

Education is an essential part of the TGA's approach to [Compliance management](#).

We provide extensive educational resources to regulated entities (sponsors, advertisers, importers and suppliers), consumers and health professionals to promote voluntary compliance with the regulatory requirements.

As a regulator, we need to be consistent, responsive, transparent, and act proportionately and appropriately when dealing with regulated entities. In turn, we expect them to understand and comply with their obligations under law and have an understanding of why we have regulation.

Providing accessible information and education about the regulatory requirements and functions of the TGA helps raise awareness about requirements to comply with the law and the potential consequences of failing to do so and provides transparency of the TGA's expectations around compliant behaviours and practices. It also helps to remove misconceptions that might foster non-compliance.

¹ There are a number of other compliance programs across our organisation that are not covered by this strategy, such as compliance activities associated with complementary medicine listings, monitoring and vigilance of medical device inclusions, the pharmacovigilance and good clinical practice inspection programs, and the GMP compliance program.

We invest in education activities because they are beneficial for both industry and consumers and are an effective way to achieve overall compliance.

Education activities assist regulated entities to apply the regulatory requirements by providing information that:

- raises awareness of their legal obligations
- helps them understand how to comply and meet their obligations, including what to expect if found to be non-compliant
- keeps them updated on changes to the regulatory requirements.

Education activities empower consumers and health professionals by:

- helping them to recognise non-compliant therapeutic goods
- ensuring that they know how to report suspected non-compliance to the TGA.

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

- the [Advertising Hub](#) and the [Compliance and Enforcement Hub](#) on our website, both of which contain educational material and other information, such as media releases and safety alerts
- our social media channels such as Facebook, Instagram, Twitter, YouTube and LinkedIn
- face-to-face engagements such as conferences, workshops, meetings and focused seminars
- webinars
- printed and electronic fact sheets and information for industry publications
- public consultations
- targeted industry communications (topic based)
- engagement with key stakeholders including through the [Therapeutic Goods Advertising Consultative Committee \(TGACC\)](#) and other industry consultation committees and forums
- responding to stakeholder [enquiries](#).

Strategy

The objective of our education strategy is to maximise compliance, and minimise inadvertent non-compliance with the regulatory requirements, 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.

Our strategy adopts a proactive, collaborative approach to the monitoring and evaluation of our education activities to ensure they remain fit for purpose.

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

- regulatory policy and legislation in Australia, including communication and education on changes
- the [Import, advertising and supply compliance priorities](#)
- the TGA's [regulatory compliance framework](#) and [approach to managing compliance](#)
- stakeholder input and needs
- emerging trends and issues.

Guiding principles

Our education strategy will be implemented through a series of education activities, which are underpinned by the [Advertising and compliance education plan](#).

There is no one-size fits all approach to delivering our education priorities. We adopt a principles-based approach to delivering information and education about the regulatory requirements because each risk and problem should be considered on its merits. This involves identifying:

- the target audience
- the required messaging
- the most effective content and channel.

Our guiding principles are:

1. We will plan for and develop communication and education products that form part of compliance plans for agreed compliance priorities.
 - Compliance plans are intended to address non-compliance in particular market segments. Having an effective communications approach is a key part of a plan that aims to achieve enhanced compliance.
2. We will ensure timely communications on regulatory changes and emerging issues.
 - This includes developing information products to accompany regulatory changes and on issues of public or industry importance. Regulatory changes that introduce new industry sectors or new product sponsors to the regulatory framework will be prioritised.
3. We will be transparent about our compliance and enforcement actions to inform the public and as a deterrent to non-compliance.
 - This includes the use of media releases associated with enforcement actions.
4. We will maintain and enhance fit for purpose educational resources and participate in training and education opportunities.
 - The [advertising and compliance education plan](#) outlines the suite of education activities and materials to be developed for the upcoming year.
5. We will engage with key stakeholders, including members of the TGACC and other key stakeholders, as partners in education and communication activities.

6. We will continue to provide an advertising enquiry management function as a key educational tool.
7. We will regularly monitor and review our education and communication products at appropriate intervals to ensure they remain fit-for-purpose, deliver our desired outcomes and meet the needs of our stakeholders.

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.

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.

