Complaint to TGA: Pharmacare Laboratories Ease-a-cold products

This is a high priority complaint to test the TGA's will to act on recalcitrant sponsors of complementary medicines.

See today's publication: https://theconversation.com/science-or-snake-oil-does-easeacold-really-help-to-shorten-your-cold-98311. Also, my comment below.

> "This product, produced by Pharmacare Laboratories, has been the subject of a previous article in "The Conversation" in 2015: https://theconversation.com/dont-believe-the-hype-your-complementary-medicines-are-unlikely-to-deliver-52139.
>
> It has also had six upheld complaints by the now abolished Therapeutic Goods Advertising Complaint Resolution Panel (CRP) from 2005 to 2016 and a referral from the CRP to the TGA in 2017 for failure to withdraw misleading representations that the product had "been 'clinically trialed' in the sense of being demonstrated to have effects such as reducing the duration, impact on daily life, or severity of symptoms of a cold".
>
> In addition, there was a decision to withdraw advertising approval (in specified media only, not the internet) by the Therapeutic Goods Administration on 11 Oct 2017, see: https://tga.gov.au/decision-withdraw-medicines-advertising-approval.
>
> Regardless, this product continues to be advertised with claims that have been repeatedly judged to be misleading and deceptive.
>
> Furthermore, Pharmacare Laboratories has the unenviable reputation of the having the most upheld complaints of any sponsor of complementary medicines over the 10-year life of the CRP.
>
> We now have a new complaint system run by the TGA which, if the TGA chooses to act, has penalties and sanctions for non-compliance that the CRP lacked, see: https://tga.gov.au/advertising-hub.
>
> I will now submit yet another complaint about this product to test the TGA's new system."

See: http://tgacrp.com.au/complaint-register/?_search=EaseaCold (4) & http://tgacrp.com.au/complaint-register/?_search=EaseaCold (2)

In addition, CRP determination 2016/07/018 is appended as attempts to download this determination produces "Invalid File crp-2016-07-018-ease-a-cold.pdf"(a known TGA database problem).

I submit that this complaint is "high priority" because the sponsor is recalcitrant, the product has had numerous upheld complaints and the varied advertising claims by the sponsor (and many others) continue to state or imply that that the product will shorten the duration and severity of a cold when it will not.

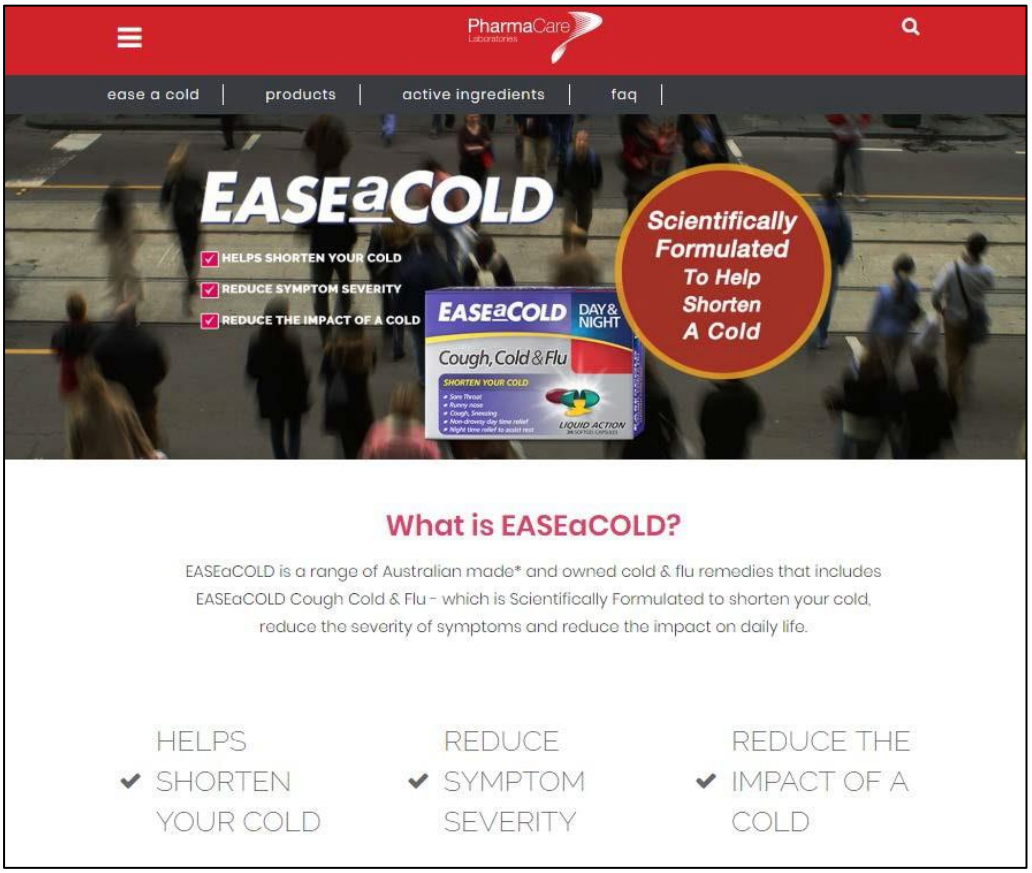
I allege (repeated) breaches of the Therapeutic Goods Advertising Code 2017, sections 4(1)(b), 4(2)(a) and 4(2)(c). These clearly impact on the consumers ability to appropriately use the good in line with their intended purpose.

