Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Complaints handling - Advertising of therapeutic goods to the public

Version 1.0, May 2018

TGA Health Safety Regulation

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1. Introduction

Effective risk-based regulation, compliance and enforcement of the therapeutic goods advertising regulatory scheme form part of our contribution to the Department of Health's vision of better health and wellbeing for all Australians, now and for future generations.

The *Competition and Consumer Act 2010* and associated state and territory laws provide consumer protections from false or misleading advertising of products and services. The *Therapeutic Goods Act 1989* (the Act) provides a primary regulatory focus on public health and safety.

While consumer protection laws also apply to the advertising of most therapeutic goods, many therapeutic goods are not ordinary items of commerce.[1] Promotion of therapeutic goods by their very nature may target specific sections of the population that are potentially vulnerable due to age, illness or disability for example.

The legislation governing therapeutic goods regulation sets out the regulatory framework and obligations when advertising therapeutic goods.[2] However, the *Therapeutic Goods Advertising Code 2015* (the code)[3] focuses on requirements that relate to advertising to the public and the special requirements that must be met when advertising to vulnerable populations.

The provisions in the legislation and regulation around advertising use broad definitions that can apply to any person (and not only sponsors who have goods included in the Australian Register of Therapeutic Goods (ARTG)). Therefore any person who advertises a product with therapeutic claims (such as the effectiveness of the product to treat an illness), can be subject to the advertising requirements for therapeutic goods.

Therapeutic claims can include where goods are represented in any way to be, or for any other reason likely to be taken to be used in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury or influencing, inhibiting or modifying a physiological process in persons.

The legislation governing therapeutic goods regulation restricts when and how therapeutic goods can be advertised and provides for compliance and enforcement provisions to achieve compliance with the TGA advertising scheme. Substantial sanctions, including heavy fines and or terms of imprisonment can apply in cases of ongoing or serious non-compliance with the advertising scheme.

2. Government's response to the expert panel's recommendations

The Australian Government's response to the Expert Panel's Review[4] of the regulation of medicines and medical devices was released on 15 September 2016. Specific recommendations were made about broadening enforcement powers to benefit consumers through appropriate compliance with advertising regulatory requirements, and to deter inappropriate and misleading advertising of therapeutic goods. These broadened powers and revised sanctions

[1] Not all therapeutic goods are considered consumer goods - e.g. X-ray machines in hospitals.
[2] *Therapeutic Goods Act 1989* (Cth), Therapeutic Goods Regulations 1990, Therapeutic Goods (Medical Devices) Regulations 2002, the Therapeutic Goods Advertising Code 2015.
[3] Therapeutic Goods Administration, Therapeutic Goods Advertising Code (2015), https://www.legislation.gov.au/Details/F2015L01787.
[4] Australian Government's response to the Expert Panel's Review, https://www.tga.gov.au/australian-government-response-review-medicines-and-medical-devices-regulation

were included in the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* which was enacted on 5 March 2018.

The Australian Government agreed to a single body approach to the management of complaints about advertising of therapeutic goods to the general public, reducing complexity and encouraging greater consistency in decision-making, thereby benefiting consumers. The Government has decided to make the TGA the single body responsible for the handling of complaints about the advertising of therapeutic goods to the public from 1 July 2018.

To progress implementation we are now consulting with stakeholders on the design of the new complaints-management process.

3. Requirements for the advertising of therapeutic goods to the public

Advertisements for therapeutic goods to the public in Australia are subject to the requirements of the *Therapeutic Goods Act 1989* (the Act). 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 to the public must also comply with the code. The code is under final review and is the subject of a separate public consultation. The object of the advertising code is 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; and
- is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and
- supports informed health choices; and
- is consistent with current public health campaigns.

Whether conduct falls within the scope of 'advertise' is considered according to the standard of a reasonable consumer to whom the advertisement is directed rather than by the actual intention of the person responsible for the advertising material. In other words, it is the anticipated impact on a reasonable audience, rather than the subjective intention of the advertiser, that defines whether or not conduct is 'to advertise' or complies with the code.

