



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Consultation Regulation Impact Statement

Regulating the advertising of therapeutic goods to the general public

Version 4.6, May 2013

TGA Health Safety
Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and biologicals.
- The TGA relies on the public, health professionals and industry to report problems with medicines, medical devices or biologicals. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

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Introduction

This consultation regulatory impact statement (Consultation RIS) has been prepared by the Therapeutic Goods Administration (TGA) with input from the wider Department of Health and Ageing.

The purpose of this Consultation RIS is to seek public comment to help inform the Australian Government in decision making on proposed regulatory reforms to improve the management of public health risks in relation to the advertising of therapeutic goods to the general public.

This Consultation RIS:

- describes the existing regulatory framework
- documents problems associated with the existing regulatory framework
- outlines the objectives for reform
- suggests options for reform
- invites comments on likely impacts of implementation of the suggested options.

After consideration of public comment on this Consultation RIS, the TGA intends to prepare a final RIS to assist Government consideration of proposed regulatory reforms.

Invitation for comment

The TGA invites comments from interested persons or organisations on this Consultation RIS by close of business **12 July 2013**.

In particular, comments are sought on:

- how your interests may be affected by the proposals outlined in this paper
- the likely impacts of the proposals on consumers and businesses
- matters relevant to the implementation of the proposals.

Key stakeholders affected by any changes to the framework for regulating the advertising of therapeutic goods include:

- The general public, including users of therapeutic goods and their representative consumer organisations
- Health practitioners and their professional organisations
- Organisations involved in the provision of public health programs
- Businesses and Industry Associations involved in the supply of therapeutic goods, including importers, manufacturers, sponsors, advertisers and retailers
- Businesses and Industry Associations involved in publishing and broadcasting of advertising material
- Industry associations with delegated responsibility for the pre-publication approval of certain therapeutic goods advertisements and for providing the secretariat to the Complaints Resolution Panel and the Therapeutic Goods Advertising Code Council
- Government agencies with responsibilities relating to the advertising of therapeutic goods. It also includes the Australian Health Practitioner Regulation Agency (APHRA) which is responsible for administering Guidelines for advertising of regulated health services
- Government agencies that regulate health claims in relation to other related goods, including the ACCC, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Food Standards Australia New Zealand (FSANZ) and the Australian Pesticide and Veterinary Medicines Authority (APVMA)
- State and Territory Health Departments. Please note that comments are not being sought on proposed reforms to enhance the TGA's investigation and enforcement powers because these proposals will have no impact on businesses that comply with the advertising regulatory requirements. They have been included for completeness.

For businesses, including health practitioners, the TGA would welcome estimates of likely regulatory impacts and compliance costs relating to the proposals.

Regulatory impacts may include:

- Changes to the number or type of products that businesses can offer as a result of complying with regulation
- Impacts on consumer demand for products as a result of:
 - increasing prices brought about by regulatory requirements
 - changing public information to ensure compliance with regulation.
- Impacts of regulation on the ability or incentives of businesses to compete in the market.

Compliance costs are those costs that businesses face as a result of dealing with the government. Compliance costs include costs relating to:

- Collection and reporting of certain information
- Keeping abreast of certain requirements and training staff
- Changing operating procedures or purchasing patterns
- Cooperating with audits or inspections
- Engaging lawyers, accountants or other advisors.

All submissions should be accompanied by a TGA submission cover sheet, available on the TGA's website at www.tga.gov.au/newsroom/consult-open.htm.

Submissions must include full personal or organisational contact details, including address, telephone number and email. They must be submitted to the TGA by close of business **12 July 2013**. Electronic submissions in MS-Word format are preferred and should be emailed to advertising.consultation@tga.gov.au.

Please include 'Advertising consultation' in the subject line of the email.

Alternatively, hard copy submissions may be mailed to:

Advertising Consultation
Recalls and Advertising Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Confidentiality

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Background

In May 2012 the TGA set out a series of options for reforms to the current advertising framework for therapeutic goods - *Advertising regulatory framework – options for reform* - May 2012. That paper indicated that an improved regulatory framework could be achieved if changes were made to the pre-approvals arrangements, to the complaints handling processes and to the sanctions and penalties that apply to advertising breaches. This consultation RIS expands on those options and provides an opportunity for feedback on their likely impact.

The advertising of therapeutic goods to consumers and health professionals is controlled by a combination of statutory measures administered by the Therapeutic Goods Administration (TGA) and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations. Advertising directed to the general public is permitted for the majority of medicines available for over-the-counter sale, while advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited.

Legislation administered by the TGA in relation to advertising of therapeutic goods includes:

- [Therapeutic Goods Act 1989](#) (the Act)
- [Therapeutic Goods Regulations 1990](#) (the Regulations)
- [Therapeutic Goods Advertising Code 2007](#) (TGAC)
- the current [Poisons Standard 2012](#).

The regulatory requirements relating to the advertising of therapeutic goods to the general public are principally (but not exclusively)¹ set out in Part 5-1 (Advertising and generic information) of the Act, Parts 2 (Advertisements) and 6 (Committees) of the Regulations and in the Therapeutic Goods Advertising Code (which is made under section 42BAA of the Act). Apart from advertising that is exclusively directed at health professionals, the requirements in Part 5-1 do not apply to advertisements for goods that have been exported or are intended exclusively for export².

Amendments to the advertising regulatory requirements may be recommended to Government for consideration following review of public submissions made in response to this Consultation RIS.

Therapeutic goods addressed in this Consultation RIS

The term “therapeutic goods” is defined in section 3 of the Act. For the purposes of this Consultation RIS, the term “therapeutic goods” refers to medicines, devices and biological

¹ The prohibitions on advertising goods for indications, uses or purposes that have not been approved are not located in Part 5-1.

² Section 42AC of the Therapeutic Goods Act.

substances that are, or are represented to be, for use in humans to prevent, diagnose, treat, cure or alleviate a health condition; or to influence, inhibit or modify a physiological process; or to test susceptibility to a disease or ailment; or test for pregnancy; or replace or modify parts of the body.

This Consultation RIS does not propose any changes relating to the advertising of prescription and certain pharmacist-only medicines to the general public, which is prohibited under the Act.

This Consultation RIS does not deal with health claims made about foods and other goods that are not regulated under the Act.

Types of advertising regulated by the TGA

This Consultation RIS is concerned with the TGA-administered regulatory framework for advertising of therapeutic goods to the general public. It does not propose reforms to processes within the self-regulatory schemes administered by industry peak bodies through their respective codes of conduct for resolving complaints about advertisements for therapeutic goods directed to health professionals³. Nor does it propose changes to the regulatory schemes administered by health practitioner registration boards under the *Health Practitioner Regulation National Law*, as in force in each state and territory. The relevant boards are those participating in the National Registration Accreditation Scheme (NRAS) administered by the Australian Health Practitioner Regulation Agency (AHPRA). This Consultation RIS does, however, consider advertising-related issues relating to the intersection between the TGA's responsibilities, NRAS and the self-regulatory schemes administered by industry peak bodies.

It is also cognisant of the work that is being undertaken elsewhere in the Department of Health and Ageing through the Codes of Conduct Advisory Group to strengthen industry self-regulation of the promotion of therapeutic goods to healthcare practitioners.

The term "advertisement" is defined in subsection 3(1) of the Act, in relation to therapeutic goods. It includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Advertising of therapeutic goods to consumers is regulated under the Therapeutic Goods Act. Types of advertising covered include:

- radio and television (including pay TV)
- telecommunications, such as the internet, SMS, telemarketing
- newspapers and magazines
- displays in public places including shopping malls, public transport and billboards

³Apart from the offence of advertising therapeutic goods for an indication, use or purpose, respectively that has not been approved by the TGA (see subsection 22(5) (medicines), section 32BJ (biological) and section 41ML (medical devices) of the Therapeutic Goods Act), the advertising offence provisions in the Act do not apply to advertisements directed exclusively to health professionals: section 42AA.

- in-store displays
- leaflets, flyers, brochures, catalogues and
- product labels

However, media such as the internet, SMS, narrowcast/ subscription transmission (includes pay TV) are currently **excluded** from the “pre-approval scheme” which requires certain advertisements to be approved prior to publication or broadcast.

The main mechanisms for controlling the advertising of therapeutic goods to the general public set out in the regulatory framework administered by the TGA are:

- prohibitions on:
 - advertising therapeutic goods for an indication or use for therapeutic goods which has not been approved by the TGA (sections 22(5)(medicines), 32BJ (biologicals) and 41ML (medical devices) of the Act)
 - certain types of advertising of therapeutic goods (section 42DL of the Act), described below
- a requirement for advertisers to comply with the TGAC (section 42DM of the Act)
- a requirement for certain advertisements broadcast or published in particular media to be pre-approved (section 42C of the Act). The pre-approval scheme⁴ is described below
- a complaints handling scheme, for which responsibility is shared by the TGA, the Complaints Resolution Panel (CRP)⁵ and relevant industry associations, as described below
- a range of compliance and enforcement powers available to the TGA, described below.

