

Position Paper and Consultation on the Promotion and Advertising Arrangements of Therapeutic Goods in Australia: A Response

Summary

While many of the measures proposed have merit I have the following major concerns:

- A reliance on industry self-regulation (which has proven to be weak and self-serving);
- Apparent failure to involve other stakeholders, especially consumers and health professionals, in developing the common high level set of Code principles proposed;
- The focus on the promotion of so-called "higher-risk" medicines and medical devices to health practitioners which ignores the fact that most of the problems in this area come from the promotion of "lower-risk" complementary medicines and medical devices to the general public. In addition, the current Code of Conduct of the Complementary Healthcare Council of Australia is arguably the weakest and least transparent of all industry Codes but this problem is ignored;
- The suggestion of referring all complaints about "efficacy" to the TGA when this organisation has a proven track record of non-responsiveness and non-transparency in complaint handling (although they do keep promising to do better).

The Consumers Health Forum and others have proposed that the current complex and convoluted co-regulatory system for therapeutic promotion would be better simplified and unified by creating one overarching principles-based Code applicable to all therapeutic claims and promotional practices supported by one monitoring process, one complaint (and appeal) process and one set of effective sanctions, including corrective advertising orders and fines related to the sales income of the product and company involved.

The system should be funded by government and administered transparently by an expert independent committee representing the therapeutic goods sector, the advertising industry, consumers, healthcare professionals and government. Specific panels could deal with promotional activities targeting health professionals on the one hand and consumers on the other.

The system should have a legislative base in the Therapeutic Goods Act &/or regulations and be capable of being enforced. This would meet the requirements of the 2007 World Health Assembly Resolution (60.16.5) on Rational Use of Medicines that urged Member States (including Australia) to, "Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines and to monitor promotion of medicines".

Introduction

On June 30, 2010 the Parliamentary Secretary for Health, Mark Butler "launched" two related initiatives at the National Medicines Policy Partnership Forum: a position paper on the promotion of therapeutic goods and a consultation paper on advertising arrangements.

- <http://www.health.gov.au/internet/main/publishing.nsf/Content/regulatory-policy-governance-publications>
- <http://www.tga.gov.au/regreform/cons-advertising.htm>

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The former was produced by the Regulatory Policy & Governance Division of the Department of Health and Ageing (DoHA) while the latter was produced by the Regulatory Reform Section of the Therapeutic Goods Administration (TGA).

The two papers are welcomed in the light of concern that the current co-regulatory system for the control of the promotion of therapeutic goods in Australia has significant flaws. I also welcome the invitation to respond. Because the papers are related I have provided a combined response which I ask to be placed in the public domain on the TGA's web site.

Position Paper on the Promotion of Therapeutic Goods

The paper states that the government's preferred position is, "that industry strengthen and standardise self-regulation through developing an industry framework for universal adherence to consistent industry-wide codes based on a common set of high level principles".

Comment:

- This position ignores the fact that other stakeholders, especially consumers and health professionals, are the recipients of therapeutic goods promotion and as such should be involved in formulating the principles to which industry-wide Codes should adhere. All stakeholders were involved in formulating the World Health Organization *Ethical Criteria for Medicinal Drug Promotion*.
- It also ignores the partnership concept on which Australian Medicines Policy is based.
- Self-regulatory Codes are inevitably self-serving. While the views of external stakeholders are now sought, most of their suggestions are ignored in Code revisions. For example, action by the Australian Competition and Consumer Commission (ACCC) was required before Medicines Australia (MA) Code disclosed, "education and hospitality expenses" (stimulated by external stakeholders). MA still refuses to disclose payments to health professionals. In contrast, the U.S. Physician Payment Sunshine Act now requires yearly reporting of all physician payments (cash or kind) over a cumulative value of \$100 dollars. In addition, the maximum fines imposed by MA for Code breaches (\$300,000) are relatively modest and unlikely to be a significant deterrent. For example, Pfizer Australia had 16 complaints upheld against MA Code over 2005-09; fines averaged only A\$55,000. This is in contrast to the U.S. Justice Department who recently fined Pfizer A\$2.7 billion for unethical conduct. In another example, the Generic Medicines Industry Association (GMiA) Code currently only requires member companies to provide public details of spending on sponsored events for prescribers; not pharmacists, despite acknowledging that pharmacists are preferentially targeted. The maximum fine for a severe breach of the GMiA Code is \$40,000.

