

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaint 2009-09-013 Homoeopathic Immunisation

Meeting held 26 November 2009

Complaint summary

Complainant	Dr Ken Harvey
Advertiser	Homoeopathy Plus!
Subject matter of complaint	Website advertisements
Type of determination	Final
Sections of the Code, Regulations or Act found to have been <u>breached</u> *	Act section 42DL(1)(a) Code sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(f), 4(5), 5(2)
Sections of the Code, Regulations or Act found <u>not to have been breached</u> *	Code section 4(7)
Sanctions	Withdrawal of advertisement Withdrawal of representations Publication of a retraction

* only sections of the Code, Act, or Regulations that were part of the complaint or were raised by the Panel are listed

The advertisement(s)

1. The complaint concerned internet advertisements published at the websites www.homeopathyplus.com.au and www.d-n-h.org.
2. The advertisement at www.homeopathyplus.com.au was headed “What is Homeopathic Immunisation” and included claims such as “homeopathic immunisation is effective against poliomyelitis, chickenpox, meningococcal disease, hepatitis (all types), Japanese encephalitis, Hib, influenza, measles, pneumococcal disease, cholera, smallpox, typhoid, typhus, whooping cough, rubella, mumps, diphtheria, malaria, tetanus, yellow fever, dysentery, and many other epidemic diseases”, and “studies have shown [that Anas Barbariae] relieves the intensity and shortens the duration of flu symptoms better than anti-virals such as *Tamiflu* and *Relenza* – and without the side-effects.”
3. This advertisement also included the claims that “recent research conducted at Swinburne University (Melbourne) by Australian homeopath, Dr Isaac Golden, confirmed that homeoprophylaxis provides the same degree, or better, protection than vaccines with none of their side-effects or complications”, and that “symptoms are sometimes removed in a few hours by just one dose while at other times two or more doses are needed before the sufferer is completely ‘flu-free’”.
4. The advertisement at www.d-n-h.org included claims of benefits including “protection against the high-risk diseases of whooping cough, pneumococcal disease, poliomyelitis, Hib, meningococcal disease, diphtheria, and tetanus” and “protection against the less serious diseases of measles, mumps, rubella, hepatitis B, and chicken pox”, and made reference to the “Australian Children’s Homeopathic Immunisation program (CHIP)” which it described as having been “based on over 200 years of clinical usage and research, including recent Australian research from Swinburne University, Melbourne” and “designed for parents and carers who have already made the decision not to vaccinate their children and who would like a safe, alternative method of protection.”
5. An excerpt of the advertisements can be viewed in the relevant Appendix to this determination.

The product(s)

6. The advertisement promoted homoeopathic immunisation kits called “Kit A” and “Kit B”, together with other homoeopathic treatment and immunisation products.

The advertiser(s)

7. The advertiser was Homeopathy Plus!

The complaint

8. The complainant was Dr Ken Harvey.
9. The complainant alleged that the advertisements breached section 42DL(1)(a) of the Act, and sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(5), 4(7), and 5(2) of the Code.
10. The complainant stated that the Isaac Golden study, to which the advertisements made reference, in fact included a statement that “the effectiveness of the [homeopathic

immunisation program] could not be established with statistical certainty given the limited sample size and the low probability of acquiring an infectious disease”.

The advertiser's response to the complaint

11. The advertiser stated that “no homeopathic remedies relating to prophylaxis have been advertised on or sold from the websites in question, either now or in the past” and “likewise no proprietary remedies have been either advertised or sold on the websites – only those that are generic, available OTC, and used by homeopaths worldwide.” The advertiser stated that “any remedies that can be purchased [on the websites] are those used for treatment and are applied according to symptom similarity rather than disease names”, and that “any person contacting [the advertiser’s clinic or the advertiser] regarding prophylactic remedies is advised that prophylactics are only discussed or dispensed in the context of a consultation”.
12. The advertiser also stated that:
 - a) the representations on the websites were supported by research;
 - b) the paragraph from the abstract of the Isaac Golden research cited by the complainant was “a pro forma statement appended to many theses prior to publication and as such is not representative of the endorsed statistical significances and confidence intervals found within the thesis”, and that in fact the thesis has reached a positive conclusion with a high degree of confidence;
 - c) the references to kits were “generic in nature and a reflection of the kits commonly compiled by homeopaths worldwide for their patients”, and “the kits do not refer to a proprietary product, nor are they kits advertised or sold from the websites”;
 - d) the Isaac Golden research “did confirm what other studies had previously found, that is, that homoeoprophylaxis provided the same degree or better protection than that of vaccines with none of their side-effects or complications”;
 - e) studies do in fact show that homoeopathic treatment of influenza can produce better and faster results than those from anti-viral medications”; and,
 - f) the World Health Organisation “did not release any official statement saying that homoeopathy was ineffective and without research” as “this was a hoax”.
13. The advertiser cited references in support of claims regarding “homoeoprophylaxis” but did not provide complete copies of the papers cited.

