



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Advertising regulatory framework

Options for reform

Version 1 May 2012

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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 and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. 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.

Copyright

© Commonwealth of Australia 2012

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0			

Historical document

Contents

Executive summary	7
Recommendations	8
Background	10
1. The pre-approval process	11
1.1 Legislative basis	11
1.1.1 Restricted representations	12
1.1.2 Approval numbers	12
1.1.3 Delegated decision making in advertising approval	12
1.2 Complaints	12
1.3 Limitations of the current pre-approvals process	17
1.3.1 Limited coverage - Products	17
1.3.2 Limited coverage - Media	17
1.3.3 The listing system (unverified claims)	18
1.3.4 Assessment of efficacy claims as part of the approval process	18
1.3.5 Approved advertisements still in breach	19
1.3.6 Limitations imposed by delegations - split coverage	19
1.3.7 Limitations of the delegations as they stand	19
1.3.8 Sanctions and penalties	20
1.3.9 Cost recovery	20
1.4 Stakeholder submissions	20
1.4.1 Submissions from consumers	20
1.4.2 Submissions from healthcare professionals	21
1.4.3 Submissions from the therapeutic goods industry	21
1.4.4 Submissions from the advertising/publishing industry	21
1.5 Options for change	21
1.5.1 Maintain the current system	21
1.5.2 Expand the current system	21
1.5.3 Remove the current system	23
1.5.4 Alternative to the current system – limited pre-approval	24
2. The complaints resolution system	26

2.1	Stakeholder submissions	26
2.2	Current arrangements	26
2.2.1	Submitting complaints	27
2.2.2	The function of the CRP	27
2.2.3	The determinations of the CRP	27
2.3	Limitations of the current complaints resolution system	28
2.3.1	Timeliness	28
2.3.2	Effectiveness of sanctions imposed by the CRP	28
2.3.3	CRP membership and perceived conflict of interest	28
2.3.4	Non-compliance with the CRP's request(s)	29
2.3.5	Repeat offenders	29
2.3.6	Transparency of the complaints resolution process	29
2.4	Volume of complaints	29
2.4.1	Straightforward complaints	30
2.4.2	Complaints about misleading advertisements	30
2.4.3	Complaints about efficacy or performance	30
2.4.4	Complaints about advertisements directed to healthcare professionals	30
2.5	Options for change	30
2.5.1	Centralised administration	30
2.5.2	Increased public awareness	31
2.5.3	Dealing with complaints	31
2.5.5	Dealing with complaints that would be more appropriately handled by the ACCC	32
2.5.6	Dealing with complaints based on the form of media in which the advertisement appeared	32
2.5.7	Dealing with complaints about advertisements that present an unacceptable risk to public health and safety	32
2.5.8	Provision of advice in relation to potential breaches of advertising requirements	33
2.5.9	Reducing the backlog of complaints in the queue for consideration by the CRP	34
2.5.10	Transparency	34
2.5.11	Resource implications	34
3.	Sanctions and penalties	35
3.1	Stakeholder submissions	36
3.2	Current sanctions under the Therapeutic Goods Act and Regulations	36

3.3	Limitations of the current sanctions and penalties related to advertising	37
3.4	Options for change	37
3.4.1	Advertising to consumers	37
3.4.2	Resource implications	39
3.4.3	Advertising to healthcare professionals	39
4.	Recommendations	40
4.1	The future of pre-approval	40
4.1.1	Efficacy claims	40
4.1.2	Delegations	40
4.2	Complaints resolution	40
4.3	Sanctions and penalties	41
	APPENDIX 1 - Acronyms	43

Executive summary

The advertising of therapeutic goods to consumers and healthcare 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 to consumers 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.

The objective of advertising pre-approval is to prevent advertisements of therapeutic goods from being published that contain claims for the treatment of serious medical conditions, on the grounds that such conditions are not amenable to self diagnosis or treatment.

The current pre-approval system is limited in its ability to prevent consumers from being exposed to advertisements for therapeutic goods that contain misleading claims or claims for the treatment of serious medical conditions in that only a sub-set of products are covered and only a sub-set of advertising media are covered.

Given this, there are several options for change. The first is to require all advertisements for therapeutic goods that are directed at consumers, be they medicines or medical devices, to be pre-approved, regardless of the medium or form in which they appear. Another option is to replace the existing arrangements for pre-approval with ones that provide a greater assurance of meeting public health objectives.

Given the volume of Internet advertising, in particular, a requirement for pre-approval of all advertisements would necessitate significant additional resources to be devoted to the pre-approval process. Cost implications for the regulated sector would need to be considered.

If the existing requirements for pre-approval are to be amended, the alternative arrangements would need to ensure that the risks to consumers as a result of exposure to misleading and potentially harmful advertising are managed. The most important of these alternative risk management arrangements would be the implementation of a robust monitoring program to identify breaches of the advertising requirements and an effective sanctions and penalties framework that would apply penalties of sufficient magnitude to deter non-compliance. Implementation of such a monitoring system would also have significant cost and resource implications.

The TGA recommends that in order to minimise the risks to consumers of misleading advertisements for therapeutic goods, changes to the existing pre-approval system be considered. These changes could include extending the pre-approval requirement to cover advertisements for medical devices and advertisements appearing on pay-television. In addition, the TGA recommends that effective and transparent arrangements are put in place to ensure that there is more detailed and effective monitoring of the performance of the pre-approval system.

Given the stated concerns over the complexity of the advertising scheme and the difficulty for consumers in determining where to submit a complaint, the TGA considers that a single point of contact would be a major benefit for consumers wishing to complain about any advertisement for any therapeutic good. A Central Mail Box established within the TGA as a one-stop point for all advertising complaints would meet this objective.

Complaints relating to efficacy of listed medicines and performance of low-risk medical devices should not be dealt with as part of the advertising complaints resolution process. Rather, complaints related to efficacy and performance should be dealt with by the relevant regulatory areas of the TGA.

Straightforward complaints and complaints about advertisements that may pose a significant risk to public health should be dealt with immediately by the TGA.

The Complaints Resolution Panel (CRP) should provide advice on whether advertisements are socially responsible, promote the quality use of therapeutic goods and do not mislead or deceive the consumer. The CRP should not be required to provide advice on the appropriateness of evidence to support efficacy or performance claims.

Complaints about advertisements directed to healthcare professionals should continue to be referred to the appropriate industry body for consideration under the relevant Code of Practice.

To support the advertising regulatory framework a public health risk-based enforcement model is required. The public health risk for each offence should be identified and a range of sanctions and penalties for each prohibited action should be provided to effectively manage that level of risk for each offence. The provision of pecuniary penalties such as civil penalties, infringement notices and enforceable undertakings, as alternative sanctions to prosecution, should be part of the enforcement model. Such a model is consistent with the Australian National Audit Office's [Better Practice Guide to Administering Regulation \(2007\)](#).

The level of penalties and available sanctions for each offence and civil penalty provisions should provide an indicator of the public health importance of that breach or contravention. Such an approach would also provide guidance to the TGA for assigning resources and priority to each individual advertising breach reported for regulatory consideration.

The TGA recommends consideration be given to an increase in the level of penalties to be imposed in relation to breaches of the advertising requirements and a corresponding civil penalty provision in relation to the same prohibited conduct. Also, the TGA proposes greater flexibility to allow the Secretary of the Department of Health and Ageing (the Secretary) to deal with complaints on his or her own motion to enable the Secretary to deal with complaints that pose serious public health risks in a timely manner.

Recommendations

Subject to further consultation as required, the TGA recommends that:

- The pre-approval requirement for advertisements for non-prescription medicines should be retained. The following amendments to the current system are recommended:
 - Coverage extended to include advertisements for medical devices directed to consumers appearing in mainstream/specified media;
 - The definition of mainstream/specified media extended to include Internet and pay-television;
 - Approval procedures modified to remove any requirement for efficacy or performance claims to be assessed as part of the advertising approval;
 - Anomalies in delegations clarified to ensure consistency of approach to approvals; and
 - Transparent processes put in place to monitor the performance of the scheme.
- A Central Mail Box should be created within the TGA as a one-stop point for all advertising complaints.
- Complaints relating to efficacy of listed medicines and intended purpose for low-risk medical devices should be dealt with by the TGA outside of the advertising complaints resolution process.
- Complaints about advertisements that may pose a significant risk to public health (and straightforward complaints) should be dealt with immediately by the TGA. This will require the Secretary to be able to deal with complaints on his or her own motion rather than on the advice of the CRP.
- The CRP should be constituted with the expertise appropriate to providing advice on whether advertisements are socially responsible, promote the quality use of therapeutic goods and do not mislead or deceive consumers.

- The level of penalties allowed under the existing advertising offence provisions should be increased to be consistent with comparable breaches of other requirements under the Act and corresponding civil penalty provisions in relation to the identified offence provisions should be created.
- The sanctions and penalties framework should provide for the greater use of infringement notices based on strict liability offences and civil penalty provisions and enforceable undertakings.

Advertising of medicines containing a Pharmacist-only (Schedule 3) ingredient to consumers should be permitted only in situations where there is a demonstrated public health benefit in doing so. Decisions to approve the advertising of products containing Schedule 3 ingredients to consumers should be completely separated from Scheduling decisions.

Background

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

- Selecting management options wisely;
- Choosing suitable medicines if a medicine is considered necessary; and
- Using medicines safely and effectively.

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

Within this context it is clearly necessary that there needs to be a robust and effective system for regulating advertising that provides confidence for consumers, knowing that the claims they read and hear are well founded.

The Productivity Commission in their [Annual Review of the Regulatory Burdens on Business: Manufacturing and Distributive Trades Research Report \(2008\)](#) expressed concerns over the plethora of interlocking and overlapping controls over marketing and advertising that include significant cross portfolio and inter- and intra-jurisdictional legislative requirements throughout the different levels of government within Australia. The Commission recommended 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 Australian Government has accepted this recommendation in principle. In relation to regulation covering the advertising of therapeutic goods it is agreed the Government will consider changes to the advertising regulatory arrangements to streamline requirements and reduce regulatory burdens.

In this context, and having regard to the Australian National Audit Office's [Better Practice Guide to Administering Regulation \(2007\)](#), a review of the requirement for the pre-approval of certain advertisements for therapeutic goods, the complaints resolution system and the sanctions and penalties relating to breaches of advertising requirements, has been undertaken.

The regulatory framework setting out the requirements for the advertising of therapeutic goods has been the subject of a number of reviews over the last decade. The current framework has more recently been the subject of public criticism around misleading advertising of therapeutic goods. This criticism has focused mainly on the complaints handling process, its lack of transparency and timeliness, and that the available sanctions and penalties do not provide sufficient deterrence.