The paper only addresses the promotion of so-called high-risk therapeutic products, "(prescription medicines, higher risk over-the-counter medicines and higher risk medical devices) more likely to direct promotional activities to health care professionals". It states that, "Promotion of lower risk listed therapeutic goods will continue under the current self-regulatory arrangements."

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Comment:

- Ironically, the major concern about the current co-regulatory system for the control of the promotion of therapeutic goods in Australia is the promotion of so-called “lower-risk” listed medicines and devices to consumers^{1,2} not the promotion of “higher-risk” products to health professionals who could also be expected to have more critical appraisal skills.
- I do not understand the term, "higher risk over-the-counter medicines"? I understood that all OTC medicines were regarded as "relatively low risk".
- The Complementary Health Care Council of Australia (CHC) Code of Practice is arguably the weakest and least transparent of all industry Codes. Their complaint system provides no details of code breaches; only summary statistics. The CHC also refers around 50% of all complaints received to the TGA whereupon no more is heard.

The paper notes, “The Australian Government expects all sponsors of high-risk therapeutic products - both members and non-members of industry associations - will comply with a relevant code of conduct.”

Comment: Expectation is not enough; compliance with a relevant Code must be a condition of registration, listing or including a therapeutic good on the Australian Register of Therapeutic Goods (ARTG) and embedded in legislation.

The paper notes that, “Non-members of industry associations will not be obliged to become members to elect to be covered by a code. Complaints about potential breaches of a code by a non-member could be referred to the relevant code of conduct committee for investigation and determination”.

Comment:

- Does this mean that non-members of an Industry association will be free-loading on members if their complaints are heard by a committee funded by members?
- Will non-members be required to pay for the cost of a complaint hearing?

The paper states, “In developing the high level principles, industry would be advised to collaborate with the Australian Health Practitioner Regulation Agency AHPRA to ensure consistent ethical standards for the interaction of health care professionals with the therapeutic goods industry”.

Comment: Other organisations such as the Royal Australasian College of Physicians have much more comprehensive guidelines for ethical relationships between medical practitioners and industry (currently being revised) which should be taken into account.³

¹ Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. MJA 2008; 188 (1): 21-25.

² Harvey K. A review of proposals to reform the regulation of complementary medicines. Aust Health Rev 2009; 33(2); 279-285.

³ <http://www.racp.edu.au/index.cfm?objectid=0E430747-9D1B-B29F-0126DC894DB73AC5>

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Advertising therapeutic goods in Australia: Consultation paper

This paper primarily addresses the advertising of therapeutic goods to consumers. The objectives put forward are admirable: consumers should receive accurate information about the benefits and risk of therapeutic goods that they can safely access without the intervention of a health professional.

Comment: The reality is very different as shown by numerous complaints about breaches of the Therapeutic Goods Advertising Code upheld by the Complaint Resolution Panel (CRP).⁴

The paper notes the inconsistency of applying a pre-approval process for advertisements for therapeutic goods directed at consumers depending on the media in which the advertisement is to be published.

Comment: While the pre-approval process does pick up some obvious breaches of the Therapeutic Goods Advertising Code there are many successful complaints about advertisements that have been pre-approved, presumably because of the limited time that pre-approval officers have to review advertisements submitted.

More importantly, this paper does not address the fundamental system problem: a down-stream advertising complaint system⁵ (especially one that is overloaded and lacks effective sanctions) is no substitute for up-stream evaluation of product effectiveness prior to marketing approval.

Many complaints occur because the TGA does not evaluate so-called “lower risk” Listed medicines and devices for efficacy. Sponsors self-certify that they hold the evidence to substantiate the indications and/or claims made for a Listed medicine or the intended purpose of a medical device but only a relatively small proportion of ARTG entries are checked by the TGA. The end result is information on the ARTG which cannot be substantiated by clinical studies, such as magnets purporting to relieve tinnitus, shingles, stiffness, restless legs, sinusitis, sprains, muscle fatigue, blood pressure, and bed sores. (ARTG no:161927) which are then used to justify advertising claims. There are many similar problems with ARTG indications for Listed medicines.