4. New powers and sanctions

As earlier noted, the range of sanctions available to the TGA to use individually or in combination to address non-compliance including advertising non-compliance was supplemented by the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018*; they include:

Substantiation Notices

- Powers to issue directions about advertisements or generic information
- Cancellation or suspension of therapeutic goods from the ARTG
- Public Warning Notices
- Injunctions
- Infringement Notices
- Enforceable Undertakings
- Preparation of a brief of evidence for criminal prosecution
- Civil action.

5. Purpose of this consultation

The purpose of this consultation is to seek stakeholder's views on the proposed complaints handling model as it relates to advertisements for therapeutic goods directed to the Australian public.

Our expanded suite of regulatory tools is sufficiently flexible to allow a choice of the most appropriate regulatory response; it facilitates an effective layered approach to compliance and enforcement. As a responsive regulator we use a risk-based framework where the level of regulatory intervention is appropriate and proportionate with the risk associated with the advertising of therapeutic goods. Our risk assessment has a particular emphasis on whether reliance on advertising claims by consumers could pose a health and safety risk to the public.

The TGA has published detailed educational and guidance information online for health professionals, consumers and the industry about advertising therapeutic goods to the public. This includes information regarding the various restrictions and exemptions to the advertising regulatory scheme. Where compliance cannot be achieved through assistance and education, more coercive enforcement actions will be undertaken.

The ultimate objective is to ensure that our regulatory actions are appropriate and proportionate with the risk that the advertising of therapeutic goods to the public poses, and to address any potential health and safety issues to the Australian public.

We are seeking your views on the TGA's proposed new complaints handling model and graduated responses to advertising non-compliance.

6. Our approach

TGA works with the public to understand needs and be responsive to expectations. We work with the regulated industry and advertisers to support better advertising outcomes.

We carefully consider how to respond to all potential breaches of the advertising requirements. While we determine the substance of each individual complaint formal compliance action will not be necessary in every matter that comes to our attention. Some matters are better dealt with using education and/or guidance.

To ensure that our finite resources are managed appropriately we consider a range of factors when deciding whether to investigate and take compliance or enforcement action. It is the substance and severity of a complaint that dictates the level of resources dedicated to it.

In the first instance, where minor non-compliance issues are identified we will often work with the advertiser using an educative approach in order to achieve compliance. However, escalation of regulatory action will be considered if the advertiser is not willing to comply or the breaches of the advertising requirements are such that there is an impact on the ability of the consumer to use the therapeutic goods safely or appropriately in line with the goods' intended therapeutic purpose.

We are less likely to investigate matters that are one-off events, unless non-compliance is a deliberate and blatant breach of the legal requirements, it is part of an ongoing pattern of non-compliance, and/or there are public health consequences from the non-compliant behavior.

Our complaints process is supported by the following principles:

- We will work ethically within our legislative framework for regulating therapeutic goods advertising
- Our approach to handling and determining complaints will be consistent
- We will be transparent in our dealings and will report on details of our performance in managing complaints
- We will expend resources appropriately by focusing on risk and addressing the most serious non-compliance, and
- We take all complaints seriously and will action them within set time frames.

Figure 1: Compliance approach

Table 1: Our Approach to Compliance

Help and Support	Inform and Advise	Correct Behaviour	Enforce
Make compliance easy	Help to become and stay compliant	Deter by detection	Administrative, civil or criminal action

Table 2: Regulated Entity - Attitude to compliance

Voluntary Compliance	Accidental Non Compliance	Opportunistic Non Compliance	Intentional Non Compliance
• Effective compliance systems • Management is compliance	• Ineffective and/or developing compliance systems • Management is	• Resistance to compliance • Limited or poor compliance systems • Management not compliance orientated	• Deliberate non compliance • No compliance systems • Criminal intent
"Committed to doing the right thing"	**"Trying to do the right thing"**	**"Don't want to comply but will if made to"**	**"Decision to be non-compliant"**

7. The complaints process

Although we prefer complaints to be made on our online advertising complaint form, complaints can also be submitted by email, telephone or posted to the TGA. Where we cannot action a complaint within the advertising framework we will endeavour to refer the complaint to the appropriate area of another agency with the appropriate jurisdiction to action it.