To investigate opportunities for improving the framework, the TGA released a consultation paper in June 2010 seeking feedback on options to enhance the operation and effectiveness of the therapeutic goods advertising regulatory scheme. Subsequently, the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, chaired a 'roundtable' meeting at Parliament House in November 2010 to discuss this feedback and how the regulation of therapeutic goods advertising could be improved. This meeting agreed to the TGA progressing certain activities for improving the framework. In particular, it proposed that the following reviews be undertaken:

- Pre-approval of advertisements;
- Complaint resolution system; and
- Sanctions and penalties.

1. The pre-approval process

1.1 Legislative basis

The advertising of therapeutic goods to consumers and healthcare professionals is controlled by a combination of statutory measures administered by the TGA and the ACCC, and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations.

Advertisements for therapeutic goods in Australia are subject to the requirements of the [Therapeutic Goods Act 1989](#) (the Act), the [Therapeutic Goods Regulations](#) (the Regulations), the [Competition and Consumer Act 2010](#) and other relevant laws. Advertisements for therapeutic goods must also comply with the [Therapeutic Goods Advertising Code](#) (the Code).

The fundamental principle for the advertising of medicines is set out in Section 22(5) of the Act which specifies that advertising of a therapeutic good can only refer to the indications which are included in the Australian Register of Therapeutic Goods (the ARTG) for that specific medicine. For medical devices, the fundamental principle is set out in Section 41ML of the Act which specifies that advertising about medical devices can only refer to a purpose accepted in relation to the inclusion of that device in the ARTG.

Advertising to consumers is permitted for the majority of medicines available for over the counter sale, while advertising prescription-only and most pharmacist-only medicines to the general public is prohibited. However, government-controlled public health campaigns that have been approved by Health Ministers are exempt from this prohibition. Advertising of **all** therapeutic goods is required to comply with the Code (Section 42DM of the Act).

In addition to these overarching principles, there are specific requirements set out in therapeutic goods legislation in relation to the advertising of specific types of therapeutic goods, in particular the advertising of non-prescription medicines (including complementary medicines) directly to consumers.

Section 42DL of the Act makes it an offence if a person publishes or broadcasts an advertisement about therapeutic goods that contains a statement referring to goods, or substances included in Schedule 3, 4 or 8 of the Poisons Standard, other than a statement authorised or required by a government or government authority. This effectively prevents the advertising of prescription medicines and most pharmacist-only medicines directly to consumers. Generally, advertisements for non-prescription medicines may be directed both to consumers and to healthcare professionals.

Section 42C of the Act makes it an offence for a person to publish or broadcast an unapproved advertisement for designated therapeutic goods in specified media. Advertisements that are required to be approved are advertisements directed to consumers for non-prescription medicines, including complementary medicines containing unscheduled or Schedule 2 (Pharmacy-only) ingredients and non-prescription medicines containing Schedule 3 (Pharmacist-only) ingredients that have been approved for advertising to consumers. Specified media include broadcast media (TV and radio); print media (newspapers and magazines); outdoor billboards (including bus shelters, sides and interiors of buses and taxi displays); and cinema films.

Regulations 5F and 5G describe how to obtain an approval for an advertisement for a designated therapeutic good to appear in specified media. An application must be made to the Secretary in writing and the prescribed fee must be paid. The Secretary will then assess the application to determine that the advertisement complies with the Code and does not contain a prohibited representation about the goods. If the Secretary is satisfied that the requirements of Regulations 5F and 5G have been met, the Secretary must approve the advertisement.

An approval may be subject to conditions imposed by the Secretary (Regulation 5G).

Although there are no specific requirements for the advertising of medical devices to consumers (i.e. they do not need to be pre-approved) the advertising of medical devices must comply with the Code and is subject to the provisions of the Competition and Consumer Act 2010 that apply to the promotion of all consumer goods.

1.1.1 Restricted representations

Advertisements for therapeutic goods must not include a '*restricted representation*'. Section 42DD of the Act defines a restricted representation as a representation in an advertisement about therapeutic goods that refers to a form of a disease, condition, ailment or defect identified in the Code as a serious form of a disease, condition, ailment or defect. This restriction applies to all therapeutic goods including medical devices.

Application for approval of the use of a restricted representation can be made to the Secretary. If the Secretary is satisfied that the representation is accurate and balanced; and the representation is not misleading or likely to be misleading, the representation can be approved for use in an advertisement under Section 42DF of the Act. In deciding whether to approve or refuse to approve the use of a restricted representation, the Secretary must take into consideration any recommendation of the Therapeutic Goods Advertising Code Council and the public interest criteria mentioned in the part of the Code dealing with restricted representations.

1.1.2 Approval numbers

Regulation 5J requires the Secretary to allocate a distinguishing number (the approval number) to each approved advertisement. Unless the approval of the advertisement is withdrawn, an approval number is valid for two years.

Under Section 42C of the Act, it is an offence to publish an advertisement in print media; outdoor billboards or cinema films unless that advertisement displays a valid approval number.

1.1.3 Delegated decision making in advertising approval

In accordance with Regulation 5Q, the Secretary has delegated his or her powers to approve or refuse advertisements, and to withdraw the approval, to the Complementary Healthcare Council of Australia (CHC) and to the Australian Self-Medication Industry Incorporated (ASMI). Regulation 5Q stipulates that the CHC's power to approve advertisements is limited to advertisements for complementary medicines and does not extend to the approval of radio or TV advertisements. ASMI's power extends to the approval of advertisements for non-prescription medicines (including complementary medicines) containing unscheduled or Schedule 2 (Pharmacy-only) ingredients to appear in all specified media including radio and TV.

1.2 Complaints

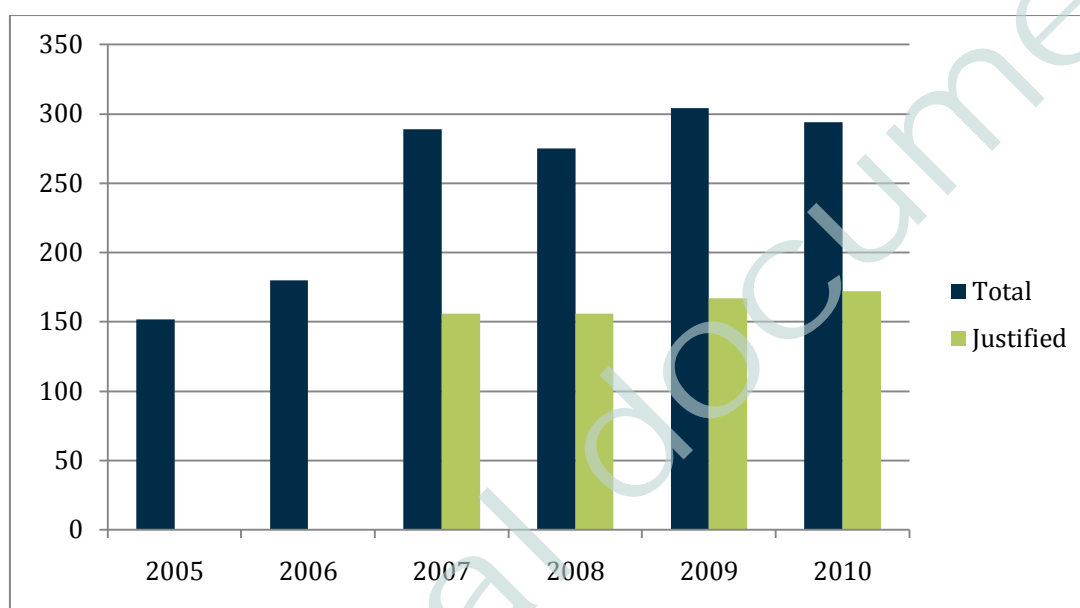
One way to gauge the success of the pre-approval process is to look at the complaints received in relation to advertisements for therapeutic goods for which advertising pre-approval is required. Advertisements for designated therapeutic goods, in specified media, are the only advertisements in Australia for which there is a statutory pre-approval process. Supporters of the process argue that the existence of the process prevents publication of advertisements that are in breach of the requirements of the Act, the Regulations and the Code. A detailed examination of the current complaints resolution system and options for the future are provided elsewhere in this document (see Sections 2.2 and 2.5).

Each year, several hundred complaints are made about the content of advertisements for therapeutic goods. These complaints are reviewed by the CRP, set up under the Regulations, to receive and consider complaints about advertisements for therapeutic goods.

An examination of the complaints upheld by the CRP shows that a number of pre-approved advertisements are found to be in breach of the requirements of the Act, the Regulations or the Code (Table 1).

Figure 1 depicts the total number of complaints dealt with by the CRP each year since 2005 and, for 2007-2010, the number of complaints upheld (justified) by the CRP.

Figure 1 – Total number of advertising complaints dealt with each year



Note: - data on justified complaints are not available for 2005 and 2006.

Figure 2 breaks down the total complaints dealt with into complaints about advertisements requiring approval (complementary and OTC medicines), advertisements for medical devices (not requiring approval) and other including advertisements for cosmetics and prescription medicines.

It would appear that the majority of complaints dealt with are for advertisements that require pre-approval; however the nature of the complaint is not clear from these raw data. For example: it is not apparent whether the complaint was because the advertisement was not approved, whether the advertisement failed to comply with the details set out in the approval or whether the advertisement complied with the approval but it was felt (by the complainant) that the advertisement was worthy of complaint. It is also not clear from these raw data whether or not the complaints were upheld by the CRP.

What is clear from Figure 2 is that the number of complaints relating to advertisements for medical devices has been steadily increasing over the last four years. This increase has meant that in 2010 the CRP dealt with approximately equal numbers of complaints about advertisements for medical devices and for complementary and OTC medicines combined. This is relevant to a consideration of the effectiveness of the pre-approval process in that advertisements for medical devices are currently not pre-approved.

