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The Hon Mark Butler MP,  
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Parliament House  
Canberra ACT 2600

Dear Mr. Bulter,

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

The **Victorian Branch of the Australian Skeptics** is part of a loose confederation of groups across Australia that investigates and debates pseudo-scientific and paranormal claims from a responsible scientific viewpoint. The Australian Skeptics publish a quarterly magazine named the Skeptic and host an annual national convention which includes prominent scientists, researchers and authors amongst the keynote speakers.

Skeptics encourage thoughtful, rational exploration of the world around us. We do not believe in the pseudoscience, miracle cures, astrology and the like. We do believe in reproducible results, recognising that sometimes not finding an expected result is an important part of the scientific process. Science has revealed many amazing things, but amazing (unjustified and/or unbalanced) claims are also used to deceive and to defraud innocent people. Unfortunately, this is particularly true of therapeutic goods; hence our interest in improving their advertising arrangements.

The attached response to your consultation paper was prepared after a public presentation and discussion on complementary medicine regulation and a committee meeting fine-tuned an initial draft prepared by one of our members.

Yours sincerely,

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## Summary

We found the split between the position paper on the promotion of therapeutic goods and the consultation paper on advertising arrangements unhelpful; we advocate both strengthened self-regulation and regulatory reform.

We support the creation of one Code and one co-regulatory Therapeutic Goods Promotional Authority (TGPA) to replace the current plethora of industry sector Code and complaint committees, the Therapeutic Goods Advertising Code and the Complaint Resolution Panel (CRP).

We are concerned that the TGA's "light-touch" approach to the regulation of Listed medicines and so-called "low-risk" devices has resulted in a flood of shonky products into the market-place and an inability of consumers (and health professionals) to separate the wheat from the chaff. We believe the TGA's current regulatory approach is no longer appropriate to a complementary medicine industry on which Australian consumers now spend over \$2 billion per annum.

We note that the consultation paper failed to address a fundamental system problem: a downstream 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. We support a number of policy suggestions to redress this situation. These include mandating that all AUSTRALIAN medicines, currently unlisted homoeopathic and anthroposophic medicines, and so-called "lower-risk" medical devices include on their label and promotional material the statement, "This medicine (or device) has not been evaluated by Australian health authorities for efficacy".

We are especially concerned by the proposal to refer to the TGA all matters relating to efficacy of the products. We point out that 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 Australian Register of Therapeutic Goods (ARTG) and no initiative in liaising with the Canadian Natural Health Products Directorate to take advantage of their expertise in this matter.

In response to questions about the role of CRP, we reiterate that we have recommended a more streamlined and efficient system (TGPA) rather than the current Therapeutic Goods Advertising Code, the CRP and the current plethora of industry sector Code and complaint committees.

Finally, we note that the proposed Trans Tasman Agency to regulate therapeutic products (now abandoned) envisaged increasing the power of the CRP, elevating it to a role of decision maker and giving it a more extensive range of more readily imposed civil penalties than currently exist. We argue that the proposed TGPA also needs the power to readily impose civil penalties, such as infringement notices involving fines and enforceable undertakings such as corrective advertising orders, de-listing products and refusal to list a product substantially similar to one that had been cancelled. In addition, the funds generated from fines should be applied to the monitoring, complaint and educational system; not lost into general revenue.

## **The need for both strengthened self-regulation and regulatory reform**

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. 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.

While this split may reflect silos within DoHA and the TGA, we believe it is unhelpful. We argue that both strengthened self-regulation and regulatory reform are required so that the strengths of one can cover the weaknesses of the other. We were disappointed that the Complementary Health Care Council of Australia (CHC) was left out of the “Working Group on Promotion of Therapeutic Products” because their Code of Practice is arguably the weakest and least transparent of all industry Codes. In addition, complaints about complementary medicines and devices far outnumber those of so-called “higher-risk” therapeutic goods.

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). As many have pointed out in response to the DoHA position paper on promotion, there must be a legislative requirement in the 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 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.

### **Support for a co-regulatory Therapeutic Goods Promotional Authority (TGPA)**

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 Panel (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 specific paper for which comment was requested.

### **Specific comment on the TGA Advertising 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.

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, 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) or by wasting money on therapy that is not evidence based. The potential for adverse outcomes unproven diagnostic techniques is equally serious. 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 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.

### **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 most consumers either do not notice or correctly understand that a product containing an AUST L number has NOT been evaluated for efficacy.'

The failure by the TGA to evaluate listed medicines has lead 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, 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 trialled. 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 required additional to those outlined in the consultation paper.**

A number of policy suggestions have been made to try and improve the current unsatisfactory situation. 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.
- Promotional phrases, such as, ‘may relieve’, ‘may prevent’ or ‘may promote’ (often used when the evidence supporting a claim is weak and/or contradictory) should be required to be changed to, ‘may or may not’.
- 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. 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. 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. 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.
  - 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”.<sup>6</sup> 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.<sup>10</sup> The proposed complementary medicine cooperative research centre (CRC) 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.

- 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 site and the TGA web site. 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 advice. 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 site 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”.

***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.’

***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.
- 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. 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 impose 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.

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

Figure 1 Regulatory Pyramid (after Braithwaite and others)