



**TGA Consultation
Regulation Impact Statement:
Regulating the advertising of
therapeutic goods to the general
public**

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About CHOICE

CHOICE exists to unlock the power of consumers. Our vision is for Australians to be the most savvy and active consumers in the world.

As a social enterprise we do this by providing clear information, advice and support on consumer goods and services; by taking action with consumers against bad practice wherever it may exist; and by fearlessly speaking out to promote consumers' interests - ensuring the consumer voice is heard clearly, loudly and cogently in corporations and in governments.

To find out more about CHOICE's campaign work visit www.choice.com.au/campaigns and subscribe to CHOICE Campaigns Update at www.choice.com.au/campaignsupporter

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Introduction

First, CHOICE has been long concerned with the protracted history of advertising regulatory reform, especially with respect to the promotion of complementary medicines (Table 1).

Table 1. History of advertising regulatory reform

Date	Initiative
2002	Report of a Review of Advertising Therapeutic Products in Australia and New Zealand
2003	Report of Expert Committee on Complementary Medicines in the Health System
2005	Description of the joint (Trans-Tasman) regulatory scheme for the advertising of therapeutic products
2007	Consultation - draft (Trans-Tasman) advertising rule
2008	MJA paper. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia
2010	TGA Consultation: Improving advertising arrangements for therapeutic goods http://www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm
2011	Consultation and Report of the Working Group on Promotion of Therapeutic Products Report of the Review to improve the transparency of the Therapeutic Goods Administration ANAO Report. Therapeutic Goods Regulation: Complementary Medicines TGA reforms: A blueprint for TGA's future
2012	Delivering reforms - Implementation plan for TGA Reforms TGA Advertising regulatory framework: Options for reform
2013	TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public

Opposition to reform proposals by vested interests appears to have produced regulatory procrastination. CHOICE is concerned that this process is continuing. To our knowledge, there are at least three current public petitions^{1,2,3} produced by naturopaths, herbalists, homeopaths,

¹ Petition: Stop the TGA and big pharma controlling information on botanical medicine and vitamins.
<http://www.communityrun.org/petitions/stop-the-tga-and-bigpharma-controlling-infomation-on-botanical-medicine-and-vitamins>

² Petition: Therapeutic Goods Administration (TGA) Australia: Stop the proposal to delete Naturopathy.
<http://www.change.org/en-AU/petitions/therapeutic-goods-administration-tga-australia-stop-the-proposal-to-delete-naturopathy>

supported by Blackmores⁴, opposing several of the reforms suggested in the latest consultation document.

Secondly, CHOICE supports the objectives of the reforms:

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

Third, we comment on the specific proposals put forward.

Proposal 1: Alternatives to the pre-approval scheme

We support option 4 (c), modified by option 2. This would mean that the TGA, not delegates from two industry associations, would undertake pre-approval for an extended range of media (adding pay-tv) and types of advertisements (adding medical devices that are promoted to the public).

Adding advertisements for medical devices to the approval process would provide important protection to the public as complaints in this area have substantially increased over recent years and in 2011-12 accounted for 43% of the 373 complaints determined by the Complaint Resolution Panel (CRP).⁵ See also our comment on Proposal 5.

TGA staff assessing pre-approvals would provide the expertise currently lacking in industry delegates to assess claims of efficacy, would eliminate inconsistency between the two industry delegates currently employed and ensure that advertisement approval, sponsor submitted ARTG indications and post-marketing product reviews were all assessed under a common framework.

Industry concern about the increased costs of expanding the pre-approval process and adequately resourcing the TGA to ensure timely approvals would be offset by the greater certainty that TGA approval would provide and also an expected reduction in the number of complaints submitted to the CRP (or its successor).

The concern about a potential conflict of interest arising from the TGA being involved in both the approval and complaints handling processes could be resolved by separating these functions administratively and establishing an independent expert advertising advisory committee to oversee both processes (see below).

³ Petition: Detrimental impact on naturopaths if advertising is changed through TGA.

<http://www.communityrun.org/petitions/detrimental-impact-on-complementary-medicine-health-professionals>

⁴ Blackmores: Your Profession is Under Threat – Action Needed Now! <http://tinyurl.com/kqbhulj>

⁵ Complaint Resolution Panel. Summary of complaints for the financial year 1 July 2011 – 30 June 2012. <http://www.tgacrp.com.au/uploaded/File/ComplaintsSummaryFor2011-2012.docx>

Proposal 2: The complaints handling process

We support option 2 (a), all complaints to be handled by the TGA. This eliminates concerns expressed about the CRP, removes duplication in the current system and would allow earlier identification of repeat and major offenders and advertisements posing a high risk to public health and safety.