Prohibited advertisements

Section 42DL of the Act prohibits, in general, the publishing or broadcasting of advertisements about therapeutic goods that:

- contain references to prescription medicines, pharmacist-only medicines (unless mentioned in Appendix H of the Poisons Standard) or controlled drugs
- contain “prohibited representations” such as, for instance anti-microbial claims, certain unqualified claims about vitamins and minerals and claims relating to serious diseases such as cancer and AIDS⁶
- contain “restricted representations”, for instance relating to serious forms of a disease or condition in relation to which self diagnosis and management by a patient, without professional advice or supervision, is generally regarded as inappropriate⁷.

⁴ See Division 2 of Part 2 of the Therapeutic Goods Regulations.

⁵ The CRP is established by regulation 42R of the Therapeutic Goods Regulations.

⁶ See section 42DD of the Therapeutic Goods Act and Part 1 of Appendix 6 to the TGAC.

⁷ See Part 1 of Schedule 2 to the Regulations and Part 1 of Appendix 6 to the TGAC.

- contain statements referring to biologicals
- contain statements referring to therapeutic goods that are only allowed under the Act to be imported or supplied for special or experimental purposes, exempt goods or devices
- are not in the Australian Register of Therapeutic Goods (ARTG) and are required to be entered in the ARTG.

Advertisements required to be pre-approved

Under the Act and Regulations advertisements for certain therapeutic goods must to be approved by the Secretary prior to publication or broadcasting.

If approval is required, then it is an offence under section 42C of the Act to publish or broadcast an advertisement if the approval has not been given, or if the advertisement is inconsistent with the approval or fails to cite the approval number correctly.

The advertising of all medicines which can be advertised to the general public (i.e. most over-the-counter and complementary medicines) must be pre-approved if:

- broadcast on free-to-air broadcast transmission
- published in mainstream print media
- included in cinema advertising
- displayed on billboards and posters or on public transport and in places such as shopping malls (other than in-store displays).

This means that advertisements for these medicines in the following media do **not** need to be pre-approved:

- internet
- email
- narrowcast/ subscription transmission (includes pay TV)
- SMS, MMS.

Advertisements for other kinds of therapeutic goods which can be advertised to the general public (therapeutic devices and medical devices) are not required to be pre-approved, irrespective of the medium of delivery.

The Secretary's power to pre-approve (or refuse or withdraw pre-approval of) advertisements has been delegated to the following two industry associations (under regulation 5Q):

- the Complementary Healthcare Council of Australia (CHC) - for advertisements for complementary medicines in the specified media other than broadcast media⁸

⁸ 'Complementary medicine' is defined for this purpose to mean 'a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use' (see regulation 2 of the Therapeutic Goods Regulations).

- the Australian Self-Medication Industry Incorporated (ASMI) – for the remaining types of advertisements that are subject to pre-approval.

CHC and ASMI currently undertake this delegated function under contract to the TGA.

Handling of complaints about advertising

While the TGA has overall responsibility for dealing with complaints about the advertising of therapeutic goods, the Regulations established a scheme in 1999 to share elements of this responsibility with the Complaints Resolution Panel⁹ and industry associations. The outcome has been viewed by many as a somewhat complex and unwieldy system as summarised in the Table 1.

⁹ Established under regulation 42R of the Therapeutic Goods Regulations and consisting of representatives of the Complementary Health Council of Australia, the Australian Self-Medication Industry Inc, the Medical Technology Association of Australia; nominees of the Australian Consumers Association, and Consumers' Health Forum, the Australian Traditional Medicines Society, the Pharmacy Guild of Australia and Pharmaceutical Society of Australia, and Royal Australian College of General Practitioners.

Table 1 - Current complaint lodgement arrangements

Type of therapeutic goods	Complaint-handling body for complaints about advertising directed to:	
	General public including retailers (other than registered pharmacists)	Health professionals
Prescription medicines	<ul style="list-style-type: none"> TGA. It is an offence under the Act to advertise prescription and certain pharmacist-only medicines to the general public. 	<ul style="list-style-type: none"> Industry Associations—such as Medicines Australia and the Generic Medicines Industry Association in relation to breaches of respective Codes of Conduct
Non-prescription medicines, including most complementary medicines	<i>Advertisements subject to pre-approval, or disseminated by internet, email, narrowcast transmission (including pay-TV), SMS, MMS</i>	<ul style="list-style-type: none"> Industry Associations – CHC and ASMI in relation to breaches of respective Codes of Conduct
	<ul style="list-style-type: none"> Complaints Resolution Panel. The Panel, after considering a complaint and requesting the sponsor to rectify contraventions, can recommend further action by the TGA. TGA (directly or after reference from Panel) 	
	<i>Other advertisements, such as in-shop displays, direct marketing brochures and catalogues</i>	
	<ul style="list-style-type: none"> CHC and ASMI TGA, but a regulation 9 order can only be made on the Panel's recommendation 	
Medical devices	<ul style="list-style-type: none"> Complaints Resolution Panel, for broadcast media, mainstream print media, billboards, cinema films TGA for other media 	<ul style="list-style-type: none"> Industry Associations such as Medical Technology Association of Australia and IVD Australia

Stakeholder submissions to the 2010 public consultation on “improving advertising arrangements for therapeutic goods” and earlier reviews of the advertising arrangements have revealed that consumers generally view the complaint resolution system for advertising therapeutic goods as cumbersome and slow, with added complexity owing to there being multiple processing pathways. It is seen as unnecessarily complex by consumers because, as indicated in Table, 1 complaints can currently be submitted either to the Complaints Resolution Panel (CRP) or various industry associations or the TGA depending on the type of product being advertised, the advertiser, the media in which the advertisement appears and the target audience.

The Complaints Resolution Panel (the Panel) currently has the function (under regulation 42ZCAB) of receiving and considering complaints about the advertising of medicines and medical devices directed to the general public through 'specified media':

- mainstream print media (such as newspapers and magazines)
- TV and radio broadcasting (including Pay TV)
- internet, email, SMS, MMS and any other means by which information is disseminated electronically in a visible or audible form or a combination of such forms
- cinema films
- displays on billboards and public transport and in shopping malls – but not displays inside shops.

Complaints about other forms of advertising for therapeutic goods directed at the general public, such as leaflets, flyers, letterbox drops and point of sale material, as well as advertising to health professionals, are managed by the relevant industry associations (CHC or ASMI) under their respective codes of practice.

The Panel can inform itself of any matter and consult with such persons as it thinks fit. It can also require the person responsible for an advertisement (who may be the advertiser or the sponsor of the goods) to produce evidence in support of a claim made in the advertisement. The Panel can also deal with a matter that is not mentioned in a complaint if it is satisfied that the advertisement contravenes the Act, the Regulations or the TGAC (see regulation 42ZCAH).

However, the Panel cannot however impose penalties, enforce sanctions or take any other regulatory action. If the Panel determines there has been a contravention of the Act, the Regulations or the Code, it may request, in writing, that the advertiser/sponsor do one or more of the following:

- withdraw the advertisement
- publish a retraction
- publish a correction
- withdraw a particular claim or representation made by the advertisement, and give the Panel a written undertaking not to use that claim or representation in any other advertisement.

The Panel notifies the complainant and the advertiser of the Panel's decision and includes the final determination in the [complaints register located on the Panel's website](#). Any private or confidential information is protected, where appropriately identified and requested.

If the advertiser/sponsor either fails to comply with the Panel's request within 14 days, or breaches an undertaking given to the Panel, then the Panel can recommend that the Secretary take one or more of the following actions:

- withdraw approval for the advertisements (if it was of a kind requiring pre-approval)

-
- suspend or cancel the ARTG entry of the advertised goods (where the sponsor was responsible for the advertisement)¹⁰
 - order the advertiser to publish a retraction or correction
 - order the advertiser to remove advertising material or generic information from the marketplace and/ or destroy such material.

The secretariat support to the Panel is currently provided by ASMI under contract to the TGA.

Enforcement powers

The compliance and enforcement powers that are available to the TGA for breaches of the advertising provisions under the Act include, but are not limited to, the following.

