



Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: The regulatory framework for advertising therapeutic goods

November 2016

TGA Health Safety
Regulation

Historical consultation document

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Historical consultation document

Contents

1.	Introduction	4
2.	Government's response to the recommendations	6
3.	Background	8
3.1	The existing regulatory framework for advertising	8
3.2	Consistency in advertising of medicines and medical devices	8
4.	Pre-approval of advertisements	9
4.1	Moving forward	9
5.	Sanctions and penalties	11
5.1	Civil penalty provisions	12
5.2	Infringement notices	13
5.3	Injunctions	14
5.4	Substantiation and warning notice powers	14
5.5	Transparency	14
6	Complaints handling	17
6.1	Centralised administration	17
6.2	2013 Advertising consultation	18
6.3	Future options	18
	Model 1 - Commonwealth Agency	18
	Model 2 - Independent non-Government Authority	18
	Model 3 - Hybrid government and non-government authorities	19
6.4	Transparency of complaint handling	20
7.	Future of the Therapeutic Goods Advertising Code, Code Council and Complaints Resolution Panel	21
7.1	The Therapeutic Goods Advertising Code	21
7.2	Future provision of expert advice	22
8.	Industry education	23

1. Introduction

In October 2014 the establishment of the Expert Review of Medicines and Medical Devices Regulation (the Review) was announced.

The Expert Panel delivered two reports that assessed the regulatory framework for medicines and medical devices in Australia, and made [58 recommendations for reform](#)¹.

The Panel's recommendations in relation to the advertising of therapeutic goods to the public aim to simplify the framework by:

- ceasing pre-approval of advertisements in favour of a more self-regulatory regime;
- implementing a more transparent and efficient complaints management process;
- establishing greater consistency across regulation of advertising of different types of therapeutic goods;
- implementing a formal education program for industry to encourage compliance; and
- broadening and strengthening the Therapeutic Goods Administration's (TGA's) investigation and enforcement powers.

The Panel made seven specific recommendations in relation to advertising, as follows:

Recommendation Fifty Two

The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the [TGA] under a legislative framework which includes an advertising code.

Recommendation Fifty Three

The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the *Poisons Standard* continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

Recommendation Fifty Four

The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.

Recommendation Fifty Five

The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

Recommendation Fifty Six

The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options:

¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation>

- A. establishing the function within the NRA (National Regulatory Authority, i.e. the TGA) or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or
- B. calling for tenders from external organisations to undertake the function.

Recommendation Fifty Seven

The Panel recommends that, further to Recommendation Twenty Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

Recommendation Fifty Eight

The Panel recommends that the [TGA] facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.

2. Government's response to the recommendations

The [Australian Government's response to the Review](#)² was released on 15 September 2016 and in relation to the specific advertising recommendations the Government has agreed the following:

Recommendation Fifty-Two

The Government accepts that **advertising of therapeutic products to the public should continue to be regulated by the TGA under a legislative framework which includes an advertising code** noting that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.

Recommendation Fifty-Three

The Government accepts that **advertising to the public should continue to be prohibited for Schedule 4 and 8 prescription medicines**. The issue of **advertising of Schedule 3 medicinal substances will be considered as part of a review of the Scheduling Policy Framework**³(*Recommendations Eleven and Twelve*).

Recommendation Fifty-Four

The Government accepts that the **future requirements for advertising therapeutic products to the public should be made consistent for all medicines and medical devices**, noting that increasing consistency of approach could help reduce complexity for advertisers. The Commonwealth also notes that the differences between medicines and medical devices means that consistency may not be appropriate in particular circumstances.

Recommendation Fifty-Five

The Government accepts that **the whole process of vetting and pre-approval of the advertising of therapeutic products to the public should be stopped** in favour of a more self-regulatory regime. The implementation of *Recommendations Fifty-Seven* (enforcement powers) and *Fifty-Eight* (sponsor education) are critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is consistent with the Government's commitment to minimising unnecessary regulatory burden.

Recommendation Fifty-Six

The Government accepts that current mechanisms for managing complaints should be disbanded and **a new mechanism established consistent with best practice principles for complaint handling**. **In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public**. A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, thereby benefiting consumers.