In addition, specific indications on the ARTG Public Summary Documents are equally misleading and deceptive, for example, ARTG no: 194706 Ease-a-cold Cough Cold & Flu Day & Night (appended):

> "Scientifically formulated/with 8 key ingredients /Clinically trialled*/*contains clinically trialled ingredients to help/ to/may/ help/shorten/the duration of /your/a/ cold/by

26%/by/up to/ 2 days/sore throat/nasal congestion/runny nose/sneezing/cough/headache/fatigue/body aches,pain,fever,headache^/"

"Scientifically formulated/with 8 key ingredients / Clinically trialled*/*contains clinically trialled ingredients to help / Found/Shown/ in a /2 year/ clinical trial/over 2 years/was found/to /help/shorten your/reduce the duration of/a/the cold, reduce/ the severity.."



Screen shot above taken today (05/07/2018) from https://pharmacare.com.au/easeacold/

Also:

- https://chemistwarehouse.com.au/buy/56819/Ease-a-Cold-Cough-Cold-Flu-Day-Night-24-Capsules
- https://woolworths.com.au/shop/productdetails/208245/ease-a-cold-tablets-cough-cold-flu
- https://priceline.com.au/brand/ease-a-cold/ease-a-cold-cough-cold-and-flu-day-night-24-capsules
- http://epharmacy.com.au/product.asp?id=57148&pname=Ease+a+Cold+Cold+%26+Flu+Day+%26+Night+24+Capsules
- https://pharmacyonline.com.au/search/go?w=ease%20a%20cold&gclid=EAIaIQobChMIqp_Y_wMyG3AIVU4yPCh2rpw1yEAAYASAAEgIQf_D_BwE
- https://amcal.com.au/easeacold-cough-day---night---24-capsules-p-9314807008567
- https://health365.com.au/easeacold-cough-cold-flu-day-night-24s
- https://goodpricepharmacy.com.au/ease-a-cold-cold-congestion-day-night-30-capsules
- etc.

Regardless of whether the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018* has been enacted, I insist on an immediate response to me as to

the priority allocated to this complaint, the measures taken by the TGA to achieve compliance and the outcome (all for publication in "The Conversation").

Sincerely,
Ken

Dr Ken Harvey MBBS, FRCPA, AM
Associate Professor
Department of Epidemiology and Preventive Medicine
School of Public Health and Preventive Medicine

Monash University
Alfred Campus
553 St Kilda Rd
Melbourne VIC 3004
Mobile: +61 419181910
Email: kenneth.harvey@monash.edu
WWW: www.medreach.com.au

5 July 2018

Public Summary

Summary for ARTG Entry: 194706 Ease-a-cold Cough Cold & Flu Day & Night

ARTG entry for	Medicine Listed
Sponsor	Pharmacare Laboratories Pty Ltd
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia
ARTG Start Date	18/02/2012
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Ease-a-cold Cough Cold & Flu Day & Night

Product Type Composite Pack **Effective date** 21/09/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Relief of symptoms of mild upper respiratory infections. [Warnings S and COLD required]

May help reduce the severity of the symptoms of colds.]Warnings S and COLD required]

May reduce the severity and duration of colds. [Warning COLD required]

May reduce the severity of colds. [Warning COLD required]

Relief of the symptoms of colds. [Warnings S and COLD required]

