

Technical Alert

Summary of Changes to the TGA Advertising Framework

6 March 2018

The amended *Therapeutic Goods Act 1989* came into effect, introducing a new advertising framework as a result of [MMDR](#) recommendations 28 and 57. The key changes introduced are a new complaints handling framework with enhanced sanctions and penalties, and a phase-out of the advertisement pre-approval system.

Pre-approved Advertisements

1 July 2020

Medicines advertised in *specified media*¹ continue to need pre-approval until this date. **Pre-approved** advertisements will not be subject to the following advertising offence provisions and would not attract accompanying sanctions and penalties:

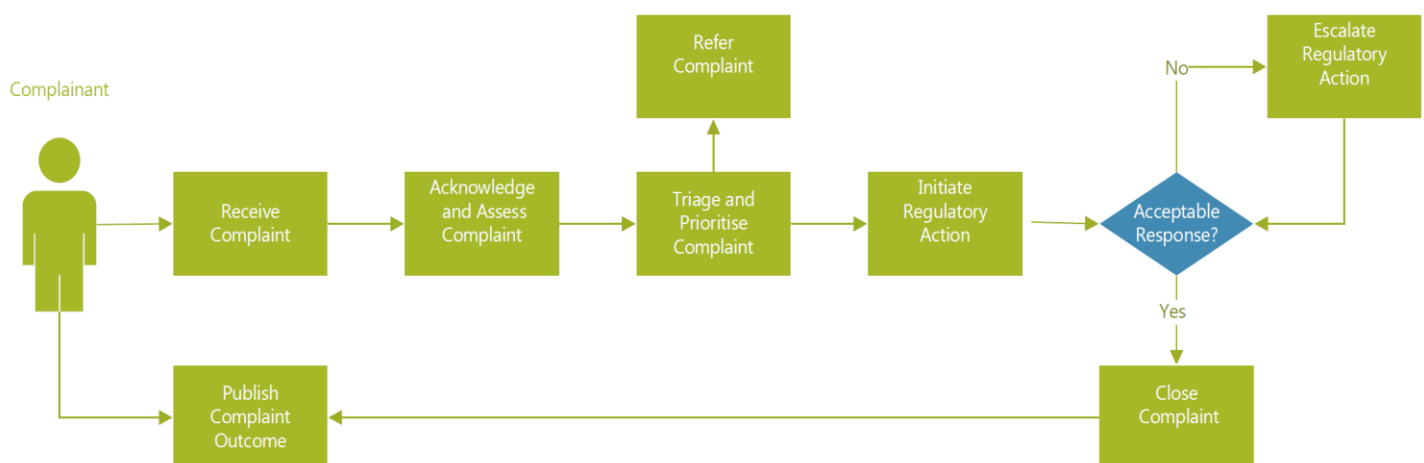
- s.42DL – General advertising offence provisions
- s.42DM – Non-compliance with the Therapeutic Goods Advertising Code.

Overview – Proposed Complaints Handling Framework

1 July 2018

- Updated Advertising Code to take effect.
- The TGA becomes the sole body handling complaints about advertising of therapeutic goods to the public.

Overview of proposed complaints framework



¹ *Specified media*: mainstream print media (magazines or newspapers), broadcast media, cinematograph films, displays about goods including posters in shopping malls (except inside individual shops); in or on public transport; and on billboards.

TGA Actions relating to Advertising breaches

Nature of Complaint	Actions and regulatory tools available to the TGA (may be used individually or in combination)
LOW One-off or isolated breach not considered serious in terms of being misleading as to the proper contents, identification or use of the goods. Non-compliance does not involve blatant or ongoing disregard by the advertiser.	TGA KPI Action 95% within 14 days. <ul style="list-style-type: none"> • Education and training • Guidance materials • Obligations notice Action: Advertiser is sent an obligations notice advising of the breach and regulatory tools available to address further noncompliance. Contains information and guidance to assist with future compliance.
MEDIUM 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.	TGA KPI Action 95% of all cases within 40 days. <ul style="list-style-type: none"> • Warning letter requiring response within 14 days • Issue a Directions Notice • Issue an Infringement notice (strict liability and civil offences) • Guidance materials / Education and training Action: Formal warning notice advising of the breach and the regulatory tools available to address further non-compliance. The notice requires a response within 14 Days.
HIGH Continued 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 purpose. Mass advertising or the potential to influence others in the industry to the detriment of consumers.	TGA KPI Action all cases within 20 days. <ul style="list-style-type: none"> • Formal contact requiring immediate action • Issue an Infringement Notice (strict liability and civil offences) • Issue a Substantiation Notice requiring response within 14 days • Issue a Directions Notice • Cancellation or suspension of the goods Action: Formal email or phone contact requiring immediate action.
CRITICAL 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	TGA KPI Action all cases within 10 days. <ul style="list-style-type: none"> • Issue a Directions Notice • Apply to court for an injunction • Public Warning notice • Investigation re criminal or civil action • Enforceable undertaking • Cancellation or suspension of the goods Action: Contact person responsible as soon as possible. Direction to address the issue immediately. Use of the most appropriate and timely regulatory tools regulatory tools.