- **Orders from the Secretary** which can be given on the recommendation of the Complaints Resolution Panel (under regulation 9 of the Regulations) to require an advertiser /sponsor to:
 - withdraw an advertisement or a particular claim or representation
 - refrain from advertising
 - publish a retraction or correction
 - recover and/ or destroy advertising material and information
 - Failure to comply with the advertising requirements may be grounds for cancellation of the entry for the therapeutic goods on the ARTG, (if the advertiser is the sponsor of the goods) or prosecution of an offence (see below).
- **Prevention notices** may be given by the Secretary to the person responsible for the publication or broadcasting of an advertisement which is false or misleading to prevent that person from doing so (see section 42DKB of the Act).
- **Enforceable undertakings**, which are written undertakings accepted by the Secretary (under section 42YL of the Act) in which the advertiser/sponsor undertakes not to do certain things or to do certain things to ensure compliance with the Act – this could for instance include undertakings not to broadcast or publish advertisements containing particular claims or representations that may otherwise breach the advertising requirements.
- **Suspension or Cancellation** of the ARTG entry for advertised goods (if the advertiser is the sponsor of the goods)

¹⁰ This can only be done after the Secretary has given the sponsor the opportunity to make submissions and taken them into account before coming to a final decision – see s.30(2)(e) of the Act.

- **Offences:** There are a range of advertising offences set out in the Act including:
 - advertising goods for an indication/use that is not approved
 - broadcasting or publishing and advertisement that is required to be pre-approved without pre-approval or not in accordance with the pre-approval
 - publishing or broadcasting an advertisement that contains a prohibited or restricted presentation, or a reference to a prescription medicine or (most) pharmacist only medicines, about therapeutic goods that are not included in the Register or which does not comply with the Therapeutic Goods Advertising Code
 - publishing or broadcasting an advertisement that contains a reference to the Act other than a listing or registration number or device number or that suggests the goods have been recommended or approved by government. (refer to Table 2 in the Proposal section below for more information on penalties associated with offences).
- **Information gathering powers:** The Act provides the TGA with various powers to gather information about goods in order to ascertain whether sponsors are complying with the Act.

Principles to guide objectives for reform

The regulation of advertising should contribute to the quality and safe use of therapeutic goods by ensuring that the general public receive accurate and balanced information about the quality, safety and efficacy (performance) of those goods. It is particularly important that patients receive credible information in advertisements about those goods so that they can make an informed assessment of the suitability of the good for their particular health needs.

The principles to guide the objectives for reform need to ensure that the regulatory framework for advertising of therapeutic goods:

- provide appropriate controls relating to the marketing and advertising of therapeutic goods to the general public, so that it is socially responsible and is not false, misleading or deceptive
- reflect the objects of the Act (section 4), in particular, to provide a national system of controls relating to the safety, quality, efficacy and timely availability of therapeutic goods used in Australia
- is not unnecessarily complex, so to maximise accessibility by complainants and minimises any perceptions of conflicts of interest in its implementation
- is consistent with wider Australian Government policies and general laws
- is consistent, as far as practicable, with Australia's international obligations.

Objectives for reform

The objectives of the reforms considered in this Consultation RIS are to:

- Improve the timeliness and simplicity of the advertising controls
- Ensure that the regulatory framework for advertising of therapeutic goods to the general public is adequate to manage the public health risks posed by exposure to false, misleading and socially irresponsible advertising of therapeutic goods
- Establish systems that effectively monitors and achieves compliance with advertising requirements and efficiently resolves complaints about non-compliance
- Improve transparency of advertising decision-making by government
- Develop more appropriate controls to facilitate timely, effective and efficient responses to breaches of the advertising controls in and under the Act
- To improve public confidence and trust in the system by avoiding potential conflicts of interest on the part of individuals or organisations that undertake advertising functions on behalf of the TGA.

The problem

False, misleading and socially irresponsible claims about therapeutic goods pose risks to public health and safety because they can lead to misuse or overuse of goods (that are otherwise safe when used in accordance with label instructions) or to consumers failing to seek medical advice where it would be appropriate to do so. A weak system of advertising regulations can also erode the credibility and public trust and confidence in the regulator.

Concerns have been expressed in submissions to a number of reviews over recent years that the current legislative framework for the advertising of therapeutic goods to the general public does not provide adequate controls to manage the relevant risks to public health and safety.

The Productivity Commission, in its Review of the Regulatory Burdens on Business: Manufacturing and Distributive Trades (2008), recommended (4.4) that:

after further consideration of the most appropriate model, the Australian Government should streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need for a simplified system for complaints about national advertising.

The Government accepted this recommendation in principle, agreed that it will consider changes to the advertising regulatory arrangements to streamline requirements and reduce regulatory burdens, and consult with interested parties on the proposed revised arrangements.

Following the Productivity Commission's review, the following review and public consultation activities have been undertaken by the Department in relation to advertising controls for therapeutic goods:

- A consultation paper, [Improving advertising arrangements for therapeutic goods](#), was released for public comment in June 2010 and submissions were considered by the TGA
- The former Parliamentary Secretary for Health and Ageing, hosted a roundtable in November 2010 for discussion of this feedback and how the regulation of therapeutic goods advertising could be improved. Key areas identified for further review included: pre-approval of advertisements; complaints handling; sanctions for non-compliance; and transparency of decision-making by the TGA
- The [Transparency Review of the TGA](#) examined the transparency of advertising decision-making and recommended that access and quality of information on the processes for regulation of the advertising of therapeutic goods (including complaints) be improved in a report published in June 2011
- The [ANAO Performance Audit Report No 3 \(2011\) Therapeutic Goods Regulation: Complementary Medicines](#) recommended that procedures for undertaking and reporting advertising complaint investigations be implemented
- The report, [Advertising regulatory framework – options for reform - May 2012](#), identified possible options to enhance the operation and effectiveness of the

advertising regulatory framework. It was based on previous advertising reviews and addressed pre-approval arrangements, the complaints handling process and sanctions and penalties available for advertising breaches

- Advertising reform activities proposed in the Transparency Review, the ANAO Audit Report and the Advertising Report have been included in the implementation plan for [TGA reforms: a blueprint for TGA's future](#), published in July 2012.

1. Pre-publication approvals of advertisements

A number of issues have been raised about the operation of the pre-approval process for particular kinds of advertisements.

Complaints about pre-approved advertisements upheld by the Panel

Notwithstanding that an advertisement has been pre-approved and that the advertisement is published or broadcast in compliance with that approval, it can be the subject of a complaint to both the Panel and to the TGA. While the proportion of advertisements pre-approved by AMSI or CHC that are the subject of a complaint may not be high, there have been occasions where the Panel has made a finding that the advertisement breached the provisions of the Therapeutic Goods Advertising Code or the other advertising requirements in the Act, notwithstanding that the approval was given on the basis of compliance with the Code and that the advertisement complied with that approval.

This may be due to differences in subjective judgements of the advertising approvals delegates about the likelihood of the claims included in the advertisement breaching the advertising requirements. It is also the case that the Panel considers the advertisement as result of a complaint of non-compliance being made and being provided with evidence of that non-compliance. The delegate asked to pre-approve an advertisement does not have the benefit of such material, nor often the time to consider the issues in the kind of detail that the Panel is able to do. The area where differences most often emerge are whether the advertisement contains therapeutic claims that the sponsor has not verified¹¹.

It might be argued that the delegation of this function to external industry bodies when complaints are handled by a separate statutory committee inhibits the ability to manage the consistency of interpretation. Currently this role is split across two associations (ASMI approves complementary medicine advertisements appearing on radio or TV, while CHC approvals are limited to print media). A further criticism of the current arrangements arises from the need to ensure that criteria (including the Advertising Code provisions) are interpreted appropriately by the organisations and adjusted in response to issues identified through compliance monitoring and in complaint determinations.

Perceptions of bias

The current arrangements have also attracted criticism on the grounds that many of the businesses whose advertisements are being regulated under the Act are also members of

¹¹ Under paragraph 4(1)(b) of the Code, the advertisement must contain correct and balanced statements only and "claims which have been verified".

either or both CHC and ASMI. A perception of bias is likely given the pre-approval function is being exercised by these bodies, often in relation to their own members. Any perception of bias has the potential to undermine public confidence in the capacity of the approvals scheme to deliver fair outcomes and protect public health and safety from the risks of false, misleading and potentially socially irresponsible advertising.

Capacity to assess claims as part of approvals process

When considering an application for approval of an advertisement, it is necessary for the Secretary's delegate (in this case, CHC or ASMI) to be satisfied about a range of matters including that the claims in the advertisement have been verified by the product sponsor¹² and that any therapeutic claims do not go beyond the indications or purposes accepted by the Secretary in relation to the inclusion of the goods on the ARTG¹³.

Medicines that are listed (rather than registered) on the ARTG are not assessed by the TGA for efficacy prior to listing. The sponsor is required to certify to the Secretary at the time of listing that the sponsor holds evidence to support any claim made about the goods (including efficacy) and this evidence must be provided at the request of the TGA at any time. The pre-approval delegate cannot approve an advertisement unless satisfied that the sponsor has verified any claims appearing in the advertisement. Further, an ARTG-listed medicine entry is unable to be relied upon by the delegate to satisfy themselves that the sponsor has verified all claims contained within the advertisement and the delegate may request evidence in order to substantiate the veracity of any advertising claims.

