Australian Government
Department of Health
Therapeutic Goods Administration

Complaints handling for the advertising of therapeutic goods to the Australian public

Version 1.1, May 2019

TGA Health Safety Regulation

Contents

As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) is responsible for ensuring that therapeutic goods available for supply and use in Australia are safe and fit for their intended purpose. The classes of goods we regulate include health products that Australians rely on every day.

The TGA regulates the supply, manufacture and advertising of:

- **medicines,** including those prescribed by a doctor or dentist, available from the pharmacy or supermarket and complementary medicines such as vitamins, herbal and traditional medicines
- **biologicals,** including human tissues and cell based products, and
- **medical devices,** from simple devices like bandages to complex technologies like heart pacemakers.

We do not regulate foods, cosmetics, general consumer goods, chemicals, veterinary medicines, health insurance matters or healthcare professionals.

The TGA administers the *Therapeutic Goods Act 1989* (the Act) which establishes Australia's national regulatory scheme for therapeutic goods. The Act is part of the framework that ensures our actions are appropriate to the risk that the goods or their use poses to the health and safety of the Australian public.

Regulatory framework for the advertising of therapeutic goods

Consumers are protected from false or misleading advertising of products and services by the *Competition and Consumer Act 2010*, administered by the Australian Competition and Consumer Commission (ACCC), and associated state and territory laws. The ACCC also prioritises product safety issues which have the potential to cause serious harm to consumers.

To protect the health and safety of Australian consumers, the advertising of therapeutic goods is subject to additional requirements, contained in the Act and regulated by the TGA. In regulating the advertising of therapeutic goods, we prioritise the health and safety of Australian consumers.

Advertisers of therapeutic goods must comply with the Act and the 2015 Therapeutic Goods Advertising Code (the 2015 code). The 2018 Therapeutic Goods Advertising Code (the 2018 code) will commence on 1 January 2019.

The Act, 2015 and 2018 codes set out when and how therapeutic goods can be advertised. The TGA undertakes compliance activity and handles complaints associated with non-compliant advertising. Substantial sanctions, including heavy fines and or terms of imprisonment can apply in cases of ongoing or serious non-compliance with the Act, especially those that may cause harm.

Advertising of therapeutic goods

The Act defines *advertise* to mean:

> ***advertise***, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:
>
> (a) is on the label of the goods; or
>
> (b) is on the package in which the goods are contained; or
>
> (c) is on any material included with the package in which the goods are contained.

Advertising of therapeutic goods can be presented in many forms. Common media include:

- product labels
- magazines
- newspapers
- television
- radio
- internet
- social media
- posters
- shelf wobblers/point of sale materials
- billboards, and
- medical journals.

Compliance with the code is necessary to ensure that marketing and advertising of therapeutic goods to consumers is conducted in a manner that:

- promotes the safe and proper use of therapeutic goods by minimising misuse, overuse or underuse of the goods
- is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance
- supports informed health care choices, and
- is consistent with public health campaigns.

The TGA handles complaints about the advertising of therapeutic goods to the public in accordance with the Act, and the relevant Code.[1]

[1] The 2015 code will apply until 31 December 2018. On 1 January 2019, the 2018 code applies.

TGA's approach to advertising complaints handling

Like other regulators, we take a risk-based approach to complaints handling. We prioritise matters that pose a risk to **public health and safety**.

Our advertising complaints handling processes are guided by principles that support our compliance strategy:

- We provide extensive tools and education resources to advertisers to aid them in managing their compliance.
- We focus our resources on alleged non-compliance that has the highest public safety risks.
- We have regard to the perceptions of and impact on the reasonable consumer when assessing advertising.
- Our compliance and enforcement actions are proportionate to the relevant non-compliance and the harm that may result.
- Our compliance and enforcement actions are evidence-based and depend on the types of behaviours identified, including demonstrated willingness of the advertiser to be compliant with the Act.
- Our processes support consistent compliance and enforcement outcomes and provide clarity for the public and advertisers about what is and what is not acceptable in advertising.

