

Submission on Consultation Paper: Improving Advertising Arrangements for Therapeutic Goods in Australia.

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Background

On June 30, 2010 the Parliamentary Secretary for Health, Mark Butler released 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. The first paper was produced by the Regulatory Policy & Governance Division of the Department of Health and Ageing (DoHA) and dealt primarily with the promotion of so-called 'higher-risk' therapeutic goods to health professionals. It advocated strengthened and more consistent self-regulation.¹ The second paper was produced by the Regulatory Reform Section of the Therapeutic Goods Administration (TGA) and dealt primarily with advertising of 'lower-risk' therapeutic goods to consumers. It outlined options regulatory reform.²

It is possible that the self-regulatory codes in place at the moment may encourage some companies to comply with standards. However, self-regulation cannot cope with companies or individuals who refuse to join industry associations and/or disregard the accepted ethical principles. The penalties applied for breaches of the Code are very small compared with the companies' incomes and publication of breaches cannot undo the impact of misleading statements that have been widely disseminated.³

What follows are comments on the paper as requested:

TGA Consultation Paper: Improving Advertising Arrangements for Therapeutic Goods in Australia

This paper primarily addresses the advertising of therapeutic goods to consumers. The objectives put forward are completely appropriate: 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.

Unfortunately, the reality is very different as shown by numerous complaints about breaches of the Therapeutic Goods Advertising Code that are upheld by the Complaint Resolution Panel (CRP), sent on to the TGA because of industry non-compliance.⁴

The TGA's categorisation of 'lower-risk' goods assumes 'lower-risk' without evidence. Without testing for efficacy there can be no assessment of risk which depends on the harm-benefit ratio. For example, it is arguable whether herbal products containing Black Cohosh should be classified as 'lower-risk' given that they have dubious benefit and have been associated with the risk of liver failure requiring transplantation (albeit infrequent).⁵

National Medicines Policy requires a legal framework to support all aspects of implementation of National Medicines Policy. In line with that requirement, there must be a

¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/regulatory-policy-governance-publications>

² <http://www.tga.gov.au/regreform/cons-advertising.htm>

³ Australian Prescriber. Medicines Australia Code of Conduct: Breaches. *Aust Prescr* 2009;32:160-161

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

⁵ <http://www.tga.gov.au/adr/aadrb/aadr0706.htm#a3>

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legislative/regulative framework controlling quality and efficacy of products before they can be marketed together with laws for enforcing ethical promotional activities. The regulatory framework must include effective penalties for breaches of the law. In addition to the legislative requirement in the Therapeutic Goods Act, all industry must commit to transparent self-monitoring, independent monitoring, Code adherence, complaint resolution procedures and education on ethics as a condition of gaining marketing approval from the Australian Therapeutic Goods Administration.

Currently, the profusion of unvalidated 'Listed' products allows consumers to persist with ineffective therapy to the detriment of their health (and sometimes life)⁶ as well as waste of money. Complementary medicines are often more expensive than prescribed medicines. The common lack of information about side-effects and interactions with other drugs or food products associated with many complementary medicines also puts consumers at risk. These issues indicate that the TGA's current approach is no longer appropriate for a complementary medicine industry on which Australian consumers now spend over \$2 billion per annum.⁷

Crucial issues that the consultation paper fails to address

The consultation paper fails to address a fundamental system problem: a down-stream advertising complaint system (especially one that is overloaded and lacks effective sanctions) is no substitute for up-stream evaluation of product effectiveness - as well as safety - prior to marketing approval. Many so-called 'low-risk' products have been found to be contaminated with heavy metals and other toxic substances.⁸ Although the focus of the consultation is on efficacy, the issue of safety also underlines the need for pre-marketing quality assurance in a regulatory framework, which cannot be ignored.

Many complaints associated with promotion 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 sponsor's new entries on the Australian Register of Therapeutic Goods (ARTG) are checked by the TGA. This has resulted in a proliferation of products in the market place with dubious or no health benefits and unknown safety profile. Public summary information on the ARTG cannot be substantiated by clinical evidence.

Even if the information on the ARTG is correct this does not stop some sponsors from making excessive promotional claims about their product and providing minimal or no information about known adverse effects including drug-drug interactions. In addition, product names such as 'Fat Magnet', 'Weight Loss Accelerate' and 'Slim-Me' are equally

⁶ <http://www.smh.com.au/national/parents-guilty-of-manslaughter-over-daughters-eczema-death-20090605-bxvx.html>

⁷ http://www.nhmrc.gov.au/files_nhmrc/file/media/noticeboard/07/CAM_forum_nov06_outcomes.pdf

⁸ Li GQ, Duke CC, Roufogalis BD. The quality and safety of traditional chinese medicines. *Aust Prescr* 2003;26:128-30

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misleading and deceptive. Medical device sponsors use similar strategies such as the 'Accent FatBlaster Radio Frequency device'.

