

A review of proposals to reform the regulation of complementary medicines

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Abstract

In 2003, the Therapeutic Goods Administration instituted a major recall of products made by Pan Pharmaceuticals Limited. Later that year, an expert committee produced 49 recommendations for complementary medicines reform, many of which were to be implemented by the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). In 2008, the Pan Pharmaceuticals affair reached some conclusion in the courts, the ANZTPA had been abandoned and the case for reform had intensified. There was widespread and increasing use of complementary medicines yet consumers were often unaware that, unlike conventional medicines, these medicines were not evaluated for efficacy. The justification of this two-tiered regulatory system was that complementary medicines are relatively low-risk products. However low risk does not mean no risk. A number of consumers have been shown to use these products for conditions where there is no evidence of effect, potentially placing them at risk. In addition, promotion often overstates their benefits while minimising and sometimes denying known adverse effects and drug interactions. Complaint procedures are overloaded and the “sanctions” available do not deter repeat offenders. A number of regulatory reforms have been suggested to overcome these problems; they are reviewed in this paper.

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IN APRIL 2003, the Therapeutic Goods Administration (TGA) initiated the recall of more than 1600 complementary medicines from the Australian marketplace. This was caused by the failure of one

manufacturer, Pan Pharmaceuticals Limited, to maintain appropriate manufacturing and quality-control standards.¹ Shortly thereafter, the company was placed into liquidation. In August 2008, the government agreed to pay Pan's founder, Jim Selim, \$55 million because the recall had not followed due process.² Subsequently, in a separate court action, the collapsed firm was fined \$10 million for issuing false certificates and other offences.³ A \$120 million class action against the government by shareholders, creditors and customers of the collapsed Pan Pharmaceuticals company is ongoing.⁴

This saga illustrates the protracted and contested history of complementary medicines regulation and reform. In 2003, in response to the Pan Pharmaceuticals affair, an expert committee produced 49 recommendations for reform, many of which were to be implemented by the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA).⁵ However in July 2007, the New Zealand Government announced that it did not have the numbers in Parliament to proceed with the ANZTPA.⁶

In January 2008, my colleagues and I reviewed the regulation of complementary medicines in Australia using “weight loss” products as an example.⁷ We noted widespread and increasing use of complementary medicines yet many consumers were unaware that these medicines (unlike conventional medicines) were not evaluated for efficacy. In addition, the promotional claims made for the products investigated were often not in accordance with the scientific evidence available. Complaint procedures were overloaded and the “sanctions” available did not deter repeat offenders. The end result was a proliferation of products of dubious efficacy with promotional claims that could not be substantiated. Our paper concluded with recommendations for regulatory reform.

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In response, the two relevant industry associations defended the current two-tiered regulatory system which they believed was appropriate for low-risk complementary medicines. The Complementary Healthcare Council (CHC) noted that, “calls for changes to the regulation of complementary medicines are misinformed and not in consumer interests” although they did support a strengthened complaint process.⁸ The Australian Self Medication Association (ASMI) agreed that some of the 2003 expert committee recommendations should be fast tracked and complaint procedures should be strengthened.⁹

In July 2008, the TGA held consultations on legislative amendments that had been deferred in anticipation of the joint regulatory scheme with New Zealand. It was hoped that these amendments would soon be introduced to the Australian Parliament.¹⁰ The need for additional reform in areas such as advertising and labelling was also mentioned. This was awaiting research on the information needs of consumers and health professionals commissioned by the National Prescribing Service (NPS); recommendation 25 of the 2003 expert committee.