We are committed to being transparent, by reporting on advertising compliance and enforcement actions taken, publishing complaints outcomes and regular reporting against key performance indicators (KPIs).

Making a complaint about the advertising of therapeutic goods

We accept complaints from anyone about the advertising of therapeutic goods. Complaints should be made in writing and submitted through our online advertising portal or mailed to the TGA Advertising Compliance Unit at PO Box 100, Woden ACT 2606.

The advertising portal uses a web form for lodging a complaint. You will be asked for specific information and can upload attachments to provide evidence about the advertising you have reported. The information you provide about the advertising and the advertiser will be used by us to properly assess your complaint.

Stages of advertising complaint management

Acknowledging your complaint of advertising non-compliance

If entered through our online portal, your complaint will be automatically acknowledged and you will be given a unique identification number for reference. At this point, your complaint is considered a lead.

If a complaint is received outside of the portal and the reporter can be identified, the acknowledgement process will be attended to manually and you will be given a unique identification number for reference within 10 working days.

Complaints that we cannot action

The TGA can only action complaints that are about therapeutic goods and within our jurisdiction. We do not have jurisdiction over overseas websites, or web based retailers with no physical or registered Australian address.

We cannot action complaints about:

- foods
- cosmetics
- general consumer goods
- chemicals
- veterinary medicines
- health insurance matters, or
- healthcare professionals.

Unlike some other regulators, the TGA does not have the legal powers to seek compensation on behalf of consumers.

We often cannot action complaints about advertising that is conducted outside Australia and there are some constitutional constraints on dealing with individuals advertising within their own state or territory (intrastate trade) and not engaged in interstate or international trade.

If you have concerns about advertising of therapeutic goods that cannot be actioned by us, you may wish to contact the consumer protection agency for your jurisdiction, as advertisers may have obligations under state and territory fair trading/consumer affairs legislation. Contact details for state and territory consumer protection agencies are available on the ACCC website.

Accepting your complaint of advertising non-compliance

If your complaint falls within our jurisdiction, it will be progressed as a case for assessment against our Risk Based Activity Model (see below). If your complaint was provided via our portal, you will receive a unique number for your reference.

We have a 'no wrong door' policy. Where we are not able to action your complaint, we will refer your complaint to the right agency with the appropriate jurisdiction to action your complaint. In these cases, you will be advised of the agency to which your complaint has been referred and the status of your complaint. However, because the complaint has now been referred to another regulator, it will be closed in the TGA advertising complaints management system.

Categorising your complaint of advertising non-compliance

We assess and prioritise complaints of alleged non-compliant advertising of therapeutic goods to the public by considering a range of factors, including the following:

- whether the claims made or reliance on the claims made in the advertising are likely to result in harm or injury to any person
- likely impact of the advertising on the ability of consumers to safely and appropriately use the goods for their intended use
- whether the alleged non-compliant advertising has been removed or amended
- previous conduct of the advertiser
- an advertiser's ability or willingness to comply with the advertising requirements, and
- the advertiser's behaviour once they are made aware that their advertising appears to be non-compliant.