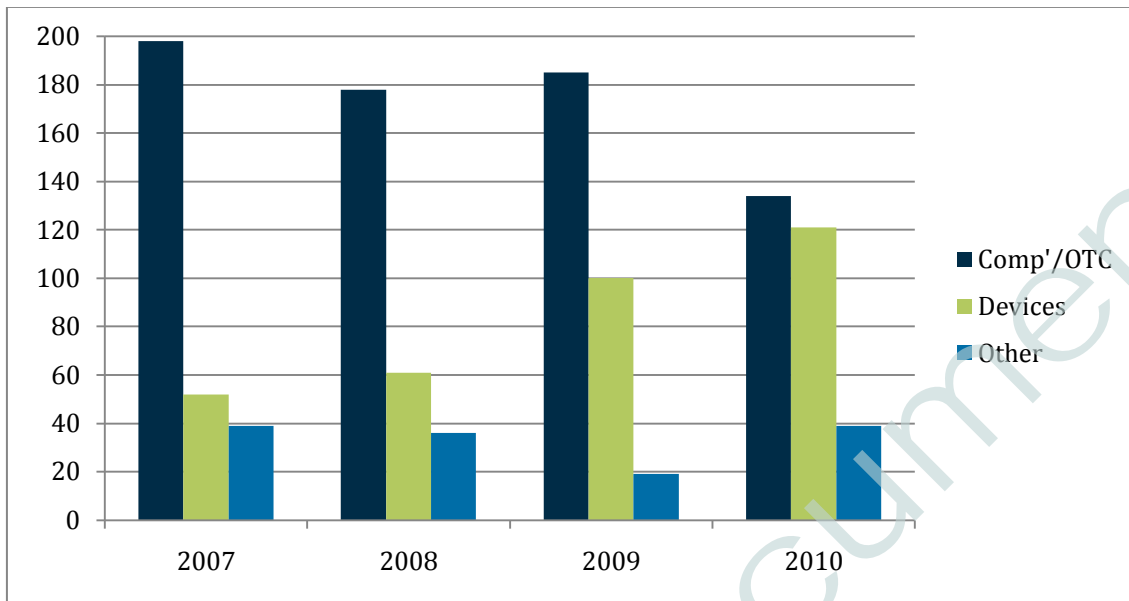
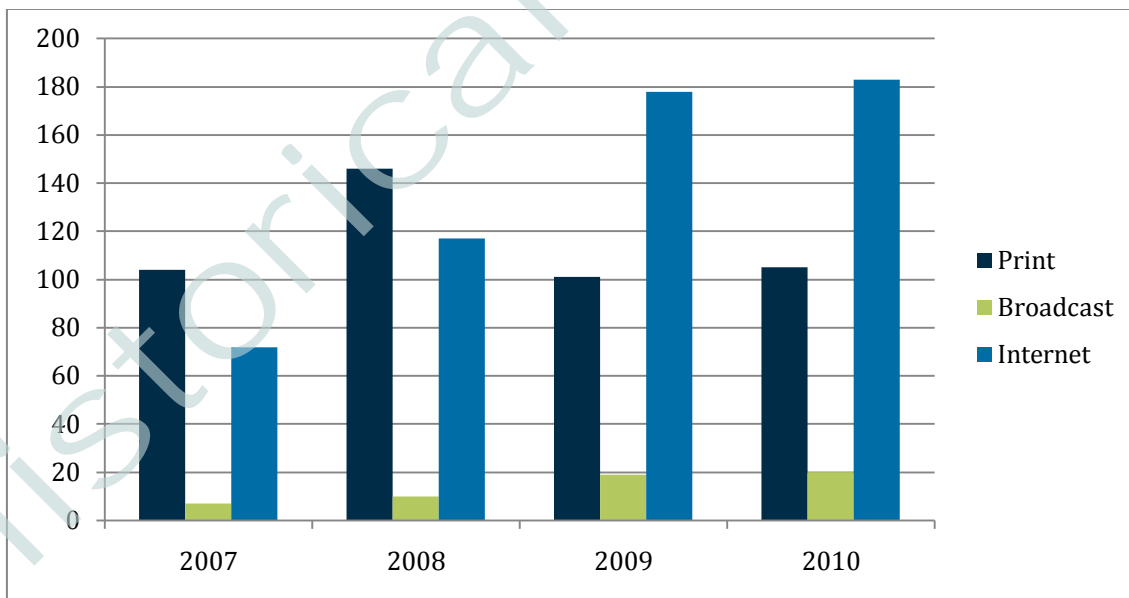
Figure 2 – Category of product involved in complaints

Figure 3 illustrates the type of media in which the advertisements that are subject to complaint are appearing. It can be seen that complaints regarding Internet advertising are steadily increasing whilst complaints relating to advertisements appearing in print media appear to be declining. This is relevant to a consideration of the effectiveness of the pre-approval process in that advertisements published on the Internet are not required to be approved.

Figure 3 – Media in which the advertisement appeared

Data provided by the CRP Secretariat for the last two years in relation to complaints received about pre-approved advertisements reveal the following:

- In 2009 and 2010, following receipt of complaints, the CRP determined that a total of 35 pre-approved advertisements were in breach of the Act, the Regulations or the Code. Table 1 summarises the nature of these breaches.
- Although a range of breaches were identified by the CRP, it is clear that the majority of breaches relate to unrealistic, misleading and unverified claims made in relation to the medicines.

Table 1 – Pre-approved advertisements breaching the Act or the Code, determined by the CRP

Section breached	Number of advertisements in breach	
Section 4(2)(a) of the Code. Must not be likely to arouse unwarranted and unrealistic expectations of product effectiveness.	8	15
Section 4(2)(c) of the Code. Must not mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions.	10	10
Section 4(1)(b) of the Code. Must contain correct and balanced statements only and claims which the sponsor has already verified.	8	7
Section 6(3) of the Code. Must contain the trade name of the goods; a reference to the approved/permitted indication(s) and where applicable, a list of ingredients or the following statement: "ALWAYS READ THE LABEL".	6	2
Section 4(5) of the Code. Comparative advertisements must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared.	3	2
Section 4(2)(d) of the Code. Must not abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.	3	2
Section 5(2) of the Code. Must not refer to serious forms of diseases, conditions, ailments or defects.	2	3
Section 4(2)(b) of the Code. Must not be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases.	2	2
Section 4(4) of the Code. Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading.	1	3
Section 4(6) of the Code. Must not contain or imply endorsement by organisations or individuals.	1	3

Section breached	Number of advertisements in breach	
Section 5(1) of the Code. Must not contain any representation regarding abortifacient action or regarding the treatment, cure or prevention of the neoplastic disease, sexually transmitted diseases, HIV AIDS and/or HCV or mental illness.	2	2
Section 6(4) of the Code. Print media advertisements must include the approval number.	4	0
Section 22(5) of the Act. Indication not on the Register.	3	0
Section 4(2)(g) of the Code. Must not contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure.	0	3
Section 4(2)(h) of the Code. Must not contain any claim, statement or implication that it is effective in all cases of a condition.	0	3
Section 4(1)(a) of the Code. Must comply with the statute and common law of the Commonwealth, States and Territories.	0	2
Section 4(2)(i) of the Code. Must not contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.	2	0
Section 4(7) of the Code. Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.	1	1
Section 42DM(1) of the Act. Must comply with the Therapeutic Goods Advertising Code.	0	1
Section 4(2)(e) of the Code. Must not contain any matter which is likely to lead persons to believe that they are suffering from a serious ailment; or that harmful consequences may result from the therapeutic good not being used.	0	1
Section 4(8) of the Code. Must not contain an offer of a sample.	0	1
Section 7(3) of the Code. Claims for weight management must have an appropriate balance between the claims and references to healthy energy-controlled diet and physical activity.	0	1

1.3 Limitations of the current pre-approvals process

The requirement for pre-approval of advertisements was introduced into therapeutic goods legislation in 1997 (*Therapeutic Goods Regulations (Amendment) 1997 No. 400*). The explanatory statement to the above amendment makes it clear that the intent of the amendment was:

'to establish a pre-clearance scheme for advertisements, about mainly non-prescription drugs, herbal remedies and like products, that are intended to be published or inserted in mainstream print media. The scheme is designed to ensure that advertisements published in mainstream media about these drugs will not include any claims that they can prevent, treat or cure major or serious medical conditions that usually require the intervention of a medical practitioner.'

1.3.1 Limited coverage - Products

Currently, prescription medicines (Schedules 4 and 8) and the vast majority of pharmacist-only medicines (Schedule 3) are unable to be advertised directly to consumers. It is generally accepted that the safe and effective use of these medicines requires the intervention of a medical practitioner and/or a pharmacist. It should be noted that there is no similar restriction on the advertising of medical devices the use of which requires the intervention of a medical practitioner.

Although advertisements for most non-prescription medicines that are directed at consumers are subject to pre-approval, there is an inconsistency in the arrangements in that advertisements directed at consumers for medical devices are not subject to pre-approval. Furthermore, an examination of the complaints received by the CRP reveals (Figure 2) that the number of complaints relating to advertisements for medical devices is similar to the number related to advertisements for medicines, and is increasing each year.

1.3.2 Limited coverage - Media

There appears to be general agreement that if the current pre-approval scheme is to continue then it would be desirable to have Internet advertising included in the scheme. As is evidenced by data on advertising complaints (Figure 3), complaints about advertisements appearing on the Internet are increasing whereas complaints about advertisements appearing in traditional print and broadcast media are declining.

Although Internet advertising for therapeutic products is widespread and growing rapidly, it is generally accepted by stakeholders that the costs of administering a process to pre-approve Internet advertising would be prohibitive.

In addition to the exclusion of Internet advertising from the pre-approval process, advertising on pay-television is also excluded from the requirement. Section 42B of the Act allows the Regulations to exempt certain means of broadcast from the requirement to broadcast only approved advertisements. The Regulations (Regulation 5BA) exempt "narrowcast transmission" from the requirement to broadcast only approved advertisements. The definition of narrowcast is found in the *Broadcasting Services Act 1992*. This was formulated for the purposes of licensing broadcasters, with the intent being to define narrowcast transmission as transmissions with limited coverage. This definition has been taken to include pay-television services such as Foxtel which is Australia's leading subscription television provider and is connected to over 1.63 million subscribing households with approximately six million viewers¹.

Given the extent of coverage of pay-television in Australia, consideration needs to be given to the appropriateness of excluding pay-television from the requirement to only transmit approved advertisements. It is likely that pay-television reaches at least as many viewers as some free-to-air

¹ Foxtel website – <http://www.foxtel.com.au> accessed 1 June 2011.

channels currently available in Australia, with advertising on these free-to-air channels requiring pre-approval.

It is clear that the current system is only serving to manage a proportion of the public health risk posed by potentially misleading advertisements for therapeutic goods.

1.3.3 The listing system (unverified claims)

A significant problem in relation to the advertising of low-risk medicines and devices arises because such products can be included on the ARTG through a process of sponsor self-certification. This system allows sponsors to enter the indications or intended purpose in relation to the products without any independent assessment of the existence or veracity of supporting evidence for these claims. Such a system allows low-risk products to be included on the ARTG with intended purposes in relation to the inclusion that have not been verified by the TGA.

Whilst such a system for an ARTG entry exists, an ARTG entry for listed medicines or lower risk medical devices cannot be considered, in itself, evidence to support claims of efficacy or performance in relation to the product.

Although advertisements that contain claims which the sponsor has not verified are in breach of the Code (and therefore Section 42DM of the Act) it is not apparent to anyone other than the sponsor that the claims have not been verified. Compliance with the Code requires that the sponsor has verified any claim appearing in the advertisement; it does not require the TGA to have verified the claim. In theory, it is only following a complaint about the advertisement, or an audit of the ARTG entry by the TGA, that the veracity of the claim and the evidence held to support it are tested.

Regulation 5F specifies that applications for approval of advertisements must be made to the Secretary in writing, in a form approved by the Secretary. Of note, the form approved by the Secretary for this purpose, includes the following statement:

'A claim/indication entered on the ARTG [the Register] will not automatically be approved as an advertising claim'.

This statement is consistent with Appendix 3 of the Code which states that listing or registration of a claim does not automatically mean that the claim may be advertised.