Specific Indications

/When you put cold/ and flu products/ under the microscope/
Scientifically formulated/with 8 key ingredients /Clinically trialled*/*contains clinically trialled ingredients to help/ to/may/ help/shorten/the duration of /your/a/ cold/by 26%/by/up to/ 2 days/sore throat/nasal congestion/runny nose/sneezing/cough/headache/fatigue/body aches,pain,fever,headache^/
Scientifically formulated/Clinically trialled*/*contains clinically trialled ingredients to help /to/ may/ help/ reduce/ severity/relieve/symptoms /of cold/and flu/by 25%/including/
- mild/Cough/blocked nose/headache
- irritated/Sore/ throat, /nasal/head/congestion
-sneezing/runny nose/associated with cold
- Helps relieve/mild/Body Aches, Pain, Fever^, Headache^, Fatigue/^Traditional ingredients to help relieve/symptoms of/Body Aches, Pain, Fever/ Headache
- Headache^/ head congestion/ Fatigue /with Valerian to help assist restful sleep/to help relieve fatigue during the day
- Non-drowsy day time relief

- Night time relief to assist rest
Scientifically formulated/ with 8 key ingredients /Clinically trialled*/*contains clinically trialled ingredients to help /to/may help/:
- May/Help/to Shorten the duration of a cold/by /up to /2 days/by 26%
- Reduce/ the/ severity/ of/ cold/ & flu/ symptoms/ including /mild/sore throat, coughing, blocked nose, body aches, headaches^ and fatigue/-irritated/Sore/ throat, /nasal/ head/ache/ congestion/s
-sneezing/runny nose/ associated with cold/by 25%
- Significantly/may help/ reduce/ the/ impact of cold symptoms/ on/ your/ daily/quality of/ life/by 17%/
--Helps relieve/ mild/Body Aches, Pain, Fever,Headache^/^Traditional ingredients to help relieve/symptoms of/Body Aches, Pain, Fever,Headache
- Help you sleep better at night so your body can rest/
- Provide non-drowsy daytime relief
Includes/scientific and/ natural /and traditional/ ingredients to help relieve cough, cold /and flu/ symptoms and/to/ may/ help shorten the life/ and/ reduce/ the severity/ of your/a/ cold.
Is /scientifically/formulated/ with 8 key ingredients/Clinically trialled*/*contains clinically trialled ingredients to help /to /may/ help relieve and reduce/the duration of/ the impact on daily life of/ the severity of/ cold/ and flu symptoms/ including /mild/Cough, Sore Throat, /Nasal/head/ Congestion/ache, sneezing, runny nose. Body Aches, Pain, Fever, Headache^ /associated with cold
Helps relieve/mild/ Body Aches, Pain, Fever,Headache^/^Traditional ingredients to help relieve/symptoms of/Body Aches, Pain, Fever,Headache and Fatigue/with Valerian to help assist restful sleep/to help relieve fatigue during the day
The day formulation /to/may/ help/s relieve cold /and flu /symptoms throughout the day /without causing drowsiness
The night formulation /continues to help relieve symptoms/ and promote a good night's sleep
Scientifically formulated/with 8 key ingredients/Clinically trialled*/*contains clinically trialled ingredients to help / to /may/ help/shorten your/a/the cold.
Scientifically formulated/with 8 key ingredients/ Clinically trialled*/*contains clinically trialled ingredients to help / Found/Shown/ in a /2 year/ clinical trial/over 2 years/ was found/to /help/shorten your/reduce the duration of/a/the cold, reduce/ the severity /of (cold)/and flu/ symptoms/ and/help/reduce the impact on daily life.
Scientifically formulated/with 8 key ingredients /Clinically trialled*/*contains clinically trialled ingredients / to help/ to /may/ help/Reduce(s) the severity of cold /and flu /symptoms including; Cough, Coughing stuff up, sore throat, head/nasal/congestion/ sneezing/runny nose.
Helps relieve/ mild/Body Aches, Pain, Fever^/^Traditional ingredients to /may/ help relieve/symptoms of/Body Aches, Pain, Fever^, headache^. hoarseness, runny nose, plugged nose, sneezing, head/ ache^/congestion, body aches^, feeling "run down, sweats, chills^, feeling feverish^, irritability, sinus pain, sinus
pressure, sinus drainage, swollen glands, plugged ears, ear discomfort, eye discomfort, head congestion, chest congestion, chest tightness, heaviness in chest, lack of energy,
May/Help/to/Shorten your cold and /so you/get/feel/ better quicker/faster
Supporting evidence/including/Based on research on /the product/undertaken by Integrated Health Group Pty Ltd and sponsored by PharmaCare Laboratories Pty Ltd.
^Traditional ingredients to help relieve/symptoms of/body aches, fever, pain, headache.
*contains clinically trialled ingredients / to help…

