

Department of Health and Ageing Therapeutic Goods Administration

Therapeutic Goods Act 1989 Therapeutic Goods Regulations 1990

Decision under regulation 9 of the Therapeutic Goods Regulations 1990 in relation to an advertisement about "homeopathic, homeoprophylaxis and homeoprophylactic products"

(Complaint No 2011/05/004)

Background

On 19 December 2011, the delegate of the Secretary to the Department of Health and Ageing (the Delegate) for the purposes of regulation 9(1) of the Therapeutic Goods Regulations 1990 (the Regulations) issued an order to "Homeopathy Plus" (the Advertiser) in relation to a website advertisement at www.homeopathy.com.au about "homeopathic, homeoprophylaxis and homeoprophylactic products"

This decision was made by the Delegate after receiving a request from the Complaints Resolution Panel (the Panel) under section 42ZCAI(3) of the Regulations on 6 September 2011 in relation to the "homeoprophylaxis" advertisement referred to above, the subject of Complaint No 2011/05/004. The recommendation to order Homeopathy Plus to carry out specified actions in relation to the website advertisement was made as Homeopathy Plus had not fully complied with the Panel's determination issued on 2 August 2011.

The Panel's findings

The Panel found that sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(2)(i), 4(4), 4(5), 5(2), and 6 of the Therapeutic Goods Advertising Code 2007 (the Code¹) were breached in relation to the advertisement on the website. The discussion in relation to these breaches is at paragraphs 22-39 of the Panel's determination which may be accessed from the Panel's Complaint Register Complaint No 2011/05/004.

Code breaches

The Delegate concluded that the advertisement which was the subject of the complaint and the advertising material on the website $\underline{www.homeopathyplus.com.au}$ when accessed between 5-19 December 2011 still breached sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(4), 4(5), 5 and 6 of the Code.

Breaches of section 4(1)(b), section 4(2)(a) and section 4(2)(c) of the Code

The Delegate maintains that the advertisements that are present on the website www.homeopathyplus.com.au remain in breach of the aforementioned sections in that statements about the vaccination of humans for potentially serious diseases via various homeopathic remedies have not been verified by the Advertiser by providing relevant supporting documents. Due to the claims of effectiveness, comparable effectiveness to vaccines or ability to prevent diseases for which no vaccines exist, the advertisements would

¹ Please refer to the webpage http://www.tga.gov.au/consumers/advertising-complaint-consumer-guide.htm for a summary of the advertising provisions that are commonly breached.



be likely to arouse unwarranted and unrealistic expectations of product effectiveness. The Delegate was of the view that the representations mislead directly or by implication that homeopathic products can be as effective as vaccines or can be used instead of vaccines when no strong scientific evidence was provided by the advertiser to support such assertion.

Breaches of section 4(2)(d) and section 4(2)(f)

The Delegate was of the view that the website uses language which is likely to cause fear and distress to the average consumer. The Delegate was also of the view that claims made on the website may influence the average consumer to avoid seeking vaccination for a potentially fatal disease and encourage the inappropriate use of a homeopathic product for the prevention of Whooping Cough. The provision of statistics from the Brazilian experience quoted on the website may mislead consumers as it states that homeopathic protection from meningococcal disease was 95%, even though no conclusive scientific information supporting such a statement was provided by the Advertiser. Consumers reading such statements may conclude that homeopathic treatment would be adequate to protect them from this infection.

The Delegate was also of the view that encouraging consumers to purchase several subsidised low priced Flu-Stop to send to family and friends and for the prevention and treatment of flu (be it bird flu, swine or any other sort) encourages inappropriate use or excessive use of therapeutic goods.

Breaches of section 4(2)(i)

It was the Delegate's view that statements such as "They (homeopathic remedies) are safe for people of all ages including babies, the elderly and the pregnant." imply that homeopathic remedies are safe for all consumers. There was no conclusive scientific information provided to support such claims.