To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process and consider whether to

² <https://www.tga.gov.au/mmdr#austgovt>

³ The review of the Scheduling Policy Framework will be addressed through separate consultations and is out of scope for this paper.

establish the function within the TGA or another existing Commonwealth agency; or to call for tenders from external organisations to undertake the function.

Recommendation Fifty-Seven

The Government accepts the need for **stronger compliance powers against misleading advertising, noting that broadening enforcement powers will benefit consumers by ensuring appropriate compliance with regulatory requirements and deter inappropriate and misleading advertising of therapeutic goods.**

Recommendation Fifty-Eight

The Government accepts that the TGA should **develop a formal education programme to provide sponsors and advertisers** with appropriate information and tools to assist them in understanding their obligations and achieving compliance with advertising requirements. This will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of *Recommendation Fifty-Five*).

3. Background

The Australian *National Medicines Policy* recognises the primary position of the consumer in the *Quality Use of Medicines* framework. This framework has been articulated to mean for the consumer:

- selecting management options wisely;
- choosing suitable medicines if a medicine is considered necessary; and
- using medicines safely and effectively.

To support this position, industry must be able to provide truthful information to potential consumers about the nature and benefits of therapeutic products. They should be able to do so through responsible advertising, where this will enhance the health outcomes of the Australian people.

In this context a robust and effective system for regulating advertising that provides confidence for consumers is required. The system should give consumers confidence that the claims they read and hear are well-founded, and it should provide a level playing field for industry.

3.1 The existing regulatory framework for advertising

The TGA currently has overall responsibility for the regulation of advertising therapeutic goods to consumers. The regulatory requirements are set out in the *Therapeutic Goods Act 1989* (the Act), the Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods Advertising Code (the Code).

3.2 Consistency in advertising of medicines and medical devices

The focus is to provide consistency in advertising requirements and in complaints handling for advertisements.

Consistency in advertising requirements for medicines and medical devices can be achieved by implementing Recommendations 55 and 56, which will remove the requirement for certain advertisements to be pre-approved and provide for greater consistency in the handling of complaints about potentially non-compliant advertisements. The option of prohibiting direct-to-consumer advertising of high-risk medical devices in the same way that direct-to-consumer advertising of prescription medicines is prohibited is not currently being considered. This is because the majority of high-risk medical devices are not available for purchase by consumers.

4. Pre-approval of advertisements

Currently advertisements for most over-the-counter (OTC) and complementary medicines published in newspapers, magazines and billboards or broadcast on free-to-air television and radio are required to be pre-approved by delegates of the Secretary of the Department of Health. These delegates are currently within the relevant industry associations (currently the Australian Self Medication Industry (ASMI) and the Complementary Healthcare Council (CHC)).

The Government has endorsed a move to a more self-regulatory framework instead of the current statutory pre-approval of advertising of these therapeutic goods.

The Government's response was clear that removal of pre-approval requirements is conditional on the implementation of other recommended consumer protections.

These protections include not only enhanced sanctions and penalties (see below) but also: strengthening of post-market monitoring (Recommendation 49); advertising claims being consistent with the permitted or approved indications specified when a product is included in the Australian Register of Therapeutic Goods (Recommendation 38); and improving the complaints management process (Recommendation 56).

This should enable the risks to consumers of a potential increase in exposure to misleading and potentially harmful advertising to be adequately managed.

4.1 Moving forward

Key considerations in removing pre-approvals are:

- the strengthening of compliance and enforcement powers in recognition of the removal; and
- whether pre-approvals should not be removed until stronger compliance and enforcement powers are in place.

The Government has left it open for industry associations and/or other commercial providers to implement a self-regulatory regime for providing pre-approvals. This recognises that the current pre-approvals process provides a level of confidence about the compliance of an advertisement for publishers or broadcasters.



A self-regulatory framework that allows for advertisements to be assessed and endorsed before publication or broadcast could be established by any third party provider to give broadcasters and publishers a level of confidence in the advertisement's compliance with the regulatory framework.