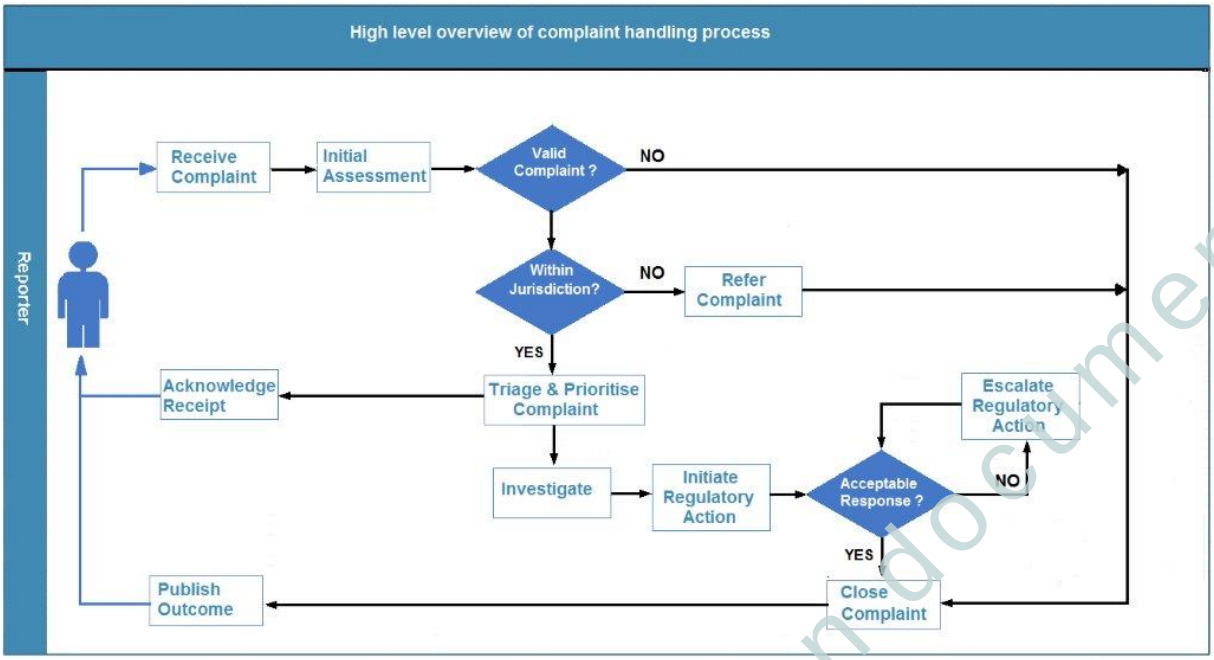
The online complaint form, that will be available on the advertising hub of the TGA website, will ask the complainant for specific information and allow them to upload digital attachments so that we have all of the information necessary about the advertisement and the advertiser to properly assess and investigate the complaint. Online complainants will receive a unique identification number visible on the form at the time of submission.

If a complaint is received outside of the online hub, and the complainant can be identified, the acknowledgement process will be manual and the complainant will, within 10 working days, be given a unique identification number for reference.

Not only do we accept anonymous complaints but we will treat the identity of a complainant who chooses to be identified in confidence.

Regardless of the way the complaint is received, it will be entered into our Complaints Handling System where the complaint will be actioned and tracked as a complaint *lead*.

At a high level, our complaints process is as follows:



7.1 Accepting your complaint lead

Leads will be assessed for validity as we can only legally action complaints about advertisements for therapeutic goods; we cannot action complaints about foods, cosmetics, general consumer goods, chemicals, veterinary medicines, and health insurance or healthcare professionals. We do not have any legislative power to seek compensation on behalf of consumers, as this falls within various consumer protection schemes and is beyond the remit of the *Therapeutic Goods Act 1989*.

There are some complaints we cannot action as they are outside the jurisdiction of the legislation we administer. We often cannot action a complaint about advertising that is conducted or that originated offshore. There are some constitutional constraints on dealing with individuals who advertise solely within their own state or territory and are otherwise not engaged in interstate trade. These matters may be referred to state or territory authorities with appropriate jurisdiction.