1.3.4 Assessment of efficacy claims as part of the approval process

The operation of the ARTG discussed above presents a complication for the pre-approval process. When considering an application for approval of an advertisement, the Secretary, or the Secretary's delegate, must consider that the proposed advertisement complies with the Code. The Code requires that the advertisement can only contain claims which the sponsor has already verified. This puts the delegate in a difficult position.

The delegate cannot approve the advertisement unless they are satisfied that the sponsor has verified any claims appearing in the advertisement. The delegate could rely on the ARTG entry as a *de facto* verification of the claims; however, independent verification of evidence in relation to claims prior to the product being listed on the ARTG is not required. It is therefore debatable as to whether the delegate can use the ARTG entry to satisfy themselves that the sponsor has verified all claims contained within the advertisement. This is confirmed by the statements appearing on the application form for advertising approval (see above). Given this, it is not unusual for the delegate to request evidence of efficacy from the sponsor so that they can satisfy themselves of the veracity of the claims contained within the advertisement². Again, this is confirmed by the Code and the application form for advertising approval which includes the following statements:

'Substantiation of all claims must be provided upon request.'

² Interview with Advertising Services Managers held on 6 June 2011.

The relevant Advertising Services Manager may request substantiation of claims (in line with levels of evidence) that the sponsor is required to hold at the time of registration or listing.

Notwithstanding the above, further substantiation may also be requested.'

This situation appears inconsistent, in that it is possible for a sponsor to list a medicine on the ARTG and to supply that medicine with unverified claims. However, unless the product has been selected by TGA for a review, it is only when the sponsor wishes to advertise the medicine in mainstream media that the evidence supporting these claims is assessed. The question also needs to be asked as to whether the delegate, for the purposes of approving advertisements, is the appropriate person to be assessing the evidence used to support efficacy claims. The delegates appointed to approve advertisements are appointed and trained to assess the suitability of an advertisement in terms of its compliance with the objects of the Code. This includes whether or not the advertisement promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer. Assessments do not extend to a detailed evaluation of the evidence used to support claims of efficacy and are more appropriately made by those specifically qualified and trained for that purpose.

1.3.5 Approved advertisements still in breach

Pre-approval of an advertisement by a delegate of the Secretary is not a guarantee that the advertisement is compliant with all of the requirements of the advertising framework. Each year a number of complaints are received in relation to pre-approved advertisements and a number of the complaints are upheld by the CRP (Table 1). The majority of these breaches relate to unrealistic, misleading and unverified claims made in relation to the medicines.

A detailed audit of approved advertisements is required in order to determine whether or not there is a systematic problem in approving certain advertisements or whether or not this is a result of a process involving the subjective assessment of social responsibility and the likelihood of an advertisement adversely impacting upon the "reasonable" person.

Such a detailed audit of the reasons that approved advertisements are found to be in breach of the advertising requirements is beyond the scope of this report.

1.3.6 Limitations imposed by delegations - split coverage

An additional potential weakness of the way in which the current system is administered is the split in responsibility between the two industry associations that are delegated to approve advertisements (see Section 1.1.3). Current delegations only allow advertisements that appear in broadcast media to be approved by ASMI. However, administrative practice requires that all advertisements for complementary medicines appearing in print media be approved by CHC. This means that for sponsors of complementary medicines wishing to advertise in broadcast and print media two separate approvals via two separate delegates are required, potentially for the same advertising content. This situation leads to potential inconsistencies between advertisements for the same product, depending on which medium is being used. This arrangement also potentially allows for the practice of "forum shopping" where sponsors will attempt to have an advertisements approved by a delegate even though an advertisement with similar content may have been refused by a delegate in the other organisation³.

1.3.7 Limitations of the delegations as they stand

The Secretary has powers to approve and refuse advertisements; however, unlike all other delegations under the Act and the Regulations, the Secretary's powers to approve or refuse advertisements have been delegated to an organisation (ASMI and CHC) rather than an individual.

³ Interviews with Advertising Services Managers held on 6 June 2011.

This situation can present a perception of bias in that it is not always clear who the ultimate decision maker is. Strict protocols exist under administrative law to ensure that a delegated decision maker reaches an independent judgement on the matter at hand. A decision maker can seek advice and assistance but should be careful to ensure that the decision they reach is their own; a decision maker cannot make a decision at the direction of another person. These procedures provide for accountability in decision making. When decisions are delegated to an organisation, there is a perception that individual decision makers may be restricted by the objectives of the organisation and may not use appropriate discretion in the making of decisions.

Both ASMI and CHC have appointed Advertising Services Managers to assess applications to approve advertisements and it is these Advertising Service Managers who are responsible for making the delegated decisions of the Secretary. Although there is absolutely no evidence to suggest that biased decision making has been a characteristic of the current arrangements, such a situation is open to the perception of bias particularly given that many of the applicants for advertising approval are members of the organisations delegated to approve the advertisements.

It should be noted that an applicant who is not satisfied with an initial decision made by the delegate of the Secretary has the right to have that decision reviewed by the Minister. However, this option is only likely to be exercised in situations where an approval has been refused.

The TGA also identified a theoretical legal mismatch between the ARTG listing process and the approval of advertisements. ARTG listing is a self-certified process whereby sponsors can certify they hold evidence for the listed claims and the Secretary must list the medicine on the ARTG. However, the Secretary must approve the content of these claims in an advertisement. This raises the question of how or why the Secretary must approve a claim to be contained within an advertisement when there is no such requirement when a claim is being included on the ARTG in relation to a listed medicine.

1.3.8 Sanctions and penalties

The sanctions and penalties in relation to breaches of the advertising requirements are reviewed in detail elsewhere (see Section 3). In the context of pre-approvals, concern has been raised that the existing sanctions and penalties regime does not provide a sufficient deterrent to prevent advertisers from breaching the legislative requirements of the framework.

1.3.9 Cost recovery

In accordance with the [Australian Government's Cost Recovery Guidelines \(2005\)](#), the costs of providing the advertising approvals services are fully recovered from the users of the services. The fees charged to users are set out in the Regulations (Schedule 9) and are designed to fully recover the cost of providing the services.

1.4 Stakeholder submissions

Stakeholder submissions regarding the current pre-approval system can be divided generally into four categories: those received from consumers; healthcare professionals; therapeutic goods industry and advertising industry. Individual stakeholder submissions are available on the [TGA website](#). Issues raised by each category of submitter are summarised below:

1.4.1 Submissions from consumers

In general, the opinion was that given the limitations of the current arrangements, the pre-approval process should be replaced by an efficient monitoring program together with effective penalties to prevent non-compliance. Of most concern to consumers was that Advertising Service Managers were not qualified to evaluate efficacy and therefore this should not be part of any pre-approval process.

1.4.2 Submissions from healthcare professionals

Healthcare professionals were in general agreement that given the lack of coverage, particularly the omission of Internet advertising, the utility of a pre-approval process in mitigating public health risk was limited. However, the burden of including Internet advertising was acknowledged and the alternative of replacing pre-approvals with effective monitoring and sanctions was generally favoured.

1.4.3 Submissions from the therapeutic goods industry

Submissions were received from various sectors of the industry and from individual sponsors and industry associations. Opinions were divided and related to industry sector. The industry associations that currently hold delegations for approving advertisements supported the current system, and both supported extending the power to approve advertisement to delegated authorities within individual sponsor companies. CHC suggested that all forms of advertisement for complementary medicines should be approved by CHC to avoid inconsistencies within the current system. ASMI suggested increasing the pre-approval requirement to cover all direct to consumer advertisements. Some industry organisations that do not hold approval delegations suggested that the system was inefficient and was biased against non-members. Individual sponsors had various views but agreed that efficacy should not be evaluated as part of the advertising process. The medical device sector felt that the current arrangements were appropriate and that medical devices should remain excluded from any pre-approval requirements.

1.4.4 Submissions from the advertising/publishing industry

This sector recommended pre-approvals be extended to advertisements for medical devices. A two-tiered system was proposed with a pre-vetting process offered as assistance and an optional pre-approval process for more complex matters with approval being a stamp of authority. Delegated authorities should also be set up outside of the industry associations.

1.5 Options for change

1.5.1 Maintain the current system

There are several options for change, with each option presenting differing risks and benefits to consumers, industry, healthcare professionals and Government.

Advertisements for medical devices and advertisements appearing on the Internet are rapidly becoming the most prevalent advertisements found to be in breach of the current advertising requirements. Whereas this can be taken as an endorsement of the current system, in that complaints about advertisements captured by the current approvals system are declining, it also serves to highlight the limited coverage of the current system.

With limited coverage there is always the possible risk that adverse health outcomes could result from advertisements that are outside of the scope of the current pre-approvals system.

1.5.2 Expand the current system

In order for a level playing field to be implemented with respect to both the products covered by the pre-approval system and the types of media required to publish or broadcast approved advertisements only, three options are set out below.



Option 1.

The range of products and the range of media need to be extended to cover advertisements for medical devices (including In-Vitro Diagnostic devices) and advertisements appearing on the Internet and pay-television.

The advantage of this proposal is that consumers would have an added level of protection from misleading advertisements for medical devices. A level playing field would also be created for all sponsors wishing to advertise their products directly to consumers.

Advertising of medical devices (whether they be low-risk consumer products or high-risk implantable devices) is controlled through a combination of Australian Consumer Law and the requirements of Sections 41ML and 42DM of the Act. This restricts advertisements for medical devices to referring only to a purpose accepted in relation to the inclusion of that device in the ARTG and requires advertisements to comply with the Code. A problem in relation to the advertising of lower risk medical devices arises because such devices can be included on the ARTG following sponsor self-certification. When lodging an application, the sponsor must certify in accordance with Section 41FD of the Act that the devices are intended for a specified purpose. Unless the application is selected for an application audit, the intended purposes certified by the sponsor are the intended purposes that appear on the ARTG in relation to those devices. Such a system has the potential to result in medical devices being included on the ARTG with intended purposes that have not been verified by the TGA. In such circumstances, that unverified intended purpose could be advertised without breaching Section 41ML of the Act. Such an advertisement may, however, breach Section 42DM of the Act which requires the advertisement to comply with the Code. Compliance with the Code requires that the sponsor has verified any claim appearing in the advertisement.

Many advertisements for medical devices are aimed directly at consumers and, given that advertisements for medical devices do not require pre-approval, there is the potential for consumers to be exposed to misleading advertisements for medical devices. Currently the only mechanism for dealing with this is a monitoring system based on complaints, rather than active monitoring, and the imposition of sanctions and penalties against the offending advertisers.

It is difficult to justify why advertisements for medical devices that are directed to consumers, and readily obtained without the intervention of a healthcare professional, should not attract the same regulatory scrutiny as advertisements for non-prescription medicines.

Likewise it is difficult to justify why, given the current extent of coverage, advertisements appearing on the Internet or on pay-television should not attract the same scrutiny as advertisements appearing on free-to-air television.