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 2

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Ascorbic acid	**250 mg**
Echinacea purpurea	**88.9 mg**
Equivalent: Echinacea purpurea (Fresh)	4 g
Garlic Oil	**833 microgram**
Glycyrrhiza glabra	**62.5 mg**
Equivalent: Glycyrrhiza glabra (Dry)	500 mg
Salix alba	**77.4 mg**
Equivalent: Salix alba (Dry)	1.2 g
Zinc sulfate monohydrate	**33.3 mg**
Zingiber officinale	**45.5 mg**
Equivalent: Zingiber officinale (Dry)	500 mg

Public Summary

2. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Echinacea purpurea	**44.4 mg**
Equivalent: Echinacea purpurea (Fresh)	2 g
Garlic Oil	**167 microgram**
Glycyrrhiza glabra	**62.5 mg**
Equivalent: Glycyrrhiza glabra (Dry)	500 mg
Salix alba	**64.5 mg**
Equivalent: Salix alba (Dry)	1 g
Valeriana officinalis	**444 mg**
Equivalent: Valeriana officinalis (Dry)	2 g

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaint 2016-07-018 Ease-a-Cold

ARTG ID: AUST L 194706

Meeting held 15 September 2016

Complaint summary^

Complainant	Requested anonymity
Advertisers	Pharmacare Laboratories Pty Ltd
Subject matter of complaint	Television and internet advertisements
Type of determination	Final
Sections of the Code, Regulations or Act found to have been breached*	Code sections 4(1)(b), 4(2)(a), 4(2)(c), 4(6)(b)
Sections of the Code, Regulations or Act found not to have been breached*	Code section 4(5)
Sanctions	Withdrawal of representations Withdrawal of advertisement

* 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 an internet advertisement, published at the website *www.easeacold.com.au* and viewed by the complainant in July 2016, and a television advertisement broadcast in July 2016.

2. The television advertisement included, as spoken words, the representations "when you put cold and flu products under the microscope, Ease-a-Cold Cough Cold and Flu Day and Night is clinically trialled to help shorten a cold. In a clinical trial over two years Ease-a-Cold was found to help shorten a cold, reduce the severity of symptoms, and Ease-a-Cold was clinically trialled to reduce the impact on daily life. Help shorten your cold and get better quicker with Ease-a-Cold. Clinically trialled to shorten a cold." It included visual imagery including a woman in a lab coat looking into a microscope, and text stating "clinically trialled to shorten a cold", "two year clinical trial", "clinically trialled to reduce the severity of symptoms – sore throats; coughing; runny nose; sneezing" and "clinically trialled to reduce the impact on daily life".

3. The relevant part of the internet advertisement included the claims "clinically proven to shorten your cold", "shorten your cold", "reduce symptom severity" and "reduce the impact of a cold".

4. An excerpt of the advertisements can be viewed in the relevant Appendix to this determination.

The product(s)

5. The advertisement promoted the product Ease-a-Cold Cough Cold and Flu Day and Night (AUST L 194706).

The advertiser(s)

6. The advertiser was Pharmacare Laboratories Pty Ltd.

The complaint^

7. The complainant requested anonymity.

8. The complainant expressed the following concerns about the television advertisement:

   a) that the claim "clinically trialled" and the associated efficacy claims caused it to breach sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code, and argued that the claim "clinically trialled" has the same meaning for "the average consumer" as the claim "clinically proven";

   b) that it breached section 4(5) of the Code because the imagery of products under a microscope implied that other products such as Codral Cold & Flu Day & Night did "not withstand scientific scrutiny". On this point the complainant argued that the products shown under the microscope, while ostensibly unbranded, were distinctively coloured and recognisable as Codral products; and,

   c) that it breached section 4(6)(b) of the Code because of the image of a woman in a lab coat.

9. The complainant expressed concern that the internet advertisement breached sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code because of the words "clinically proven" and the associated efficacy claims.

10. The complainant referred to a prior complaint involving very similar advertising material, namely complaint 2015/07/001 Ease-a-Cold.