On the question of when pre-approvals will be removed, the Government has agreed that enhanced penalties and sanctions will be implemented first. Implementation of enhanced penalties and sanctions will be subject to the passage of legislative changes.



The requirements for pre-approval of certain advertisements for OTC and complementary medicines will not be removed until such time as a stronger penalties and sanctions framework has been implemented, an efficient and effective complaints resolution process is in place and a formal industry education program has been established.

Also, acceptance by the Government of Recommendation 39 of the Review will mean that following independent pre-market evaluation of supporting evidence by the TGA, certain complementary medicines could make claims that exceed the current permitted indications for listed complementary medicines. Implementing this recommendation will require a careful consideration of the advertising allowed for such products. It is envisaged that for these products the Australian Register of Therapeutic Goods (ARTG) entry process may include an assessment of the appropriateness of proposed promotional claims prior to ARTG entry.

5. Sanctions and penalties

The Panel noted that, across all stakeholder groups, there was a view that the current sanctions and penalties available to the TGA in respect of breaching the advertising requirements are insufficient, do not meet community expectations, and should be enhanced to incentivise greater compliance. The Government has agreed that legislative changes can be made that include increasing the regulator's enforcement powers with respect to advertising.

As noted on page 65 of the Panel's Stage Two Report, the deterrents provided under the Therapeutic Goods Act are at odds with powers available to some overseas regulators. For example, in the UK the MHRA is able to commence proceedings as a criminal or civil offence, and penalty and enforcement powers provide for a fine and up to two years imprisonment for breaches of advertising requirements.

In addition, the option of taking swift action should be available when advertising of therapeutic goods poses risks to public health and safety, or the advertisement contains false or misleading representations. The TGA does not currently have the power to apply to a court for an interim or permanent injunction to immediately restrain a person from publishing or broadcasting such advertisements.

This contrasts with other Australian regulatory schemes, such as the Australian Consumer Law (Schedule 2 to the *Competition and Consumer Act 2010*), which allows the Australian Competition and Consumer Commission to apply for interim, consent and permanent injunctions in relation to false or misleading representations or misleading conduct about consumer goods.

The Panel stated explicitly that updates to, and increases in, sanctions were needed particularly given the Panel's recommendation (subsequently accepted by Government) to remove the pre-vetting process for advertising of therapeutic goods. The Panel acknowledged that an effective deterrent regime will require that the investigation and enforcement enhancements must be complemented through increased post-market monitoring activities and compliance reviews to identify breaches (Recommendation 49 refers) and concluded that "*without an enhancement to the TGA's sanctions regime and powers to take action in response to advertising breaches, there is a risk that the self-regulatory scheme may lead to greater non-compliance with regulatory requirements*".

To support the advertising regulatory framework a range of sanctions and penalties for each prohibited action should be provided to effectively manage the level of risk for each offence. The provision of pecuniary penalties such as civil penalties, infringement notices and enforceable undertakings, as alternative sanctions to prosecution, should be part of the enforcement model.

The 2013 TGA [Consultation Regulation Impact Statement \(RIS\)](#)⁴ on the Advertising Regulatory Framework considered whether the current range of investigation and enforcement powers should be broadened and enhanced.

Approximately 85% of respondents supported enhanced investigation and enforcement powers, rather than the *status quo*. These proposed enhancements (as outlined in the RIS) included amendments to the legislation to:

- **Increase the level of penalties for offences relating to contraventions of advertising requirements consistent with the level of penalties for other similar offences under the Act** (refer to Table 1 below for current penalties and the proposed changes).

⁴ <https://www.tga.gov.au/consultation/consultation-regulation-impact-statement-regulating-advertising-therapeutic-goods-general-public>