CHC and ASMI, in acting as delegates for the Secretary in pre-approving advertisements on the basis of compliance with advertising requirements in the legislation do not necessarily have the technical expertise available to assess whether such claims can be verified and thus be satisfied that the advertisement should be approved. This means that pre-approval may potentially be granted when the delegate has not been in a position to make an informed judgement about whether the advertising requirements have actually been met. This in turn can lead to complaints in relation to advertisements which are deemed compliant by virtue of having gone through a pre-publication approvals process.

Some stakeholders have argued that it may not be appropriate for a delegate in an industry association to have responsibility for assessing scientific evidence to satisfy themselves of the veracity of advertising claims when that evidence has not been vetted by the TGA or a skilled professional, authorised under legislation, with expertise in assessment of scientific data relevant to the type of product that is proposed to be advertised.

Multimedia campaigns

The CHC has not been delegated the function of approving advertisements for complementary medicines in broadcast media as, under the Regulations, that function can only be delegated to ASMI¹⁴. This has produced an anomaly (and a rather complicated process) in that approval of advertising of complementary medicines is split across the

¹² See paragraph 4(1)(b) of the Code.

¹³ See paragraph 4(1)(a) of the Code which requires the advertisement to comply with the Therapeutic Goods Act which includes the relevant offences in s.22(5), s.32BJ(3) and s.41ML of the Act.

¹⁴ See subregulation 5Q(3).

two organisations. This means that advertisers wishing to run multi-media campaigns for complementary medicines must apply to both CHC and ASMI for approval. This has led to inconsistencies in decision-making and industry criticism of inconsistency in the standards being applied by the two bodies.

Advertising of medical devices not covered

Medical devices are not subject to the pre-approval scheme. The argument could be made that non-compliant advertising for medical devices which can also lead to risks to public health and safety and that, at least in relation to certain kinds of media, it is appropriate for the public to be protected from false and misleading advertisements by applying pre-publication approvals procedures prior to broadcasting or publication rather than rely on complaints afterwards. Consideration will need to be given to the degree of public exposure to select medical device advertisements, since many medical devices are used by health professionals to treat patients.

Limited media coverage

The current scheme for pre-publication approval of advertising claims was designed prior to the emergence of pay-TV, the internet, social media, mobile phones and SMS. The pre-approval scheme does not cover advertising via these media, however complaints about over-the-counter and complementary medicines and medical device advertisements in these media can be considered by the Panel. The public increasingly seek and receive health and medical information via these media and are thus also exposed to advertising for therapeutic goods. The result is that larger numbers are exposed to advertising claims that have not been subject to pre-approval to ensure compliance with the therapeutic goods advertising requirements.

The current resources available for pre-approvals are insufficient to deal with the growing volume of advertising across all electronic media and it may, in the case of the internet and social media, be impractical (including because the location of those responsible for the content of websites that are hosted off-shore) to apply the pre-approvals process. However, the situation may be different with advertisements on pay TV where there would appear to be little difference from advertising on free-to-air TV.

2. The complaints handling processes

The current processes for handling complaints about therapeutic goods advertisements have been criticised on the basis that it can inhibit enforcement of the advertising legislative requirements. This has the consequence that sanctions in the Act have a limited deterrent effect and public health and safety are not adequately protected from the risks posed by false, misleading or socially irresponsible advertisements.

The problems that have been identified include:

- delays in consideration of complaints
- multiple lodgement points and complaint-handling bodies
- multimedia advertising campaigns considered by multiple complaint-handling bodies

- lack of public knowledge of complaint-handling bodies and processes
- capacity of the peak body delegates and Panel to assess efficacy (performance) claims
- duplication of effort by the Panel and the TGA, where complaints are made to both
- lack of compliance with requests made by the Panel after determination of non-compliance
- perception of bias may discourage complaints from the public
- potential conflicts of interest arising from the representative nature of membership of the Panel.

Delays in consideration of complaints

Timeliness is critical when dealing with unacceptable advertising of therapeutic goods, especially when claims about the goods have the potential to pose risks to public health and safety. Each day that such an advertisement is in circulation can increase the risks.

While the Panel produces complaint determinations that are considered to be of high quality, the volume of complaints is such that the average time taken by the Panel to make a final determination about a complaint was 85 days in 2011-2012. Rapid decision making is not well supported by the Panel's structure and the complex processes set out in the Regulations.

The regulatory framework does not allow for a quick decision to be made whether a complaint should be either:

- acted upon immediately by the TGA in order to prevent harm to consumers and to deal with repeat, deliberate and potentially significant public health issues
- handled by the Panel or an industry association, which may only be appropriate where the alleged non-compliance poses low risks to consumers.

Further, the regulation 9 provisions (which allow the Secretary to order an advertiser/sponsor to order withdrawal of an advertisement/publication of a retraction/correction etc) are not available to the TGA unless and until the Panel makes a recommendation to the Secretary after the advertiser/sponsor has failed to comply with the Panel's request to withdraw the advertisement, publish a retraction or correction etc.

Therefore, the fact that in many instances a complaint will be first considered by the Panel can inhibit the ability of the TGA to:

- take enforcement action before an advertising campaign has already caused harm to consumers or public health and delivered the full marketing benefit to the advertiser
- quickly determine the level of enforcement action that is appropriate for each case
- identify repeat or deliberate offenders for whom early and strong enforcement action would be appropriate.

Multiple complaint-handling bodies and portals

Public submissions to the previous reviews have suggested that consumers experience difficulty finding out how to make a complaint. This appears to be due to both:

- the allocation of responsibility for complaint handling to different organisations depending on the type of media used by the advertiser. (For example, if a person wishes to complain about an advertisement that appears in both newspapers and in-store flyers, the complaint must be directed to both the Panel for consideration about the newspaper version, and the relevant industry association for consideration of the identical content in the in-store flyer.)
- the low profile of complaint-handling bodies and lodgement mechanisms.

While the TGA and the Panel publish website information for lodging complaints about the advertising of therapeutic goods, these pages may not be as accessible to the public as they could be. (TGA page is at <http://www.tga.gov.au/industry/advertising-complaint.htm#lodging> and the Panel page at [http://www.tgacrp.com.au/.](http://www.tgacrp.com.au/)) It is probably the case that the person with a concern about an advertisement will not know where to begin to look.

The number of complaints received each year by the Panel is in the order of 300-400. The majority of complaints received are from the therapeutic goods industry, rather than members of the public. It may be that consumers are confused about where to direct their complaints and therefore discouraged from making complaints. For instance, the relationship between the Panel and the TGA is not particularly clear and while the TGA is offered as an alternative recipient to complaints, it is not made clear when the TGA will deal with the complaint and when it will be dealt with by the Panel or one of the industry organisations.

Multi media campaigns – Multi complaint-handling bodies

The responsibility for handling complaints about the same advertisement in different media by different bodies can lead to unnecessary:

- confusion and effort for complainants
- duplication of time and effort by the complaint-handling bodies
- potential for inconsistent treatment of the same content in different media.

Coordination of complaints through a single point would:

- streamline the process for complainants
- allow more consistent and comprehensive action to address all the elements of a multi-media campaign.

Capacity of Panel to assess efficacy (performance) claims

The question of whether advertising of therapeutic goods complies with legislative requirements will often involve questions about whether there is evidence to support claims being made for the goods in the advertisement. The Panel is not currently constituted so as to ensure or require there is expertise needed to evaluate scientific evidence to support claims of efficacy or performance. Despite the best efforts of Panel members, this can contribute to delays in handling complaints which involve consideration of the validity of therapeutic claims.

Poor advertiser compliance with requests from Panel

Of the advertisers/sponsors in relation to whom the Panel makes a request to rectify compliance issues with their advertising, about 20 percent fail to do so. It has been argued by some that this lack of willingness to comply underlines that the current scheme for dealing with unacceptable advertising does not provide an effective deterrent to non-compliance (given that the only outcome being that the Panel can refer the matter to the Secretary for further action by the TGA).

However, industry has pointed to the fact that there is no mechanism under the current legislative provisions for a company to whom such a request has been made by the Panel to lodge an appeal¹⁵. If, as a result, the Panel makes a recommendation to the Secretary, action taken by the Secretary as a consequence (for instance the making of an order under regulation 9 of the Therapeutic Goods Regulations to withdraw the advertisement or publish a retraction or correction etc) would be subject to both internal review and, if required, review by the Administrative Appeals Tribunal (AAT)¹⁶.

Lack of enforcement options after failure to comply with a regulation 9 order

This situation arises where a person has not taken actions in relation to a non-compliant advertisement requested by the Secretary in an order made under regulation 9 of the Therapeutic Goods Regulations. Currently, the legislative framework does not provide sanctions against persons who ignore an order. Further, regulatory action may be limited where the advertiser is not the sponsor of the therapeutic good being advertised or where the therapeutic good is not required to be entered in the ARTG.