In 1985 The WHO established and circulated widely *Ethical Criteria for Medicinal Drug Promotion* which provided general principles for ethical standards which could be adapted by governments to national circumstances. The above examples clearly violate those ethical standards. Although there was no mechanism for countries to 'sign up' to the ethical criteria standards, Australia did endorse the 2007 World Health Assembly Resolution (60.16.5) on Rational Use of Medicines that urged Member States:

'to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non-promotional information on medicines'.

The failure by the TGA to evaluate Listed medicines has led to a serious misconception by consumers and many health professionals that all complementary medicines containing the same ingredients are equally effective (and safe). Furthermore, research has shown that many consumers do not understand that a product showing an AUST L number has NOT been evaluated for efficacy.⁹

The reality is that complementary medicines, especially herbal medicines, are complex products with numerous biologically active components. This means that evidence of benefits (and possible harm) are specific to the product tested and cannot necessarily be extrapolated. In addition, the manufacturing process varies enormously and GMP and safety cannot possibly be guaranteed generically. The 'generic' concept which is valid for conventional medicines, for example the interchangeability of paracetamol containing products, so long as they adhere to GMP and other quality provisions, is invalid for complementary medicines.

It is difficult for consumers and health professionals to know which complementary medicines available in the Australian market offer a genuine health benefit and which do not. This situation is most unsatisfactory for both consumers and health professionals and also limits the development of an evidence-based complementary medicines industry.

I believe that – ideally – all Listed products should face the same examination as products that will be Registered. That strategy would cope with safety and quality issues as well as efficacy. However, implementation would require a stepwise approach and in the interim I support the suggestions that have been outlined below.



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⁹ MacLennan AH, Myers SP, Taylor, AW. The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004. *Med J Aust* 2006; 184: 27-31.

http://www.mja.com.au/public/issues/184_01_020106/mac10324_fm.html

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Important policy initiatives additional to those outlined in the consultation paper.

A number of policy suggestions have been made to try and improve the current unsatisfactory situation.¹⁰ I especially support the following:

- AUST L medicines, currently unlisted homoeopathic and anthroposophic medicines and so-called 'lower-risk' medical devices should include on their label and promotional material the statement, 'This medicine (or device) has not been evaluated by Australian health authorities for efficacy'. The US Food & Drug Authority uses a similar disclaimer. Such a disclaimer would at least be an accurate statement of the current regulatory situation.
- The provision of better information about the benefits and risks of so-called 'lower-risk' therapeutic goods. Research by the National Prescribing Service (NPS) has shown that consumers and health professionals need access to an up-to-date, independent source of information about complementary medicines.¹¹ In addition, a recent survey of 1,121 pharmacy customers showed that 82 per cent wanted more detailed product information for all complementary medicines, similar to prescription medicines.¹² There are at least three approaches to achieving these information needs (not necessarily mutually exclusive):
 - One approach would be to use product monographs prepared by the Canadian Natural Health Products Directorate.¹³ These monographs could also be used to limit claims made by sponsors and ensure appropriate warnings and other information was provided in promotional material. This generic information about the ingredients in complementary medicines would need to be augmented with specific information about whether or not products on the Australian market were identical (or bio/phyto/equivalent to) products proven in clinical trials.
 - Another approach would be to require sponsors to add key evidence supporting each indication on the ARTG with entries checked by TGA staff (and coded with respect to therapeutic indication to assist searching). Sponsors would only be allowed to use clinical trial evidence relating to other products where their own product has been shown to have therapeutic equivalence. This information would be added to the public summary document currently available on the TGA web site.

¹⁰ Harvey K. A review of proposals to reform the regulation of complementary medicines. *Aust Health Rev* 2009; 33(2); 279-285

¹¹ http://www.nps.org.au/research_and_evaluation/current_research/complementary_medicines

¹² Braun LA, Tiralongo E, Wilkinson JM et al. Perceptions, use and attitudes of pharmacy customers on complementary medicines and pharmacy practice. *BMC Complementary and Alternative Medicine* 2010, 10:38 doi:10.1186/1472-6882-10-38

¹³ <http://webprod.hc-sc.gc.ca/nhp/nd/bdipsn/monosReg.do?lang=eng>

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- The third approach would be to set up an opt-in independent evaluation system. Sponsors could choose to submit their product for independent evaluation of its effectiveness by paying an additional fee. Products shown to be efficacious for specific indications by well-conducted clinical trials, ethically promoted, and with appropriate consumer medicines information would be awarded a trademark of approval similar to the Australian National Heart Foundation 'red tick'.⁶ Such products would not require the disclaimer 'This medicine has not been evaluated by Australian health authorities for efficacy'. In the survey of pharmacy 1,121 pharmacy customers mentioned above, 87 per cent thought complementary medicines should have a 'tick of approval' from a recognised government body.¹⁰ The proposed complementary medicine cooperative research centre (CRC)¹⁴ could be an appropriate body to undertake this work.