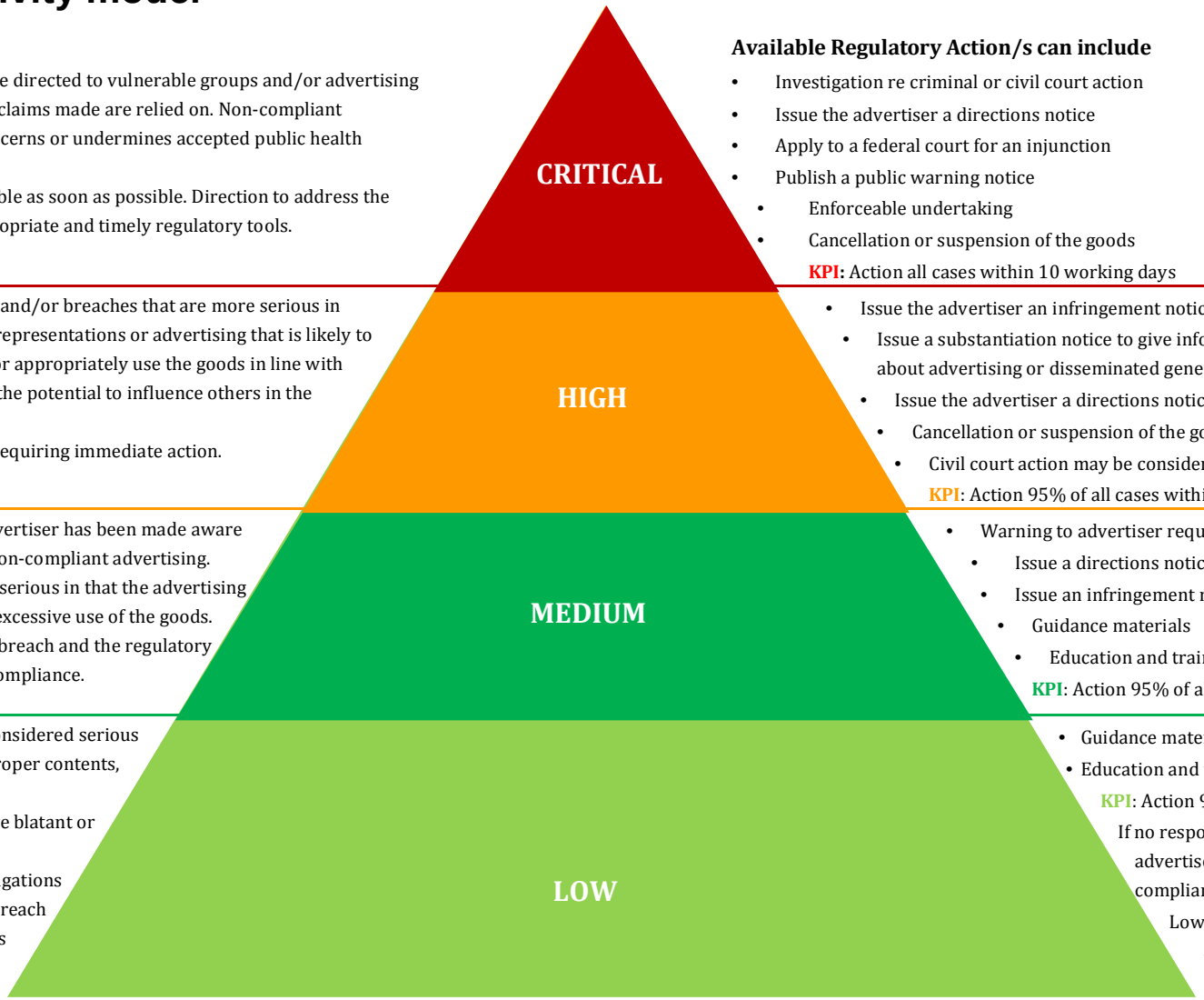
The TGA (not the person or organisation reporting the complaint) is responsible for assessing and categorising cases based on the information provided in a complaint, and any other relevant information that may be available to the TGA. Following assessment, complaints of alleged non-compliant advertising will be categorised as: low, medium, high or critical.

Reporters will be advised by email or mail as soon as practical of the category assigned to their complaint of alleged advertising non-compliance.

Risk based regulatory action

The Risk Based Activity Model outlines the regulatory actions we may take based on the categorisation allocated to a report of advertising non-compliance. This diagram and risk category descriptions are indicative only as the decision to use a particular action is taken on a case by case basis. These actions may be used alone or in combination to achieve the most timely and efficient compliance outcomes.

Risk based activity model



Nature of alleged breach

Extensive or targeted advertising may be directed to vulnerable groups and/or advertising that is likely to lead to harm or injury if claims made are relied on. Non-compliant advertising that raises public health concerns or undermines accepted public health messages.

