

Health Action International Asia Pacific - Submission on Consultation Paper: Improving Advertising Arrangements for Therapeutic Goods in Australia



Background

Health Action International Asia-Pacific (HAI AP) is part of the HAI global network and works to increase access to essential medicines and improve rational use in the Asia Pacific region through research excellence and evidence-based advocacy. HAI AP promotes civil society participation in the development and implementation of health and drug policies and at the national, regional and international levels.

HAI AP is currently involved in two international projects in which Australian participation has been invited: “Measuring the Impact of Pharmaceutical Promotion Regulation”¹ and “Practical Implementation of the WHO Ethical Criteria”.²

There has been considerable regional interest in the two papers recently released in Australia by the Parliamentary Secretary for Health, the Hon Mark Butler MP. The first paper dealt primarily with the promotion of so-called “higher-risk” therapeutic goods to health professionals. It advocated strengthened and more consistent self-regulation.³ The second paper dealt primarily with advertising of “lower-risk” therapeutic goods to consumers. It outlined options regulatory reform.⁴ We commend the Parliamentary Secretary for these initiatives which we believe fit nicely with the 2007 World Health Assembly Resolution (60.16.5) on Rational Use of Medicines⁵ that urged Member States to,

“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”.

We have already responded to the first paper and we now wish to address the second. But first we would like to reiterate the need for **both** strengthened self-regulation and regulatory reform. We accept that self-regulatory codes may encourage some companies to lift their game and they are obviously attractive to a government committed to cost containment (although the cost of self-regulation is inevitably passed on to consumers). However, self-regulation cannot cope with companies or individuals who refuse to join industry associations and/or flagrantly disregard collective norms. Braithwaite’s regulatory hierarchy is required (Figure 1).⁶

As we have pointed out in response to the position paper on promotion, there must be a legislative requirement in the Australian Therapeutic Goods Act for all industry to commit to transparent self-monitoring, independent monitoring, Code adherence, complaint resolution procedures, sanctions and education on ethics as a condition of gaining marketing approval from the TGA. At the moment

¹ <http://tinyurl.com/mr9bdd>

² <http://tinyurl.com/28cq9fq>

³ <http://www.health.gov.au/internet/main/publishing.nsf/Content/regulatory-policy-governance-publications>

⁴ <http://www.tga.gov.au/regreform/cons-advertising.htm>

⁵ http://apps.who.int/gb/ebwha/pdf_files/EB120/b120_r12-en.pdf

⁶ Braithwaite, J. Regulatory Capitalism: How it Works, Ideas for Making it Work Better. Cheltenham, Edward Elgar, 2008

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there is only a requirement for the sponsors of prescription medicines to commit to only some of the provisions of Medicines Australia Code of Conduct.

We have also argued that independent monitoring; Code revision and complaint resolution would be more effectively and efficiently carried out under the auspices of one co-regulatory Therapeutic Goods Promotional Authority (TGPA) with representation from all stakeholders; rather than the current plethora of industry sector Code and complaint committees, the Therapeutic Goods Advertising Code and the Complaint Resolution Committee (CRP). Each industry sector would contribute to Code formulation (which would include specific provisions for each sector) and also have adequate representation on monitoring and complaint panels dealing with sector specific issues. Failure to comply with TGPA determinations would lead to the imposition of civil or criminal penalties.

Having made these important general points we now turn to the second paper for which comment was 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 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.

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,⁷ whereupon complainants hear no more and the misleading promotion usually continues. If the TGA ever does get involved its actions are never publicised and complainants are left with the perception that the TGA does not take consumer protection seriously.