The advertiser's response to the complaint^

11. The advertiser initially argued that "the subject matter of this complaint is presently the subject of an investigation by the TGA" and that "in those circumstances, any substantive response would be premature." In this initial response the advertiser also provided material showing that the television advertisement had been approved for broadcast.

12. The advertiser (through its legal representative) subsequently provided a further response, in which it reiterated that "in circumstances where the subject matter of this complaint is presently the subject of an investigation by the TGA, a substantive response would be premature", but nevertheless provided a more detailed response. The further response is only briefly summarised below but was considered in detail by the Panel.

13. The advertiser referred to a document entitled "Evidence guidelines - Guidelines on the evidence required to support indications for listed complementary medicines" in support of the proposition that "scientific indications for listed goods, which would include for example 'clinically proven', can be used by sponsors if appropriate scientific evidence is held for such claims". The advertiser stated that the Guidelines "make clear… clinical trials, particularly randomised, placebo-controlled and blinded trials, provide the most robust information regarding the potential efficacy of a particular intervention."

14. The advertiser referred to a 2012 clinical trial that it said was "a randomised placebo-controlled and double blinded clinical trial conducted on the actual therapeutic good being advertised" and that the advertiser "rejects the findings of the Panel on which the complainant in this instance relies."

15. In relation to the website, the advertiser stated that it had been amended on 2 August 2016 so that it stated "clinically trialled" and not "clinically proven".

16. In relation to the words "clinically trialled", the advertiser argued that "just because a product has been 'clinically trialled' does not mean that it has been 'clinically proven'. It may be for example that a clinical trial took place but the results supported a number of secondary outcomes but was less decisive as to the primary outcome."

17. In relation to the alleged breach of section 4(6)(b) of the Code, the advertiser argued that a scientist working in a medical laboratory did not fall within the definition of a "healthcare professional" found in section 42AA of the Act. The advertiser expressed the view that no reasonable member of the public would regard the woman in the lab coat as a "clinician" and provided a dictionary definition of a "clinician".

18. In relation to the alleged breach of section 4(5) of the Code, the advertiser argued that the advertisement did not make the comparison alleged by the complainant to have been made. On this point the advertiser also argued that the generic product images in the advertisement did not in fact resemble Codral products.

19. The advertiser did not provide evidence material such as a copy of the study with its response.

Findings of the Panel

the internet advertisement

20. The Panel found that the internet advertisement that was supplied by the complainant, although not identical, was substantively the same as internet advertisement considered in complaint 2015/07/001 Ease-a-Cold as it still included the claim "clinically proven" previously found in breach, and not the new claim "clinically trialled". The Panel was satisfied that it was essentially the same subject matter already dealt with by the Panel, and therefore, did not consider this aspect of the complaint.

21. The remainder of the Findings of the Panel therefore relates to the television advertisement only.

the prior complaint about this product, 2015/07/001

22. The Panel was satisfied that the television advertisement in the present complaint was sufficiently different from the television advertisement considered in 2015/07/001 Ease-a-Cold, that it was not the same subject matter and could not be regarded as a matter already dealt with by the Panel.

23. The Panel considered the present complaint without regard to the prior complaint, other than noting that evidence material had been provided by the advertiser in response to complaint 2015/07/001 Ease-a-Cold and that the Panel had considered this evidence in some detail. The Panel noted that the advertiser had failed to provide any evidence material in relation to the present complaint. The Panel did not accept the argument of the advertiser that consideration of the complaint would be "premature" while the prior complaint, about material which had an important difference to the present material, was the subject of deliberation by the Secretary. This was because the Panel formed the view that the matters in the present complaint were sufficiently different from the prior complaint to warrant further consideration.

24. The Panel also noted that the Code had been amended so that it contained different provisions as to endorsement by health professionals from those that applied to the prior complaint.

what did the advertisement convey?

25. Section 1(3) of the Code states that the Code should be interpreted with an emphasis on the object and the principles of the Code, and the total presentation and context of the advertisement. Section 3(2) of the Code states that the conformity of an advertisement with this Code should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed. In assessing the advertisement, the Panel was mindful not only of the particular words cited by the complainant, but of the entire context of the advertisement and its likely impact on a reasonable consumer.

