



Australian Government
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 the product 'black salve'**
(Complaint No. 2012-04-022)

Background

On 13 May 2013, 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) decided to order 'the Australian Vaccination Network Inc' (the AVN) to carry out actions in relation to a website advertisement at www.avn.org.au promoting the product 'black salve' and a DVD entitled 'One Answer to Cancer'.

The decision was made by the Delegate on review of the recommendation from the Complaints Resolution Panel (the Panel) under section 42ZCAI(3) of the Regulations on 31 January 2013 in relation to the 'black salve' internet advertisement, the subject of Complaint No. 2012/04/022. The recommendation to order the AVN to carry out specified actions in relation to the website advertisement was made as the AVN had not fully complied with the Panel's determination issued on 3 December 2012.

The Panel's findings

The Panel found that sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(e)(ii), 4(2)(f), 4(2)(g), 4(2)(h), 4(2)(i), 4(5), 4(7), 5(1) and 6(3) of the *Therapeutic Goods Advertising Code 2007* (the Code) and section 42DL(1)(g) of the Therapeutic Goods Act 1989 (the Act) were breached in relation to the advertisement on the website. The discussion in relation to these breaches is at paragraphs 12-33 of the Panel's determination which may be accessed from the Panel's Complaint Register - [Complaint No. 2012/04/022](#).

Code breaches

The Delegate concluded that the advertisement, which was the subject of the complaint, breached sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(e)(ii), 4(2)(f), 4(2)(g), 4(2)(h), 4(2)(i), 4(5), 4(7) and 5(1) of the Code and section 42DL(1)(g) of the Act.

Breach of section 42DL(1)(g) of the Act

The Delegate found the advertisement to be in breach of section 42DL(1)(g) of the Act because the advertised goods are not entered in the Register.

Breach of section 5(1) of the Code

Cancer is a neoplastic disease and is a prohibited representation as specified in Part 1 of Appendix 6 of the Code; because the advertisement expressly promoted 'black salve' for the treatment of 'skin cancer and other cancerous conditions' the Delegate found therefore it was in breach of section 5(1) of the Code.

Breach of section 4(1)(a) of the Code

For the breaches referenced below, the Advertisement does not comply with the Act and the Code and is therefore in breach of section 4(1)(a) of the Code.

Breach of sections 4(1)(b) and 4(2)(a) of the Code

The Advertiser was not able to produce valid supporting evidence in relation to their claims, nor was there any referenced or highlighted medical evidence in the advertisement to support the representations. The advertisement promoted 'black salve' as a '*safe, effective, natural remedy...used for over 2,000 years to treat skin cancers and other cancerous conditions, leading to a total remission of the disease*'. The Delegate considered that, based on these statements, consumers would be entitled to expect that 'black salve' will cure them of cancer when, in fact, there is no credible, reliable clinical or scientific evidence to demonstrate that the product is effective in the treatment of any cancer. The Delegate found the advertisement was unverified, was not correct and raised unrealistic and unwarranted expectations of product effectiveness therefore in breach of sections 4(1)(b) and 4(2)(a) of the Code.

Breach of sections 4(2)(b) and 4(2)(c) of the Code

The 'black salve' product was advertised both as a cure for cancer and as a legitimate alternative to 'Aldara' a conventional medicine. It was the Delegate's view that this comparison could mislead consumers into incorrectly believing that 'black salve' was a natural safe alternative which was more effective than conventional medicines and that the advertisement sought to give credibility to 'black salve' over clinically proven alternatives. The Delegate considered that statements made in the advertisement could lead to consumers inappropriately relying on 'black salve' to treat skin cancer to the exclusion of clinically proven conventional medicine and that the suggestion that 'black salve' will '*help people cure their own cancers*' may lead to self-diagnosis and a failure to seek out proper medical attention for a potentially fatal disease. The Delegate found the advertisement was likely to lead to inappropriate treatment of a potentially serious disease and was misleading, therefore in breach of sections 4(2)(b) and 4(2)(c) of the Code.

Breach of sections 4(2)(d) and 4(2)(e) of the Code

It was the Delegate's view that the advertisement portrayed 'black salve' as a cure for cancer which would exploit a person's vulnerability when seeking an alternative to conventional cancer treatments, especially without diagnosis. The advertisement used language that, in the Delegate's view, would bring about fear or distress by making people fearful of the consequences if they did not use 'black salve' or, alternatively, if they relied on conventional medicine for treatment. The Delegate also found that promoting 'black salve' as a guaranteed safe alternative exploited the lack of knowledge that consumers have about the treatment of cancer and the different treatment modalities that may be required depending on the type of cancer diagnosis. For these reasons the Delegate considered that the advertisement breached sections 4(2)(d) and 4(2)(e) of the Code.