Likely Action: Contact person responsible as soon as possible. Direction to address the issue immediately. Use of the most appropriate and timely regulatory tools.

Available Regulatory Action/s can include

- Investigation re criminal or civil court action
- Issue the advertiser a directions notice
- Apply to a federal court for an injunction
- Publish a public warning notice
- Enforceable undertaking
- Cancellation or suspension of the goods

KPI: Action all cases within 10 working days

Continued alleged advertising breaches and/or breaches that are more serious in nature such as prohibited or restricted representations or advertising that is likely to impact the consumer's ability to safely or appropriately use the goods in line with their intended use. Mass advertising or the potential to influence others in the industry to the detriment of consumers.

Likely Action: Email or phone contact requiring immediate action.

- Issue the advertiser an infringement notice
- Issue a substantiation notice to give information or produce documents about advertising or disseminated generic information
- Issue the advertiser a directions notice
- Cancellation or suspension of the goods
- Civil court action may be considered

KPI: Action 95% of all cases within 20 working days

Alleged ongoing breaches where the advertiser has been made aware of their obligations and has continued non-compliant advertising.
Also relates to breaches not considered serious in that the advertising is not likely to lead to inappropriate or excessive use of the goods.

Likely Action: Warning advising of the breach and the regulatory tools available to address further non-compliance.
Response required within 14 Days.

- Warning to advertiser requiring response within 14 days
- Issue a directions notice
- Issue an infringement notice
- Guidance materials
- Education and training

KPI: Action 95% of all cases within 40 working days

One off or isolated alleged breach not considered serious in terms of being misleading as to the proper contents, identification or use of the goods.
Alleged non-compliance does not involve blatant or ongoing disregard by the advertiser.

Likely Action: Advertiser is sent an obligations letter. The letter advises of the alleged breach and regulatory tools available to address further non-compliance and contains information and guidance to assist with future compliance but a response is not required. Advertiser can contact the TGA to dispute/discuss the alleged breach.

- Guidance materials
- Education and training

KPI: Action 95% within 14 working days

If no response case closed, details of advertiser and goods not published in our compliance outcomes.

Low level priority cases can be assurance reviewed to monitor current or ongoing advertising compliance.

Categorising complaints by risk

Low

A complaint will be categorised as **low** where it is a one-off or isolated advertising non-compliance and where the TGA has not previously engaged with the advertiser on the matter.

Categorisation will be informed by whether the advertising is misleading as to the content or proper use or identification of the therapeutic goods. An example of this category includes promotion of therapeutic goods in a manner that is misleading as to their proper use, but where the product is ineffectual in its use for a minor or self-limiting condition and therefore highly unlikely to cause harm.

Medium

A case will be categorised as **medium** where it involves ongoing advertising breaches or where the advertiser has been made aware of their advertising obligations and blatantly advertises therapeutic goods in a non-compliant manner.

Categorisation will be informed by the likelihood of the advertisement encouraging excessive or inappropriate use of the therapeutic good being advertised, the type of therapeutic good and the condition the product purports to treat. Examples include where a Schedule 3 (pharmacist-only medicine) is being advertised to the public in a way that encourages unnecessary or excessive use.

High

A case will be categorised as **high** where it involves continued alleged non-compliant advertising despite evidence that the advertiser is aware of their obligations.

High category cases include alleged non-compliance that we consider more serious in nature such as advertising containing prohibited or restricted representations around the indications (conditions) that the product is claimed to treat or manage. This category could also include advertising that is likely to lead to excessive use, or impact on the ability of consumers to use the therapeutic goods safely or appropriately in line with the good's intended therapeutic use.

Examples include where a reference is made to a serious medical condition where choosing the product over conventional medical treatment could have a significant impact on the consumer's prognosis.

Critical

A case will be categorised as **critical** where it involves advertising of therapeutic goods that claim to treat serious or very serious conditions which generally requires medical practitioner's diagnosis and ongoing treatment.