26. The Panel formed the view that the words "clinically trialled" conveyed the same meaning as the words "clinically proven" to consumers. While the statements are different, the Panel was of the view that the reasonable consumer to whom the advertisement is directed would be likely to assume that the claim "clinically trialled" is equivalent to "clinically proven" because, in context, it is likely to imply demonstrated efficacy of the product rather than conveying a simple statement of fact that it was subject to a small, unpublished clinical trial. The Panel noted that there would, quite obviously, be cases where the words "clinically trialled" would mean something quite different to "clinically proven" – as, for example, when used in a context such as "clinically trialled, and shown not to be effective."

27. The Panel reviewed the advertisement and was satisfied that it represented:

    a) that the advertised product would "shorten" or reduce the duration of a cold;

    b) that the advertised product would reduce the impact of a cold on daily life;

    c) that the advertised product would reduce the severity of cold symptoms;

    d) that the advertised product had been the subject of a clinical trial lasting two years ("the trial");

    e) that the trial had demonstrated that the advertised product would have the benefits noted above;

    f) by implication, that the trial should be regarded by consumers as good and persuasive evidence in support of the efficacy claims noted above;

    g) by implication, that because of the trial a consumer should have a high level of confidence that the advertised product would have the benefits noted above; and,

    h) through the idiom "put… under the microscope", that the advertised product had been the subject of intensive, detailed, exacting, and careful scientific examination, so that the efficacy claims in the advertisement were made on the basis of a comprehensive examination of the full body of evidence available.

28. As to the image of the woman in lab coat, the Panel's consideration is set out below.

the evidence material in support of the claims

29. The Panel considered it sufficient to note that the trial referred to in the advertisement:

    a) was said by the advertiser to have involved the advertised product as an intervention;

    b) was a single study;

    c) had not been published;

    d) did not include any detailed statistical analysis;

    e) measured outcomes by way of a questionnaire completed by the study subjects, and did not involve objectively quantified measures of any results; and,

    f) had not been reinforced by further studies showing similar results.

misleading, unverified, etc

30. 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".

31. As noted (in more detail) above, the advertisement conveyed that the clinical trial to which it referred was a sound basis upon which consumers could conclude that the advertised product

had been subjected to comprehensive scrutiny, and demonstrated to have the effects of reducing duration, severity of symptoms and impact on daily life of a cold. It conveyed that because of the trial, consumers could be confident that the advertised product would have those benefits for cold sufferers.

32. The Panel did not need to form any formal view, and did not form any formal view, as to whether the trial was of no value as evidence, was of high value, or was at some point between those extremes. The Panel was satisfied that whatever value as evidence the trial might have, it was insufficient to support the representations conveyed by the advertisement as set out above. Indeed, any single, unpublished study would be very likely to fall short of supporting such representations except in the most exceptional circumstances – for example, in a case where there existed a further body of evidence that was robust, substantial, and comprehensively consistent with the results of the trial relied upon. No such exceptional circumstances appeared to be applicable in the present case, on the basis of the material before the Panel.

33. The Panel noted the argument of the advertiser relating to the Guidelines. The Panel did not see any persuasive basis in that submission for a position that a single unpublished study could be regarded as supporting the claims, including the implied claims, made in the advertisement. In any event, the Panel was satisfied that the core question of whether the trial could support the claims made in the advertisement was one that could be answered only by close consideration of the advertisement itself and the trial, in their total context, on the basis of the material available to the Panel.

34. The Panel was, therefore, satisfied that the advertisement contained representations that had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations as to the effectiveness of the advertised product, and were misleading, in breach of sections 4(1)(b), 4(2)(a) and 4(2)(c) of the Code. These were the representations in relation to the "clinically trialled" claim:

    a) that the trial had demonstrated that the advertised product would reduce the duration of a cold, would reduce the impact of a cold on daily life, and would reduce the severity of cold symptoms;

    b) by implication, that the trial should be regarded as good and persuasive evidence in support of these claims of product effects;

    c) by implication, that because of the trial a consumer should have a high level of confidence that the advertised product would have the benefits noted above; and,

    d) through the idiom "put… under the microscope", that the advertised product had been the subject of intensive, detailed, exacting, and careful scientific examination, so that the efficacy claims in the advertisement were made on the basis of a comprehensive examination of the full body of evidence available.

35. The Panel found, therefore, that these aspects of the complaint were justified.

healthcare professional endorsement

36. Section 4(6)(b) of the Code prohibits certain representations that therapeutic goods are endorsed by health professionals.

37. The complainant alleged that the advertisement breached this provision because of the woman in a lab coat depicted in the advertisement.