Concerns about sponsor self-certified information on the ARTG can be sent to the TGA and is referred to the Regulatory Review Section. They state, “due to the Privacy and Confidentiality provisions that apply to regulatory investigations the TGA is unable to discuss the progress or outcomes of these reviews.” Occasionally, in response to complaints, a therapeutic good is removed from the ARTG. This is currently notified only in the Government Gazette where it is, to all practical purposes, invisible. Promotion and use of such goods invariably continues.

In addition, while the CRP will recommend remedial action for advertisements determined to breach the Therapeutic Goods Advertising Code they have no power to enforce their determinations. It takes multiple complaints before non-compliance by a sponsor is passed to the final regulator; the TGA. That organisation tells complainants nothing and publicises nothing. Meanwhile, retractions asked for by the CRP are not complied with and unethical claims continue.

⁴ <http://www.tgacrp.com.au/index.cfm?pageID=13>

⁵ Complaint Resolution Panel: <http://www.tgacrp.com.au/>

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Options suggested

The TGA could publish on its web site information relating to products removed from the ARTG for advertising offences.

Comment:

- This should include products removed for other reasons as well, for example when a review finds that the sponsor cannot substantiate indications listed on the ARTG, or when a sponsor de-lists a product themselves rather than face a review.
- The TGA web site should also include details of all complaints (and their outcome) referred to it by other bodies such as the CRP and the CHC Complaint Resolution Committee.

The CRP could refer directly to the TGA all matters relating to efficacy of the products.

Comment:

- This has been done with Listed weight loss products and products containing glucosamine and ginkgo biloba. **It has not been a productive exercise.**
- In 2007, the TGA was asked to review the efficacy of all ingredients used in Listed weight loss products in the hope that up-stream evaluation would reduce the need for down-stream complaints. It was suggested that all ingredients that lacked evidence of efficacy for weight loss should be proscribed for use in such products until such time as a sponsor convinced the Complementary Medicines Evaluation Committee that new evidence was available. Industry concern apparently watered down the scope of this review to a draft document (released in February 2009) that merely reviewed the evidence that might support a claim for weight loss products. A number of consumer and health professional organisations wrote submissions expressing concerns about the limitations of the draft document, especially the lack of any implementation plan. A public consultation was called, in Canberra, on October 26, 2009. Many concerns were reiterated and the TGA promised to revise the document. Eight months later no more has been heard.

The Government could move to increase and broaden the level of penalties and sanctions associated with breaches of advertising requirements.

Comment:

- S42(DM) of the Therapeutic Goods Act, 1989 says: “(1) A person is guilty of an offence if: (a) the person publishes or broadcasts an advertisement about therapeutic goods; and (b) the advertisement does not comply with the Therapeutic Goods Advertising Code. Penalty: 60 penalty units”. I understand that this provision is ineffectual because the TGA has to put a criminal case to the public prosecutor to get action and the latter has more important priorities.

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- Clearly, the CRP and/or the TGA need to be able to use civil penalties to enforce their determinations with fines, corrective advertising orders and de-listing of products for repeat offences.

The Government could reconstitute the membership of the CRP to ensure greater independence

Comment:

- Members of the CHC are nominated by the Australian Consumers' Association (Choice), the Australian Self-Medication Industry (ASMI), the Australian Traditional Medicine Society (ATMS), the Complementary Healthcare Council (CHC), the Consumers Health Forum Inc (CHF), the Pharmacy Guild of Australia (PGA), the Pharmaceutical Society of Australia (PSA) and the Royal Australian College of General Practitioners (RACGP). The TGA and the Food Standards Australia New Zealand (FSANZ) have observer status.
- I have submitted many complaints to the CRP and I have not had a problem with their determinations. I presume that they have conflict-of-interest procedures to ensure independent decision-making; it would be sensible if these were outlined on their web site.⁶

Consultation questions

Are the current arrangements for advertising of therapeutic goods in Australia known to you?