This categorisation may also be assigned to advertising clearly directed to vulnerable or disadvantaged consumers with a risk that use may result in or is likely to result in harm or injury due to reliance on the claims made or because of the indications advertised. It may also be assigned where the advertising may cause harm or injury to a large group of consumers, or particular individuals.

Complaints of alleged non-compliant advertising that undermines public health campaigns in contravention of the 2015 code, or accepted public health messages, raises significant public health issues or has the potential to undermine public confidence in government, industry or the TGA may also be categorised as critical. An example of a critical case includes advertising a product for the treatment of cancer where the product has either not been evaluated by the TGA or is listed complementary medicine or registered over-the-counter medicine on the Australian Register of Therapeutic Goods (ARTG).

Managing advertising complaints by risk category

Low

For **low** cases an obligations letter will be sent to the advertiser. The obligations letter will inform the advertiser of the alleged non-compliance and will provide information and guidance to rectify the advertising and to assist with future advertising compliance. **This is not regulatory action at law**; no formal investigation is undertaken and no formal regulatory finding is made in these cases. It does, however provide an opportunity for the advertiser to be assisted with their compliance without penalty or sanction. The advertiser will be advised of the compliance and enforcement actions available to the TGA to address any further advertising non-compliance.

Obligations letters do not require a written response from the advertiser. The case will be closed when the notice is sent. If the advertiser wishes to dispute or discuss the information in the notice they are encouraged to email the Advertising Compliance Unit at tga.advertising@tga.gov.au or in certain cases meet to discuss more complex examples. Note, however that this may result in the TGA initiating a new case categorised as medium to allow for an investigation to be conducted (which consequently attracts publication requirements for medium cases).

If any further complaints are received about the same advertising, they will not be acted upon until the advertiser has been allowed reasonable time to review their obligations and address any advertising non-compliance. After that time, the advertising may be selected by TGA for compliance checking as part of our compliance assurance program, especially if we are aware or made aware that non-compliance has continued. If non-compliance has continued a new medium or higher priority case may be opened.

Matters categorised as low will be recorded in our Complaints Handling System and reported on publicly as part of our performance metrics. For reasons of natural justice, TGA reporting of closed low priority matters will not specify the details of the advertiser or the goods involved because the TGA has not investigated nor made a formal finding in relation to the advertising.

Medium

For **medium** cases, the advertiser will be sent a warning by email or letter as soon as possible. The warning will advise the advertiser of the alleged advertising non-compliance and provide information and guidance to rectify their advertising and aid future compliance. The advertiser will also be advised of the compliance and enforcement actions available to the TGA to address any further advertising non-compliance.

Warnings request the advertiser to respond to the TGA outlining the steps that they intend to carry out to achieve compliance, and in what timeframe. Advertisers can dispute the alleged advertising non-compliance with the TGA. Failure to respond or a response demonstrating no

intention to comply with the advertising requirements may result in escalation of the regulatory action taken or referral for criminal prosecution.

The TGA will review any representations made in relation to the alleged advertising non-compliance. If the TGA accepts the representations of no breach, the matter will be closed and reported as no breach without details of the person or the goods being published.

If the advertiser revises their advertising to ensure compliance the matter will be closed. In all medium cases the advertiser's details and details of the goods involved will be published as part of the compliance outcome.

High

For **high** cases, the TGA will contact the advertiser by telephone and ask them to address the alleged non-compliance issues immediately. They will be requested to provide evidence that they have undertaken the required action. If the non-compliance is immediately rectified the TGA may close the case. The advertiser's willingness to comply and the nature and extent of the alleged advertising breach will inform the regulatory action undertaken by the TGA.

The TGA may consider compliance or enforcement actions that could include an infringement notice, directions notice, substantiation notice, a public warning notice, an injunction or cancellation of the therapeutic good from the ARTG (where the advertiser is the Sponsor of the therapeutic good). Prosecution of a civil penalty provision may be undertaken in certain cases.

Critical

For **critical** cases, the TGA will contact the advertiser by telephone and ask them to address the alleged non-compliant advertising immediately; this will also be confirmed by email. If the non-compliance is immediately rectified the TGA may close the case. The advertiser's willingness to comply and the nature and extent of the alleged advertising non-compliance, will inform the compliance or enforcement actions taken by the TGA to effect compliance.

