

Graeme Hanigan

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Emeritus Professor Lloyd Sansom AO

Mr Will Delaat AM

Professor John Horvath AO

Dear Sirs,

I write to you as a former consumer of so called “complementary and alternative medicines” and ask that you accept my suggestions for consideration under the current review, ‘Reforms to the regulatory framework for complementary medicines.’

My experience with CAM began in 1992. I suffered a back injury for which the medicine of the day was unable to provide a treatment which was not without unpleasant side effects or risks, however the discomfort that I was experiencing drove me to desperation.

It was suggested by a trusted friend that I try CAM, which I subsequently did, and consequently wasted a vast amount of money over several years, on chiropractic, osteopathy, naturopathy, homeopathy, to name just a few ‘modalities’, with no real long term benefit, despite the claims of the various practitioner’s to the contrary.

It was my son giving me a copy of the ‘The Skeptics Dictionary’ that revealed to me that these so called “complementary and alternative medicines” make claims of efficacy that are, in most cases, completely unsupported by credible evidence. What a revelation that was!

In the industry of called “complementary and alternative medicines” any notion of consumer protection was and still is appallingly and noticeably absent. There is almost complete reliance on a placebo response to give these treatments the appearance of efficacy.

On the basis of my experience as a consumer, and with regard to the following recommendations I wish to put forward the following suggestions.

RECOMMENDATION FORTY THREE

The Panel recommends that where a medicinal product is listed in the ARTG, the sponsor be required to publish on the sponsor’s website or, if the sponsor does not have a website, on another website nominated by the NRA, the evidence that it holds to support all indications included in the ARTG entry.

From my own experience and from my observation of consumers in the CAM market, the vast majority of consumers do not have the necessary skills to determine the difference between credible evidence and junk evidence. I certainly didn't!

I suggest that the sponsor be obliged to reference that particular treatment or remedy on offer, as reviewed by an accepted credible reference, such as the NCCAM or the Cochrane Library.

RECOMMENDATION FORTY FOUR

The Panel recommends that where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.

I imagine that this would apply to remedies that are not listed in either the NCCAM or Cochrane Library.

These should carry a clear unambiguous disclaimer to the effect that 'This product has not been independently tested, and has no known efficacy beyond that of a placebo response.'

'Traditional use' is not evidence of efficacy and in many cases claims of traditional use have been shown to be demonstrably false.

RECOMMENDATION FORTY NINE

The Panel recommends that the NRA develops a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicinal products. Such a scheme should include:

an increase in the number of products subject to random/targeted post-market review;

provisions to allow the NRA to complete a post-market review in the event that the sponsor withdraws the product from the ARTG during the course of the review;

timely availability of information for consumers for each listed product in relation to whether the product has been subject to post-market review, and the timing and outcome of any review;

integration and timely analysis of any available datasets, including eHealth and hospital records, to provide a more streamlined and cost-effective approach to post-market monitoring (Recommendation Twenty Seven refers), particularly of products including newly approved ingredients;

provision for electronic reporting of adverse events; and

enhanced collaboration with overseas NRAs to share information relating to safety or efficacy of comparable products.

In the absence of any credible associations governing CAM practitioners, I suggest an independent public portal for CAM consumers to report both unethical activity and adverse reporting of treatments offered by CAM practitioners.

With regards to adverse events reporting there would appear to be reluctance by CAM practitioners to engage in this activity.

It has only been thanks to the diligence of medical doctors that has revealed the dangers of chiropractic. <http://edzardernst.com/2013/10/twenty-things-most-chiropractors-wont-tell-you/>

RECOMMENDATION FIFTY FIVE

The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

Whilst I can imagine the impost this must be, I would be delighted to see an example of self-regulation working in the favour of consumer interest. It's just not going to happen!

May I offer quote attributed to Ben Franklin here, "There are no greater liars in the world than quacks — except for their patients."

In the case of pharmacies who work under the auspices of a scientifically trained pharmacist, I suggest that pharmacies be obliged to offer information to customers explaining the placebo effect and how this applies to all relevant products on offer, including medicines.

Surely there can be no harm in having a well-informed consumer, unless you as a seller are interested in committing some sort of deception, deliberate or otherwise.

Warm Regards

Graeme Hanigan