In November 2008, the NPS released two of their three research reports.^{11,12} Despite increasing use of complementary medicines by consumers, the NPS found that many were unaware of potential risks such as side effects, toxicity, allergies and interactions with conventional medicines. Around half the consumers surveyed did not report their use of complementary medicines to their medical practitioners (and the latter often failed to ask about these medicines). In addition, a number of consumers used these products for conditions where there was no evidence of effect, potentially placing them at risk.¹¹

NPS research also showed that both general practitioners and pharmacists believed they did not have enough access to evidence-based information about complementary medicines. As a result they were not confident in discussing these medicines with their patients. They expressed a need for easily accessible, independent and evidence-based information provided in a range of formats. The survey also revealed that more than

80 per cent of GPs and community pharmacists felt that complementary medicines needed more scientific testing.¹²

In March 2009, the NPS released their third research report; a review of the quality of CM information resources.¹³ Only a limited number of resources provided quality content information, good coverage across the range of categories defined as complementary medicines and the ability to answer common questions asked by consumers and health professionals. Areas of deficiency were especially around the safety, efficacy and dosing of CM. There was also a lack of direct linkage between evidence and the specific CM formulation/extract/salt used in Australian products.

This paper compares the regulation of complementary medicines with conventional medicines, summarises the problems that have been documented and comments on suggested reforms.

Regulation of complementary medicines compared with conventional medicines

The objectives of the *Therapeutic Goods Act 1989* (Cwlth) are to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.¹⁴ Complementary medicines are defined by the TGA as medicinal products containing vitamins, minerals, herbs, homoeopathic medicines, traditional Chinese medicines, Ayurvedic (Indian) medicines and Australian Indigenous medicines.¹⁵

Most complementary medicines are regulated as “listed” products by the TGA. They are identified by an AUST L number on the product label. Sponsors self-enter details of their product on the Australian Register of Therapeutic Goods (ARTG) using a web-based electronic listing facility. The only routine check made is that the ingredients are on the TGA’s “relatively low-risk” list. Product efficacy is not evaluated. Indication and claims are meant to be “low-level” relating to health maintenance, health enhancement or non-serious, self-limiting conditions. Sponsors must cer-

tify that they hold evidence supporting the indications and claims made about their product; this information is said to be reviewed by the TGA in around 20% of new listings. The listing system provides rapid market entry at minimal cost.

By contrast, most conventional medicines (“registered” products) are thoroughly evaluated by the TGA for safety, quality and efficacy before they are allowed onto the market. They are identified by an AUST R number on the product label. Generic versions of clinically proven products must demonstrate therapeutic equivalence. Sponsors of both innovator and generic products must negotiate approved product information with the TGA and also provide consistent consumer medicines information and promotion. Registration fees are substantial and the time taken can be protracted.

The production of both listed and registered medicines is required to be in accord with good manufacturing practice and both are subjected to post-marketing surveillance, prioritised according to risk. The latter includes monitoring reported adverse reactions and random and targeted audits and testing of products and ingredients.

The promotion of medicines is subject to a complex system of co-regulation underpinned by the *Therapeutic Goods Act 1989* (Cwlth) and the *Trade Practices Act 1974* (Cwlth).¹⁶ The Therapeutic Goods Advertising Code provides the standard for all advertising directed to consumers. In addition, there are three relevant industry codes of practice. The system includes pre-clearance by industry associations of advertisements directed to the public in “specified media” (but not the Internet) and various complaint systems depending on the type of medicine, the media in which the promotion is placed and whether it was directed to consumers or health professionals. There are substantial differences in the timeliness, transparency and the sanctions applied by the different systems to complaints about the promotion of complementary compared with conventional medicines.¹⁷

The justification of this two-tiered regulatory system is that complementary medicines are low-risk products. However low risk does not mean

no risk. In addition, consumers are often unaware that complementary medicines are not specifically tested by the TGA for efficacy.¹⁸ The need for regulatory reform is highlighted by the delays that have occurred in introducing the recommendations of the 2003 expert committee, the increasing use of these products and the wide gap between the public perception of their safety and efficacy and the available evidence; a perception often reinforced by inappropriate promotion.