38. The advertiser responded at some length on this point, in particular by noting the reference to "healthcare professionals" in section 42AA of the Act and the amendment of that provision to omit reference to "scientists working in medical laboratories". The advertiser also pointed out that the woman was captioned as a "research scientist" in the advertisement.

39. Section 42AA of the Act states:

> This Part not to apply to advertisements directed at health professionals etc.
>
> (1) This Part does not apply to advertisements directed exclusively to:
>
> (a) medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; or
>
> […]
>
> (c) herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a State or Territory

40. The Code does not include a definition of healthcare professional or health professional in its current form. The 2007 version of the Code stated that "*Healthcare Professional* includes a person that meets the description of a healthcare professional in subsection 42AA(1), (2), (3) of the Therapeutic Goods Act 1989 (see Appendix 2) and any other person represented directly or indirectly to be a healthcare professional."

41. The current version of the Code does not include this definition. It does, however, make reference to section 42AA of the Act, stating in section 4(6)(b) that:

> Advertisements must not contain or imply endorsement by:
>
> […]
>
> (iii) individual or groups of health professionals referred to in section 42AA of the Act or any other person or group of persons represented directly or indirectly to be health professionals, other than where the emphasis is on the availability, which may include the price of therapeutic goods through his/her retail business; or
>
> (iv) by individuals, who are health professionals by way of their representation in advertisements or academic qualifications, and/or who are likely to be known as health professionals by the reasonable person.

42. As should be clear, the prohibition in section 4(6)(b) of the Code is not confined to those health professionals who are expressly listed in section 42AA of the Act. It includes, pursuant to subsection (iii) a prohibition on claims of endorsement by the health professionals described in section 42AA of the Act, and pursuant to subsection (iv) a prohibition on claims of endorsement by health professionals "by way of their representation in advertisements or academic qualifications, and/or who are likely to be known as health professionals by the reasonable person".

43. These are plainly two distinct prohibitions, and it is unsurprising that the range of health professionals under section 4(6)(b) of the Code should be broader than the range described in section 42AA of the Act, because section 42AA of the Act is directed at exempting certain

advertisements (those directed exclusively at health professionals) from the application of certain advertising rules, while section 4(6)(b) of the Code is directed at preventing claims that products are endorsed by health professionals. As the provisions have different purposes, it would be surprising if the list of health professionals set out in section 42AA of the Act were sufficiently comprehensive to work as the sole definition of "health professional" for the purposes of section 4(6)(b) of the Code.

44. In relation to the caption, "research scientist", the Panel reviewed the advertisement in its total context and noted that:

    a) the caption in the advertisement did represent at least an attempt to identify the woman depicted in a lab coat and using a microscope as a "research scientist". However, it was somewhat lacking in prominence and so could be given only limited weight as an element of the advertisement or as a factor in a consumer's likely interpretation of the advertisement; but,

    b) in any event, while a "research scientist" would not necessarily be a health professional for the purposes of section 4(6)(b) of the Code, the fact that a person is identified as a "research scientist" would not eliminate the possibility that the person was *also* a health professional for the purposes of section 4(6)(b) of the Code.

45. The Panel had no way of knowing whether or not the person depicted in the advertisement was in fact a health professional. She may have been an actor without any relevant professional or academic qualifications. Or, she may have been a scientist. The Panel noted that she was the speaker for the advertisement and reported the claimed results of the clinical trial. The Panel was satisfied that for this reason the advertisement conveyed that she had been involved in the trial and indeed that she was a principal investigator or senior member of the research team.

46. The Panel was satisfied that a reasonable consumer would expect a principal investigator or senior member of the research team for a clinical trial to be a health professional such as a medical doctor, nurse, or other health professional. The Panel noted that a consumer might well take the view, as set out at the website *www.australianclinicaltrials.gov.au*, that "a clinical trial team includes doctors and nurses and may also involve other health care professionals, social workers, biostatisticians and trial coordinators and monitors", or be aware that investigators conducting clinical trials should have appropriate qualifications for the trial, provide medical care to trial participants in the event of adverse events.

47. While it is undoubtedly true that a clinical trial research team will often include members who are not health professionals by any definition, the Panel was satisfied that a consumer would be likely to form a view that, on the balance of probabilities at least, a person depicted in a lab coat, who appeared to be part of the research team for a trial related to the relief of cold symptoms, would be a health professional. In forming this view the Panel noted that a consumer, regarding such a clinical trial, would be likely to expect that the trial could not be conducted without significant knowledge as to the ordinary course of a cold, and the effects of intervention that ought to be measured. The Panel was satisfied that a consumer would expect such knowledge to be the province of a health professional.