Findings of the Panel

14. An advertisement for therapeutic goods is defined in the Act to include “any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.”
15. As a preliminary matter, the Panel noted that material may constitute an advertisement for therapeutic goods whether or not the material offers those goods for sale, and whether or not the therapeutic goods referred to are “proprietary” or are available from many different sources.

16. The Panel was satisfied that the two websites essentially constituted, jointly, an advertisement for therapeutic goods, namely the “Kit A” and “Kit B” products, the homoeopathic products available for sale on the www.homeopathyplus.com.au website, and numerous other products such as Flu Stop, Smoke Stop, Eat Easy, Hangover Help, Bites and Stings Complex, Burns Complex, Bruises, Earache, Sprains and Strains, Colic Relief Complex, Fracture Complex, Grief Complex, Gum Abscess Complex, Hayfever Complex, Jet Lag Complex, Motion Sickness Complex, Mastitis Complex, Mouth Ulcer Complex, Panic Stop, Snore No More, Cough Relief (Moist), Cough Relief (Dry), Reflux Complex, Children’s Fever Complex, Toothache Ease, Sunburn Complex, and many other products.
17. The websites were therefore advertisements, or an advertisement, for therapeutic goods under the Act.
18. Section 42C of the Act makes it an offence to publish certain advertisements for therapeutic goods in specified media that does not have an approval number, or to publish an advertisement without its approval number, and through reference to the Regulations, applies to “advertisements for designated therapeutic goods published or inserted, or intended to be published or inserted, for valuable consideration, in specified media.”
19. Section 42DL(1)(g) of the Act prohibits the publication of advertisements for therapeutic goods that are not included in the Register. The Panel noted that the product is not included in the Register, and that therefore any of the material in the advertisement that presented the product as being for therapeutic use (as defined in the Act) would be sufficient to render the material in breach of section 42DL(1)(g). The Panel considered that the claims relating to “the conversion of fat components into energy” were therapeutic claims which ought not to have been made, and that the material therefore constituted a breach of section 42DL(1)(g) of the Act. The Panel therefore found this aspect of the complaint justified.
20. Section 4(1)(b) of the Code requires that advertisements for therapeutic goods “contain correct and balanced statements only and claims which the sponsor has already verified.” Section 4(2)(a) of the Code prohibits representations that are “likely to arouse unwarranted and unrealistic expectations of product effectiveness”. Section 4(2)(c) of the Code prohibits representations that “mislead directly or by implication or through emphasis, comparisons, contrasts or omissions”.
21. The Panel did not find that the material provided by the advertiser could be regarded as adequate to support the strong and extensive claims made in the advertisements. The Panel noted the position of the National Health and Medical Research Council to be that:

Homoeopathic ‘immunisation’ has not been proven to give protection against infectious diseases; only conventional immunisation provides a measurable immune response. The Council of the Faculty of Homoeopathy, London, issued a statement in 1993 which reads: “The Faculty of Homoeopathy, London, strongly supports the conventional vaccination program and has stated that vaccination should be carried out in the normal way, using the conventional tested and proved vaccines, in the absence of medical contraindications.” The Executive Director of the Australian Natural Therapies Association has stated that no properly qualified natural therapist would recommend homoeopathic ‘immunisation’ as an alternative to conventional immunisation.