In these cases the complainant will be advised that their complaint has been closed and they will be consulted as to whether they want us to refer the case to a more appropriate authority.

If a complaint is assessed as a valid complaint, within our jurisdiction, the *lead* will be moved to a *complaint* case and the complainant will receive an email or letter confirming this with the case identification number.

If a number of *leads* are received that may relate to different advertisements and different *responsible entities*, but relate to similar classes of therapeutic goods (for example cosmetic injections), we will consider grouping these *leads* into one *case* so they may be dealt with in one action – say by way of a targeted educational campaign and/or by notifying the responsible entities involved and making them aware of their regulatory obligations. We will report on the number of complaints as well as the case outcome.

7.2 Triaging of complaints

Staff within the TGA will assess and triage complaint cases about advertisements taking into consideration attributes of the complaint including but not limited to the frequency of advertising, the likelihood of consumer harm and the intent of the advertiser. Like other regulators we will have a process to deal with vexatious complaints. Following assessment, complaints will be triaged into one of four priority categories; low, medium, high and critical.

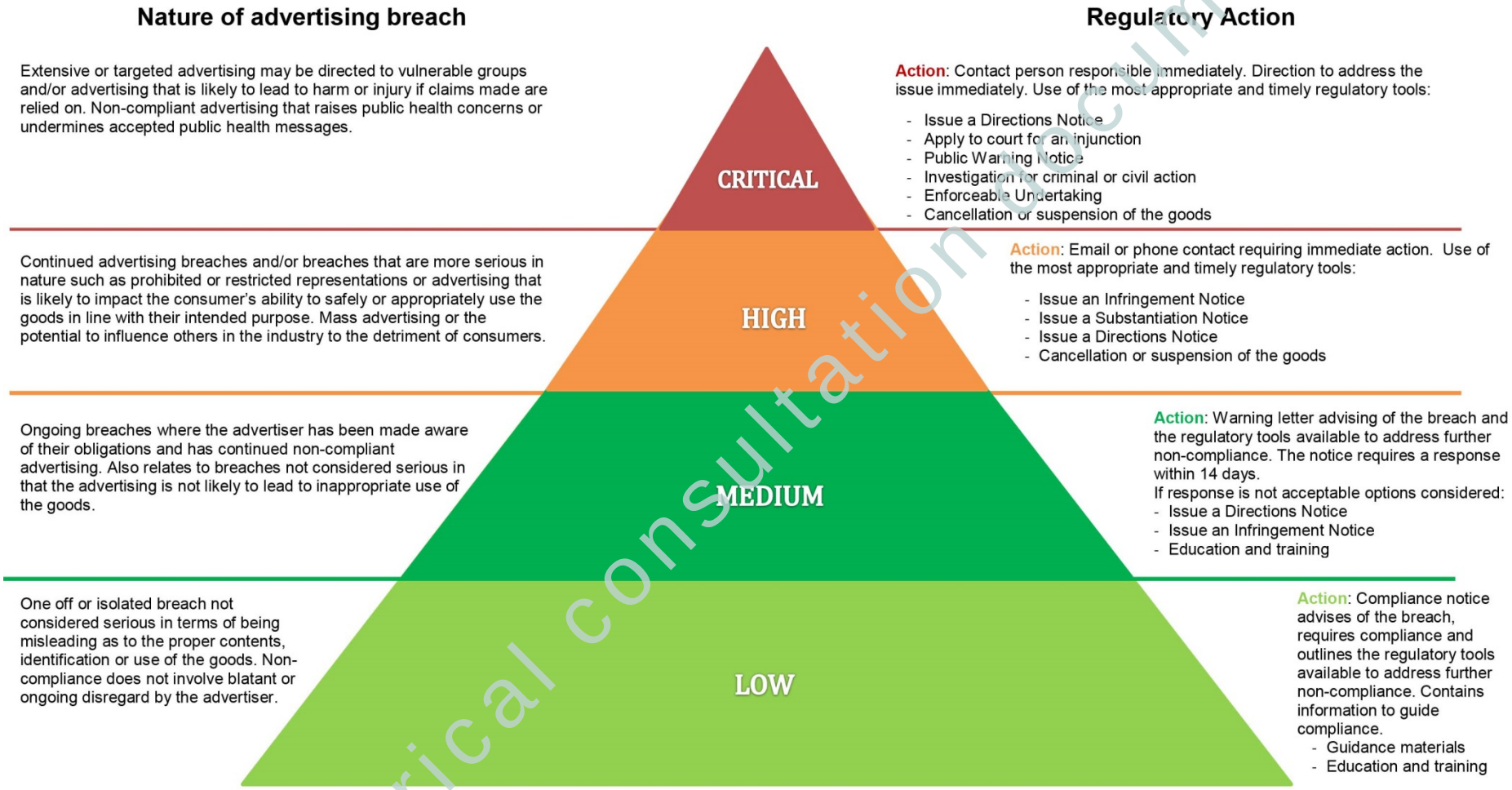
8. Priority based complaints handling model