The TGA's "risk-management" approach to regulation appears predicated upon the assumption that its role in consumer protection is limited to minimising adverse events with serious health consequences by what they regard as "higher-risk" therapeutic goods. The TGA does not appear to accept that promotional claims of so-called "lower-risk" goods that lack an evidential base can harm consumers indirectly by encouraging them to persist with ineffective therapy, such as homeopathic medicines, to the detriment of their health (and sometimes life)⁸ or by wasting money on therapy that is not evidence based. The TGA apparently does not accept that allowing sponsors to provide misleading or no information about adverse effects of so-called "lower-risk" therapeutic goods, such as drug-drug interactions of Listed complementary medicines, also puts consumers at risk. We argue

⁷ <http://www.tgacrp.com.au/index.cfm?pageID=13>

⁸ <http://www.smh.com.au/national/parents-guilty-of-manslaughter-over-daughters-eczema-death-20090605-bxvx.html>

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that the TGA's current "light touch" approach is no longer appropriate to a complementary medicine industry on which Australian consumers now spend over \$2 billion per annum.⁹

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 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 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 public summary information on the ARTG which cannot be substantiated by clinical evidence.

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.

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

Furthermore, research has shown that many consumers do not understand that a product containing an AUST L number has NOT been evaluated for efficacy.¹⁰

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. The reality is that complementary medicines, especially herbal medicines, are complex products with numerous biologically active components. This means that evidence of benefits (and risks) are specific to the product tested and cannot necessarily be extrapolated. The "generic" concept which is valid for conventional medicines, for example the interchangeability of paracetamol containing products, is invalid for complementary medicines. Thus, a prescription for "St John's wort" for example, is not reliable as St John's wort is not one substance. In addition, meta-analyses and systematic reviews of a "substance", for example a herb,

⁹ http://www.nhmrc.gov.au/files_nhmrc/file/media/noticeboard/07/CAM_forum_nov06_outcomes.pdf

¹⁰ 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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or glucosamine, are easily misinterpreted because the products made from that “substance” can be so different that any conclusions drawn can only be applied to the specific products trialed.^{11,12} The end result is that 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.

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.¹³ We 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.¹⁴ 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.¹⁵ 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.¹⁶ 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.

¹¹ Pollard NA | Santoro A | Kotsirilos V | Masters CS | Harvey KJ, Korczak VS, Marron LJ, Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia *Med J Aust* 2008; 189 (1): 50-53. [Letters]

http://www.mja.com.au/public/issues/189_01_070708/letters_070708_fm-2.html

¹² Vlad SC, LaValley MP, McAlindon TE, Felson DT. Glucosamine for pain in osteoarthritis: why do trial results differ? *Arthritis Rheum* 2007; 56: 2267–77.

¹³ Harvey K. A review of proposals to reform the regulation of complementary medicines. *Aust Health Rev* 2009; 33(2); 279-285

¹⁴ http://www.nps.org.au/research_and_evaluation/current_research/complementary_medicines

¹⁵ 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

¹⁶ <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/monosReq.do?lang=eng>

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- 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.
- 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)¹⁷ 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

¹⁷ <http://www.nicm.edu.au/content/view/146/267/>

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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.

- 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 site¹⁸ and the TGA web site.¹⁹ 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 advice²⁰. 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 site²¹ 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”.²²

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.^{23,24}

¹⁸ <http://www.tgacc.com.au/index.cfm>

¹⁹ <http://www.tga.gov.au/docs/html/advcomplaint.htm>

²⁰ <http://www.tgacrp.com.au/>

²¹ <http://www.nps.org.au/home>

²² <http://tinyurl.com/2bdoca8>

²³ 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

²⁴ ²⁴ 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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Do you find advertisements for therapeutic goods helpful?

- 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 procedures to ensure independent decision-making; it would be appropriate if these were outlined on their web site.²⁵

²⁵ <http://www.tgacrp.com.au/index.cfm?pageID=5>

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- 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.²⁶ 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.²⁷
- In addition, the funds generated should be applied to the monitoring, complaint and educational system instead of being lost into general revenue.

²⁶ <http://www.anztpa.org/advert/advmodel.pdf>

²⁷ <http://www.tga.gov.au/legis/enfguidelines.pdf>

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Figure 1 Regulatory Pyramid (after Braithwaite and others)