- Allow for **civil penalty provisions** corresponding to the offences in subsection 22(5), section 41ML and Part 5-1 of the Act (these provisions **make it an offence to advertise therapeutic goods for an indication/use/purpose for which they have not been approved by the TGA**) and any other new offence provisions that may be put in place as a result of these reform proposals.
- Provide the Secretary with a **power to require an advertiser/sponsor to provide information to substantiate any aspect of an advertising claim** and about any other matter in relation to the advertisement and to make it an offence to provide information that is false or misleading in a material particular in response to such a request.
- Provide the Secretary with a **power to apply for interim, consent and permanent injunctions to restrain a person from contravening or continuing to contravene the advertising requirements** under the Act or the Regulations. These powers may be modelled on Division 2 of Part 5-1 of the Australian Consumer Law (Schedule 2 to the *Competition and Consumer Act 2010*).
- Provide the Secretary with a **power to order the advertiser/sponsor to undertake specified actions in specified timeframes in relation to the advertisement including publish a retraction or correction, withdraw the advertisement, withdraw a claim or representation in the advertisement and undertake not to use it again.**
- **Create an offence and civil penalties where a person to whom such an order is given fails to comply** within relevant timeframes.
- Provide a power to the Secretary to **suspend/cancel the advertised product(s) from the ARTG without notice** where such an order given to a sponsor is not complied with in the relevant timeframe.
- Provide **information and document gathering powers** in relation to the advertiser responsible for potentially non-compliant advertisements.

It is proposed to increase the level of penalties to be imposed in relation to breaches of the advertising requirements and to introduce a corresponding civil penalty provision in relation to the same prohibited conduct.

The level of penalties and available sanctions for each offence and civil penalty provision should be based on the public health importance of that breach or contravention.

5.1 Civil penalty provisions

Civil penalties are not currently available under the Therapeutic Goods Act in relation to contraventions of advertising requirements. The inclusion of civil penalties as part of the sanctions package for advertising requirements would provide additional deterrence from non-compliance with advertising requirements.

Some non-compliance may be profit driven and may not be attributed to behaviour that is reckless or negligent or characterised by a serious pattern of continuous intentional contraventions. A civil penalty (which only requires proof on the balance of probabilities, and not beyond reasonable doubt as is the case for a criminal penalty) would be appropriate to enable advertisers to be fined for breaches where other sanctions, such as criminal prosecutions, may not be appropriate or effective in the circumstances.

Civil penalty provisions corresponding to the following advertising offences in the Act are proposed as follows:

- subsection 22(5) - **offence if a person advertises therapeutic goods for an indication other than the indication accepted** in relation to the goods
- subsection 32B(3) – **offence if a person advertises a biological for an indication other than an indication accepted** in relation to the goods
- section 41ML – **offence if a person advertises a medical device as being for purpose that is not accepted** in relation to the goods
- section 42DL – general advertising offences
- section 42DM – requirement for **compliance with the Therapeutic Goods Advertising Code**

5.2 Infringement notices

Infringement notices have not been available for use when advertising requirements are breached because they are based on civil penalty provisions which do not currently apply to the advertising offences.

Specifically, regulation 9 orders (i.e. those currently made by a delegate of the Secretary under regulation 9 of the Therapeutic Goods Regulations 1990 after a referral from the Complaints Resolution Panel) cannot be enforced directly against the sponsor (offences and suspension/cancellation from the ARTG would require proof of the original breach, not just failure to comply with the order). **Instead, it is proposed that failure to comply with a regulation 9 order should be a separate ground for suspension/cancellation of the ARTG entry and an offence giving rise to an infringement notice.**

Additionally, regulation 9 orders cannot currently be enforced against advertisers who are not the sponsor of the product on the ARTG. **It is proposed that failure to comply with a regulation 9 order by a non-sponsor advertiser should be an offence giving rise to an infringement notice.**

It is proposed that infringement notices will apply to strict liability offences⁵ and civil penalty provisions. The level of pecuniary penalty under the infringement notice scheme would be set out in regulations and would not exceed 5% of the maximum pecuniary penalty for a civil penalty provision.

Infringement notices will only be used where there is clear objective evidence of a breach of the advertising requirements (e.g. advertising for an indication that is not accepted in relation to the goods or failure to comply with a regulation 9 order). In this way the matter can readily be taken to court if the respondent chooses not to comply. If the decision by the alleged offender is not to pay the infringement notice, the matter will be taken to the appropriate court to determine whether the person is in breach or not, as well as the nature and level of the sanction to be applied.

⁵ For a strict liability offence the prosecution is not required to prove actual negligence or intent to harm.