Breaches of section 4(4) and section 4(5)

The Delegate was of the view that the links in the advertising material to articles and papers are in breach of the aforementioned sections of the Code in that the information presented is not balanced and is likely to be misleading. Research results must identify the researcher and financial sponsor of the research. The Delegate agreed with the Panel that although the Advertiser provided some evidence in relation to representations made in the advertisement, the evidence as a whole was not adequate in scope (for example as it relates to clinical trial procedures), quality or type, to support such those representations. For example, the paper titled "Whooping Cough Epidemic Caused by Virulent New Pertussis Strain – And It's the Result of Vaccine" contains information that is presented from one point of view that is not supported by accurate, scientifically proven information. Additionally, the statements mislead consumers to believe that immunisation against Whooping Cough leads to a spread rather than the reduction of the disease. The advertisement represented the advertised products as being capable of preventing infectious diseases with comparable effectiveness to vaccines and of preventing "diseases" for which no vaccine exists. However, no conclusive scientific evidence was presented to support such assertions.

Breaches of section 5

The Delegate concluded that the advertisements that are present on the website www.homeopathyplus.com.au remain in breach of section 5 of the Code in that they include references to Autism, Anxiety, HIV and AIDS and the immunisation issues page includes references to Hepatitis B, Meningococcal Disease, Aids, Cancer, Malaria, Japanese Encephalitis and Dengue Fever.

Breach of section 6.

The advertisements that are present on the website www.homeopathyplus.com.au do not have the required mandatory warning statements included in the website material.

The Order made to Homeopathy Plus

Under regulation 9(1) the delegate of the Secretary ordered Homeopathy Plus to:

- (a) withdraw the website advertisement which is the subject of the complaint and determination by the Panel found at the Homeopathy Plus website (www.homeopathyplus.com.au) from further publication;
- (b) withdraw any representations that the homoeoprophylactic products can prevent or otherwise have benefits in relation to infectious diseases, can prevent or otherwise have benefits in relation to meningococcal disease, are comparable in efficacy to vaccines, can prevent diseases for which no vaccine exists, are 90.4% effective in relation to childhood communicable diseases, or have been 95% effective against meningococcal disease, or that the Flu-Stop product can treat or prevent flu, together with any representation that the advertised products are safe or are safe for particular categories of consumer;
- (c) not use the representations in (b) above in any other advertisement unless Homeopathy Plus satisfies the TGA the use of the representations would not result in a contravention of the *Therapeutic Goods Act 1989* (the Act), the Regulations or the *Therapeutic Goods Advertising Code 2007* (the Code).
- (d) where the representation has been provided to other parties such as retailers or website publishers, and where there is a reasonable likelihood that the representation has been published or is intended to be published by such parties, to advise those parties that the representations are to be withdrawn;
- (e) arrange for the publication on the website www.homeopathyplus.com.au of a retraction in the form of, and in accordance with, the conditions set out in the attachment to this order (Attachment A).

Conditions imposed on the order

Pursuant to section 9(2) of the Regulations, the order is subject to the following conditions:

- (a) within 10 working days of being notified of this order, Homeopathy Plus will provide to the Delegate of the Secretary:
 - (i) evidence of compliance with this order; and
 - (ii) a written response indicating that Homeopathy Plus will continue to abide by this order.

Outcome

As of 26 March 2012, no response has been provided by Homeopathy Plus.

Form of retraction

A retraction to appear on the home page of the website <u>www.homeopathyplus.com.au</u> at the earliest opportunity.

A copy of the retraction advertisement is to be provided to the Therapeutic Goods Administration for approval before publication.

RETRACTION

An advertisement for "homeopathic protection", "hoemprophylaxis", or "homeoprohylactic" products, which we published on this website, should not have been published.

In the advertisement we unlawfully made claims that the homeopprohylaxis products could prevent some serious infectious diseases, including meningococcal disease.

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. The evidence we provided was wholly inadequate to support the claims we made. The Panel therefore found that the claims were unlawful, misleading, and unverified and breached the Therapeutic Goods Advertising Code.

The Therapeutic Goods Administration therefore ordered that we publish this retraction.

The full text of the determination can be found at: www.tgacrp.com.au/complaints

No other copy should be included in the retraction.

Location:	Website front page, so that it can be viewed without scrolling the page
Size:	No less than 500 pixels wide and 200 pixels high
Heading:	Arial or Helvetica
	Red on a white background
	The letters should be no less than 20 pixels in height, and should be no smaller than any other body text on the page
	Bold
Text:	Arial or Helvetica
	Red on a white background
	The letters should be no less than 14 pixels in height, and should be no smaller than any other body text on the page
	Bold
Text Box:	Red on a white background
Duration:	150 days