However, publishing the details of the regulation 9 order on the TGA website provides some deterrent value.

Duplication of effort

When the Panel recommends to the TGA that further action be taken in relation to an advertisement, the TGA typically must reinvestigate the matter to ensure the information being acted upon is up to date and accurate and to provide procedural fairness to the advertiser/sponsor.

A delegate of the Secretary considers the complaint material referred by the Panel and any further submissions and decides whether to make an order under regulation 9 of the

¹⁵ It is possible for a company to seek judicial review of the Panels determination as was done in *Swisse Vitamins Pty Ltd v The Complaints Resolution Panel* [2012] FCA 536 (25 May 2012).

¹⁶ See regulation 48 of the Therapeutic Goods Regulations.

Therapeutic Goods Regulations requiring the advertiser to for instance, withdraw the advertisement, publish a retraction or correction etc. This can compound the delays in dealing with the complaint by extending the period between the publication of an advertisement and any corrective action such as publication of a retraction. The current system therefore inhibits the TGA from implementing a strategic, timely, efficient and effective approach to compliance and enforcement action.

Potential conflicts of interest

The Panel is established under regulation 42R of the Regulations and is comprised of representatives nominated by the therapeutic goods industry associations, consumer bodies and healthcare professional organisations. Concern has been expressed that the current membership arrangements could lead to a potential source of conflict of interest.

3. Compliance and enforcement tools

The TGA has a range of compliance and enforcement tools to deal with unacceptable advertising of therapeutic goods.

Injunctions

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. 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.

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

Civil penalty provisions

Civil penalties are not currently available under the Act in relation to contraventions of advertising requirements. The inclusion of civil penalties as part of the sanction package for advertising requirements may provide additional deterrence. 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) is 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 could be considered:

- subsection 22(5) - offence if a person advertises therapeutic goods for an indication other than the indication accepted in relation to the goods

- subsection 32BJ(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 42C - offences relating to publication of advertisements for which approval is required
- section 42DL – general advertising offences
- section 42DM – requirement for compliance with the TGAC
- section 42DP – offences regarding publication of generic information.

Consideration could also be given to civil penalty provisions for any new offences proposed as part of the reforms of the advertising provisions.

Substantiation and warning notice powers

Other common regulatory tools that are not available to the TGA, and could be considered as part of the advertising sanctions regime package include:

- broad substantiation powers in relation to advertisers who are not product sponsors
- powers to publish public warning notices in relation to dangerous advertising claims (as opposed to dangerous products).

4. The Therapeutic Goods Advertising Code

The Therapeutic Goods Advertising Code (TGAC) 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 consumer¹⁷.

It sets out principles and minimum requirements for the acceptable and unacceptable content and effects of advertisements for therapeutic goods directed to consumers. Compliance with the TGAC is a requirement for pre-approval of an advertisement that is required to be pre-approved to be broadcast or published¹⁸. It is also an offence under the Act (section 42DM) if a person publishes or broadcasts an advertisement about therapeutic goods that does not comply with the TGAC.

Complaints can be made to the TGA and to the Panel about the compliance of advertisements for therapeutic goods with the TGAC.

¹⁷ See paragraph 1(1) of the Code.

¹⁸ See regulation 5G of the Therapeutic Goods Regulations.

5. The Therapeutic Goods Advertising Code Council

The Therapeutic Goods Advertising Code Council (TGAC Council) is established under regulation 42A of the Regulations. Its functions include, among others

- to consider advertising requirements and changes to the TGAC
- to make recommendations to the Minister about
 - uniformity in approval processes and advertising standards
 - applications to use of restricted representations in advertising¹⁹; and
 - requests for review of a decision of the Secretary in relation to the pre-approval of an advertisement under regulation 5G of the Regulations²⁰.

There are 15 members and 5 observers on the Council²¹. The Regulations require Council members to be nominated by the therapeutic goods manufacturer and supplier industry associations, advertising and media industry associations, consumer organisations, healthcare professional bodies and government. Additionally, the Chair of the Complaints Resolution Panel and the ASMI Advertising Service Manager routinely attend Council meetings. The Council's current membership balance may give rise to a perception of bias in recommendations to the Minister in favour of industry interests, rather than protection of public health.

Further, Council's consideration of restricted representation applications and pre-approval decisions can lead to delays in processing these requests, increasing periods of uncertainty for affected advertisers and reducing the efficiency of the processes.

Since 1998, the Council has been responsible for overseeing the advertising arrangements including the maintenance and revision of the Code. However, the potential for unnecessary delays and perceptions of bias may be regarded as inconsistent with the primary object of the Act (set out in section 4 of the Act), which is to provide and maintain controls relating to the quality, safety, efficacy and timely availability of goods that are, or are represented to be, for a therapeutic use.

6. Advertising of high risk medical devices

At present, advertising to the general public is allowed for all medical devices included in the ARTG, regardless of the risks to consumers inherent in the device and whether the device is actually available for direct purchase by the general public. In contrast, prescription and most pharmacist-only medicines cannot be advertised to the general

¹⁹ The Secretary can under section 42DF of the Act approve the use by a person of a restricted representation in advertising. Under that section she is required to take into consideration any recommendation of the Council.

²⁰ Decisions of the Secretary under regulation 5G in relation to pre-approvals (which under the current arrangements are made by ASMI and CHC as delegates of the Secretary) are subject to internal review (by a delegate of the Minister) and then AAT review.

²¹ Membership is defined in Regulation 42C. It includes 5 manufacturer/supplier members; 2 advertising industry members; 2 consumer members; and 3 healthcare professional members; 1 media industry member and 2 TGA members.

public, on the basis that it is generally accepted that the use of these medicines should be under the supervision by a registered medical practitioner or other healthcare professional. Prescription medicines include medicines that contain substances listed in Schedule 4 or Schedule 8 of the current Poisons Standard.

Many kinds of medical devices are only used by healthcare professionals as part of their treatment of a patient e.g. artificial hips, catheters, orthodontics and pacemakers. While advertising of such devices directly to the public is not common, it could be argued that for the same reason that medicines that require the judgement and expertise of a registered healthcare practitioner cannot be advertised to the public, the same limitation should apply to these high risk medical devices.

Separate to consideration being given to excluding some kinds of high risk medical devices from advertising to the public, it may also be appropriate for the advertising of medical devices (or particular kinds of medical devices) to be subject to the pre-approvals regime prior to advertising in mainstream media, including newspapers (i.e. in the same media in relation to which complementary and OTC medicines are required to be pre-approved).

7. Advertising directed to health professionals

Advertising directed exclusively to “health professionals” is excluded from the requirements regulating advertising in Part 5-1 (Advertising and generic information) of the Act, which is designed to apply to advertising to the general public. The types of health professionals who are the subject of the exclusion are listed in section 42AA of the Act. The list includes some categories of health practitioners that are not currently covered by the National Registration and Accreditation Scheme (NRAS) administered by the Australian Health Practitioner Regulation Agency.

Practitioners registered with national boards participating in the NRAS can be taken to be appropriately qualified, insured and subject to professional and ethical conduct requirements.

In the context of therapeutic goods, NRAS can provide the TGA with a degree of assurance that practitioners registered under the scheme are either:

- appropriately qualified and capable of assessing advertising material about therapeutic goods, or
- restricted by conditions of registration, or via insurance policies, from using or administering therapeutic goods in relation to which they are not appropriately qualified.

The TGA has no formal mechanism to determine that all practitioners in the groups listed under section 42AA of the Act are more competent than ordinary consumers to assess advertising about therapeutic goods. Therefore, the TGA has no formal assurance that those groups of practitioners not included in the NRAS are able to exercise specialist judgement when either treating consumers with advertised therapeutic goods, or advising consumers about the use of advertised therapeutic goods.

Another problem is that some health practitioner groups that are regulated under NRAS are not included in the exemption list in section 42AA of the Act. This means that advertising directed to these practitioners must comply with the laws in Part 5-1 of the

Act, designed to apply to consumer advertising. The relevant practitioner groups include Aboriginal and Torres Strait Islander health practitioners, medical radiation practitioners and occupational therapists.

8. Advertising of Pharmacist-Only Medicines

Australia's regulatory scheme for restricting the supply of 'poisons' to the general public involves assessing the safety of these substances and including them if required in an appropriate schedule to the current Poisons Standard. The current Poisons Standard is a legislative instrument prepared by the Secretary (or delegate) under Part 6-3 of the Act.

"Pharmacist only" medicines contain substances that are included in Schedule 3 to the current Poisons Standard on the basis that:

- the safe use of the substance requires professional advice
- the substance should nevertheless be available to the public from a pharmacist without a prescription²².