5.3 Injunctions

An injunction is an order made by a court requiring a party to do a particular thing or requiring a person to stop doing a particular thing. The option of taking swift action should be available when advertising of therapeutic goods poses risks to public health and safety, or the advertisement contains false or misleading representations that contravene the requirements relating to quality use of medicines or medical devices. The TGA does not currently have power under the Act to apply to a court for an interim or permanent injunction to immediately restrain a person from publishing or broadcasting those advertisements.

It is proposed that the power to apply for an injunction be introduced, by adoption of the powers in the *Regulatory Powers (Standard Provisions) Act 2014*.

5.4 Substantiation and warning notice powers

It is proposed that the TGA would be given powers to publish public warning notices in relation to advertising claims that are likely to cause or result in harm or injury. This is similar to the TGA's current practice of publishing consumer alerts about potentially dangerous products. Also, the TGA will have broad substantiation powers in relation to advertisers who are not product sponsors.

5.5 Transparency

Depending on the final model agreed for complaints handling, where a matter is referred to the Secretary to take action and this does not result in the appropriate response (because the respondent has not sufficiently complied), the TGA will publish that information on its website so there is a full picture of the outcome. This publication would be supported by an authorising instrument made under s.61(5C) of the Act.

These additional enforcement options, higher level of penalties and greater transparency will enhance the TGA's ability to secure timely and better compliance with the advertising requirements.

Table 1 - Proposed new advertising offence provisions

The proposed penalty amount is the **maximum** penalty that could be applied; it will be up to a court to determine the actual penalty amount based on the particulars of the offence. Currently one penalty unit is equal to \$180.

Current provision or offence provision under the Act or Regulations	Current penalty levels	New offence provision and penalty	Corresponding civil penalty provision
Subsection 22(5) Section 41ML Subsection 32BJ (3) Advertising a medicine, medical device or biological for a purpose not included in the ARTG entry for that product	60 penalty units	(a) Offence for culpable conduct resulting in harm or injury—5 years imprisonment and/or 4000 penalty units (b) Normal offence—12 months imprisonment and/or 1000 penalty units (c) Strict liability offence ⁶ —500 penalty units	For an individual—5000 penalty units For a body corporate - 50,000 penalty units
Section 42C Offences related to publication or broadcast of advertisements that require pre-approval⁷	Strict liability offence -60 penalty units	Strict liability—125 to 250 penalty units	For an individual—1000 to 1250 penalty units For a body corporate—10,000 to 12,500 penalty units
Section 42DKB False or misleading advertising	60 penalty units under paragraph 42DL(1) (d)	(a) Offence for culpable conduct resulting in harm or injury—5 years imprisonment and/or 4000 penalty units (b) Strict liability offence—500 penalty units	For an individual—1000 to 1250 penalty units For a body corporate—10,000 to 12,500 penalty units
Regulation 9 Corrective action ordered by the Secretary	No sanction for not complying with the order.	(a) Offence for culpable conduct resulting in harm or injury—5 years imprisonment and/or 4000 penalty units (b) Strict liability offence—500 penalty units	For an individual—5000 penalty units For a body corporate—50,000 penalty units

⁶ For a strict liability offence the prosecution is not required to prove actual negligence or intent to harm.

⁷ These offences may no longer be required with the removal of the requirement for pre-approval of advertisements.

Current provision or offence provision under the Act or Regulations	Current penalty levels	New offence provision and penalty	Corresponding civil penalty provision
Section 42DL <i>Publication / broadcast of advertisement containing restricted or prohibited representations, reference to prescription medicines, biologicals or unapproved products, etc.</i>	60 penalty units	1000 penalty units This offence is now proposed to apply to all advertisements for therapeutic goods, instead of only applying to advertisements of therapeutic goods that do not require pre-approval.	For an individual—5000 penalty units For a body corporate—50,000 penalty units
Section 42DM <i>Advertisement does not comply with the Code</i>	60 penalty units	(a) Offence for culpable conduct resulting in harm or injury—5 years imprisonment and/or 4000 penalty units (b) Strict liability offence —1000 penalty units This offence is now proposed to apply to all therapeutic goods, instead of only applying to advertisements of therapeutic goods that do not require pre-approval.	For an individual—5000 penalty units For a body corporate—50,000 penalty units
Section 42DP <i>Publication of generic information that does not comply with the Code</i>	60 penalty units	Strict liability offence—500 penalty units	For an individual—5000 penalty units For a body corporate—50,000 penalty units
New offences		Compliance with requirement to provide information. General offence—1000 penalty units Strict liability offence—250 penalty units Offence of providing information that is false or misleading	For an individual—500 penalty units For a body corporate—5000 penalty units