Problems with the current regulatory system

Product efficacy

Herbal products are comprised of a complex mix of ingredients; just as all red wine is not Grange Hermitage, different products containing the same herb are not necessarily chemically or therapeutically equivalent.¹⁹ Variability can be caused by the use of different species or sub-species, growth conditions, methods of cultivation, the time of year and stage of growth cycle harvested, extraction methods, and formulation and storage of the finished product. Even glucosamine (used for arthritis) is available as several salts: glucosamine sulphate, glucosamine hydrochloride, and also as N-acetyl glucosamine, in vastly different formulations and with varied evidence of efficacy from clinical trials.²⁰

The TGA does not require clinical trial data to support the efficacy of listed products, nor evidence of therapeutic equivalence with proven products. Evidence of “traditional use” is the minimum standard required. However, “traditional use” is no guarantee of safety or efficacy; the blood letting that was performed for centuries by the medical profession is a classic example. Scientific investigation is required. While the listing process ensures that the ingredients used in complementary medicines are of “relatively low risk” it provides no certainty that all formulations of complementary medicines on the Australian market are efficacious. For example, when investigating St John’s Wort (used for mild depression), Choice (the Australian Consumers’ Association)

found that a number of sponsors declined to provide any evidence that their extract of this herb was equivalent to those proved efficacious in clinical trials.²¹

Adulterated and substandard products

The TGA has detected dangerous adulteration of some complementary medicines such as Zhen De Shou weight loss capsules found to contain sibutramine (a prescription drug) and Herbal Health International products, Excite for women and Ultimates for men, found to contain an analogue of sildenafil (Viagra).^{22,23} These products have been taken off the market.

Other types of adulteration do not concern safety but rather truth in labelling and product integrity. For example, products containing *Ginkgo biloba* in the United States of America have been shown to be frequently adulterated or “spiked” with less expensive sources of flavonol glycosides, such as rutin (from buckwheat), that can trick routine testing to make a product with little or no real ginkgo appear to be the real thing.²⁴ The CHC declined to comment on whether Australian sponsors routinely test for such adulteration and the TGA is currently investigating this matter.

Substandard products containing low levels of active ingredients (eg, *Echinacea* species) have also been found in Australia by Choice.²⁵ Once again, the size of this problem is unclear.

Harm

While complementary medicines are regarded as “relatively low-risk” products they are not without adverse effects and interactions with conventional drugs. For example, *Echinacea* can cause allergic reactions, black cohosh has been associated with very rare cases of liver failure requiring liver transplantation and St John’s wort interacts with a wide range of conventional drugs including oral contraceptives.²⁶ Recognition of such problems can be difficult because many patients do not tell their doctors that they are taking complementary medicines and doctors often do not ask. As a result, adverse effects of complementary medicines are almost certainly under-

recognised. In addition, ineffective complementary medicines have a significant adverse effect on consumers’ hip pockets (or purses) and, more importantly, they can delay or prevent the use of more evidence-based therapy.

Product claims, names and warnings

Research on complementary medicines used for weight loss showed that some sponsors self-entered indications and/or claims on the ARTG that could not be substantiated.⁷ These were then used in promotional material. Other sponsors made conservative claims on the ARTG but then made very different claims in promotional campaigns. In addition, product names such as “Xantrax High Potency Weight Loss Formula”, “Fat Blaster”, “Fat Magnet”, “Weight Loss Accelerate” and “Slim-Me” appear equally misleading and deceptive.

The problem of unsubstantiated claims is not limited to weight loss products. Some recent examples submitted to the Complaint Resolution Panel (CRP) include Blooms Health Products Pty Ltd who claimed, “All adults should take vitamins to prevent chronic disease”, Optigen Ingredients Pty Ltd, who claimed that a homoeopathic preparation of human growth hormone “may help to delay the effects of the ageing process”, Symbion Consumer who claimed that, “glucosamine could reduce the risk of osteoarthritis progression by 54%” and Arkopharma Australia Pty Ltd who claimed that, “there are no reports in the literature of an interaction between glucosamine and warfarin”. None of these statements are in accord with the scientific literature, and the last one also contradicts warnings by the Australian Adverse Drug Reactions Advisory Committee (ADRAC).

Currently, the only way to correct such inaccuracies is by submitting complaints. However, the CRP is under-resourced, overloaded and lacks effective sanctions.⁷ It even lacks resources to follow up its own determinations, which makes them easily ignored. It can take multiple complaints before non-compliance with a CRP determination is passed to the TGA. That organisation, citing “commercial-in-confidence” considerations, currently tells complainants nothing and publicises nothing.

