

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaints 2012-12-007 Scala BioPromise Shapewear and BioFIR Fitness wear

Meeting held 7 March 2013

Complaint summary^

Complainants	Dr Ken Harvey
Advertiser	Brazcom Imports Pty Ltd
Subject matter of complaint	Print and internet advertisements
Type of determination	Final
Sections of the Code, Regulations or Act found to have been <u>breached</u> *	Act section 42DL(1)(g) Code sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(4), 4(5), 4(6)(b), 4(7), 7(3)
Sections of the Code, Regulations or Act found <u>not to have been breached</u> *	None
Sanctions	Publication of retractions 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 advertisements published in the magazines *Virgin Voyeur* and *Jetstar Traveller*, and at the websites www.scalabiopromise.com.au and www.brazcom.com.au, which were viewed by the complainant in December 2012.
2. The advertisement in *Jetstar Traveller* magazine was headed “Scientifically proven! Scala Fat-Blaster garments”, and included representations such as “revealed – how millions of women worldwide are reshaping their bodies without painful diets or surgery”, “do you feel like you will never get rid of the jelly belly, baby fat, orange peel skin or muffin top? Then Scala BioPromise shapewear will do for you what it has done for millions of women around the world – help you to shave off inches and reshape your body”, “known as the ‘fat-buster’, the incredible Scala BioPromise undergarments deliver the most impressive results in body shapewear ever achieved”, “through modern science, researchers have developed a patented technology exclusive to Scala called Active BioCrystals, which emit a type of energy called Far Infra Red Rays (FIRRs). These FIRRs have been clinically proven to kick-start what is known as the *BioPromise effect*, which leads to a dramatic improvement in the appearance of your silhouette and skin while getting rid of those embarrassing lumps and bumps”, “effective even after you have taken it off”, “costs less and safer than any cosmetic and surgical procedure”, “in-built Far Infra Red technology shaves off inches and reshapes your body simply by wearing it”, “helps tired, swollen legs, ideal for those who work on their feet all day”, and other claims. It also included “before and after” images, and “thermal imaging” said to show “the incredible BioPromise effect visible after just one hour!”.
3. The advertisement in *Virgin Voyeur* magazine was substantially similar to the *Jetstar Traveller* advertisement.
4. The advertisement at the website www.scalabiopromise.com.au covered several webpages and included representations such as “fabric contains unique Active BioCrystal scientifically proven to: shave off inches; reduce the appearance of cellulite while instantly slimming the silhouette”; “the amazing ‘Fat-Blasting’ undergarments”, “the only shapewear for women that uses far-infra-red technology to shave off inches, reshape your body and reduce the appearance of cellulite! “dramatically reduce dress size”, “Scala Shapewear is clinically proven to reduce your measurements in your tummy, hips and thighs and improve the appearance of your skin – all from simply wearing our slimming shapewear”, “the only affordable and scientifically proven alternative to messy and wasteful creams that get washed down the drain every day, and risky and expensive surgery”, “BioFirm Fitness combines Scala’s exclusive Far Infra Red technology with compression shaping to provide the ‘Bio Firm Effect’ which has the following scientifically proven effects: reduced muscular fatigue and improved performance and recovery from exercise; helps to reduce the drop in skin temperature that occurs during exercise, leading to a feeling of better regulation of skin temperature; loss of inches and reduction of body measurements and dress size; [and] reduction of the appearance of loose, dimpled skin and cellulite”, and many other representations.
5. It included quotations from a range of magazines, including material that appeared to be testimonial material, such as “the revolutionary bottom wear that actually works to fight cellulite, as opposed to just concealing it... I’m only five days into the trial and so far I’m really liking the way the tights feel and how they shape my lower half”, “the fat-busting underwear range from Brazil”, “the fabric contains ‘active biocrystals’ to stimulate blood flow”, “the front of my thighs appear smoother and slightly firmer, and the dimpling on my buttocks appears to be less obvious”, and others.
6. It referred to scientific research through words such as “Dr Tim Nielsen, Scala representative in Australia, describes the incredible results of the clinical trials evaluating BioPromise: ‘82% of women who wore Scala BioPromise for six hours a day saw a significant improvement in the appearance of

their bodies and also the appearance of their skin after only 30 days, with the improvements continuing over the course of the 120-day study”.