We will assess and triage complaints about advertisements for therapeutic goods into one of the four priority categories after taking into consideration:

- whether the claims made or reliance on the claims made in the advertisement is likely to cause public harm
- the likely impact of the advertising on the ability of consumers to safely and appropriately use the goods for their intended purpose
- the frequency and likely impact of the non-compliant advertising and its influence on other advertisers to the detriment of consumers
- the advertisers' awareness of their advertising obligations.

The priority level assigned to each case will determine how quickly we commence investigation, notify the person responsible for the advertising, and ultimately the regulatory tools used to achieve compliance, and dictate our key performance indicators.

Overview of proposed complaints handling model once a breach is established



8.1 Investigation phase

Following assessment and triage, complaints will undergo investigation to examine the advertising material subject of the complaint, to establish the person responsible for the advertisement (responsible entity) and to consider whether the alleged breach has been committed. The investigation phase allows the responsible entity an opportunity to respond to assertions of non-compliant advertising and, where there has been non-compliance, to demonstrate a willingness to rectify, and actually rectify, the non-compliance in a timely manner. Using this response and the priority assigned to the complaint case, we determine the most appropriate regulatory tools to address the non-compliant advertising.

8.2 Low priority cases

These are cases of one-off or isolated advertising breaches that are not considered serious in terms of being misleading or confusing as to the content or proper use or identification of the therapeutic goods and do not involve ongoing or blatant non-compliance by the advertiser.

- Advertisers identified as the responsible entity for the alleged breach of the advertising scheme will be sent a regulatory obligations notice by email or letter.
- The regulatory obligations notice will advise the entity of the alleged breach and will have accompanying information to guide compliance.
- The responsible entity will be asked to review their advertising material for compliance and will be advised of the regulatory tools available to the TGA to address any further non-compliance.
- The matter will be closed when the notice is sent.
- Closed matters may be subject to a later review to ensure compliance has been met and is ongoing.

Regulatory obligations notices will not seek a written response from the responsible advertiser; however any response received will be addressed.

All low priority matters will be recorded in our Complaints Handling System and reported on. Recorded information may form part of a later review and/or how we address further or more serious non-compliance by the advertiser.

8.3 Medium priority cases

These are cases of ongoing advertising breaches where the advertiser has been made aware of their advertising obligations and continues to advertise the therapeutic goods in a non-compliant manner. This category relates to advertising breaches that are not considered serious in nature as they are unlikely to result in unsafe or inappropriate use of the therapeutic goods.

- Advertisers identified as the responsible entity will be sent a formal warning by email or letter as soon as possible.
- The warning letter will advise the entity of the alleged advertising breach and will have accompanying information and guidance on the advertising scheme.

- The responsible entity will be advised of the regulatory tools available to the TGA to address non-compliance.
- The warning letter will request a written response within 14 days seeking information on what action the entity intends to remedy the non-compliance.

An acceptable response will move the matter to closed status. If no response is received within 14 days or the response is not sufficient to warrant closing the matter, we will pursue this with the responsible entity and it may require escalation of our regulatory response.

The information from this case will form part of our considerations in cases of further or more serious non-compliance by the responsible entity.