Successful complaints have focused on product categories such as weight loss, memory enhancement and arthritis relief. In 2007, the TGA was asked to review the efficacy of all ingredients used in weight loss products in the hope that upstream evaluation would reduce the need for downstream complaints. A draft report was provided for comment in early 2009.²⁷ The review of ingredients had been changed to a review of evidence required for listed weight loss products; “traditional” evidence was still acceptable, and no details were provided as to how these proposals were to be implemented. The CRP has also asked the TGA to review the efficacy of products containing *Ginkgo biloba* and glucosamine. No time-frame has been given for these reviews and meanwhile the disputed promotional claims continue.

NPS research shows a major disconnect between consumers’ perception of complementary medicines as “natural” and “risk free” and the reality that they contain pharmacologically active substances capable of producing drug–drug interactions and adverse effects. My own analysis of advertisements for complementary medicines suggests that this perception is created and/or maintained by extensive promotion that emphasises the word “natural” and the use of associated imagery and colour. In addition, as noted above, promotion of these products often overstates their benefits while ignoring and sometimes denying known adverse effects and drug interactions.

Warnings about serious drug side-effects and drug–drug interactions are currently communicated by ADRAC Bulletins. In addition, the TGA may require sponsors to add key warnings to the medicine label. The following is a recent example, “Warning: In very rare cases, Black cohosh has been associated with liver failure”.²⁸ However, there are now numerous Australian Internet sites from which consumers can purchase complementary medicines without having the opportunity to read a product label; there is no requirement that important safety information should be communicated on these web sites and there is variable implementation of such warnings.

Similarly, the perception that complementary medicines are part of a “holistic” approach to

“maintaining good health” ignores the reality that many of these products are devised and marketed (in isolation) to take advantage of consumer anxieties and concerns. For example, while there is good evidence that some formulations of Hawthorn extract can be an effective treatment for heart failure,²⁶ its common promotion for “Heart health” would appear to be the health-promotion version of “disease mongering”.²⁹

Research

From an industry perspective, difficulties in protecting intellectual property (IP) of complementary medicines significantly inhibit investment in research. Once an ingredient is listed it can be used by any sponsor and the claims made are not restricted to specific formulations that have shown clinical efficacy.

In 2007–08, in recognition of the need to strengthen the evidence supporting complementary medicines, the Australian Government announced more than \$7 million in research grants. Funding of \$1.74 million was awarded to establish three National Institute of Complementary Medicine (NICM) Collaborative Centres and a further \$5.3 million for 13 projects funded by the National Health and Medical Research Council (NHMRC).³⁰ However, even with enhanced government funding, Australian clinical trials can only evaluate a handful of the 16 000 listed products currently available in the market.

Regulatory reforms

A number of legislative amendments that were deferred awaiting the ANZTPA are currently being introduced to the Australian Parliament.¹⁰ Those relevant to the issues mentioned above include the power for the TGA to suspend medicines from the ARTG rather than cancel their listing or registration (which was the only option available in the Pan Pharmaceuticals case). In addition, an improved regulatory framework for homoeopathic medicines is aimed at preventing products such as homoeopathic growth hormone that bear no relation to the homoeopathic paradigm.

Additional reforms have been proposed in the *Medical Journal of Australia* and subsequently debated in their correspondence columns and elsewhere.^{7,31} These are listed (with comments) below:

1. AUST L medicines (and homoeopathic medicines) should include on their label (and promotional material) the statement, “This medicine has not been evaluated by Australian health authorities for efficacy”.

Comment: This measure is opposed by industry, who argues it may cast doubt for consumers about complementary products without informing them. However, the US Food & Drug Authority insists on a similar disclaimer. It would at least be an accurate statement of the current regulatory situation.

2. A campaign to educate the public about complementary medicines is needed.

Comment: NPS research shows that both consumers and health professionals need access to an up-to-date, independent source of information about complementary medicines.