There appears to be general agreement that if the current pre-approval scheme is to continue then it would be desirable to have Internet advertising included in the scheme. As is evidenced by data on advertising complaints (Figure 3), complaints about advertisements appearing on the Internet are increasing whereas complaints about advertisements appearing in traditional print and broadcast media are declining. However, given the volume of Internet advertising, a requirement for pre-approval of Internet advertisements would necessitate considerable additional resources to be devoted to the pre-approval process.

Requiring the pre-approval of direct-to-consumer advertisements for medical devices would have resource implications for the TGA and would involve additional costs for industry. Mechanisms would need to be put in place which may, as is the case for medicines, involve co-regulatory arrangement with the medical device industry.

Whilst there is general agreement amongst stakeholders that if the pre-approval system is to be maintained it would be desirable to include Internet advertising, there is also general agreement that the burden on the system would be excessive.

It seems that whilst non-compliant Internet advertising is becoming an increasing problem, a system that requires pre-approval of Internet advertisements would not necessarily solve this problem, for two reasons. Firstly, the volume of Internet advertisements that would need approval would be prohibitive. Secondly, authority to approve Internet advertisements would only extend to Australian-based sites with the potential that non-compliant advertisements would simply be published on overseas based sites and therefore outside Australian jurisdiction.

Risks to the pre-approval process presented by the increase in workload could be managed by ensuring that the increased costs recovered as a result of increased volume of work were sufficient to cover the increase in resources required.

1.5.3 Remove the current system

Alternatively, the requirement for approving advertisement could be removed entirely. This would present a level playing field for all sponsors of therapeutic goods that are permitted to be advertised to consumers and to all publishers and broadcasters.



Option 2.

Advertisements for therapeutic goods directed at consumers should not require pre-approval but rather, rely on an efficient monitoring system and the deterrent value of appropriate sanctions and penalties for breaches of the advertising requirements.

A relatively comprehensive review of the effectiveness of the pre-approval system in preventing breaches of the Code was performed seven years ago in 2004⁴. In the absence of a more up-to-date analysis it is not possible to assess the current compliance rate for advertising of therapeutic products and the contribution of the pre-approvals process in preventing non-compliance. Further work in this aspect of the advertising framework may be warranted.

As can be seen from a review of the CRP data, pre-approval of an advertisement by a delegate of the Secretary is not a guarantee that the advertisement is compliant with all of the requirements of the advertising framework.

The major risk in removing the current requirement for pre-approval is the increased risk of exposing consumers to misleading advertisements for non-prescription medicines. This risk is difficult to assess. Although the CHF has expressed a preference for maintaining a pre-approvals system in some form, the CHF has also acknowledged that alternative mechanisms may be acceptable. Other consumers have expressed a preference for replacing the pre-approvals system with alternative mechanisms.

If the requirement for pre-approval was to be removed in its entirety then a robust system for monitoring non-compliance with the advertising requirements would need to be introduced. This would also need to be supported by an appropriately proportionate framework of penalties and sanctions that are capable of effectively deterring non-compliance.

In the absence of a pre-approvals system, both industry and consumers would need clarity as to what is acceptable advertising. This is an area where prescriptive detail of both necessary and prohibited statements would simplify and objectify the regulatory environment. The simplest way to achieve this would be to align the requirements for advertising with the information contained within the ARTG for a particular product.

⁴ Report to the TGA on the rates of compliance of advertisements for therapeutic goods with the Therapeutic Goods Advertising Code, July 2004, Deon Schoombie in association with Oceania Health Consulting. Located as Attachment 3 in the Interim Advertising Council Report, 2004 <http://www.anztpa.org/advert/iacreportoct04.pdf>

In particular, closer alignment of advertising claims with indications (or intended purposes for devices) included in the ARTG should be a primary objective of any new requirements. This is particularly so for complementary medicines where a change to coded indications and corresponding alignment of claims may do much to reduce the likelihood of unsubstantiated claims for these products.

A recognised by-product of the current pre-approvals process is that it provides a level of certainty about the legality of an advertisement for publishers or broadcasters.

Removal of the pre-approval system may be opposed by the industry associations that are currently administering the system. It could be argued that the pre-approval system plays an important role in ensuring that non-compliant advertisements do not reach the public. However, as discussed above, the current system does not cover the total number of ways in which advertisements can reach the public.

1.5.4 Alternative to the current system – limited pre-approval

A third option is also presented for consideration and this is a limited pre-approval process that is a targeted risk management procedure for “offenders only”. Here a sponsor who repeatedly breaches any of the provisions on advertising would be subject to pre-approval of all their advertising. In this model the additional cost burden of pre-approval is effectively a further sanction on an offender which would serve to minimise continued breaches by an advertiser.



Option 3.

All advertisements for therapeutic goods directed at consumers should be entered on a central database. Audit of the database could identify advertisements that breached advertising requirements. Sponsors identified as repeatedly breaching advertising requirements would need to have future advertisements pre-approved.

In May 2003, an Interim Advertising Council (IAC) was established to develop recommendations for consideration by the Australian and New Zealand governments as part of a proposal for a Trans-Tasman therapeutic products advertising scheme. The IAC reported in October 2004⁵. Reference to the IAC report provides further insight to how an option of limited pre-approval could work.

The IAC proposed that all advertisements for therapeutic products directed to consumers be entered into a central notification database to support the implementation of an effective structured and targeted monitoring and audit program.

Under a limited pre-approvals process a central notification database could be established and legislative arrangements put in place to mandate lodgement of all advertisements for therapeutic goods directed at consumers into this database. Consideration could also be given to requiring, as part of the lodgement, a certification by the sponsor that the advertisement complies with all advertising requirements.

Regular audits could then be conducted of first-time advertisements or on an as needs basis. The advertisements could either be selected at random, or targeted, with review designed to allow an independent assessment of conformity with the advertising requirements.

As part of any review, the sponsor could be requested to provide information relating to the evidence held to substantiate any claims included in the advertisement. For example: in the case where the advertisement contained a testimonial, a copy of the signed statutory declaration from the person

⁵ <http://www.anztpa.org/advert/iacreportoct04.pdf>

making the testimony could be required. Failure to supply requested information within an appropriate timeframe could result in the sponsor being required to have their advertisements pre-approved. Similarly, sponsors found to be responsible for publishing advertisements which fail to comply with the advertising requirement could be required to have all of their advertisements pre-approved. This would be particularly appropriate where repeat offenders were involved. The requirement for pre-approval could be removed once the sponsor was able to satisfy the TGA that appropriate corrective action had been taken to ensure that future advertisements complied with the requirements.

Similarly, sponsors who were found to have failed to record a notification of an advertisement directed to consumers on the central database (and potentially failed to certify compliance with the advertising requirements) could also be required to have future advertisements pre-approved.

An additional component of this model could be the automated issuing of validated lodgement numbers following the necessary self-certification of compliance with all advertising requirements. This number could be used by advertisers to assure consumers, publishers and broadcasters that they had made a legally binding statement of compliance with existing requirements.

This option would obviously require legislative change.

Industry associations that are currently involved in the pre-approvals process could redirect their resources to assisting members to comply with the new arrangements.

The absence of a pre-approval step in this option means that consumers are at an increased risk of being exposed to misleading advertisements.

2. The complaints resolution system

Although a brief exploration of the complaints handled by the complaints resolution process appears above, the discussion that follows is a more detailed analysis of the timeliness and effectiveness of the existing advertising complaints handling processes administered by the Complaints Resolution Panel (CRP).

2.1 Stakeholder submissions

Stakeholder submissions regarding the current complaints resolution system have revealed that consumers generally view the system as cumbersome and slow with multiple processing pathways, procedures and resolution bodies depending on:

- Nature of the complaint;
- Therapeutic goods sector;
- Advertising media; and
- Target audience for the advertisement.

In addition there were multiple concerns regarding perceived conflicts of interest by CRP members which have affected community confidence in the complaints handling process. Overall, this has resulted in proportionally lower participation in the complaints system by consumers compared with the therapeutic goods industry who tend to utilise the system for submitting complaints about competitor product advertising and evidence used to support therapeutic claims.

Individual stakeholder submissions are available on the [TGA website](#).

2.2 Current arrangements

The CRP was established as a committee under the Regulations and began considering complaints about the advertising of therapeutic goods in mainstream media in the first half of 1999.

The CRP consists of eight members, comprising:

- The chairperson (nominated by the Therapeutic Goods Advertising Code Council);
- Two industry representatives (Australian Self Medication Industry and Complementary Healthcare Council of Australia);
- Two consumer representatives (Choice and Consumers Health Forum of Australia);
- Three healthcare professional representatives (Australian Traditional Medicines Society; joint representative from the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia; and the Royal Australasian College of General Practitioners).

If the CRP is to consider a complaint about an advertisement for a medical device, the chairperson will nominate a ninth member with expertise in medical devices to attend. The TGA and Food Standards Australia and New Zealand (FSANZ) have an observer at CRP meetings.

The CRP considers complaints about advertisements directed to consumers for medicines and medical devices that appear in:

- Mainstream print media (such as newspapers and magazines);
- Broadcast media (radio and television);
- Cinema films;
- Outdoor billboards;
- Posters; and
- Internet.

Complaints about other forms of consumer advertising such as leaflets, flyers, letterbox drops and point of sale advertising for therapeutic goods, as well as advertising to healthcare professionals, are managed by the relevant industry associations under their individual industry codes of practice. The complaints are considered by the relevant industry associations' Code of Conduct Committee.

Complaints about other forms of advertising, for example: advertising by end users, service providers, or healthcare professionals, are managed by the TGA.

2.2.1 Submitting complaints

A person may complain to the CRP about an advertisement for a medicine or medical device that is published or inserted in specified media and is perceived to be in breach of the Code or the Act. Complaints about other advertisements must be directed to the appropriate industry association:

- CHC for complementary medicines;
- ASMI for non-complementary OTC medicines;
- Medicines Australia for scheduled medicines;
- Medical Technology Association of Australia for medical devices; and
- The TGA for complaints about other forms of advertising or about other therapeutic goods.

2.2.2 The function of the CRP

The function of the CRP is to determine whether a complaint is justified, based on the material presented. However, the CRP is not bound by rules of evidence and there is no onus of proof on the complainant. The CRP does observe the requirements of procedural fairness, giving both the complainant and the advertiser sufficient opportunity to make submissions in relation to the complaints and provide relevant documents. The CRP processes are set out under the Regulations.

2.2.3 The determinations of the CRP

The CRP has powers under the Regulations to request information relating to specific complaints and has the power to request withdrawal of an advertisement or publication of a retraction or correction statement. The CRP has no power to impose penalties or enforce sanctions as an outcome of the determinations.

If the CRP determines there has been a contravention of the Act, the Regulations or the Code, it may request, in writing, that the advertiser do one or more of the following:

- Withdraw the advertisement;
- Publish a retraction;
- Publish a correction; and/or

- Withdraw a particular claim or representation made by the advertisement, and give the CRP a written undertaking not to use that claim or representation in any other advertisement.