Options suggested

All options listed, except the following, reappeared as consultation questions and will be dealt with under that heading.

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

- This has been done with Listed weight loss products and products containing glucosamine and ginkgo biloba. **It has not proved 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.
- In short, the TGA Office of Complementary Medicines has shown no interest in evaluating the efficacy of Listed complementary medicines, no interest in correcting gross misinformation about these products on the ARTG and no initiative in liaising with the Canadian Natural Health Products Directorate to take advantage of their expertise in this matter.

¹⁴ <http://www.nicm.edu.au/content/view/146/267/>

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- Accordingly we do NOT support the CRP (or the proposed TGPA) referring matters of efficacy to the TGA.

Consultation questions

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

- Yes.

Should these be better known or understood?

- Information is available on the Therapeutic Goods Advertising Code Committee (TGACC) web site¹⁵ and the TGA web site.¹⁶ 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 advice¹⁷. Unfortunately, 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 site¹⁸ 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'.¹⁹

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

- See the sections of this submission titled, 'Crucial issues that the consultation paper fails to address' and several published papers.^{20,21}

Do you find advertisements for therapeutic goods helpful?

¹⁵ <http://www.tgacc.com.au/index.cfm>

¹⁶ <http://www.tga.gov.au/docs/html/advcomplaint.htm>

¹⁷ <http://www.tgacrp.com.au/>

¹⁸ <http://www.nps.org.au/home>

¹⁹ <http://tinyurl.com/2bdoca8>

²⁰ 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.
http://www.mja.com.au/public/issues/188_01_070108/har10522_fm.html

²¹ Harvey K. A review of proposals to reform the regulation of complementary medicines. Aust Health Rev 2009; 33(2); 279-285.

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- 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?

- Advertising approvals officers, acting under delegation from the Secretary, are not evaluators and do not have either support for, or in some cases the expertise required, to evaluate claims based on the indications. In addition, given that the pre-approval process only applies to certain media, it misses many problems and is a cost burden on industry.
- It can be argued that it would be more cost-effective to replace the pre-approval process with a less-expensive (but still funded) promotional monitoring program (including industry, health professional and consumer education) as long as the monitoring program interfaced with a complaint process capable of imposing effective sanctions (the TGPA).

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

- The TGA web site should include products removed for any reason, 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.
- It would also be helpful for the TGA web site to list all new products added to the ARTG on a weekly basis.
- All the above information should be made available by subscription to a TGA email alert system.

Should the CRP be reconstituted as an independent body?

- Members of the CHC are currently 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.
- People who have submitted many complaints to the CRP and have not complained about CRP determinations. We presume that the CRP has conflict-of-interest

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procedures to ensure independent decision-making; it would be appropriate if these were outlined on their web site.²²

- However, we have recommended a more streamlined and efficient system (TGPA) than the current Therapeutic Goods Advertising Code, the CRP and the existing plethora of inconsistent industry Codes and complaint systems.

Should the CRP consider complaints about all forms of advertising?

- Yes! It is time-wasting and inefficient that advertisements to consumers in leaflets, brochures, catalogues, shelf talkers, etc have to go to industry self-regulatory bodies (ASMI or the CHC) when the same advertisement in other media goes to the CRP.
- Once again, we advocate transforming the CRP into a broader-based TGPA.

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

- Straightforward matters such the lack of a required warning should be dealt with by the CRP (or TGPA) Secretariat and not require consideration by the CRP (or TGPA).

Should civil penalties apply for breaches?

- 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'. We 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.
- We note that the ill-fated Trans Tasman Agency to regulated therapeutic products envisaged increasing the power of the Panel, elevating it to a role of decision maker and proposed a more extensive range of penalties than currently exist.²³ For example, the application of on-the-spot fines for 'black and white' misdemeanours, such as lack of approval number and lack of mandatory warning statements, was supported.
- Clearly, the CRP and/or the TGA and/or the proposed TGPA need to be able to use civil penalties such as infringement notices and enforceable undertakings involving fines, corrective advertising orders, de-listing products and refusal to list a product substantially similar to one that had been cancelled.²⁴

²² <http://www.tgacrp.com.au/index.cfm?pageID=5>

²³ <http://www.anztpa.org/advert/advmodel.pdf>

²⁴ <http://www.tga.gov.au/legis/enfguidelines.pdf>

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- In addition, the funds generated should be applied to the monitoring, complaint and educational system instead of being lost into general revenue.