6 Complaints handling

The Government has accepted the recommendations of the Panel to disband the current mechanisms for managing complaints (including the Complaints Resolution Panel) and establish a new mechanism that is consistent with best practice principles for complaint handling, including a single agency to be responsible for receiving and managing complaints relating to advertisements of therapeutic goods (Recommendation 56).

6.1 Centralised administration

It was also agreed by the Government that complaints will be managed and resolved in line with best practice principles such as those set out in the Commonwealth Ombudsman's Better Practice Guide to Complaints Handling.

It was noted by the Panel that health care providers and consumers, in particular, were concerned that the current complaints handling system for advertisements does not provide an appropriate level of procedural fairness; lacks transparency about complaints outcomes; timeframes for complaint resolution are overly long; a number of bodies are involved (causing confusion about lodging a complaint); and the sanctions and penalties available to the regulator are ineffective.

While the Government endorsed a single point of contact for anyone who has a complaint about an advertisement, the Panel was of the view that, with appropriate resourcing, the function of receiving and managing complaints could be established within the TGA, another Commonwealth agency, or could be outsourced.

Stakeholder [submissions](#)⁸ in response to previous consultations have revealed that consumers generally view the current complaints system as cumbersome and slow with multiple processing pathways, procedures and resolution bodies depending on:

- nature of the complaint
- therapeutic goods sector
- advertising media
- target audience for the advertisement.

The key issues of concern with the existing complaints handling processes relate to:

- timeliness of the processes
- effectiveness of the determinations
- inconsistency in decision-making
- perceived conflict of interest of members of the Complaints Resolution Panel (CRP) and industry self-regulatory panels.

⁸ <https://www.tga.gov.au/submissions-received-consultation-regulation-impact-statement-regulating-advertising-therapeutic-goods-general-public>

6.2 2013 Advertising consultation

The 2013 TGA [Consultation Regulation Impact Statement \(RIS\)](#) on the Advertising Regulatory Framework considered whether, in relation to complaints handling, the *status quo* should remain or whether all complaints about advertising of therapeutic goods to the general public should be handled by a single body, either the TGA, or an independent statutory office holder.

Responders to the Consultation RIS almost uniformly supported a single complaint handling scheme although there were differences in opinion as to who should have operational responsibility.

At the time, most consumers and health care practitioner groups saw this as being the responsibility of the TGA. By contrast, there was support (particularly from industry stakeholders) for the alternative option of establishment of an independent statutory authority to consider advertising complaints.

There was also limited support for complaints about therapeutic goods advertisements to the public to be handled by the ACCC and for the establishment of a self-regulatory complaints system, similar to the New Zealand scheme.

From the 2013 consultation there appeared to be two options that could be developed further:

- for the TGA to handle all complaints about advertising of therapeutic goods to the public with full and immediate access to all statutory powers; or
- self-regulation of complaints handling arrangements, noting that improved sanctions and penalties for advertising therapeutic goods to the public would be essential to underpin this alternative.

6.3 Future options

Model 1 - Commonwealth Agency

With regards to the Panel's recommendations, other than the Department of Health (i.e. the TGA) it is considered unlikely that any other Commonwealth agency would be suited to taking on this role, as any agency assessing complaints about therapeutic goods advertising would require the appropriate expertise – both technical expertise (medical and scientific knowledge relating to therapeutic goods) and a good understanding of the regulatory framework. This model is likely to offer the benefits of improved consistency and timeliness in the consideration of complaints. It would also simplify current processes by replacing multiple complaint handling arrangements with a single process. Additionally, with the introduction of sanctions and penalties that provide an effective deterrent, location within the TGA would provide access to the full range of criminal and administrative provisions. Where justified by the risk to public health, this would include urgent removal of non-compliant advertising.

