

## Controlling complementary medicine claims

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Despite the widespread and increasing use of complementary medicines, few of these products have been evaluated for efficacy or therapeutic equivalence. There has also been a proliferation of products of dubious efficacy, with promotional claims that cannot be substantiated. However, complaining about them is not straightforward.<sup>1</sup> Complaint procedures are overloaded and the 'sanctions' available may not deter repeat offenders. There is a need for regulatory reform.

Two industry associations agree that certain measures are required to maintain confidence in the regulatory framework. The Australian Self-Medication Industry (ASMI) believes that evidence-based information about the benefits and risks of complementary medicines should be available, that advertising complaint mechanisms need to be adequately resourced and that appropriate penalties and sanctions are required for breaches of the Therapeutic Goods Advertising Code.<sup>2</sup> The Complementary Healthcare Council also supports initiatives to enhance the timeliness of the current complaint process and implement a broader range of sanctions.<sup>3</sup> However, some people believe that increased regulation will damage the complementary medicine industry.

### In this issue...

The current global financial crisis shows that markets cannot be left completely to their own devices. While Australia has been innovative in its regulation of complementary medicines, Ken Harvey argues that there needs to be greater scrutiny of the way these products are advertised. A tightening of the code of conduct for the advertising of prescription drugs has resulted in more companies being found in breach of the code.

The top ten drugs show that we spend a lot of money treating an unhealthy lifestyle. Nancy Huang, Karen Duggan and Jenni Harman remind us that lifestyle management is important in hypertension, and Ken-Soon Tan and David Johnson have similar recommendations for renal disease.

I believe that dubious claims, which cannot be substantiated by scientific evidence, would be better dealt with at the time the sponsor of the complementary medicine makes a marketing application, rather than by submitting complaints about its advertising some time later. Currently, sponsors are able to enter their own indications for their products on the Australian Register of Therapeutic Goods (ARTG). As long as the sponsor certifies that it has evidence to back its claims, the ingredients are on the Therapeutic Goods Administration (TGA) 'relatively low risk' list and the necessary fee has been paid, the automated system will list the product on the ARTG. Recent exposure of the ARTG to greater public scrutiny<sup>4</sup> has shown that dubious promotional claims are being entered on the ARTG at the time of listing. This practice should be reviewed.

In addition, a herbal product can be listed using evidence relating to other products. I believe that the TGA should only allow sponsors to do this once the products have been shown to be therapeutically equivalent. This is comparable to the requirement that generic copies of prescription drugs show bioequivalence.

Herbal products consist of a complex mix of ingredients. Just as all red wine is not Grange Hermitage, different products containing the same herbal extract are not necessarily chemically or therapeutically equivalent.<sup>5</sup> Even glucosamine is available as several salts (glucosamine sulfate, glucosamine hydrochloride, and also as N-acetyl glucosamine) in vastly different formulations and with varied evidence of efficacy.<sup>6</sup> However, data specific to each individual glucosamine-derived product are not required by the TGA. Neither health professionals nor consumers can therefore be confident that Australian formulations of glucosamine (or any other complementary medicine) are efficacious.

Following the recall of products made by Pan Pharmaceuticals in 2003, the Australian government set up an expert committee to examine complementary medicines. This committee recommended that sponsors of listed medicines should submit a summary of the evidence to support the efficacy of their products to the TGA.<sup>7</sup> ASMI agreed that there should be access to the ARTG and the summary of evidence submitted by sponsors. However, it recommended that this information should be limited to industry advertising services managers and

the Complaints Resolution Panel. I believe that this information should be publicly available and open to challenge.

The expert committee also recommended that the TGA should increase the level of random auditing of the evidence for complementary medicines.<sup>7</sup> Particular scrutiny could be given to certain categories, such as 'weight loss' products. However, a review of complementary 'weight loss' products was commissioned by the TGA in mid-2007, but is yet to be made public. The TGA also claims to randomly review the labels, product specifications and evidence for listed indications in about 25% of new listings. However, until such time as the TGA is able to conduct audits in a transparent manner there can be little confidence in their value.

The Australian government has provided \$7 million for complementary medicine research. However, Australian clinical trials can only evaluate a handful of the 16 000 listed products currently available in the market. Choice (formerly the Australian Consumers' Association) has proposed a pragmatic solution to this problem – an independent evaluation of complementary medicines on an opt-in, cost-recovery basis. Efficacious products, ethically promoted, with appropriate consumer medicine information could be awarded a mark of approval similar to the National Heart Foundation's 'tick' for healthy food. Choice has set up a multidisciplinary working party to explore the practicality of this proposal.

In conclusion, the current Australian regulatory system neither adequately controls complementary medicine claims nor encourages an evidence-based industry. This is unacceptable given that Australians spend an estimated \$1.31 billion on these medicines each year. The challenge for the government is to overcome industry self-interest, and the perception of regulatory 'capture', and to institute the reforms required. This will require continued advocacy by health professional and consumer groups.

## References

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## Further reading

McEwen J. What does TGA approval of medicines mean? *Aust Prescr* 2004;27:156-8.

*Dr Harvey is a member of the Choice Policy Advisory Group.*

## Letters

Letters, which may not necessarily be published in full, should be restricted to not more than 250 words. When relevant, comment on the letter is sought from the author. Due to production schedules, it is normally not possible to publish letters received in response to material appearing in a particular issue earlier than the second or third subsequent issue.

### Paediatric analgesia

Editor, –The article on paediatric analgesia (*Aust Prescr* 2008;31:63–5) provides a valuable quick reference on the subject. There is an additional purported mechanism of action for paracetamol, which may have implications in the setting of polypharmacy, especially perioperatively, or associated with chemotherapy.

A serotonergic mechanism of action has been reported for paracetamol.<sup>1,2,3</sup> The inhibition or obliteration of

paracetamol-induced analgesia by 5-HT<sub>3</sub> antagonists, commonly used as antiemetics perioperatively, may warrant consideration when prescribing paracetamol concurrently with drugs from this class. Ondansetron, perhaps the most likely drug from the class to be prescribed to a child, may be less likely to inhibit analgesia, particularly in comparison to tropisetron.<sup>4</sup>

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