This is different to requirements for Schedule 2 'Pharmacy only' medicines which are available for sale via pharmacies without the need for the pharmacist intervention.

The advertising of most substances listed in Schedule 3 of the Poisons Standard is like the advertising of Schedule 4 (Prescription medicines), an offence under paragraph 42DL(1)(f) of the Act. However, there is an exception to the offence for those Schedule 3 substances listed in Appendix H to the current Poisons Standard.

Currently, a prospective advertiser may apply to the Secretary for an amendment of Appendix H (under section 52EAA of the Act) to include a Schedule 3 substance – thereby allowing that substance to be advertised to the general public.

The Council of Australian Governments' *Review of Drugs, Poisons and Controlled Substances Legislation* (the 'Galbally Review') in 2001 recommended (Recommendation 22) that the Commonwealth amend the Act to include all controls on advertising for medicines for human use. It has been agreed that the process for deciding to allow the advertising of a particular medicine containing a Schedule 3 substance should be separate from the process by which the substance is scheduled. Indeed, the existing controls on advertising of Schedule 3 medicines were retained in the Poisons Standard as an interim measure until revised advertising arrangements have been developed and implemented.

9. The Price Information Code of Practice

The Price Information Code of Practice (PICP) provides a mechanism for pharmacists to publish information to the general public about the retail prices of prescription medicines and certain pharmacist-only medicines (that is, medicines included in Schedules 3, 4 and 8 of the current Poisons Standard) that are registered on the ARTG. The PICP sets out

²²This is not the same as Schedule 2 "Pharmacy medicines" which are substances that can only be sold in a pharmacy but, unlike Schedule 3 substances, the safe use of which does not require the professional advice of the pharmacist.

conditions that allows for publications about these medicines where such publication is only limited to information relating to the prices of such medicines and not for promoting the use of a specific medicine. For example, the PICP provides that price information and any accompanying information cannot promote the sale or use of a medicine over any other medicine.

The PICP was made in September 2006 to implement recommendation 11(c) of the 'Galbally Review'. The PICP states that it "can be implemented on a voluntary basis".

Paragraph 3(1)(c) of the TGAC states that it does not apply to information material which complies with the PICP. This in turn means that it will not be an offence under section 42DM of the Act (failing to comply with the TGAC) to publish or broadcast an advertisement that complies with the PICP.

Section 3 of the TGAC refers to the PICP, however, the TGAC does not provide for a definition of the PICP. It is therefore not clear which instrument is being referred to as the PICP. In addition, there are some terms in the PICP which are not defined and may result in uncertainties in determining whether a person publishing price information has contravened the TGAC.

Moreover, while the TGAC may not apply to an advertisement that complies with the PICP, it is not clear that it will not be caught by other offence provisions (such as in section 42DL) to the extent that it refers to a prescription or pharmacist only medicine.

Proposals for reform

The following section provides a series of proposals for addressing the problems outlined earlier in this paper. **The proposals include various options which should be considered both individually and in combination in order to provide potential solutions to the issues identified.**

Proposal 1: Alternatives to the pre-approval scheme

Several options to the current scheme for approving advertisements in specified media prior to publication exist:

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Extend the current system to:
 - a) include pre-approval for medical devices
 - b) cover subscription broadcasting ('narrowcasting') (pay-TV).
- **Option 3:** Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisements.
- **Option 4:** Retain pre-approvals (modified or not as per option 2 or 3) and:
 - (a) maintain the current pre-approval delegations to industry associations, such as ASMI and CHC (with an appropriate medical devices industry group if option 2(a) is endorsed); or
 - (b) appoint an independent statutory office holder to undertake pre-approval function; or
 - (c) TGA to undertake the pre-approval function.
- **Option 5:** Remove the pre-publication approval scheme.

Option 1: Status quo - maintain the current system

This option does not address the problems identified with the existing scheme of pre-approvals for advertisements. However, enhanced education and training for those making pre-approval decisions as delegates of the Secretary, together with closer TGA oversight and quality control could address the issues related to inconsistency but will not address other concerns about coverage and perceptions of lack of independence.

Option 2: Extend the current system to include pre-approval for medical devices and to cover subscription broadcasting

- (a) Extend the pre-approvals scheme to cover medical devices (including in vitro diagnostic devices (IVDs)). Consideration would need to be given to whether advertising requirements for medical devices would apply to all types of medical

devices or whether there is a sub-set of medical devices that should be covered, e.g. limit pre-approvals to those that can be purchased by the public (see Proposal 5 below about the advertising of medical devices that are only available in clinical or other healthcare settings).

- (b) Include pay TV (but not the internet, social media etc) in the range of media in relation to which advertising must be approved prior to publication.

Advantages:

- Option 2(a) would treat medical devices, or an agreed sub-set of medical devices, in the same way as medicines.
- Option 2(b) recognises of the growing use of the subscription broadcasting medium (pay TV).

Disadvantages:

- Both options introduce new costs to industry.

Option 3: Only “higher risk” advertisements to be pre-approved

The main elements of Option 3 are:

1. The requirement for pre-approval would be confined to categories of advertisements determined, in an instrument made by the Minister, to be “higher risk”.
2. Criteria for designating advertisements as “higher risk” would recognise that representations about therapeutic goods can pose unacceptable risks to the public and to public health.
3. Criteria would therefore focus on risks such as those currently identified in the TGAC, such as:
 - a. the registered/listed indications for the goods that are prohibited or restricted representations permitted by the Secretary in relation to the goods (an equivalent approach could be taken for the intended purpose(s) applying to medical devices)
 - b. where the advertisement is intended by the advertiser to be directed at, or influence, children or other vulnerable consumer groups or where there has been a history of breaches in relation to advertisements of that type of product (an example could be advertisements for weight loss products)
 - c. the level of risk inherent in the normal use of the advertised goods
 - d. advertisements from particular advertisers/sponsors with a poor compliance record.
4. The current mechanisms for limiting the advertising of ‘prohibited representations’ or ‘restricted representations’ would be retained.
5. This option could also allow an advertiser/sponsor to seek pre-approval for advertisements that do not come within the criteria to provide more legal certainty.

Advantages:

- Expected to reduce the number of advertisements requiring pre-approval and therefore reduce costs to business.

Disadvantages:

- Would expose the public to some advertisements that breach advertising requirements to which they are not exposed now because under this approach compliance would always be by means of post-broadcast/publication review.
- Could decrease levels of certainty for business in the following ways:
 - For those advertisements that did not have to be assessed, businesses would have less assurance that their advertisements were compliant with the law – mainstream broadcasters and publishers may be disinclined to accept advertisements that did not have pre-approval to minimise risk (this could be overcome if there was optional pre-approval for advertisements that do not come within the criteria)
 - It may be difficult for businesses to decide whether an approval was necessary, if the criteria for requiring pre-approval were complicated or unclear. This uncertainty may lead to applications being made when they were, in fact, not required.

Option 4: Retain pre-approvals and consider who could undertake the pre-approval function

If the pre-approval requirement is maintained in some form (whether or not it is expanded as proposed in options 2 and/or 3), then there are three possibilities for consideration as to who should undertake this function:

- a. maintain the current roles of industry body, for example (ASMI and CHC) for approving complementary and over the counter medicines advertisements and engage an appropriate industry body for approving medical device advertisements; or
- b. delegate the function to an independent statutory office holder; or
- c. TGA undertake the function.

a. industry body pre-approvals

The main advantage of the current arrangements is that it reflects a shared responsibility with industry for an effective advertising framework. Improvements to the current arrangements could be made through TGA having a stronger quality control oversight role such as by reviewing a representative sample of advertising approvals rather than relying entirely on the complaints process to identify what may appear to be deficiencies in the pre-approvals given by these bodies. Further, the difficulties with the current split delegation for approving complementary medicine advertisements between ASMI and CHC would need to be addressed if shared arrangements are to be maintained.

A disadvantage of maintaining the industry approval delegations is that concerns raised about inconsistencies in outcomes between the organisations are not addressed and, more significantly, nor is the perception of a conflict of interest which is inherent in industry

organisations pre-approving advertisements put forward by their own members and/or those involved in their industry. This concern is currently exacerbated by the fact that the same groups are represented in the complaints handling process (through membership of the Complaints Resolution Panel) and on the Therapeutic Goods Advertising Code Council.

b. An independent statutory office holder performs the function

An independent statutory office holder undertaking pre-approvals would address the conflict of interest issue, especially where this office holder is not responsible for advertising complaint handling. Consistency of decisions across all kinds of pre-approvals would result, but consistency between pre-approvals and the outcome of complaints would not necessarily follow (it would still be possible that a complaint about an advertisement that had been pre-approved would be upheld).