However, adoption of this model could be seen by industry as the TGA assuming a role that traditionally has been shared with industry.

Model 2 - Independent non-Government Authority

An alternative model for complaints handling would be to outsource the process to an independent (non-Commonwealth) authority. There are two ways an independent authority could operate. For both, an independent authority would be conferred with statutory powers to receive, investigate and determine complaints.

For the first way, the independent authority would need to be conferred with the same statutory powers as the TGA to administer sanctions and penalties in relation to advertising as set out in the therapeutic goods legislation. The authority would administer the entire complaints handling process from receipt and assessment of complaints through to enforcement of compliance for advertisers in breach of the advertising requirements.

For the second way, the independent authority would rely on voluntary undertakings to achieve compliance. It is possible that an independent authority may demonstrate success in enforcing compliance through voluntary undertakings. However, without statutory powers to enforce compliance any additional punitive measures would need to be subsequently referred to the TGA for action as is currently the case with CRP.

The first way is likely to offer the timeliness of Model 1 but it is likely that there would be need to duplicate TGA evaluation and post-market expertise to determine if therapeutic claims made in an advertisement are misleading or not. Having two separate organisations effectively evaluating the same material may lead to inconsistent interpretations. Such a functional duplication could be avoided by the TGA undertaking the role of expert but this may increase the cost and complexity for the external authority. This proposal may also raise the question of whether the handling of complaints that encompass questions of efficacy can be achieved within an organisation outside of the TGA.

Model 3 - Hybrid government and non-government authorities

A third model for complaints handling would be a hybrid of the two models discussed above. The advertising complaint function would remain the responsibility of the TGA, which (as suggested by the Panel) could provide a single entry point for all advertising complaints, triage those complaints and refer less serious complaints and/or ones that centre on non-therapeutic advertising claims rather than therapeutic claims to an external body, leaving the TGA to focus on complaints that relate to more serious breaches or that involve persistent offenders. A similar model operates in the UK. A weakness of this approach is that compliance with the finding from such a body would be voluntary and in the event of non-compliance is likely to perpetuate delays evident in the current complaint handling arrangements. On the other hand, the approach would allow TGA to direct resources to dealing with the more problematic issues and balances the preferences expressed through the 2013 consultation.

The full cost of an outsourced arrangement (Models 2 and 3) is unknown. Any additional costs arising from the various models would need to be borne by industry.



The TGA seeks the views of stakeholders on whether the TGA should take on administration of a new, centralised, advertising complaints handling process or whether an outsourced arrangement should be more formally investigated, such as through calling for tenders.

As part of an improved complaints handling framework, it is proposed that the complaints resolution process could also be used to deal with potentially non-compliant advertisements that are not the subject of an actual complaint. That is, the TGA could independently use the complaints handling process to determine whether or not a particular advertisement(s) was compliant. This process could be used to deal with potentially non-compliant advertisements identified as part of the TGA's enhanced post-market monitoring of advertising.

6.4 Transparency of complaint handling

At present, there is little transparency in how cases brought to the Complaints Resolution Panel progress through review. Advertisers (and complainants) have no way of tracking the status of a complaint and learning where it sits in the queue. This lack of transparency leads to the perception of an unfair system as some complaints appear to progress faster than others.

The TGA does publish Regulation 9 orders on its website, however these only represent situations where an order is made due to non-compliance with CRP requests. The complaints received and the outcomes of complaints (whether upheld or not) are currently not routinely published although the TGA is moving to publishing all recommendations of the CRP.

Adopting a centralised complaint management process would improve the capacity to monitor the progress of complaints and increase transparency, as all complaints could be logged, tracked and published via a central database. Any centralised complaints handling arrangement will be expected to operate with maximum transparency consistent with procedural fairness requirements.