8.4 High priority cases

These are cases of continued advertising in breach of requirements despite evidence the advertiser is aware of their obligations and has previously been provided education and or guidance material by the TGA. This would also involve advertising breaches:

- that are considered more serious in nature such as advertisements containing prohibited or restricted representations
- claims that will likely lead to inappropriate use
- advertising that is likely to have an impact on the ability of consumers to use the therapeutic goods safely or appropriately in line with their intended therapeutic purpose.

A higher priority may also be given to mass advertising campaigns because of the potential to influence other advertisers in the industry to the detriment of consumers.

- Advertisers identified as the responsible entity will be sent a warning by email or contacted by telephone as soon as possible and asked to address the non-compliance issue immediately.
- A determination will be made as to the most appropriate regulatory tools to be used.

The information from this case will form part of our considerations in cases of further or more serious non-compliance by the responsible entity.

8.5 Critical priority cases

These are cases where the advertising claims made, or reliance on them, may result in or is likely to result in harm or injury to consumers. Critical priority may also be given to advertising which is directed to the most vulnerable consumers or that undermines public health campaigns, raises significant public issues or has the potential to undermine public confidence in government, industry or the TGA.

- We will seek to identify the person responsible for the offending advertising either through direct contact or using open or closed source information.
- An advertiser identified as the responsible entity for breaches of a critical priority will be contacted by email or telephone immediately and required to address any non-compliance issues immediately.
- Subject to the responsible entity's action and the seriousness of the breach the TGA will determine what regulatory tools it uses for regulatory compliance and enforcement.

- It is unlikely that a matter assessed as critical would be closed simply by receipt of a response from the responsible entity.

If an acceptable response and action is not immediately forthcoming by the responsible entity of an advertising matter of critical priority, we will escalate our response and employ regulatory tools to enforce compliance, which may include civil or criminal litigation.

8.6 Monitoring and trend analysis

The TGA will link incoming complaints to a responsible entity involved in previous compliance cases. Closed compliance cases may be selected for monitoring and review.

Information on complaint trends will be published in bi-annual reports. This information will inform the identification and prioritisation of compliance risks, and the targeting of our education and compliance work.

9. Reporting outcomes and measuring performance

The proposed use of a case identification number will allow monitoring of individual complaints throughout the process. When matters are finalised and closed, outcomes will be published.

Some sections of the therapeutic goods legislation require us to publish information such as when we issue directions. Other sections of the legislation allow us to publish information such as Public Warning Notices.

We will publish the outcomes of complaint cases and information on enforcement outcomes, including those that are administrative actions such as cancellation or suspension of therapeutic goods from the ARTG.

Like other regulators, we will publish information on our website on specific actions:

- enforceable undertakings that we enter into
- information about infringement notices
- court outcomes
- directions notices
- public warning notices.

Publishing information about such matters is central to the requirement for the TGA to be transparent in its advertising complaints handling process. Our new regulatory tools mean that persons who publically advertise in contravention of the therapeutic goods advertising scheme can potentially face both a financial penalty and reputational damage from having their name reported on the TGA's website.

- **Low priority outcomes**, we will not disclose the identity of those persons who have been sent a regulatory obligations notice, however the case identification number, date received, date completed and the outcome will be published.
- **Medium priority outcomes**, where an acceptable response is received to a warning letter, the details of the responsible entity along with the case identification number, date

received, date completed, the therapeutic goods involved, compliance action/s taken and the outcome will be published.

- **High priority outcomes**, where these matters are resolved, the details of the responsible entity, the case identification number, date received, date completed, the therapeutic goods involved, the compliance action/s taken and the outcome will be published.
- **Critical priority outcomes**, where these matters are resolved, the details of the responsible entity, the case identification number, date received, date completed, the therapeutic goods involved, the compliance action/s taken and the outcome will be published.

New key performance indicators (KPIs) will be reported in bi-annual reports. We will use two metrics for reporting time to action complaints and time to close complaints.