Comment: Yes.

Should these be better known or understood?

Comment:

- Useful information is available on the Therapeutic Goods Advertising Code Committee (TGACC) web site⁷ and the TGA web site.⁸ However, in order to find out how to submit complaints one must follow a link to another web site (CRP) which has a very useful online complaint form and advice⁹. Ironically, the TGA site provides no internet link to the CRP site.
- The TGA web site should provide cross-links to the CRP web site and the TGACC & CRP web sites should be consolidated. In addition, the National Prescribing Service (NPS) web site¹⁰ should also contain information about how to complain about unethical promotion and cross-link to the above.
- The TGA and/or the NPS should also educate consumers and health professionals on the importance of submitting complaints about promotion (as a crucial part of post-marketing surveillance) as the U.S. FDA is currently doing with their "Bad Ad Program".¹¹

⁶ <http://www.tgacrp.com.au/index.cfm?pageID=5>

⁷ <http://www.tgacc.com.au/index.cfm>

⁸ <http://www.tga.gov.au/docs/html/advcomplaint.htm>

⁹ <http://www.tgacrp.com.au/>

¹⁰ <http://www.nps.org.au/home>

¹¹ <http://tinyurl.com/2bdoca8>

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Do you have comments or complaints about the current advertising arrangements?

Comment: See the totality of this submission and my journal publications referenced above.

Do you find advertisements for therapeutic goods helpful?

Comment: They can be helpful by alerting consumers and health professionals to new products or improvements in old ones but only if the claims are accurate and the benefits promoted are balanced by information about adverse effects, drug-drug interactions, cautions, etc.

Should the current pre-approval process be retained?

Comment: Given that the pre-approval process only applies to certain media, it misses many problems and is a cost burden on industry I believe it would be more cost-effective to replace the pre-approval process with a less-expensive (but still funded) promotion monitoring program (including industry, health professional and consumer education) as long as the monitoring program referred concerns to a complaint process that was capable of imposing effective sanctions.

Should the TGA publish on its web site products removed from the ARTG?

Comment: This question has been asked before under options (see page 5)

Should the CRP be reconstituted as an independent body?

Comment: This question has been also asked before under options (see page 6)

Should the CRP consider complaints about all forms of advertising?

Comment: Yes! It is time-wasting and inefficient that advertisements to consumers in leaflets, brochures, catalogues, shelf talkers, etc have to go to ASMI or the CHC when the same advertisement in other media goes to the CRP.

Could trivial or straightforward complaints be better dealt with rather than requiring CRP consideration?

Comment: Straightforward matters such the lack of a required warning should be dealt with by the CRP Secretariat and not require consideration by the CRP.

Should civil penalties apply for breaches?

Comment: This question has been also asked before under options (see page 5)

Conclusion

While some of the measures proposed have merit I have the following major concerns:

- A reliance on industry self-regulation (which has proven to be weak and self-serving);
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See appended poster presented at the 2010 National Medicines Symposium.

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A Single System to Ensure the Ethical Promotion of Medicines and other Therapeutic Goods

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Ethical promotion is an important goal of National Medicines Policy.

Australia currently has a variety of complex and convoluted co-regulatory systems for the control of therapeutic claims and promotional practices.

Complaint submission and comparison of the various Codes has shown that they are inconsistent with respect to timeliness, transparency, sanctions and effectiveness.

We advocate one principles-based ethical Code applicable to all therapeutic claims and promotional practices administered transparently by an independent expert committee representing all stakeholders.

The Code would be supported by one monitoring process, one complaint (and appeal) process and one set of effective sanctions, including corrective advertising orders and a sliding scale of fines.

The new system requires a legislative base in the Therapeutic Goods Act and/or regulations and compliance would be a requirement for inclusion of products on the Australian Register of Therapeutic Goods (ARTG).

This reform would create a level ethical playing field for members of different industry associations and, in particular, for non-members who currently provide the majority of promotional problems.

It would also make a nice response to the World Health Assembly Resolution (60.16.5) on Rational Use of Medicines which urged Member States (including Australia) to, “*Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines and to monitor the promotion of medicines*”.