The TGA can consider compliance and enforcement actions that could include (but are not limited to) a direction or an injunction to cease the advertising, publishing a public warning notice, cancellation of the goods from the Register. Prosecution of a civil penalties provision may be undertaken. The most serious matters may be referred to the Commonwealth Director of Public Prosecutions for criminal prosecution.

Complaints where no non-compliance is identified

Where we receive a complaint and do not identify a breach of the advertising requirements, we will close the case. The reporter will be advised of this outcome. The outcome of the case will not be published.

Where a **potential non-compliance of high or critical impact** has been clearly identified but the non-compliance is averted through negotiation between the advertiser and the TGA, the outcome will be published but it will be made clear that potential non-compliance was averted through such negotiation and voluntary action by the advertiser.

Compliance toolkit

We have a broad range of compliance and enforcement tools available to ensure compliance with the advertising requirements for therapeutic goods. Our compliance toolkit has four tiers of activity:

1. **Voluntary compliance**

   Most responsible entities want to comply with their obligations. We provide education and guidance tools to aid advertisers with voluntarily complying with the advertising requirements.

2. **Assisted compliance**

   Where advertisers may be unaware of, or fail to understand how to comply with the advertising requirements we inform and/or warn them of the consequences of failing to comply.

3. **Regulatory compliance**

   Where we use the powers provided in the Act to ensure compliance.

4. **Compliance assurance**

   We undertake a compliance assurance program to ensure that advertisers who come to our attention maintain their compliance.

We use a graduated risk-based approach to advertising non-compliance. The tools we use in response to non-compliance will depend on whether there is a potential for detriment to the health of consumers, and an advertiser's behaviour prior to and in relation to the reported non-compliance. We may provide assistance through the form of obligations letter or warnings. Or it may be that use of a regulatory tool under the Act is more appropriate.

Taking a risk-based approach means our response is tailored to the risk posed by the non-compliant advertising. Further escalation of regulatory action may be considered against risk factors associated with additional or continued non-compliance. An example is where the advertiser is not willing to comply or the alleged advertising non-compliance is such that there is an impact on the ability of the consumer to use the therapeutic goods safely or appropriately.

Voluntary compliance through education and guidance

The TGA provides education and guidance material to assist advertisers to understand their obligations and achieve behavioural change. We empower consumers by helping them to understand advertisers' obligations and how they can report issues they identify with therapeutic goods advertising. We invest in these activities because they are the best way to assist responsible advertisers to produce compliant advertising.

We publish educational material about the operation of the Act. This includes an online learning module, a short video, webinars, interactive tools and presentations which will be continually updated. Further information on our education program can be viewed online in our advertising hub.

Assisted compliance

An **obligations letter** informs an advertiser that their advertising may not be compliant and advises them of their obligations. The letter also provides educational and guidance material to assist the advertiser with reviewing their advertising and ensuring compliance. The letter does not seek a response but an advertiser can dispute or discuss the alleged advertising non-compliance with the TGA.

A **warning** informs an advertiser that their advertising is non-compliant. The letter sets out the alleged non-compliance and requires the advertiser to respond to the TGA including outlining the steps they will carry out and the timeframe required to achieve compliance. Failure to respond may result in further regulatory action.

Regulatory compliance and enforcement

A **substantiation notice** requires an advertiser[2] to provide specific information relating to their advertisement. An example includes where an advertiser makes a scientific claim, they may be required to provide evidence that substantiates the claim being made.

A **directions notice** requires an advertiser[3] to take specific action in relation to their advertisement. The action required may include:

- ceasing the advertisement or particular claim/representation
- retracting the advertisement
- correcting the advertisement, or
- recovering or destroying the advertisement.

Failure to comply with the direction is a criminal offence.

We may **Cancel or Suspend** the relevant therapeutic goods from the ARTG.