7. Future of the Therapeutic Goods Advertising Code, Code Council and Complaints Resolution Panel

The Government has agreed that the advertising of therapeutic products to the public will continue to be regulated by the TGA under a legislative framework which includes an advertising code. However, consistent with its Smaller Government Agenda, it has also agreed to the abolition of the Therapeutic Goods Advertising Code Council. The abolition of the Code Council and the CRP has implications for the future provision of expert advice on advertising to the TGA.

The Code Council is established under the Therapeutic Goods Regulations 1990 and its functions include consideration of advertising requirements and changes to the Code and making recommendations to the Minister about advertising standards and the use of restricted representations in advertising⁹.

The CRP is also established under the *Therapeutic Goods Regulations 1990*. The Chair of the CRP is nominated by the Code Council.

7.1 The Therapeutic Goods Advertising Code

The Therapeutic Goods Advertising Code is a legislative instrument made by the Minister under the Act. Its objects are to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.¹⁰

The Code sets out principles and minimum requirements for the acceptable and unacceptable content and effects of advertisements for therapeutic goods directed to consumers. It is an offence under the Act if a person publishes or broadcasts an advertisement about therapeutic goods that does not comply with the Code.

A number of amendments to the Code have been on hold until the outcomes of the Review were known. It is proposed that these amendments, including those designed to address the parity of the Code in relation to medicines and medical devices will now proceed in consultation with the current Code Council. The new Code is expected to be in force before (or at the same time as) other proposed changes to the advertising framework and will be the subject of separate consultation.

In improving the Code considerations will include:

- the adequacy of the current definitions of “prohibited” and “restricted” representation, particularly in the light of new diagnostic techniques (such as those involving direct-to-consumer genetic testing) and the plan to allow enhanced efficacy claims for certain complementary medicines (Recommendation 39 of the Review refers)
- making reference to obesity a restricted representation
- making reference to a “serious medical intervention” a restricted representation

⁹ The Secretary can under section 42DF of the Act approve the use by a person of a restricted representation in advertising. Under that section he is required to take into consideration any recommendation of the Code Council.

¹⁰ Paragraph 1(1) of the Code.

- amending the section on “Scientific Information” including ensuring that any scientific information in an advertisement is identifiable and accessible to consumers
- the use of testimonials in advertisements
- the offering of free samples of therapeutic goods as part of an advertisement.

In addition to these specific considerations, the Code will be redrafted with a view to providing more objective tests for breaches of the Code, particularly given the possible introduction of strict liability offences for breaches of the Code (see section 5 above)

7.2 Future provision of expert advice

With the Government’s decision to abolish both bodies, both the TGACC and the CRP will be replaced by alternative mechanisms for providing advice to the TGA on matters relating to advertising.

The Australian Government has agreed to rationalise the number of statutory expert advisory committees currently set out in the Therapeutic Goods Regulations 1990. Following the necessary amendments to the Regulations, seven expert advisory committees will be established to provide advice to the TGA on all matters relating to therapeutic goods. These committees will be supported by a panel of expert advisers that can be called upon to provide specific advice about particular matters when required.

The makeup of membership of these committees and expert advisers will need to include expertise relevant to matters relating to the advertising of therapeutic goods. When expert advice on advertising matters is required the matter will be referred to the committee with the most relevant expertise (supplemented by expert advisers as required) to advise on the specific matter.

8. Industry education

In the absence of an advertising pre-approvals system, industry (including publishers and broadcasters), healthcare providers and consumers will need clarity as to what is acceptable advertising. This is an area where education on the detail of both necessary and prohibited statements will simplify the regulatory environment. The simplest way to achieve this would be to align the requirements for advertising with the information contained within the ARTG for a particular product. This will require greater clarity within the Advertising Code and a disciplined approach to what claims are allowed to be included on the ARTG (see Recommendation 38 of the Review).

An education program will be developed for sponsors and advertisers. It could potentially be co-delivered with industry associations and provide information and tools to help them achieve compliance with advertising requirements under a new regulatory framework.

Formal education has the potential to improve compliance and promote greater quality and consistency of advice on therapeutic goods advertising requirements and to help manage the public health risks associated with inappropriate advertising.

Historical consultation document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 1605
<https://www.tga.gov.au>

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