22. The Panel further noted that the advertiser had not disputed that the Golden paper, upon which the advertisements placed considerable weight, did in fact include a statement that “the effectiveness of the [homoeopathic immunisation program] could not be established with statistical certainty given the limited sample size and the low probability of acquiring an infectious disease”. Whether such statements are often made within academic theses was not, in the Panel’s view, relevant to the question of whether the Golden paper could support the claims made in the advertisement.
23. None of the material provided by the advertiser persuaded the Panel that the claims made in the advertisement were in fact verified and not misleading, and were not likely to arouse unwarranted expectations in relation to the advertised products. On the contrary, the Panel was satisfied that the claims made had not been verified, were misleading, and were likely to arouse unwarranted expectations in relation to the advertised products. The advertisements therefore breached sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code, and these aspects of the complaint were justified.
24. Section 4(2)(d) of the Code prohibits advertisements which “abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.”
25. Given the Panel’s finding that the claims made in the advertisements were misleading and unverified, it was clear that the advertisements also abused the trust or exploited the lack of knowledge of consumers. Moreover, the Panel noted that the use of words such as “do no harm initiative” appeared likely to create fear and distress in consumers by implying that vaccination is harmful. This aspect of the complaint was therefore justified..
26. Section 4(2)(b) of the Code prohibits advertisements that are “likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases”.
27. Section 4(2)(b) of the Code prohibits advertisements that are “likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases”.
28. Section 5(1) of the Code prohibits advertisements that “contain, expressly or by implication, a representation specified in Part 1 of Appendix 6.” The representations specified in Part 1 of Appendix 6 of the Code include representations regarding the treatment, cure, or prevention of neoplastic diseases. Section 42DL(1)(a) of the Act provides that a person must not publish or broadcast an advertisement about therapeutic goods that contains a prohibited representation (whether in express terms or by necessary implication) about those goods, essentially imposing the same requirement as section 5(1) of the Code.
29. Section 5(2) of the Code prohibits advertisements that “refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in Part 2 of Appendix 6, unless prior approval is given under the Therapeutic Goods Act 1989.” The diseases and conditions specified in Part 2 of Appendix 6 of the Code include “serious forms of” a wide range of health concerns.
30. There were countless references to serious conditions within the advertisement, and to their prevention, treatment or cure. These included poliomyelitis, chickenpox, meningococcal disease, hepatitis (all types), Japanese encephalitis, Hib, influenza, measles, pneumococcal disease, cholera, smallpox, typhoid, typhus, whooping cough, rubella, mumps, diphtheria, malaria, tetanus, yellow fever, and dysentery. The advertisements also made unqualified reference to “many other epidemic diseases”, which

in the Panel's view (in the absence of clear qualifying words) would be taken by the ordinary consumer to include infectious diseases such as HIV.

31. The advertisements were therefore in clear breach of sections 4(2)(b) and 5 of the Code, and section 42DL(1)(a) of the Act. These aspects of the complaint were therefore justified.
32. Section 4(2)(f) of the Code prohibits representations that "encourage inappropriate or excessive use" of therapeutic goods. Given the Panel's findings in relation to the claims made in the advertisements, it was clear that they also encouraged inappropriate use of the advertised products. This aspect of the complaint was therefore justified.
33. Section 4(1)(a) of the Code requires advertisements for therapeutic goods to comply with the statute and common law of the Commonwealth, States and Territories. On the basis of the Panel's other findings, this aspect of the complaint was clearly justified.
34. Section 4(5) of the Code prohibits the inclusion in advertisements of comparisons that "imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual", and provides that comparative advertisements "must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which [they are] compared". The advertisements implied, in the Panel's view, that both vaccines and anti-viral medicines are harmful or ineffectual. Moreover, the Panel was satisfied that the comparisons made between the advertised products and vaccines or anti-viral medicines were not balanced and were misleading. The Panel therefore found this aspect of the complaint justified.
35. Section 4(7) of the Code requires that testimonials included in advertisements for therapeutic goods "must be documented, genuine, not misleading and illustrate typical cases only." The Panel did not find that the material before it included testimonials. This aspect of the complaint was therefore found not to be justified.
36. The Panel also noted, without making any formal finding, that the advertisements appeared likely to breach section 4(2)(i) of the Code.