A disadvantage of this arrangement would be that the office holder would not necessarily have the technical knowledge, or expertise available, to assess the validity of advertising statements where an understanding of the scientific evidence supporting efficacy claims is required. Such skills would need to be developed by the independent office holder or obtained by outsourcing that could negatively impact on the timeliness of the approval process. There would be additional costs associated with establishing this office that would be required to be cost recovered by TGA from industry. These costs may well be greater than retaining industry involvement or alternatively having the TGA undertake the pre-approval function.

c. TGA to undertake advertising pre-approvals

An advantage of this arrangement would be that the skills needed to assess advertising claims that are based on efficacy studies already reside within the TGA. Improved consistency in decision-making would be expected. It would ensure that the same understanding of the advertising regulatory requirements is brought to bear in relation to all matters where compliance with those regulatory requirements is an issue i.e. in evaluating applications for inclusion of therapeutic goods on the Register, in reviewing regulatory compliance of therapeutic goods on the Register, in determining whether therapeutic goods should be suspended or cancelled because of failure to comply with advertising requirements or when considering complaints that a particular advertisement has breached the advertising requirements.

A disadvantage of this proposal is that TGA would be involved in both the approval and complaints handling processes which could be seen as a potential conflict of interest. Situations where TGA may have approved a particular advertisement but subsequently take compliance action on that advertisement may also be seen as questionable by stakeholders. TGA would also need to ensure adequate resourcing for this new function to ensure timely approval outcomes.

Option 5: Remove the requirement for pre-approval

Under Option 5:

- The current requirements for certain advertisements to undergo pre-approval would be removed.

This option would not however preclude industry bodies providing an advertising 'approvals advisory' service to advertisers, but outside the scope of Therapeutic Goods legislation; or preventing advertisers/sponsors and broadcasters/publishers entering into

commercial arrangements to satisfy the latter that an industry-based 'approval' has been obtained prior to an advertisement being broadcast/published so as to mitigate risk of a breach of advertising requirements.

Advantages:

- Removes the potential conflict between the Secretary's responsibility to approve advertisements and the responsibility to take enforcement action in cases where an approved advertisement is found to be non-compliant with therapeutic goods legislation after publication
- Allows sponsors and advertisers to either undertake their own compliance assessment or choose a compliance vetting service provider to review the advertisement on their behalf
- Allows the market to determine the need for and price of compliance vetting services (instead of the TGA setting a fee for pre-approval of advertisements)
- Simplifies government administration by removing fees for pre-approval of advertisements.

Disadvantages:

- Would likely expose the public to a greater number of advertisements that breach advertising requirements because compliance would always be by means of post broadcast/publication review
- No option to require advertisers/sponsors who have history of breaching to subject their advertisements to a pre-approval process (thus protecting the public) as an effective adjunct to other enforcement options
- A lesser degree of certainty for advertisers in comparison with approvals from a delegate of the Secretary. (However, approval of an advertisement does not preclude enforcement action by the TGA if the advertisement is judged to be non-compliant after publication/broadcast.)

Proposal 2: The complaints handling process

A number of options can be considered to address the concerns raised about the timeliness and inconsistencies associated with the current complaints handling mechanisms for advertising of therapeutic goods to the general public.

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** All complaints about advertising of therapeutic goods to the general public to be handled by a single body, either:
 - a. the TGA; or
 - b. an independent statutory office holder.

Option 1 does not address the concerns raised about lack of clarity, timeliness or the potential for conflict of interest.

Option 2 provides for a single body responsible for handling complaints about therapeutic goods advertised to the general public. This would facilitate earlier action in relation to:

- advertisements that pose a high risk to public health and safety
- advertisers with a history of non-compliance
- deliberate or major contraventions of the advertising provisions in the Act, the Regulations and the TGAC.

Advantages:

- Provides clarity for the public, health professionals and to industry
- Removes duplication from the system, thereby streamlining the complaints handling process and improving efficiency
- If the complaints handling process was undertaken by the TGA (Option 2(a)), it would
 - ensure appropriate expertise is applied to assessing advertising claims at an early stage
 - facilitate more efficient and effective handling of advertising compliance
- Enables identification at an early stage of repeat and major offenders and advertisements posing a high risk to public health and safety
- Enables earlier compliance and enforcement action, which is likely to be more effective and thereby lead to a greater deterrence to non-compliance
- Allows for separation of the approvals and complaints handling functions and thereby eliminates concerns over conflict of interest
- Would promote greater public confidence and trust in the regulatory system.

Disadvantages:

- Reduces the therapeutic goods industry role in determining complaints about therapeutic goods directed to the general public
- A statutory office holder performing the function would need to either build the capacity to assess efficacy/performance claims in advertisements or outsource it. The statutory office holder option would potentially be more expensive than TGA conduct of complaints handling and the additional costs would need to be cost-recovered from industry.

Proposal 3: Provision of advice in relation to advertising matters

Two options are suggested in relation to proposal 3:

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Establish an expert advertising advisory committee.

Option 1 would require retention of the Complaints Resolution Panel and the Therapeutic Goods Advertising Code Council in their current form. This may not lead to the improvements in the advertising arrangements that are expected by stakeholders; i.e. a system that is efficient, responsive, effective and timely. The Panel is established in the regulations and has to follow complex regulatory procedures that can often lead to delays in effective outcomes arising from complaints. With the likelihood of increasing numbers of complaints, maintaining a statutory 'decision-making' committee that can only request an advertiser/sponsor to take action but is required to consider all complaints within its jurisdiction is a barrier to achieving acceptable levels of improvement in efficiency and timeliness.

The membership of the Therapeutic Goods Advertising Code Council is currently large (15 members and 5 observers) but still does not represent all groups that may have a role in therapeutic goods advertising. To increase the size of the Council to accommodate these extra groups would make it unwieldy and inefficient.

Option 2 involves the establishment of one statutory advisory committee to replace the Panel and Council to provide advice to the Secretary (or delegate) or an independent statutory office holder (if that option is implemented) with advice on advertising decisions. To assist the decision-maker, it is proposed that the expert advertising advisory committee have expertise appropriate to providing advice on advertising matters generally (including from the consumer point of view) and to provide advice on complex advertising complaints, restricted representations and other advertising applications, such as approvals to advertise "pharmacist-only" (Schedule 3) medicines (see proposal 7).

This approach would be consistent with other regulatory decision making processes under the Act.

Advantages:

- Removes potential for bias
- Ensures that decision-makers have available to them appropriate expertise if and when required.

Disadvantage:

- Reduces current representative contribution to advertising regulatory decision making.

Proposal 4: Investigation and enforcement powers

- **Option 1:** Status quo - maintain the current system
- **Option 2:** Enhance investigation and enforcement powers

Option 1 will not address the concerns about the absence of meaningful sanctions and penalties for advertising breaches in the Act.

Option 2 will provide additional powers to enable the TGA to implement strategic, timely, effective and efficient responses to breaches of the advertising controls.

The amendments made to the Act in 2006 which introduced additional enforcement options to the TGA that include a tiered offences regime and civil penalties, did not cover breaches of advertising requirements. This was because a review of those requirements was being undertaken at the time the sanctions package for the Australia New Zealand Therapeutics Agency was being developed for implementation.

The purpose of the advertising reforms package as a whole is to try to ensure that the public is not exposed to advertising that is not socially responsible, does not promote the quality use of therapeutic goods or that misleads or deceives (or such exposure is minimised to the greatest extent possible).

These proposals are intended to effectively deter contraventions of existing advertising regulatory requirements under the advertising framework set out in the Act, the Regulations and the Advertising Code and to ensure that appropriate penalties can be sought in the event of a breach. It is also intended to provide other enforcement sanctions appropriate to specified circumstances and achieve better regulatory outcomes with minimum delay.

It is proposed to amend 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 2 below for current penalties and the proposed changes)
- 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 for providing 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 Register 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.

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

Disadvantages: None identified.

Table 2 – Current and proposed penalties for breaching the advertising requirements

Current provision or offence provision under the Act or Regulations	Current penalty levels	Proposed new offence provision and penalty	Proposed corresponding civil penalty provision
Subsection 22(5) Section 41ML Subsection 32BJ (3) <i>Advertising a medicine, medical device or biological for a purpose not included in the ARTG entry for that product</i>	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—500 penalty units	For an individual—5000 penalty units For a body corporate - 50,000 penalty units
Section 42C <i>Offences related to publication or broadcast of advertisements that require pre-approval</i>	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 <i>False or misleading advertising</i>	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 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 <i>Corrective action ordered by the Secretary</i>	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

Current provision or offence provision under the Act or Regulations	Current penalty levels	Proposed new offence provision and penalty	Proposed 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 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

Proposal 5: Advertising of higher risk medical devices

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Prohibit the advertising of higher risk medical devices.

Option 1 would mean that advertisements for higher risk medical devices can continue to be directed to the general public.