Time to action complaints means the time from when the complaint was received, assessed and triaged to when we have made our initial engagement with the person responsible for the advertising. These times depend on the priority given to each accepted complaint and include:

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

Time taken to close complaints means the time from when the complaint was received, assessed and triaged to when we assess that no further action is required. These times are our intended timeframes in which to close out matters and depend on the priority given to each accepted case:

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

9.1 Exceptions to the metrics

Some complaints may be referred internally within the TGA such as where the complaint triggers an efficacy or safety review which may also, in more complex matters, require external advice or a submission to an advisory committee. In these cases we will monitor progress and report on outcomes when the matter is finalised.

Matters that require court action can take some time to properly investigate and assemble, for example for criminal prosecutions. Outcomes that are dependent on court decisions either civil or criminal can, according to available court resources, take longer to resolve and close. In these cases we will report on outcomes when the matter is finalised.

If we have referred the matter for action to an external agency such as another Commonwealth or State regulator we will report the time taken from receipt of the complaint to referral to that agency.

We seek the views of stakeholders on our proposed complaints handling model.

10 Governance

A new non-statutory committee, the Therapeutic Goods Advertising Committee, will be formed. The TGAC would meet three or four times per year, most likely in association with some meetings of the TGA Consultative Committee (TCC) who meet twice a year.

This committee will have wide representation across stakeholders involved in therapeutic goods advertising and will include representation from:

- patient and health consumer representative bodies
- therapeutic goods industry
- publishers and broadcasters (including social media and internet)
- healthcare practitioners, and
- advertising and other parts of the media industry.

The committee will act as a forum for engagement on advertising issues and will provide advice on thematic issues in advertising complaints, compliance priorities and education plans.

The committee will review the TGA's KPIs in managing complaints and provide advice on the bi-annual report.

The committee will also advise on the policy settings for therapeutic goods advertising, including for products such as medical devices that were formerly not completely included within the advertising regulatory framework.

11 Education and guidance

Education and guidance are a key strategy in support of compliance, and will inform the public about the appropriate advertising of therapeutic goods and in how to make a complaint.

To assist advertisers to understand their obligations we will provide an e-learning program on our website, along with guidance and information materials. The program is expected to be available mid-2018, and modules may be added over time.

We will develop a number of guidance documents and will work with key stakeholders to discuss specific needs. We will raise awareness about the new advertising complaints handling process and the role of the TGA in the regulation of advertising for therapeutic goods.

A number of resources and channels will be engaged:

- TGA website advertising hub
- Stakeholder workshops and roadshows
- Twitter
- YouTube
- Printed and online fact sheets, and material for industry publications
- E-learning program and other training materials
- SME Assist seminars.

12 The TGA website advertising hub

The TGA website advertising hub will have a selection of ways to access information about the advertising of therapeutic goods to the public, and to make contact with the TGA on advertising matters. You will be able to:

1. **View our education and guidance material**

2. **Make an enquiry about therapeutic goods advertising**

   Enquiries received through the hub will be automatically acknowledged and given an identification number. While it is not the role of the TGA to act as a regulatory consultant, we will strive to assist and will respond to enquiries with relevant information by email.

3. **Make an application to advertise therapeutic goods with a restricted representation**

   Please note that this facility will not become available until later in 2018 as a minor legislative amendment is required to allow for online submissions.

   Until the online submission option becomes available the current application form will continue to be used. The form can be downloaded from the TGA website as a PDF or Word document and when completed should be emailed back to the TGA. The form can be accessed at Application for approval to use a restricted representation in advertising.

   Advertisements for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in the code as restricted representations, unless prior approval is given under the Act.

   By selecting the *"make an application to advertise therapeutic goods with a restricted representation"* option on the TGA advertising hub you will be able to make an application to advertise therapeutic goods with a restricted representation. When available, online applications will be acknowledged automatically by return email with an identification number.

   In considering an application for approval to include a restricted representation in an advertisement, the decision-maker must be satisfied that the representation is accurate and balanced and is not misleading or likely to mislead. The decision-maker can seek advice and will also ensure that public interest criteria are applied. Further information on restricted representations can be found at Restricted representations.

4. **Make a complaint about an advertisement**

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Advertising Compliance Unit	May 2018

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