However, the TGA must be properly resourced in order that complaints received are processed in a timely and transparent manner. There is currently great concern at the time taken by the TGA to process referrals by the CRP for non-compliance. The CRP has stated, 'Regulation 9 orders issued by TGA for advertising complaint determinations finalised by the Panel after 1 November 2010 will be publicised on the TGA's website'. Since November 2010 at least 88 complaints have been referred to the TGA by the CRP because of non-compliance of which only 14 have an 'outcome' recorded on the TGA website. This does not engender confidence in the TGA's ability to deal with all complaints in a timely and transparent manner.

In addition, some of these 'outcomes' merely record years of continued non-compliance with CRP and/or TGA Regulation 9 orders, for example, Bayer's Berocca Performance (Complaint No. 2010-10-017), and Homeopathy Plus (Complaint No 2011/05/004).⁶ This highlights the current impotence of the TGA with respect to imposing timely and effective sanctions on advertising violations, a matter addressed in Proposal 4, option 2.

To reduce the concern expressed about a potential conflict of interest coming from the TGA being involved in both the approval and complaints handling processes these functions should be separated administratively. One possibility would be the Market Authorisation Group approving advertisements with the Monitoring and Compliance Group handling complaints. In addition, setting up an independent expert advertising advisory committee to oversee both processes would also assist, as suggested in proposal 3, option 2.

Proposal 3: Provision of advice in relation to advertising matters

We support option 2, establishing a statutory expert advertising advisory committee to replace the current CRP and Therapeutic Goods Advertising Code Council. Its role would be to oversee the TGA advertising approval and complaint handling process, provide advice to the Secretary about these matters and also about any changes needed to the Therapeutic Goods Advertising Code. This committee could also deal with applications for restricted representations and other advertising applications such as approvals to advertise "pharmacist-only" medicines (see proposal 7).

Proposal 4: Investigation and enforcement powers

We support option 2, enhanced investigative and enforcement powers. These have been long needed and long awaited (see Table 1 above). It is hard to know why this proposal has taken so long to implement although opposition from vested interests and lack of political will are clearly relevant factors.

⁶ Decisions under Regulation 9 of the Therapeutic Goods Regulation 1990 in relation to complaints about advertisements. <http://www.tga.gov.au/industry/advertising-reg9.htm>

Currently, the TGA is regarded as a paper tiger with respect to policing advertising violations directed at consumers. The lack of TGA enforcement powers have produced a proliferation of shonky products in the market place and a race to the bottom by sponsors, because they know that if they don't take advantage of the lax regulatory environment, others will. The end result is that consumers are being ripped off by numerous products that make promotional claims that cannot be substantiated. Sponsors of evidence-based products are also being put at a disadvantage because it is difficult for consumers to separate the evidence-based wheat from the promotional hype.

We reiterate, option 2 must be implemented as a matter of urgency to ensure consumer protection and TGA credibility.

Proposal 5: Advertising of higher risk medical device

We support option 2, prohibit the advertising of higher risk medical devices including Class 4 in vitro diagnostic devices (those with a high public health risk).

Naturopaths have expressed concern that this measure will reduce access to their tools of the trade because they will not be able to advertise various diagnostic and therapeutic techniques. However, many of the dubious devices⁷ used by naturopaths are Class I (low risk) devices, for example ear candles to remove wax⁸ or have not been included on the ARTG such as the Hemaview® live blood analysis machine. So, by itself, this proposal is not going to “remove naturopath’s tools of trade”. However it may produce a useful evidence-based debate about the efficacy of these “tools’ and how they are promoted.

Proposal 6: Advertising directed to health professionals

We support option 2, update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the Health Practitioner Regulation National Law.