A **public warning notice** may be issued if the TGA reasonably suspects non-compliant advertising or dissemination of generic information about therapeutic goods to the public or a section of the public and is satisfied it is in the public interest to issue that notice. A public warning notice may also be issued if a person who has been given a substantiation notice fails to comply with it and the TGA is satisfied that it is in the public interest to do so. An example includes where the advertiser fails to provide evidence in response to a substantiation notice, in circumstances where there is a public safety risk, a public warning notice may be issued.

The TGA may seek an **injunction** in the Federal Court or Federal Circuit Court to stop or prevent a person from contravening the Act or compel a person to comply with the Act. An example of the circumstances where the TGA would seek an injunction is where advertising is planned for a defined event (e.g. a promotion at a particular major rock concert), there is a risk to public health and safety posed and it is time critical.

An **infringement notice** may be issued where a person has, within 12 months contravened a strict liability offence or civil penalty provision of the Act. The person can choose to pay an amount to the Commonwealth as an alternative to having court proceedings brought against them in relation to the contravention.

[2] Or a person apparently responsible for the advertisement
[3] Or a person apparently responsible for the advertisement

An advertiser may choose to give an **enforceable undertaking**, a promise able to be enforced by a court. An example includes where the advertiser undertakes to establish, review or improve their advertising processes to be compliant with the requirements in the Act and to make regular reports to the TGA for the period of the undertaking.

The TGA may commence prosecution of a **civil penalty** provision. This can result in large fines being imposed and recovered. The most serious matters may be referred to the Commonwealth Director of Public Prosecutions for **criminal prosecution** of offences under the Act.

Publication of complaint outcomes

Our complaints handling system allows us to report on each unique identification number, supporting case monitoring as matters are progressed. When matters are finalised and closed, outcomes will be published. Details about the advertiser and product of complaints prioritised as low will not be published. Those details will be published for all other advertising cases at the medium, high or critical priority levels where a complaint is sustained.

We publish information about the compliance and enforcement actions we take on our website. The Act requires us to publish information such as when we issue directions about advertising or generic information or enter into an enforceable undertaking.

The Act allows us to publish information such as public warning notices. We will publish outcomes of our advertising complaint cases[4], information on enforcement outcomes including those that are administrative actions such as cancellation or suspension from the Register. Where a potential non-compliance of high or critical impact has been clearly identified but the non-compliance is averted through negotiation between the advertiser and the TGA, the outcome will also be published.

We will also publish information about infringement notices and directions notices. If a matter is referred for investigation and results in formal court action, those matters will also be published when the case is finalised. We see publishing information about such matters as being central to the transparency of our advertising complaints handling process.

Measuring our performance

The time taken to action and the time taken to complete alleged non-compliant advertising cases will be measured.

Time to **action complaints** is the period of time starting from when your complaint is received including categorisation and ending on our initial engagement with the advertiser. The relevant period of time that will apply for the TGA to action a complaint will depend on the priority given to that complaint and includes:

Low Priority	Medium Priority	High Priority	Critical Priority
95% in 14 days	95% in 40 days	95% in 20 days	100% in 10 days

[4] Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018, Federal Register of Legislation, https://www.legislation.gov.au/Series/F2018L00916

Time taken to **complete and close** cases means the period of time starting from when your complaint was received, categorised and progressed as a case, to when we have engaged with the advertiser to achieve a successful compliance outcome and no further action is required. These times will be our intended timeframes for this KPI. The time in which we close out matters will also depend on the priority given to each accepted case and include:

Low Priority	Medium Priority	High Priority	Critical Priority
100% in 20 days	90% in 90 days	90% in 90 days	90% in 60 days

Application of a 'stop clock'

When calculating the days lapsed a 'stop clock' will be applied where further information is requested from third parties, including:

- complainants
- advertisers
- external experts
- sponsors
- state, territory or federal government bodies
- professional standards bodies, or
- other parties external to the TGA.

It will also be applied where a matter is the subject of court proceedings. The clock restarts when the TGA receives the requested information, or when the court proceedings are finalised.