48. The Panel was satisfied that, whatever her actual profession, the woman depicted in the advertisement would be taken by an ordinary and reasonable consumer to be a health professional "by way of [her] representation in [the] advertisement", and that the advertisement represented the advertised product to be endorsed by her.

49. The Panel found, therefore, that this aspect of the complaint was justified.

comparison

50. Section 4(5) of the Code requires that comparisons made in advertisements must be balanced and must not be misleading or likely to be misleading, and 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."

51. The complainant alleged that the advertisement breached this provision because product images in it were similar to Codral product images.

52. The Panel did not find the images to be sufficiently similar.

53. Moreover, the Panel did not find the advertisement to convey any comparison falling within the scope of section 4(5) of the Code, and on balance was satisfied that the claims in the advertisement were claims about the advertised product and not about other products.

54. The Panel found, therefore, that this aspect of the complaint was not justified.

Sanctions

55. The Panel requests Pharmacare Laboratories Pty Ltd, in accordance with subregulation 42ZCAI(1) of the *Therapeutic Goods Regulations 1990*:

    a) to withdraw the advertisement from further publication;

    b) to withdraw any express or implied representations:

        i) that the 2012 clinical trial had demonstrated that the advertised product would reduce the duration of a cold, would reduce the impact of a cold on daily life, and would reduce the severity of cold symptoms;

        ii) that the trial should be regarded as good and persuasive evidence in support of these claims of product effects;

        iii) that because of the trial a consumer should have a high level of confidence that the advertised product would have the benefits noted above;

        iv) that the advertised product had been the subject of intensive, detailed, exacting, and careful scientific examination, so that the efficacy claims in the advertisement were made on the basis of a comprehensive examination of the full body of evidence available;

        v) that the advertised product had been "clinically trialled" in the sense of being demonstrated to have effects such as reducing the duration, impact on daily life, or severity of symptoms of a cold; or,

        vi) that the advertised product is endorsed by any health professional;

    c) to give a written undertaking not to use the representations in (b) above in any other advertisement*;

    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; and,

e) 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.

56. 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.

Dated 17 January 2017

For the Panel

Allan Asher
Chairman

Appendix A: Definitions and footnotes

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). It should be noted that HTML metatags and other information which can be retrieved by internet search engines, whether or not it is ordinarily viewed directly by consumers, constitutes advertisement material.

^Readers of the determination should note that the sections "complaint summary", "the advertisement(s)", "the complaint", and "[a party]'s response to the complaint", are summaries that are intended to aid readers of this document. In reaching its decision, the Panel considered all of the material before it, including material that may not be mentioned specifically in the summaries. The summaries do not form part of the Panel's reasoning.

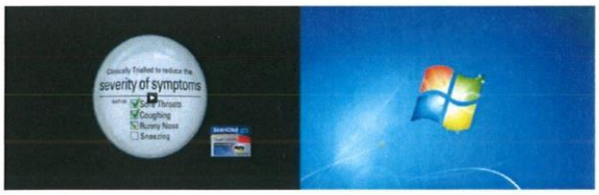
**Under regulation 42ZCAI of the Regulations, the Panel may request that a representation not be used in any other advertisement unless the advertiser satisfies the Panel that the use of the representation would not result in a contravention of the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990 or the Therapeutic Goods Advertising Code. Under the Panel's procedures, the Panel will not ordinarily give additional consideration to such a matter unless significant new material that was not available at the time of the Panel's determination has become available, or until at least 12 months have passed since the Panel's request was made.*

Appendix B: Excerpt of the Advertisement

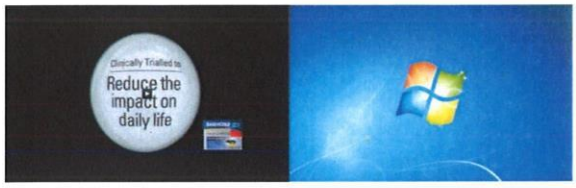
When you put cold and flu products under the microscope

Easeacold Cough, Cold & Flu Day & Night was clinically trialled to help shorten a cold

In a clinical trial over two years, Easeacold was found to help shorten a cold,



reduce the severity of symptoms



and Easeacold was clinically trialled to reduce the impact on daily life

Help shorten your cold and get better quicker with Easeacold

Clinically trialled to shorten a cold