7. It included representations similar to those in the print advertisements, including the words “through modern science, researchers have developed a patented technology exclusive to Scala called Active BioCrystals, which emit a type of energy called Far Infra Red Rays (FIRRs). These FIRRs have been clinically proven to kick-start what is known as the *BioPromise effect*, which leads to a dramatic improvement in the appearance of your silhouette and skin while getting rid of those embarrassing lumps and bumps.”
8. It also included a number of before and after images and the same “thermal imaging” as the print advertisements.
9. The advertisement at *www.brazcom.com.au* included the same “thermal imaging” images, together with some before and after images. It also included representations such as “BioPromise is made from a special microfiber containing Scala’s patented Active BioCrystals, which emit a type of energy called Far Infra Red Rays (FIRRs). These FIRRs have been scientifically proven to kickstart what is known as the ‘BioPromise effect’, shaving off inches, smoothing out the skin, and reducing dress size while reducing the appearance of cellulite.”
10. Excerpts of the advertisements can be viewed in the relevant Appendix to this determination.

The product(s)

11. The advertisement promoted a range of Scala BioPromise and Scala BioFir garments.

The advertiser(s)

12. The advertiser was Brazcom Imports Pty Ltd.

The complaint^

13. The complainant was Dr Ken Harvey.
14. The complainant alleged that the advertisements breached section 42DL(1)(g) of the Act and sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(4), 4(5), 4(6)(b), 4(7) and 7(3) of the Code.

The advertiser’s response to the complaint^

15. The advertiser stated that some aspects of the complaint were similar to previous complaints, and that due to the timing of complaints and determinations, they had continued to use material while awaiting determinations for previous complaints. They stated that “now that we have received a determination on this first complaint, we intend to comply fully with the Panel’s requests to withdraw or modify certain of our advertising claims where necessary.” They stated that they had “conducted a systematic and thorough review of all our marketing and promotional material with the assistance of expert legal counsel, with the specific aim of avoiding the possibility of inadvertent future breaches of the regulations... [and] another review will be conducted in response to the present complaint.”
16. The advertiser initially provided five items of supporting material as part of their response and later provided a sixth supporting item comprising the published version of one of the five items initially provided.

17. In relation to the alleged breaches of section 42DL(1)(g) of the Act, the advertiser stated that they did not regard the advertisements as representing the products to be for “therapeutic use” as defined in the Act. They argued that the advertisements used “only ‘cosmetic’ claims.”
18. They also argued at some length that all of the representations in the advertisements were supported by appropriate evidence and were factually correct.