If the advertiser does not comply with the request within 14 days, the CRP may recommend to the Secretary one or more of the following:

- Withdrawal of approval for the advertisements (if the advertisement were of the type that required approval);
- Cancellation of Listing or Registration of the product;
- Publication of corrective advertising;
- Publication of a retraction;
- Removal of advertising material or generic information from the marketplace; and/or
- Destruction of advertising material or generic information removed from the marketplace.

Once the parties to the dispute have been notified of the CRP's decision, a copy of the final determination is published on the [complaints register section of the CRP website](#) except to the extent necessary to protect privacy or confidential information.

2.3 Limitations of the current complaints resolution system

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

- Timeliness of the processes;
- Effectiveness of the determinations; and
- Perceived conflict of interest of members of the panels, particularly the members of the CRP who represent sponsors or manufacturers who are members of the respective industry self-regulatory panels.

2.3.1 Timeliness

In many cases it can take months from the time the complaint is received by the CRP to a final determination and the advertiser indicating compliance with the sanctions imposed. Figures received from the CRP for the financial year 2010/11 indicate that the average length of time from receipt of the complaint to the determination being sent to the advertiser was 85 days.

These timelines are further extended in situations where the advertiser chooses not to comply, and the matter is referred to the TGA with recommendations to impose sanctions.

2.3.2 Effectiveness of sanctions imposed by the CRP

In cases where the CRP finds that a complaint is justified, it can make a request of the advertiser to cease publication of the advertisement and print a retraction but has no mechanisms in place to verify if the advertiser has complied with the request; and has no delegated powers under the Act to mandate compliance.

2.3.3 CRP membership and perceived conflict of interest

Concern has been expressed that the current membership arrangements (see Section 2.2) could lead to a potential source of conflict of interest, both perceived and actual. As part of the 2010 public consultation, the question was asked "Should the CRP be reconstituted as an independent body?".

The majority of respondents were in favour of retaining the current membership structure, arguing that the composition has the expertise and knowledge-base to deal with the complaints raised. Many respondents believed there were mechanisms in place to handle any potential conflicts if they arose.

2.3.4 Non-compliance with the CRP's request(s)

The CRP is empowered to recommend various courses of action to advertisers. If an advertiser refuses to comply with these recommendations, the CRP may refer the matter to the TGA, whereupon a delegate of the Secretary may make an order under Regulation 9 requiring the advertiser to comply. This process extends the period between the publication of an advertisement and any corrective action such as publication of a retraction. Approximately one third of CRP determinations are referred to the TGA after advertisers have declined to fully comply with the CRP recommendation.

There are no mechanisms for the parties affected by a CRP determination to lodge an appeal and the CRP does not have any powers under the Act to enforce any proposed action.

If an advertiser chooses not to comply with one or more requests made by the CRP, the CRP can refer the matter to the TGA with recommendations to:

- Order the advertiser to comply with one or more of the CRP requests; or
- Cancel the ARTG entry; or
- Suspend the ARTG entry.

The actions that can be requested by the CRP or referred to the TGA only relate to the person responsible for the advertisement. In many cases the advertiser is not the Australian sponsor of the therapeutic good, and sanctions against the sponsor in these situations may not be appropriate. The advertiser can delay or opt to not comply with a request of the CRP, knowing that the CRP is powerless to enforce compliance. It is arguably in the interest of the advertiser to delay compliance with a CRP request until such time as the advertising campaign is finished.

2.3.5 Repeat offenders

Each complaint received by the CRP is assessed on its merits. There are no provisions to treat repeat offenders differently to first-time offenders. Situations have arisen that have resulted in the repeated publishing of non-compliant advertisements, which may or may not result in a complaint to the CRP. If a complaint is lodged, the process of complaint handling begins again with no real effective outcome.

2.3.6 Transparency of the complaints resolution process

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

In order to improve transparency about what occurs after a complaint has been referred to the TGA by the CRP, the TGA has started to publish Regulation 9 orders on its website. These orders set out the expectations of TGA following an advertiser's non-compliance with CRP requirements.

2.4 Volume of complaints

The number of complaints dealt with by the CRP almost doubled from 152 in 2005 to 295 in 2010 (Figure 1). The reasons for the increase may be a reflection of the greater awareness of the existence of the complaints mechanism driven by media reporting; or it may reflect an increasing tendency for

industry members to utilise the system for submitting complaints about competitor advertisements. Whatever the reason for the increase, its practical effect has been an increase in the time taken for complaints to be considered.

The complaints managed by the CRP can be grouped into four main categories: complaints that are straightforward; complaints that the advertisement is misleading, but of low public health risk; complaints about the therapeutic claims or intended purpose contained within the advertisement and complaints about advertisements directed to healthcare professionals.

2.4.1 Straightforward complaints

The CRP manages many complaints about advertisements that are considered to be straightforward as they either do not breach the advertising provisions or the breaches of the Code are minor in nature and do not impact on public health.

2.4.2 Complaints about misleading advertisements

The second category of complaints relate to advertisements that are misleading or contain claims that have the potential to mislead, are inaccurate or breach the Code (other than Section 4(1) of the Code) or contain restricted or prohibited representations, but are not concerned with the fundamental question of product efficacy. These types of complaints are well suited to the CRP process. The members have the appropriate skills and diversity of expertise to manage these effectively. They can also be dealt with effectively by requesting withdrawal of representations, or requesting the publication of corrections and retractions. These complaints normally involve relatively straightforward submissions of the parties and evidence that can be assessed readily.

2.4.3 Complaints about efficacy or performance

One of the fundamental concerns regarding the current complaints resolution process is the escalating number of complaints about lack of evidence to support claims of efficacy or performance made in advertising. These complaints generally involve low-risk therapeutic goods which are entered onto the ARTG without pre-market assessment of the evidence supporting those claims by the TGA. However the CRP receives complaints that the therapeutic claims made in advertising breach Section 4(1) of the Code. This Section relates to the requirement that claims made in advertising must be already verified by the sponsor. When complaints are received in relation to breaches of this part of the Code, the CRP in considering the complaint is required to essentially evaluate the strength of the evidence to support the claims for efficacy. This is not the role of the CRP. The additional work required by panel members to review clinical and technical data has served to delay the CRP from dealing with alleged breaches of the advertising requirements.

2.4.4 Complaints about advertisements directed to healthcare professionals

Complaints about advertisements directed to healthcare professionals are routinely referred to the relevant industry association to be dealt with under their Code of Practice.

2.5 Options for change

2.5.1 Centralised administration

There is concern over the complexity of the advertising scheme and the difficulty for consumers in determining where to submit a complaint. This issue, along with the benefits of a centralised monitoring and evaluation of outcomes, support the ongoing need for a centralised mailbox for triage and distribution of complaints.

A single point of contact would be a major benefit for the consumer who has a complaint. However, there is a question of with whom and where this point would be established. Options include:

- Retain the Central Complaints Mail Box through the CRP Secretariat;
- Establish a Central Mail Box within the TGA; or
- Contract out to an independent clearing house.



Option 4.

Establish a Central Complaints Mail Box within the TGA, thereby creating a “one-stop-shop” for submitting all complaints regarding advertisements for therapeutic goods.

The TGA considers that the Central Mail Box should be located and managed within the TGA. This would improve the capacity to monitor the progress of complaints and increase transparency, as all complaints will be logged and tracked on a central database. This would also enable the TGA to determine whether the complaints relate to any other regulatory activities involving that particular therapeutic good (for example: product review, adverse event investigation, product recall).

The extension of the existing mail box to cover all complaints would have cost implications. However, this may be balanced through the improvements in monitoring the progress of individual complaints and the compilation and assessment of responses to complaints.

2.5.2 Increased public awareness

Education is required to increase public awareness of the controls on advertising, the mechanism for submitting complaints and the complaints handling process. Increased public awareness has the potential to deter or reduce misleading and deceptive marketing and advertising of therapeutic goods.

2.5.3 Dealing with complaints

Anonymous complaints should continue to be accepted. However, the default position for release of the complainant’s name where known should be changed to make it confidential except where explicit agreement of the complainant has been given to the release of their name.

Straightforward complaints should be resolved by TGA staff who manage the Central Complaints Mail Box. This would reduce the number of complaints that require consideration by the CRP, and increase the efficiency of the complaint resolution process.



Option 5.

Straightforward complaints should be dealt with directly by the TGA.

2.5.4 Dealing with complaints about advertisements that relate to efficacy

Complaints about therapeutic claims should be managed by the TGA under existing processes for reviewing ARTG entries for regulatory compliance. Under the Act, sponsors of low risk therapeutic goods must certify in the application for entry on the ARTG that they hold evidence to support any therapeutic claims included in the indications for use or intended purpose. The TGA has a program of random and targeted audits of this evidence to ensure that it does support the claims. Also, the majority of complaints of a breach of paragraphs 4(2)(a) and (c) of the Code relate to complaints about the underlying evidence rather than the advertisement, and it is arguably inappropriate for them to be handled by an advertising complaints mechanism.



Option 6.

Complaints relating to efficacy of listed medicines and complaints about the evidence to support the intended purpose for a low-risk medical device should be dealt with directly by the relevant areas of the TGA.

Complaints relating to efficacy of listed medicines should be referred to the TGA's Office of Complementary Medicine for review, and complaints about the evidence to support the intended purpose for a low-risk medical device should be forwarded to the TGA's Office of Devices Authorisation.

Consideration could be given to removing paragraphs 4(2)(a) and (c) from the Code and either inserting similar requirements into the Act; or including the provisions as conditions of entry on the ARTG. This would enable the TGA to implement appropriate regulatory sanctions for breaches of these provisions following a review of the ARTG entry.

Complaints about advertisements directed to healthcare professionals should continue to be referred to the appropriate industry body for consideration under their Code of Practice. Section 3.4.3 further discusses advertisements directed to healthcare professionals.

2.5.5 Dealing with complaints that would be more appropriately handled by the ACCC

The TGA is currently exploring whether selected categories of complaints can be handled under Australian Consumer Law.

2.5.6 Dealing with complaints based on the form of media in which the advertisement appeared

Under existing arrangements, a complaint about the same advertisement in a newspaper and in an in-store flyer must be directed to two different places, even if the substance of the advertisement and the complaint is the same.

The CRP considers complaints about individual advertisements; however these individual advertisements are usually only a part of a much broader multi-media advertising campaign. The overall message of the advertising campaign when viewed in totality often has a much stronger message than the written text or visual message in a single advertisement.

There are no provisions under the Act for the CRP to consider or impose sanctions for an advertising campaign. Sanctions imposed on a single advertisement will have minimal impact on the overall campaign.

It is time wasting and inefficient that advertisements to consumers in leaflets, brochures or shelf-talkers have to be considered by the industry associations when the same advertisement is determined by the CRP. The separation of these functions creates confusion and inconsistency, and processes should be streamlined for the purposes of accountability, transparency and ease of use for the complainant.

A central complaints mailbox will ensure consistency of approach in handling advertisements that are part of a multi-media advertising campaign.