Channel	Purpose
Guidance materials	<ul style="list-style-type: none"> • Provide information about regulatory requirements for our regulated entities so they are better able to comply with their obligations and change behaviour if necessary. • Guidance materials are published on the TGA website.
Fact sheets	<ul style="list-style-type: none"> • Provide succinct summary information on the rules and how to apply them or important changes, pointing to where to find more detailed guidance. • May be published on the TGA website, or disseminated directly regulated entities, e.g., at conferences or face-to-face training.
Media releases and web statements	<ul style="list-style-type: none"> • Provide succinct information about compliance and enforcement actions or emerging issues in a format suitable for dissemination to and by media outlets. • Alert regulated entities advertisers to important information to help achieve general deterrence of similar non-compliant conduct.
Alerts	<ul style="list-style-type: none"> • Information about possible risks, specific or ongoing safety issues or actions that should be taken by consumers and health professionals for therapeutic goods.
Education sessions, conferences, forums, presentations and webinars	<ul style="list-style-type: none"> • Used to facilitate education and information sharing relating to the legislation, TGA policies and practices on specific topics.
Stakeholder engagement, meetings, and correspondence	<ul style="list-style-type: none"> • Targeted discussions and workshops on specific topics. • Targeted mailouts; education based or warning based.

Channel	Purpose
Industry and health care professional newsletters and journal content	<ul style="list-style-type: none"> • Raise awareness of the advertising requirements, generally or in relation to specific compliance issues
Case studies	<ul style="list-style-type: none"> • Analytical educational tools to demonstrate the application of the requirements in practice. They provide valuable insights into how the TGA interprets and applies the rules.
Decision trees	<ul style="list-style-type: none"> • Assist with the application of the advertising requirements in particular circumstances, particularly where more complex concepts are involved.
Checklists	<ul style="list-style-type: none"> • Assist regulated entities to self-assess whether they have met all relevant regulatory requirements.
Social media (e.g. Facebook, Twitter)	<ul style="list-style-type: none"> • Alerts and advice distributed through the TGA's social media channels. • Promotion of a call to action to read more about the regulatory rules: <ul style="list-style-type: none"> – Choice of social media channel(s) will be informed by intended target audience.
TGA corporate publications including the Therapeutic Goods Advertising Compliance Annual Report	<ul style="list-style-type: none"> • Provide information and awareness of compliance activities and outcomes and to raise awareness and provide transparency about our approaches to compliance and enforcement.

Further channels suitable for general correspondence, consultation, feedback.

Channel	Purpose
TGACC	<ul style="list-style-type: none"> Engagement on a range of issues pertinent to advertisers, health professionals and consumers Assistance with development of priorities for education content Assistance with development and distribution of content to their stakeholders Providing ongoing feedback to the TGA on a range of matters, including performance of, or need for educational materials and activities
Email – targeted and/or bulk	<ul style="list-style-type: none"> Providing information to specific stakeholders to raise awareness about regulatory requirements or alter them to TGA activities or events
Meetings – virtual or face to face	<ul style="list-style-type: none"> Interactive, consultative and participatory engagement to explore more complex issues
Enquiries	<ul style="list-style-type: none"> We respond to enquiries about the advertising requirements. To make an enquiry, visit the Advertising Enquiry form.
Phone or face to face conversations	<ul style="list-style-type: none"> Coordination and issues management Consultation and advice
Surveys	<ul style="list-style-type: none"> Feedback, consultation and research

Evaluation

The strategy will be reviewed each year to ensure alignment with the TGA's education priorities.

The TGA Stakeholder Survey will evaluate the effectiveness of TGA communications to ensure that our activities and products remain contemporary, fit for purpose, and distributed through the appropriate channels. Stakeholder feedback will also be sought through the TGACC.

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

Reach

- Website analytics will assist us to track the reach of educational products published on the TGA website.

- Direct engagement with TGACC member organisations to ensure wide dissemination of education products.

Impact

- Level of sustained compliance following TGA contact with entities
- Observed trends in enquiries and reports submitted
- Outcomes from relevant questions in the annual TGA Stakeholder Survey

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Compliance Branch	July 2021
V1.1	Minor updates to links	Regulatory Compliance Branch	February 2023
V2.0	Updated to include import and supply education in the strategy	Regulatory Compliance Branch	July 2023

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