This proposal has created the greatest opposition from naturopaths, herbalists, homeopaths and Blackmores.¹⁻⁴

Currently, “health professionals” are defined in the *Therapeutic Goods Act 1989*, s.42AA, both as practitioners registered under the National Registration Accreditation Scheme (NRAS) administered by AHPRA and also complementary practitioners such as herbalists, homoeopaths, naturopaths, who are members of an Australian branch of one of the bodies listed in Schedule 1 of the Regulations.⁹

Proposal 6, option 2 replaces the current list in Schedule 1 with reference only to AHPRA registered health practitioners, thereby excluding herbalists, homoeopaths, naturopaths and other complementary medicine practitioners who have not gained AHPRA registration. This

⁷ CHOICE: Alternative diagnostics. <http://www.choice.com.au/reviews-and-tests/food-and-health/general-health/therapies/dodgy-diagnostics.aspx>

⁸ ARTG no: 185554 - Alnet Health & Detox - Naturhelix Ear Candles - Applicator, ear, single use; assisting in cleansing the ear of wax and impurities.

⁹ Extract from the Therapeutic Goods Act 1989. <http://www.tga.gov.au/industry/advertising-schedule1-explained.htm#att1>

would mean that advertising to practitioners not registered by NRAS would be regulated in the same way as advertising to the general public.

Advertisements directed to the general public (whether published by or on behalf of the sponsor or a healthcare professional) must comply with a range of requirements specified in the Act, including the Therapeutic Goods Advertising Code which prohibits false, misleading and socially irresponsible advertising of therapeutic goods. The Code also prohibits reference to serious forms of conditions which require the diagnosis and/or management of a healthcare professional (among other matters).

In contrast, advertisements directed to “health professionals” are exempt from TGA advertising requirements¹⁰ on the grounds that health professionals have the requisite knowledge to separate promotional wheat from chaff (an assertion that is often disputed¹¹). In addition, TGA advertising requirements do “not apply to advice or information given directly to a patient by a healthcare professional, in the course of treatment of that patient”. Promotion to health professionals are subject to industry Codes of Conduct (of which there are many, regrettably with varied standards).

The TGA’s rationale for Proposal 6, Option 2 is that they are not assured that non-NRAS registered health practitioners are able to exercise specialist judgement when either treating patients with advertised therapeutic goods, or advising them about the use of advertised therapeutic goods.

This appears to be the main point of contention by the naturopaths, herbalists, homeopaths and Blackmores who are vigorously opposing this option. They argue that complementary health care practitioners are educated and approved by government in both the higher education as well as the vocational education and training sectors. They note that many complementary medicine courses are based on degree level science and subject to ongoing continuing education and regulatory measures via their professional organisations. In addition, they point out that many NRAS professions such as Optometry, Physiotherapy and Podiatry have no training in complementary medicine and yet would be able to receive promotional material and give advice that qualified complementary professionals could not.

The reality is that naturopaths, herbalists and homeopaths have not achieved national registration for a number of reasons¹² including the plethora of organisations that represent them and their many and varied educational and professional standards. It is acknowledged that there are well trained complementary health care practitioners whose practice is evidence-based and who know when and whom to refer patients appropriately. However, there are many others who use shonky diagnostic and therapeutic techniques⁷ such as bio-impedance analysis and live blood analysis and are unaware of their limitations.

In short, proposal 6, option 2 is appropriate. False, misleading and socially irresponsible advertising of therapeutic goods should be prohibited as should giving advice about serious conditions that require the diagnosis and/or management by an AHPRA-registered healthcare

¹⁰ Schedule 1 of the Therapeutic Goods Regulations explained. <http://www.tga.gov.au/industry/advertising-schedule1-explained.htm>

¹¹ Spurling GK, Mansfield PR, Montgomery BD, et al. Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. PLoS Med 2010; 7(10): e1000352. doi:10.1371/journal.pmed.1000352. <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000352>

¹² Wardle J. Reining in cowboys of complementary medicine. The Conversation, April 1, 2011. <http://theconversation.com/reining-in-cowboys-of-complementary-medicine-242>

professional. This proposal may also provide the stimulus required for the complementary health care professions to get their act together to achieve registration status.

Proposal 7: Advertising of Pharmacist-Only medicines

We support option 2: transfer from the scheduling framework the responsibility for approving advertising of Pharmacist-Only (Schedule 3) medicines to the general public.

This implements an outstanding deferred recommendation from the 'Galbally Review' (2001) and allows all therapeutic goods advertising functions to be administered by the area within the TGA responsible for overseeing the advertising regulatory framework

Proposal 8: The Price Information Code of Practice

We support option 2, provide legislative underpinning to the Price Information Code of Practice. This replaces a document that is only mandated in some states and territories with a new Commonwealth legislative instrument that will provide greater clarity, consistency and compliance.