2.5.7 Dealing with complaints about advertisements that present an unacceptable risk to public health and safety

There is currently no effective mechanism in place for urgently dealing with advertisements that are likely to present an unacceptable risk to public health and safety.

The CRP is bound by complex regulatory procedures that delay its capacity to reach judgement. Moreover, once a determination is reached, if the complaint is upheld, the CRP has no powers to enforce its determination other than referral to the TGA.

Several months can elapse between lodgement of a complaint and remedial action, during which time the advertising campaign has run its course and any potential damage to public health and safety may have already occurred.



Option 7.

Advertisements that present an unacceptable risk to public health should be dealt with, in an expedited manner, directly by the TGA.

In order to deal with a genuine public health risk in an expedited manner, the Secretary would need to be given additional legislative power to allow the Secretary to deal with complaints on his or her own motion, without necessarily having to wait for a recommendation by the CRP. Additional powers under Regulation 9(1) of the Regulations and under the Act to suspend, cancel and/or recall the advertisement would be required. Currently the TGA can only exercise the provisions of Regulation 9(1) on the recommendation of the CRP.

Such a power could be used, for example, in cases where an advertisement for a low-risk product refers to serious diseases or makes comparative claims with higher risk medicines and devices.

The Secretary's powers could also be linked to its established power to enter products on the ARTG. Conditions of registration and listing should include the requirement to comply with the Code. Failure to comply with an order would represent a breach of a condition of registration or listing and could lead to the ARTG entry being cancelled. This power could also be used to deal with repeat offenders.

2.5.8 Provision of advice in relation to potential breaches of advertising requirements

The above options are centred around providing the Secretary, or delegates of the Secretary, with the legislative powers to deal with breaches of the advertising requirements either following a complaint or on their own motion. This is entirely consistent with the exercise of other regulatory decision making powers under the Act or Regulations by delegates of the Secretary.

Consistent with other regulatory decisions it would be appropriate for the Secretary to be able to seek expert advice from an appropriately constituted expert advisory committee when making regulatory decisions in regard to the advertising of therapeutic goods. The CRP could be re-established under the Regulations as the expert Advisory Committee on the Advertising of Therapeutic Goods, whose functions are to consider advertisements and generic information and make recommendations to the Secretary⁶. Such an approach would enable the administration of the committee to be consistent with other expert advisory committees established under the Regulations creating a uniform approach to the handling of such issues as potential conflict of interest.

⁶ Consideration could be given to this committee also taking on some of the current role of the Therapeutic Goods Advertising Code Council.

**Option 8.**

Re-establish the CRP under the Regulations as the expert Advisory Committee on the Advertising of Therapeutic Goods.

An expert advisory committee could be established with the expertise appropriate to providing advice on whether advertisements are socially responsible, promote the quality use of therapeutic goods and do not mislead or deceive the consumer. The committee would not be required to provide advice on the appropriateness of evidence to support efficacy or performance claims.

2.5.9 Reducing the backlog of complaints in the queue for consideration by the CRP

The current CRP is made up of eight members and TGA and FSANZ observers. While most members have nominated an alternative member, it is not always possible for them to attend. This is particularly problematic when the representative from the medical devices industry is not able to attend as complaints about devices cannot be considered in the representative's absence.

The CRP received 325 complaints, and held 21 meetings in the financial year 2010/11. Approximately 10 to 14 complaints were considered in each meeting, with a total of about 250 complaints.

If straightforward complaints and complaints related to efficacy or performance are dealt with by the TGA, and complaints about advertisements directed to healthcare professionals were referred to the appropriate industry sector association body for consideration under their Code of Practice or Code of Conduct, then the number of complaints requiring consideration by the expert advisory committee would be significantly reduced.

2.5.10 Transparency

Complaints handling, in terms of both process and outcome should be transparent. Publishing on its website the outcomes of all complaints in relation to the advertising of therapeutic goods would achieve this and would be consistent with the recommendation about TGA's transparency.

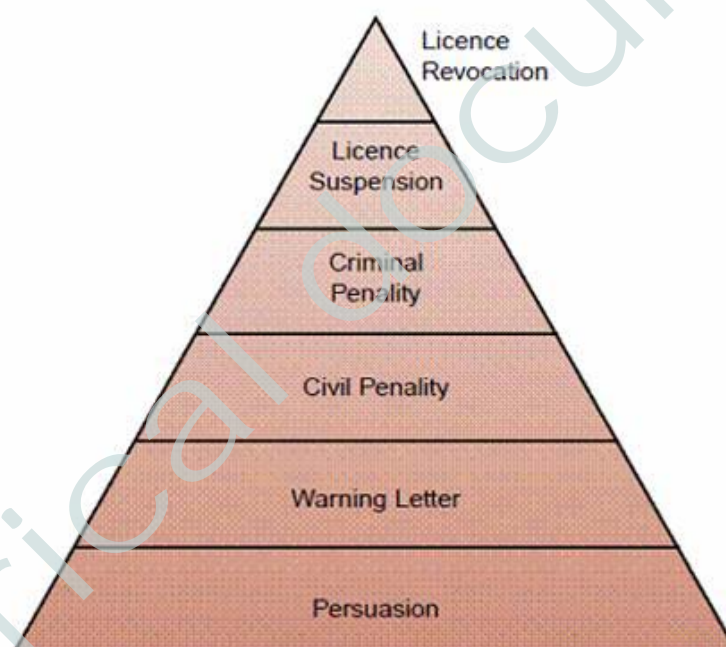
2.5.11 Resource implications

An assessment would be required of the resource implications in establishing a central complaints mailbox, providing education for consumers and healthcare professionals about changes to the regulatory framework for therapeutic goods advertising, and how to make a complaint if there are concerns about an advertisement.

3. Sanctions and penalties

The role of sanctions and penalties in promoting compliance with legislative requirements has been extensively discussed in the literature but has been best expressed through the regulatory pyramid model proposed by Ayres and Braithwaite⁷. This model describes a pyramid of regulatory compliance options commencing at the base with educational methodologies and culminating at the peak with the severest monetary and criminal penalties along with removal of privileges conferred by the legislation. The model is widely supported by a majority of stakeholders as evidenced through references to the regulatory pyramid in submissions from consumers and industry⁸.

Figure 4 – Pyramid of regulatory compliance options



Source: Ayres and Braithwaite (1992).

The adoption of this model provides a useful point of reference for consideration of the role and place of sanctions and penalties in promoting compliance with the advertising requirements of the *Therapeutic Goods Act 1989* and its subordinate legislation (collectively the Therapeutic Goods advertising legislation).

Acceptance of this model however carries important implications for this discussion. The most important is the interaction between layers. Each layer relies in part for its effectiveness on the effectiveness of the base layer. As the whole relies on a base of education, the TGA supports a much greater educational effort by the therapeutic goods industry.

⁷ Ayres and Braithwaite (1992) "Responsive Regulation: Transcending the deregulation debate".

⁸ Public consultation by the TGA on Options for The Advertising of Therapeutic Goods 2010.

3.1 Stakeholder submissions

Stakeholder submissions regarding sanctions and penalties related to breaches of the advertising requirements were generally supportive of provision of more effective sanctions and penalties to deter breaches of the advertising requirements. This is exemplified by the following:

- The need to introduce civil penalties for breaches of requirements and the sanction provisions need overall review (21 submissions received from industry associations and consumers).
- Make penalties proportionate to the business benefit of the breach (13 submissions received from healthcare professionals and industry).
- Make penalties proportionate to the risk to consumers of the breach (2 submissions received).
- Increase penalties for advertising breaches (16 submissions received from industry associations, healthcare professionals and consumers).
- The need for special penalties for repeat offenders.

Four submissions supported no changes to the current sanctions and penalties.

Individual stakeholder submissions are available on the [TGA website](#).

3.2 Current sanctions under the Therapeutic Goods Act and Regulations

In May 2006 the Act was amended to enhance the ability of TGA to secure better compliance under the Act, in order to ensure adequate protection of public health and safety. These amendments introduced new alternative sanctions or enforcement options that were more appropriate in particular circumstances to achieve better regulatory outcomes with minimum delay. This suite of sanctions includes the following:

- A tiered offences regime, which include offences of strict liability and higher penalties for more culpable conduct resulting in harm or injury. Depending on the consequences of the offending conduct, the penalties range from a maximum penalty of five years imprisonment and/or 4,000 penalty units, 2,000 penalty units for the strict liability offence, and twelve months imprisonment and/or 1,000 penalty units.
- High level of penalties for specified breaches of the Act, in particular in relation to those breaches of requirements that address public health risks.
- Alternative verdicts for various tiered offences to the effect that if the jury acquits a person of an offence specifying an aggravating element, but is satisfied beyond reasonable doubt of facts that prove that the person is guilty of a lesser offence with no aggravating element, the jury may convict the person of the lesser offence.
- A civil penalty regime for breaches of the Act which provides for a maximum penalty of 5,000 penalty units for an individual or 50,000 penalty units for a body corporate in most cases.
- Infringement notices for strict liability offences under the Act and for breaches of civil penalty provisions.
- The provision of enforceable undertakings to remedy breaches of regulatory requirements, or give undertakings not to engage in future conduct that would breach regulatory requirements.
- Extension of the liability of a body corporate to executive officers who are directly involved in the day-to-day management of the company.

However, these amendments did not apply to advertising requirements under the Act as they were being reviewed at that time.

3.3 Limitations of the current sanctions and penalties related to advertising

The unamended sanctions and enforcement strategies for advertising breaches maintain significantly lower pecuniary penalties applying to advertising breaches or contraventions. The advertising breaches attract a maximum penalty of 60 penalty units compared to other comparative breaches under the Act which attract up to five years imprisonment and/or 4,000 penalty units, or twelve months imprisonment and/or 1,000 penalty units for offences which do not require culpable conduct resulting in harm or injury to any person.

In view of the low penalty levels for advertising breaches no prosecution has ever been commenced by the Commonwealth Director of Public Prosecution (CDPP). However, if prosecution is commenced and the defendant found guilty of the offence, it would be unlikely for the court to impose the maximum penalties which in this case is \$6,600 for an individual or \$33,000 for a company. This is because this maximum penalty will only be imposed where the person is a repeat offender and the consequence of the prohibited action was a serious public health risk.

In view of the low level of penalty, and in accordance with prosecution policy, the CDPP may refuse to commence proceeding even if there is a strong case. Offence provisions which attract low level penalties may be assessed by the CDPP as being a trivial offence or they may consider that there may be other available and effective remedies instead of commencing a prosecution proceeding.