Sanctions

37. The Panel requests Homeopathy Plus!, in accordance with subregulation 42ZCAI(1) of the *Therapeutic Goods Regulations 1990*:
 - a) to withdraw the advertisement from further publication;
 - b) to withdraw any representations that the advertised products, including the Kit A, Kit B, and Anas Barbariae products, have benefits in relation to poliomyelitis, chickenpox, meningococcal disease, hepatitis (all types), Japanese encephalitis, Hib, influenza, measles, pneumococcal disease, cholera, smallpox, typhoid, typhus, whooping cough, rubella, mumps, diphtheria, malaria, tetanus, yellow fever, dysentery, or any "epidemic diseases", or that they are equivalent to, superior to, or a replacement or alternative for, vaccines or anti-viral drugs;
 - c) not to use the representations in (b) above in any other advertisement unless Homeopathy Plus! satisfies the Panel that the use of the representation would not result in a contravention of the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990* or the *Therapeutic Goods Advertising 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 representation(s) should be withdrawn;
 - e) to arrange for publication on the websites www.homeopathyplus.com.au and www.d-n-h.org of a retraction in the form of, and in accordance with, the conditions set out in the attachment to this determination; and,
 - f) within 14 days of being notified of this request, to provide evidence to the Panel of its compliance, including a response in writing that they will comply with the Panel's sanctions, and where appropriate, supporting material such as copies of instructions to advertising agents or publishers, or correspondence with retailers and other third party advertisers.
38. The advertiser's attention is drawn to the provisions of sub-regulations 42ZCAI(3) and (4) which permit the Panel to make recommendations to the Secretary in the event of non-compliance with this request, including a recommendation that the inclusion of the goods on the Register be cancelled.

Dated 15 January 2010

For the Panel



Jason Korke
Chairman

Appendix A: Definitions

In this determination, unless otherwise specified:

- a) “the Act” means the Therapeutic Goods Act 1989;
- b) “the Regulations” means the Therapeutic Goods Regulations 1990;
- c) “the Code” means the Therapeutic Goods Advertising Code;
- d) “the Register” means the Australian Register of Therapeutic Goods;
- e) “any other advertisement” appearing in sub-regulation 42ZCA1(1)(d) is not confined to advertisements in specified or broadcast media (in relation to which complaints may be made to the Panel under Regulation 42ZCAB).

Appendix B: Retraction

An advertisement is to appear on the home page of the websites www.homeopathyplus.com.au and www.d-n-h.org at the earliest booking opportunity.

A copy of the retraction advertisement, and the page on which it will be published, is to be provided to the Complaints Resolution Panel for approval before publication.

RETRACTION

An advertisement for homeopathic immunisation products, which we published on this website, should not have been published.

In the advertisement we unlawfully made claims that homeopathic "immunisation" products could aid immunity, were alternatives to vaccination, and that they could prevent or protect against infectious diseases, including serious infectious diseases. We also made claims that an advertised homeopathic product was more effective than anti-viral medication.

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. We did not provide adequate evidence to support the claims made in the advertisement, and the Panel found that the claims were unlawful, misleading, and unverified and breached the Therapeutic Goods Advertising Code.

The Panel therefore requested that Homeopathy Plus! publish this retraction.

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

No other copy should be included in the advertisement.

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, black and blue on a white background, per above 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:	180 days
HTML	In the case of website retractions, the retraction is to be presented in ordinary and valid HTML 4 in the body of the page. Pop-ups, Flash objects, or images are not acceptable formats for website retractions.



Homeopathy plus!

Information • Remedies • Immunisation

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Fact Sheet -- Homeopathic Immunisation

(A PDF version of this page is available [here](#))

What is Homeopathic Immunisation?

Homeopathic immunisation - also known as homeoprophylaxis - is a safe and effective way to protect you and your family against childhood and other epidemic diseases. It will even protect your farm and companion animals. The prophylactics (medicines or remedies) do not have to be given by a practitioner; they are safe for you to use yourself.

Homeopathic immunisation is effective against poliomyelitis, chickenpox, meningococcal disease, hepatitis (all types), Japanese encephalitis, Hib, influenza, measles, pneumococcal disease, cholera, smallpox, typhoid, typhus, whooping cough, rubella, mumps, diphtheria, malaria, tetanus, yellow fever, dysentery, and many other epidemic diseases. Communities around the world have used its protective effect for over two hundred years.

<http://homeopathyplus.com.au/hplus/immunisation-issues/fact-sheet---homeopathic-immunisation.html>