Examples of the application of this procedure include when the TGA:

- seeks verification of an advertising complaint from the complainant
- seeks a copy of the advertisement from the originator, i.e. the print media publisher or television station
- requests data/evidence from the advertiser to substantiate the claims made
- seeks external expert advice or input from external agencies
- pursues legal proceedings, for example has applied for an injunction from the court.

The stop clock does not apply to internal review and decision making, for example when the TGA undertakes an evidence review for misleading claims, or undertakes a review which results in the development of policy or guidance relating to new and emerging advertising issues.

The days during the period that the 'stop clock' is applied do not count toward the calculation of the (non-statutory) KPI timeframes.

Consultation and governance

A new advisory committee, the Therapeutic Goods Advertising Consultative Committee (TGACC) has been formed and is expected to meet four times per year.

The TGACC has representation from:

- consumer representative bodies
- patient representative bodies
- therapeutic goods industry (including medicines, devices, IVD and biological sectors)
- publishers and broadcasters (including print, TV, radio, social media and internet)
- healthcare practitioners, and
- advertising and media industry.

The committee will act as a forum for engagement on advertising issues and assist with shaping our transparency and reporting metrics as well as providing advice on emerging themes in advertising complaints handling.

Further information and resources

We use our website and a number of resources and channels to distribute news and information about advertising of therapeutic goods including but not limited to:

- the advertising hub on TGA Website which contains news, information and educational or guidance material
- advertising e-learning module
- workshops and roadshows
- Twitter
- YouTube Video
- printed and electronic fact sheets and printed advertising for industry publications
- webinars and other training materials, including updated PowerPoint slides and videos
- targeted engagement with core affected groups
- public consultations
- the new Advertising Committee, and
- roadshows, workshops and focused Small to Medium Enterprise (SME) Assist Advertising Seminars.

The Advertising Hub also allows you to:

- Make an enquiry about the advertising regulatory scheme
- Make an application to advertise with a restricted representation
- Make a complaint about advertising of therapeutic goods to the public

Make an enquiry about the advertising regulatory scheme

This option allows you to make an enquiry about the TGA advertising regulatory scheme online via a web form. Enquiries received through the portal will be automatically given a unique number for reference. While it is not the role of the TGA to act as a regulatory consultant to industry, we will strive to assist you to understand regulatory obligations and requirements and we will respond to enquiries with relevant general information in a timely manner directly by email. We will answer all telephone and mail enquiries.

Make an application to advertise therapeutic goods with a restricted representation

The Act was amended in September 2018 to remove the requirement for applications to advertise using restricted representations to be signed, and allow them to be submitted online. A web form will be available shortly to allow applications to be made via the portal.

Each application received through the portal will be acknowledged automatically by return email with a unique identification number for reference.

In considering an application for approval to include a restricted representation in an advertisement, the Secretary (or delegate) must be satisfied the representation is accurate and balanced and is not misleading or likely to mislead. The Secretary (or delegate) can seek advice and will also ensure that public interest criteria are applied. Further information on restricted representations can be viewed on the advertising hub online.

View our education and guidance material on the advertising hub

We have posted a great deal of information on many aspects of the therapeutic goods advertising regulatory scheme to help advertisers understand their obligations and the legal requirements around advertising therapeutic goods to the public. The advertising Code is a legislative instrument and carries the weight of law. Many of the obligations on advertisers and requirements for advertisements about therapeutic goods are set out in the code. We strongly encourage anyone who advertises or is considering advertising therapeutic goods to be conversant with the code and to read the Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG).

You will not be required to give us your details to view news and information via the hub.

The advertising hub also contains information directed towards consumers on advertising requirements for therapeutic goods, things to look out for in medicine advertisements, the stages of our complaints handling and how to report or make a complaint about misleading or illegal therapeutic goods advertising.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Education and Compliance	28/09/2018
V1.1	Update of document to include information on Application of stop clock and minor editorial corrections	Regulatory Education and Compliance	10/05/2019

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