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Ernie Waldstein

From: Ernie Waldstein
Sent: Monday, 30 April 2012 2:25 PM
To: 'meryl' [REDACTED]
Subject: Complaint 2012/04/022 Black Salve
Attachments: Advertising Complaint Procedures.pdf; Commonwealth Legislation.pdf; Guidelines for respondents.pdf; Response Form 2012.doc; TGACC Advertising Code.pdf; TGACC Seminar Brochure 2012.pdf; 2012-04-02 Black Salve.pdf

Ms Meryl Dorey
 Australian Vaccination Network, Inc

Dear Ms Dorey

Complaint 2012/04/022 Black Salve

The Complaints Resolution Panel* has been established under the Regulations (Regulation 42R) to consider advertisements and generic information about designated therapeutic goods, medical devices and other therapeutic goods, published in mainstream print, broadcast media including TV, radio and the internet, cinema and outdoor media (Regulation 42ZCAB). Complaints must be made in writing.

The Complaints Resolution Panel (CRP) has received a complaint about an advertisement for Black Salve in www.avn.org.au on 19 April 2012.

Please find attached a copy of the advertisement and the complaint.

You should respond to the complaint. If you do not provide a response, the Panel may determine the complaint on the basis of the material before it.

We interpret the complaint as alleging breaches of section 42DL(1)(g) of the Act and 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(4), 4(5), 4(7), 5(2) and 6(3) of the Code. You should provide a response to each allegation.

Pursuant to regulation 42ZCAH, following a preliminary review of the complaint, please respond as well to each of the following possible breaches of the Code, Regulations and/or Act:

- Section 42DL(1)(g) of the Act, because the advertisement promotes Black Salve for therapeutic use, when these product/s may not be included in the Register
- Section 5(1) of the Code because of representations about cancer

Pursuant to regulation 42ZCAE, the Panel requires you to produce evidence in support of claims made in the advertisement. Please take this into account when preparing your response. Should you wish to provide supporting material for any claims challenged, you must provide an explanation as to how the material supports the complaint and identify relevant parts in the material. Please provide **pivotal** evidence to support the efficacy of the product with respect to the claims subject to complaint. The attached documents may assist you in preparing your response.

You should also provide the following additional information:

In addition to responding to the particulars of the complaint as noted above, the Panel also requests that you provide the following:

- The completed Response Form (attached)
- A statement as to whether the subject matter of the complaint is also the subject of legal proceedings that have not been finally disposed of (regulation 42ZCAJ)
- If the advertised products are included in the Register, the ARTG number and a copy of ARTG entries for each advertised product
- Any approval that was required for the publication of the advertisement and/or representations within it

You should also be aware of the following matters:

The Panel must consider a complaint and decide whether the complaint is justified having regard to written submission and documents given to the Panel, the results of its inquiries and information obtained about the complaint (regulation 42ZCAD).

After the parties have received a copy of the final written determination of the Panel concerning this complaint, that determination will be made available to the public on request and will be included on the website www.tgacrp.com.au under "Complaint Register". Before making the determination public in these ways, the identity of the complainant will be omitted if the complainant has so requested. Also, any information accepted by the Panel as confidential will be omitted.

The TGA observer to the Panel appointed by the TGA may be entitled to use any information provided to the Panel (whether confidential or not) pursuant to section 61(8) of the *Therapeutic Goods Act*.

When the Panel considers the complaint, it may decide to raise other matters. If it does so, you will be notified in writing and asked to provide a further response.

If the complaint is found to be justified, you may be asked to withdraw the advertisement, withdraw certain representations and not use them in future advertisements, publish corrective information or publish retraction/s. Where the Panel requests withdrawal of representations, the validity of the representations will not generally be reconsidered (per Regulation 42ZCAI(1)(d)) unless:

- at least 12 months have elapsed since the Panel made its request or
- genuinely new evidence has become available that was not available at the time of the complaint.

Your response must be provided to the Panel no later than 14 May 2012. Should no response be received, the Panel may, nevertheless, consider the complaint at its next meeting.

If you do not understand the complaint or are unsure as to how to respond, you may need to seek legal advice or the advice of a regulatory consultant.

Attached for your information please find a copy of each of the Therapeutic Goods Advertising Code 2007, the Complaints Resolution Panel procedures and some relevant clauses from the therapeutic goods legislation. The Code and procedures document also can be found on the website at www.tgacrp.com.au.

Should you require any further information, please let me know.

Please acknowledge receipt of this email.

*In this correspondence, references to the Code, Regulations, and Act are references to the Therapeutic Goods Advertising Code 2007, the Therapeutic Goods Regulations 1990 and the Therapeutic Goods Act 1989. References to the Register are references to the Australian Register of Therapeutic Goods. References to the Panel or the CRP are references to the Complaints Resolution Panel. References to the TGA are references to the Therapeutic Goods Administration.

Yours sincerely

Ernest Waldstein
for Judith Brimer, Executive Officer
Complaints Resolution Panel
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Enrol at www.tgacc.com.au/events for the 2012 TGACC Advertising Seminar courses:

Fundamentals

Sydney	Wed 20 June; Wed 24 October
Melbourne	Fri 11 May; Thurs 22 November
Perth	Fri 27 July
Adelaide	Wed 25 July
Brisbane	Fri 25 May; Fri 9 November

Advanced

Sydney	Wed 19 September
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