Option 2 would prohibit such advertisements through an amendment to the advertising offence provisions in the Act. It is proposed that “higher risk medical devices” would include Class III and Active Implantable Medical Devices as well as Class 4 in vitro diagnostic devices. Class III medical devices that contain a listed or over-the-counter medicine that is currently able to be advertised directly to the general public will not be affected by this proposal. This would align the advertising regulation of higher risk medical devices with the arrangements for prescription medicines and the majority of pharmacist-only medicines and reflects the fact that such medical devices are generally only available in clinical or other healthcare settings.

Advantages: The advertising of higher risk medical devices would be on the same basis as the prohibition on advertising of higher risk medicines given the similar risk profiles and that there is a need for the involvement of a healthcare practitioner to ensure safe use of the product.

Disadvantage: Sponsors would not be allowed to advertise higher risk medical devices to the public which could have an impact on their business.

Proposal 6: Advertising directed to health professionals

Two options are proposed to ensure that only appropriately qualified health professionals are exempted from the advertising requirements:

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the *Health Practitioner Regulation National Law*.

Option 1 would see the current lists of health professionals in section 42AA of the Act retained (refer to Table 3 below).

Advantages: Advertisers could continue to publish/broadcast advertising directed exclusively to the groups of health professionals listed in section 42AA of the Act including those that are not regulated under the *Health Practitioner Regulation National Law*.

Disadvantages: This option would perpetuate the problems that:

- The TGA would not be assured that the non-NRAS registered health practitioners are able to exercise specialist judgement when either treating patients with advertised therapeutic goods, or advising them about the use of advertised therapeutic goods

- Advertising to some nationally regulated practitioners, such as medical radiation practitioners, occupational therapists and Aboriginal and Torres Strait Islander health practitioners (who are not currently in the list in section 42AA), would continue to be subject to all the controls designed to apply to advertising directed to the general public.

Option 2 is to replace the current lists of 'health professionals' in section 42AA of the Act with references to 'health practitioners' who are registered with a National Board that is a signatory to a Health Profession Agreement under the [National Registration Accreditation Scheme](#) (NRAS). Advertising to groups of practitioners who are not registered with NRAS would be regulated in the same way as advertising to the general public.

Table 3 below compares the health practitioner groups covered by NRAS with the professional groups to whom advertising may be directed exclusively without invoking the controls in Part 5-1 of the Act, that apply in relation to advertising to the general public.

Table 3 – Comparison of health professional groups under the Act (Part 5-1) and the Health Practitioner National Law

Health Professions to whom advertising may be directed exclusively without invoking Part 5-1 of the <i>Therapeutic Goods Act 1989</i> (Section 42AA)	Corresponding health practice boards registering practitioners under the <i>Health Practitioner Regulation National Law</i> and the NRAS (administered by AHPRA)
Medical practitioners	Medical Board of Australia
Psychologists	Psychology Board of Australia
Pharmacists	Pharmacy Board of Australia
Optometrists	Optometry Board of Australia
Chiropractors	Chiropractic Board of Australia
Physiotherapists	Physiotherapy Board of Australia
Nurses and Midwives	Nursing and Midwifery Board of Australia Registering Midwives and Nurses in the following Divisions: Registered nurse (Division 1) and Enrolled nurse (Division 2)
Dentists	Dental Board of Australia Registering Dental Practitioners in the following Divisions: Dentist (including specialists), Dental therapist, Dental hygienist, Dental prosthetist, Oral health therapist
Dental hygienists	
Dental prosthetists	
Dental therapists	
Osteopaths	Osteopathy Board of Australia
Herbalists	<i>Nil</i>
Homeopathic practitioners	<i>Nil</i>
Naturopaths	<i>Nil</i>
Practitioners of traditional Chinese medicine	Chinese Medicine Board of Australia Registering Chinese Medicine Practitioners in the following Divisions: Acupuncturist, Chinese herbal medicine practitioner, Chinese herbal dispenser
Podiatrists	Podiatry Board of Australia
	Aboriginal and Torres Strait Islander Health Practice Board Registering Aboriginal and Torres Strait Health Practitioners
	Medical Radiation Practice Board of Australia Registering Diagnostic radiographers, Nuclear medicine technologists, Radiation therapists
	Occupational Therapy Board of Australia

The effect of the proposed amendments to section 42AA of the Act would be that advertising to the following practitioner groups would be regulated in the same way as advertising to the general public, unless or until those groups were recognised under the NRAS:

- Herbalists (other than Chinese herbal medicine practitioners registered by the Chinese Medicine Board of Australia)

- Homeopathic practitioners
- Naturopaths

The proposal would also have the effect of exempting advertising addressed exclusively to the following practitioner groups from the advertising controls in Part 5-1 of the Act (that apply to advertising to the general public):

- Aboriginal and Torres Strait Health Practitioners, registered by the Aboriginal and Torres Strait Islander Health Practice Board
- Diagnostic radiographers, nuclear medicine technologists and radiation therapists, registered by the Medical Radiation Practice Board of Australia
- Occupational therapists, registered by the Occupational Therapy Board of Australia.

Advantages:

- Advertising purporting to be directed exclusively to herbalists, homeopathic practitioners and naturopaths would be regulated by the TGA under Part 5-1 of the Act unless or until national boards registering those groups became accredited under NRAS and those groups became regulated health services under the *Health Practitioner Regulation National Law*. This would provide a degree of protection to the public that is not provided by the current law
- Advertising to some nationally-regulated practitioners, such as medical radiation practitioners, occupational therapists and Aboriginal and Torres Strait Islander health practitioners, would no longer have to comply with controls in Part 5-1 of the Act, designed to apply to advertising directed to the public on the basis that such professionals have been recognised under the *Health Practitioner Regulation National Law*
- There would be no need to update the therapeutic goods legislation in future when groups of health practitioners were either included in, or withdrawn from NRAS.

Disadvantages: Advertisers targeting practitioner groups currently covered by section 42AA but outside the NRAS scheme would have to comply with the advertising requirements so the change would be seen as an additional regulatory impost.

Proposal 7: Advertising of Pharmacist-Only medicines

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Transfer from the scheduling framework the responsibility for approving advertising of Pharmacist-Only (Schedule 3) medicines to the general public.

Option 1 is contrary to the agreement of the Council of Australian Governments to implement 'Galbally Review' recommendation 22 relating to the advertising of human medicines. This agreement requires decisions about advertising of Pharmacist-only medicines to be separate from scheduling considerations.

Under **Option 2** the responsibility for approving the advertising of Pharmacist-Only (Schedule 3) medicines would be moved out of the drugs and poisons scheduling

processes to within the advertising regulatory framework. The scheme, possibly within Part 5 of the Act (which is where the current prohibition on advertising S3 substances is located), would allow a prospective advertiser to apply to the Secretary for approval to advertise products that contain a Schedule 3 ingredient. Appropriate criteria to guide the Secretary when considering such an application would need to be developed, noting that the former National Coordinating Committee on Therapeutic Goods guidelines only allowed such advertising where there was a demonstrated public health benefit.

Advantages:

- Implements an outstanding deferred recommendation from the 'Galbally Review' (2001) and allows all therapeutic goods advertising functions to be administered by the area within the TGA responsible for overseeing the advertising regulatory framework
- Ensures that all advertising requirements are located in one place.

Disadvantages: None identified.

Proposal 8: The Price Information Code of Practice

- **Option 1:** Status quo - maintain the current system.
- **Option 2:** Provide legislative underpinning to the Price Information Code of Practice.

Under **Option 1** the Price Information Code of Practice (PICP) will be maintained as a document that is mandated in some states and territories thus perpetuating the current uncertainty for advertisers.

Under **Option 2** the PICP would be replaced with a new legislative instrument and/or provisions in the Regulations using language that is more consistent with the legislation. This will have the effects of both mandating requirements of the kind described in the PICP and providing greater certainty to advertisers and the general public about their meaning and relationship to offences and other provisions in the Act, the Regulations and the TGAC.

Advantages: Greater clarity resulting in improved compliance with the PICP advertising requirements.

Disadvantages: None identified.

Acronyms and Glossary

ACCC	Australian Competition and Consumer Commission
ACMA	Australian Communications and Media Authority
AHPRA	Australian Health Practitioner Regulatory Agency
CRP	Complaints Resolution Panel - established by the Regulations
NRAS	National Registration Accreditation Scheme
Poisons Standard	Standard for the Uniform Scheduling of Medicines and Poisons
PICP	Price Information Code of Practice - a voluntary code which limits the application of the TGAC in relation to price lists published by registered pharmacists.
Secretary	Secretary of the Australian Government Department of Health and Ageing
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code 2007 – made by the Minister under section 42BAA of the Act
TGACC	Therapeutic Goods Advertising Code Council - established by the Regulations
the Act	<i>Therapeutic Goods Act 1989</i>
the Regulations	<i>Therapeutic Goods Regulations 1990</i>
WHO	World Health Organization

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