However, information about generic complementary medicines has major limitations because, unlike conventional (registered) medicines, complementary (listed) medicines are not evaluated for efficacy or therapeutic equivalence. Sponsors currently perpetuate the misconception that all complementary medicines containing the same ingredients are equally effective. As pointed out above, 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) is specific to the product tested and cannot necessarily be extrapolated. Because of this, one of the “Tier 1” resources recommended by the NPS (the US “Natural Medicines Database”) provides specific brand name products that have been studied in clinical trials with a unique effectiveness rating (NMBER) based on the evidence specific to that product. In addition, independent testing of product quality by the US Pharmacopoeia (who provide a USP trademark) also contributes to the NMBER rating.

In short, to be useful, any database of generic information about 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. This is what the opt-in, independent evaluation system suggested by Choice and others would provide.³¹

3. Ethical codes of conduct, complaint procedures and appeal mechanisms for complementary medicines, over-the-counter and prescription drugs should be streamlined, harmonised and brought under one adequately resourced authority. Consistent (and meaningful) sanctions should be imposed on companies that repeatedly breach codes (for example, corrective advertising orders and fines linked to company turnover, with the money used to support the complaint system).

Comment: Both the ASMI and the CHC support improved complaint procedures and appropriate penalties for breaches of the Therapeutic Goods Advertising Code.

4. The ARTG database should be updated with respect to listed products. Sponsors should be required to add key evidence supporting each indication on the ARTG and entries should be checked by staff of the regulatory body and coded with respect to therapeutic indication. This information should be publicly available on the Internet.

Comment: The TGA has recently made more information on the ARTG available to the public in the form of public summary documents. This has highlighted a number of claims by sponsors that appear to lack substantiation. The additional availability of an evidence summary would assist external assessment, as would the ability to search for all products within a properly coded therapeutic category. Industry oppose making an evidence summary public.

5. The TGA should only allow sponsors to use clinical trial evidence relating to other products where their own product has been shown to have therapeutic equivalence.

Comment: This measure is crucial to IP protection and encouraging sponsors to undertake their own clinical trials. It is supported by the sponsors of evidence-based products but opposed by industry associations who represent a broader range of sponsors.

6. In the longer term, the listing system should be scrapped, and complementary medicines should be assessed for efficacy and de-listed if evidence is lacking.

Comment: This proved the most controversial of all recommendations. It was argued that the lack of high quality evidence to validate efficacy does not necessarily mean that complementary medicines are clinically ineffective. It was also said that this proposal would decimate the complementary medicines industry.

Subsequently, a pragmatic compromise was suggested.³¹ 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, with appropriate consumer medicines information would be awarded a trademark of approval similar to the Australian National Heart Foundation “red tick”.

A formal consultation between all stakeholders (government, industry, health professionals and consumers) is required to examine the above proposals. It is hoped this will take place in 2009. Government bodies that should be involved in this consultation include the Complementary Medicines Implementation Reference Group (CMIRG) that was set up to provide advice on and oversee the implementation of the 2003 expert committee recommendations and the Complementary Medicines Evaluation Committee (CMEC) which provides scientific and policy advice about the safety and quality of new complementary medicines proposed for listing.

Conclusion

The current Australian regulatory system neither controls complementary medicines claims nor supports an evidence-based industry. This is

unacceptable given that Australians spend \$1–2 billion on these medicines each year. It also represents a failure of Australian Medicines Policy. The challenge for the Federal government is to overcome industry self-interest and the perception of regulatory “capture” and institute the reforms required. Equally, the complementary medicines industry must accept that its future will be based on evidence, not hype. Finally, the challenge for both health professionals and consumers is to learn more about the benefits and risks of complementary medicines and be more open to discussing these matters with each other.

Competing interests

I am a member of the National Prescribing Service (NPS) Research and Development Working Group which has reviewed the NPS research referred to in the article. I have also been a member of a Choice working group on complementary medicines which has supported the creation of Complementary Medicine Evaluation Pty Ltd, a not-for-profit civil society organisation that would offer sponsors of evidence-based complementary medicines an independent evaluation service and provide information to consumers and health professionals. This concept is recommended in the article. Subsequently, in common with Prof. Paul Komesaroff and others, I have agreed to be a Director of this company.

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