Obligations notice – Advisory notice to assist with ongoing and future compliance.

Warning letter – Notice advising of the breach and requiring a response within 14 days.

Substantiation notice (s.42DR) – Require an advertiser to supply information or documents within 14 days.

Direction notice (s.42DV) – Require action by advertiser to cease, retract or fix advertising.

Infringement notice (s. 42DL, s. 42DM) – Can be applied to strict liability and civil offences.

Injunction – Powers to restrain a person from contravening the Act or to compel a person to comply.

Public Warning notice (ss. 42DY(1)) – The TGA may issue a warning to the public if satisfied it is in the public interest.

Complementary Medicines Australia

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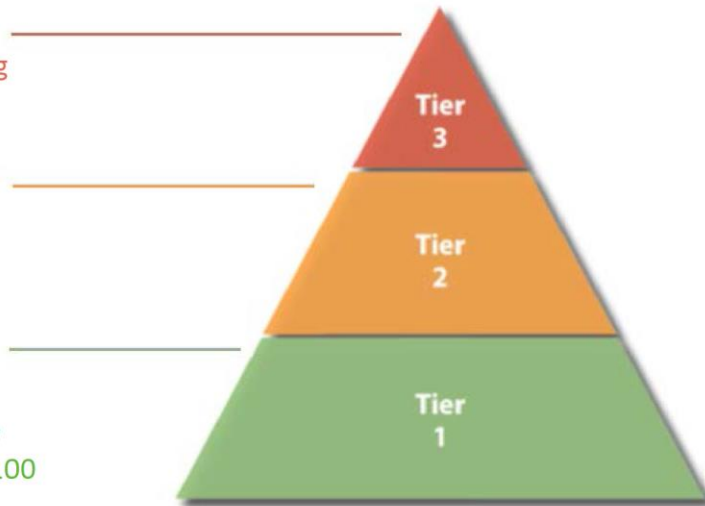
Revised sanctions and penalties

There will be a graduated response to compliance and enforcement. Where offences occur, the vast majority will fall under “Strict liability offences”. However, in the first instance, the TGA will often work with the advertiser using an educative and preventative approach to achieving compliance.

Fault-based aggravated offence now includes **likelihood of harm** into existing circumstances of aggravation (penalties remain the same)

Fault-based offence without harm (remain the same in structure and penalty unit amount)

Strict liability offence
Removal of *likelihood of harm* from all strict liability offences and reducing the maximum penalty units from 2,000 to 100



Strict liability offences are offences that have occurred (e.g. breach of the Advertising Code) and there does not need to be proof of fault, recklessness or intent. Offences of strict liability can occur without any knowledge of the wrongness of the act. The majority of offences would fall into this category, rather than civil or fault-based offences.

- Removal of “*likelihood of harm*”. Proof of harm is not required for a strict liability offence to apply.
- Maximum penalty units applicable by a court: **100** (reduced from 2,000 in the previous T.G. Act).
- In an infringement notice, there will be a choice to pay a specified amount as an alternative to court proceedings. Paying the amount is not an admission of guilt. If a person chooses not to pay the amount, court proceedings may be brought against the person in relation to the contravention.
- The maximum amount payable as an alternative to court proceedings for a *strict liability offence* is **12** penalty units where the person is an individual, or **20** penalty units for a body corporate (one fifth of the maximum applicable penalty units of 100).
- Each commonwealth penalty unit is **\$210**. The unit value increases in line with the CPI (consumer price index) from 1 July 2020, and every three years after.
- *Civil offences* and *fault-based offences* attract different and higher penalties to strict liability offences under the Therapeutic Goods Act, but would be used more rarely.

Education & Guidance

- The TGA are working on **education material, guidance** and a new **web hub** to support the changes to the advertising system, once the revised Code is in place on 1 July.
- From May 2018, **competency based training modules** will become progressively available.
- The TGA will also publish online detailed educational information and other resources about advertising therapeutic goods to the public, including restrictions and exemptions to the TGA advertising regulatory scheme. Information will be tailored and targeted to health professionals, consumers and industry.