Breach of section 4(2)(f) of the Code

It was the Delegate's opinion that it would be inappropriate for consumers to rely on 'black salve' as a treatment for cancer (diagnosed or not) in preference to, or to the exclusion of, other conventional treatments. As there were no instructions surrounding the use of 'black salve' in the advertisement it was the Delegate's view that misdiagnosis by a consumer would cause greater harm to themselves and that by not seeking appropriate medical help, incorrect application of "black salve" could cause extensive, irreparable damage to their skin. The Delegate found the advertisement was likely to encourage inappropriate or excessive use of the product and therefore was in breach of section 4(2)(f) of the Code.

Breach of sections 4(2)(g) and 4(2)(h) of the Code

The Delegate found that the advertisement encouraged those consumers who may have eschewed conventional medical practice and who were seeking alternative curative measures to use the 'black salve' product. In the absence of any information to the contrary the use of the phrase '*total remission*' was in the Delegate's view representing this product as a guaranteed treatment for cancer and that it would be effective in all cases, and was therefore in breach of sections 4(2)(g) and 4(2)(h) of the Code.

Breach of section 4(2)(i) of the Code

The advertisement promoted 'black salve' as a '*safe, effective, natural remedy*' and that it was '*time-tested*'. The advertisement does not mention that 'black salve' can cause harm or has any side effects, nor did it advise the consumer that 'black salve' can burn the skin (which may require medical attention) and can cause permanent scarring. The Delegate found therefore the advertisement to be in breach of section 4(2)(i) of the Code because it promoted the product as safe, without side effects and that no harm could come from its use.

Breach of section 4(5) of the Code

The advertisement compared 'black salve' with an 'S4' 'Prescription Only' medicine *Aldara*, stating that *Aldara* was '*dangerous and ineffective*', that it caused '*serious systemic and fatal reactions*' and was '*known to CAUSE cancer*'. The advertisement stated that the author of the DVD entitled 'One Answer to Cancer' was '*almost killed by Aldara*' which is a '*dreadful poison*' that has '*ruined or cut (lives) short*'. This promotion of 'black salve' was in the Delegate's view, misleading in comparison with the recognised conventional medicine *Aldara* because it stated that it was both harmful and ineffective in comparison with "black salve" and the advertisement therefore was in breach of section 4(5) of the Code.

The Order made to the AVN

Under regulation 9(1) the Delegate ordered the AVN as the Advertiser to:

- (a) not to use any representations that 'black salve' is for any therapeutic use, is safe or free of side effects, or offers any benefits in relation to cancer (including skin cancer), together with any representations that compare 'black salve' with cancer medicines or imply that cancer medicines are harmful or ineffective;
- (b) not to use the representations in (a) above in any other advertisement including in the promotion of the DVD 'One Answer to Cancer'; and
- (c) to arrange for publication on the website www.avn.org.au of a retraction in the form of, and in accordance with, the conditions set out in the attachment to the order.

Conditions imposed on the order

- (a) within 10 working days of being notified of this order, the AVN will provide evidence to the Delegate of compliance with this order; and
- (b) within 10 working days of being notified of this order, the AVN will provide a written response to the Delegate that the AVN will continue to abide by this order.

R13/347755

RETRACTION

An advertisement promoting illegal therapeutic goods under the name “Black Salve”, which we published on this website, should not have been published. In publishing the advertisement, we misled and abused the trust of consumers.

In the advertisement we unlawfully made claims that Black Salve is safe, and that it can be used as an effective treatment for cancers including skin cancer. We also claimed that cancer medicines are harmful and cause cancer, and are ineffectual.

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. We provided no evidence whatsoever to support the claims we made, and the Panel found that the claims were unlawful, misleading, and unverified and breached the Therapeutic Goods Advertising Code (Code).

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

The delegate of the Secretary for the purposes of regulation 9 of the *Therapeutic Goods Regulations 1990* also found that the claims and representation in the advertisement were unlawful, inaccurate and misleading in breach of the Code.

The attention of consumers is directed to the safety information from the Therapeutic Goods Administration at:
<http://www.tga.gov.au/consumers/information-salve-cansema.htm>

Retraction conditions

- (1) The retraction is to appear on the homepage of the Australian Vaccination Network website (presently www.avn.org.au).on the website www.avn.org.au at the earliest opportunity;
- (2) A copy of the retraction advertisement as set out above is to be provided to the TGA Advertising Unit for approval before publication on the Australian Vaccination Network website (presently www.avn.org.au).
- (3) The Retraction is to be published with the following specifications:

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:	60 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.