Regulation 9 authorises the Secretary to order a person to do one or more actions in relation to an advertisement or generic information about therapeutic goods. This is the only legal basis for the Secretary to order particular actions in relation to an advertisement. It is not always the case that the advertiser is the sponsor of the therapeutic goods. These actions include: withdrawal of an advertisement, publication of a retraction, publication of a correction, recovery of any advertisement or generic information, destruction of an advertisement or generic information and withdrawal of a particular claim or representation made by the advertisement or generic information. However, these actions can only be ordered by the Secretary on the recommendation of the CRP. The actions that the Secretary can order is limited by the actions that the CRP has recommended. If new breaches are identified by the Secretary, the Secretary is unable to raise these new breaches and may need to wait until another complaint is received by the CRP before the Secretary can order an action to stop the regulatory breach. Consideration by the CRP can take time and therefore limit the authority of the Secretary to deal with complaints about therapeutic goods in a timely and effective manner.

3.4 Options for change

3.4.1 Advertising to consumers

The TGA proposes a stepwise, public health risk-based enforcement model as expressed in the papers by Ayres and Braithwaite (1992).

The public health risk for each offence should be identified and a range of sanctions and penalties for each prohibited action should be provided to effectively manage that level of risk for each offence. The provision of pecuniary penalties such as civil penalties, infringement notices and enforceable undertakings, as alternative sanctions to prosecution, are also proposed.

The level of penalties and available sanctions for each offence and civil penalty provisions should provide an indicator of the regulatory and public health importance of that breach or contravention. Such an approach would also provide guidance for assigning resources and priority to each individual advertising breach reported for regulatory consideration.



Option 9.

The levels of penalties for breaches of the advertising requirements should align with comparable offences and civil penalty provisions in other Commonwealth legislation.

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

Provisions applying to conduct by directors, servants and agents and relevant provisions of the *Criminal Code 1995* such as infringement notices, enforceable undertakings or application to an executive officer of a body corporate should apply to breaches of advertising requirements. It is proposed that infringement notices will apply to strict liability offences and civil penalty provisions. The level of pecuniary penalty under the infringement notice scheme would be 20 per cent of the maximum penalty for the offence provision and 5 percent of the maximum pecuniary penalty for a civil penalty provision.

Each identified advertising behaviour associated with a public health risk should be included in an offence or civil penalty provision that signals the regulatory effort needed to mitigate that risk. For example: advertising a therapeutic good containing a substance included in Schedule 4 of the current Poisons Standard to consumers. The sanction or penalty should be comparable with equivalent risks and their mitigation strategies in other Australian and Commonwealth legislation.



Option 10.

Introduction of a general offence and civil penalty provision for breaching the principles of the Code.

A general offence and civil penalty provision is proposed for breaching the principles of the Code. This is in preference to specific penalties for breaches of specific provisions of the Code.

A corollary of these proposals is the intent of exemptions from, or defences to an offence must be clear in their intent and must not compromise the intended application of the offence.

The TGA proposes greater flexibility to allow the Secretary to deal with complaints on his or her own motion, without necessarily having to wait for a recommendation by the CRP. This will enable the Secretary to deal in a timely manner with complaints about therapeutic goods that pose serious public health risks. This would also allow the Secretary to consider and order actions in relation to advertisements of all therapeutic goods and without the restriction imposed on the jurisdiction of the CRP.



Option 11.

Introduction of a greater flexibility to allow the Secretary to deal with complaints on his or her own motion.

There are circumstances where the person ordered by the Secretary under Regulation 9 ignores the order. Where the therapeutic goods are not entered in the ARTG there are no alternative sanctions to enforce against the person who has breached the advertising requirements. The TGA therefore proposes the provision of sanctions against persons who ignore the orders of the Secretary in relation to an advertisement about therapeutic goods.



Option 12.

Introduction of sanctions against persons who ignore the orders of the Secretary in relation to an advertisement about therapeutic goods.

To enable the TGA to respond quickly to an advertising campaign that breaches regulatory requirements, consideration could be given to a provision enabling the TGA to seek an injunction from the Federal Court to restrain conduct that contravenes relevant advertising provisions. An injunction could also be available for conduct that constituted attempting, assisting or being knowingly concerned with a contravention. Section 80 of the *Competition and Consumer Act 2010* provides a suitable model for this provision.

3.4.2 Resource implications

A change to the formulation of offences and the introduction of new sanctions has resource implications for the TGA. Enforcement guidelines will need to be prepared and implemented. Additional investigational and legal resources will be required to carry through to sanction or prosecution as appropriate.

Infringement notices and enforceable undertakings require active management in the same way as any other contract. This will require staff with the requisite experience and knowledge.

3.4.3 Advertising to healthcare professionals

The responsibility for regulating the advertising of therapeutic goods does not reside solely with the TGA. The ACCC is responsible for the administration of the *Competition and Consumer Act 2010*, the objective of which is to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection. In addition, the *National Registration and Accreditation Scheme 2010* (NRAS) has established a national scheme for the protection of the public by ensuring that only professionals who are suitably trained and qualified to practise in a competent and ethical manner are registered. These objectives clearly differentiate between the protection of public health (TGA), the economic protection of consumers (ACCC), and the practice of healthcare providers (NRAS), respectively. Application of this principle would aid and guide regulatory effort by each agency, bring certainty to industry and clarify the regulatory roles for consumers and healthcare providers.

Accordingly the TGA recommends that the therapeutic goods legislation is amended to implement this intent. As a result, the use of Schedule 1 of the Regulations to identify healthcare professionals for the purposes of the therapeutic goods advertising legislation should be phased out and replaced with references to healthcare professionals accredited through the NRAS. These changes would be seen as an important improvement by all stakeholders. For example: a specific offence of advertising a therapeutic good containing Schedules 3, 4 8 or 9 substance to a consumer for a therapeutic purpose could be created.

4. Recommendations

4.1 The future of pre-approval

On balance, the TGA recommends that the requirement for mandatory pre-approval of advertisements for non-prescription medicines should be retained.

The scope of the current system should be extended to cover advertisements for medical devices that are directed to consumers and to cover pay-television advertising.

4.1.1 Efficacy claims

A fundamental problem with the current system of pre-approval relates to the treatment of efficacy and performance claims appearing on the ARTG and the treatment of efficacy and performance claims permitted in advertisements. The delegates appointed to approve advertisements assess the suitability of an advertisement in terms of its compliance with the objects of the Code. The Code includes the requirement that advertisements contain only claims which the sponsor has already verified. Given that the delegate cannot rely entirely on the ARTG entry to assure themselves that the sponsor has verified all claims that appear in the ARTG, the delegate is placed in a difficult position of having to assess whether or not the sponsor has verified the claims proposed in the application for approval. The TGA considers that such an assessment is more appropriately made by those specifically qualified and trained for that purpose and appointed as delegates of the Secretary for that purpose.

4.1.2 Delegations

For sponsors of complementary medicines wishing to advertise in broadcast and print media, two separate approvals via two separate delegates are required. To prevent the potential for forum shopping, it is recommended that the same delegate has authority to approve advertising content irrespective of the type of media in which the advertisement is to appear.

4.1.3 Transparency of operation and costs

It is recommended that arrangements are put in place to ensure that the various advertising approval services are undertaken in a manner consistent with the [Australian Government's Cost Recovery Guidelines \(2005\)](#).

4.2 Complaints resolution

In considering previous reports and the outcomes of the advertising consultation process of June 2010, the TGA recommends that a Central Mail Box be established within the TGA as a one-stop point for all advertising complaints.

Straightforward complaints should be resolved by TGA staff who manage the Central Complaints Mail Box.

Complaints relating to efficacy of listed medicines should be dealt with outside the advertising complaints resolution process and referred to the TGA's Office of Complementary Medicine for review. Complaints about the evidence to support the intended purpose for a low-risk medical device should be forwarded to the TGA's Office of Devices Authorisation.

Complaints about advertisements that may pose a significant risk to public health should be dealt with immediately by the TGA.

These recommendations require providing the Secretary with the legislative powers to deal with breaches of the advertising requirements either following a complaint or on his or her own motion. It is recommended that the CRP is retained with the expertise appropriate to providing advice on whether advertisements are socially responsible, promote the quality use of therapeutic goods and do not mislead or deceive the consumer. The CRP should not be required to provide advice on the appropriateness of evidence to support efficacy or performance claims.

It is recommended that complaints about advertisements directed to healthcare professionals should continue to be referred to the appropriate industry body for consideration under the relevant Code of Practice.

4.3 Sanctions and penalties

The TGA recommends exploration of the greater use of infringement notices based on strict liability offences and civil penalty provisions and enforceable undertakings provided for under the Act. The introduction of cumulative penalties should also be considered for repeat and serial offenders.

The TGA proposes consideration be given to the level of penalties imposed under the existing advertising offence provisions being increased consistent with comparable breaches of other requirements under the Act. The TGA also proposes corresponding civil penalty provisions in relation to the identified offence provisions.

The following table summarises the existing offence provisions and the proposed penalty provisions. Overall a proposed increase in the level of penalties to be imposed in relation to breaches of the advertising requirements and a corresponding civil penalty provision in relation to the same prohibited conduct is recommended.

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 4,000 penalty units (b) Normal offence – 12 months imprisonment and/or 1,000 penalty units (c) Strict liability offence - 500 penalty units	For an individual – 5,000 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 – 1,000 to 1,250 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)	(a) Offence for culpable conduct resulting in harm or injury – 5 years imprisonment and/or 4,000 penalty units Strict liability offence - 500 penalty	For an individual – 1,000 to 1,250 penalty units For a body corporate - 10,000 to 12,500 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
	(d)	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 4,000 penalty units (b) Strict liability offence - 500 penalty units	For an individual – 5,000 penalty units For a body corporate - 50,000 penalty units
Section 42DL <i>Publication or broadcast of advertisement containing restricted or prohibited representations, reference to prescription medicines, biologicals or unapproved products, etc.</i>	60 penalty units	1,000 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 – 5,000 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 4,000 penalty units Strict liability offence - 1,000 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 – 5,000 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 – 5,000 penalty units For a body corporate - 50,000 penalty units

APPENDIX 1 - Acronyms

ACCC	Australian Competition and Consumer Commission
ASMI	Australian Self Medication Industry (Association)
ARTG	Australian Register of Therapeutic Goods
ATMS	Australian Traditional Medicines Society
CDPP	Commonwealth Director of Public Prosecution
CHC	Complementary Healthcare Council of Australia
CHF	Consumers Health Forum of Australia
CRP	Complaints Resolution Panel
DoHA	Department of Health and Ageing (Australia)
FSANZ	Food Standards Australia New Zealand
GMiA	Generic Medicines Industry Association
IAC	Interim Advertising Council
NCCTG	National Coordinating Committee on Therapeutic Goods
NRAS	National Registration and Accreditation Scheme 2010
OTC	over the counter
PGA	Pharmaceutical Guild of Australia
PSA	Pharmaceutical Society of Australia
RACGP	Royal Australasian College of General Practitioners
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
the Act	Therapeutic Goods Act 1989
the Code	Therapeutic Goods Advertising Code
the Regulations	Therapeutic Goods Regulations 1990
the Secretary	the Secretary, Department of Health and Ageing

Historical document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605

www.tga.gov.au

Reference/Publication #