Findings of the Panel

the advertisements generally

19. As a preliminary matter, the Panel gave some general consideration to the advertisements and the representations contained within them. The Panel noted that, while the advertisements differed slightly in their particulars, they were substantially similar and contained common elements, and could appropriately be dealt with collectively.
20. 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.
21. On this basis, the Panel was satisfied that the advertisements represented the advertised garments to have an effect on the body that resulted from their emission of far infrared rays (“FIRRs”), and that they would effect fat or cellulite removal or reshaping that would persist after the garments had been removed. The Panel was satisfied that the advertisements represented these effects to be a consequence of biological activity or physical changes to the body caused by the garments and the FIRR emissions, and not merely compression caused by the snug or tight fit of the garments. The Panel did not accept the argument of the advertiser that representations in the advertisement were “simply suggesting that the product can markedly reduce the wearer's perceived girth due to its immediate compression effect” or were “relate[d] to the immediate cosmetic benefits of the shapewear in improving a person's appearance and silhouette through its compression (‘tucking in’) effect on the body, which does not relate to any physiological process or therapeutic effect.”
22. A range of specific effects were also described in the advertisements such as measurement reduction and reduction in clothing size. The Panel was satisfied that these effects were also represented to result from the emission of FIRRs by the garments and consequent biological or physiological effects on the body, and not merely from compression by the garments. The Panel was satisfied that, in so affecting the body and tissue within the body, the advertised products would be influencing, inhibiting, or modifying a physiological process in the wearer, such as the physiological process by which fat or other tissue is stored, retained, altered, or eliminated within the body, or physiological processes such as the circulation of body fluids. The Panel accepted that, to some degree, the advertisements would be taken to convey that part of the effect of the products was caused by simple physical compression. However, the Panel was also satisfied that any reasonable consumer would interpret the advertisements as conveying very clearly that the effects of the products were not caused exclusively by such compression effects and were caused predominantly, over time, by the biological or physiological effects of the FIRRs emitted by the “biocrystal” content of the garments.
23. The Panel was also satisfied that the advertisements represented these benefits to be clinically or scientifically demonstrated or proven.

24. The Panel noted that the evidence material provided by the advertiser supported a view that the products were represented to be for therapeutic use, and not merely cosmetic use.

were the advertisements advertisements for therapeutic goods?

25. Therapeutic goods are defined in the Act to include goods that are represented in any way to be for therapeutic use, as well as goods “that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be... for therapeutic use”. Therapeutic use is defined to include use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or influencing, inhibiting, or modifying a physiological process in persons.

26. The Panel did note the argument of the advertiser that a representation such as “reduce the appearance of cellulite’ could not be interpreted as a therapeutic claim since it explicitly pertains to improvements in ‘appearance’. This claim relates the benefit that the BioPromise shapewear has in reducing the appearance of cellulite and improving the appearance of the skin.” This argument of the advertiser did not appear to take into account the definition of “therapeutic use” found in the Act. Where a change in appearance is effected, or said to be effected, because a product acts by “preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or influencing, inhibiting, or modifying a physiological process in persons”, the product is for therapeutic use as defined in the Act. That representations are confined to “appearance” does not cause a product to be a “cosmetic” or to act in a way that is not therapeutic use. The advertisements clearly conveyed that the advertised products had their effects because they emitted far-infrared rays, and those rays had their effects influencing, inhibiting, or modifying a physiological process in the wearer, such as the physiological process by which fat or other tissue is stored, altered, retained, or eliminated within the body, or physiological processes such as circulation of fluids in the body.

27. For the reasons already noted, the Panel was satisfied that the advertisements represented the advertised garments to be for therapeutic use as defined in the Act, as the garments were represented to have effects in influencing or modifying a physiological process in persons, or in alleviating a defect in persons. The Panel was therefore satisfied that the advertisements were advertisements for therapeutic goods.

28. Section 42DL(1)(g) of the Act prohibits the publication of advertisements for therapeutic goods that are not included in the Register. The advertised products were not included in the Register, and therefore breached section 42DL(1)(g) of the Act. The Panel therefore found this aspect of the complaint justified.

the evidence material submitted by the advertiser

29. As a preliminary matter, the Panel noted that the appropriateness of evidence depends on the context in which it is advanced. Evidence that appropriately supports a statement made by one scientist to another scientist does not necessarily provide appropriate support for a representation made in an advertisement directed to consumers who are not scientifically trained. This is because the impact of a representation is different depending on the person to whom it is directed, as section 3(2) of the Code makes clear when it 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.” The Panel did not consider whether the evidence provided by the advertiser would be adequate to support representations made in contexts other than advertisements directed to consumers.

30. The advertiser initially provided five items of documentary evidence material, which were described as “supporting item one” through to “supporting item five.”

31. Supporting item one was an article entitled “Tissular biostimulation by ceramic-impregnated fabrics”. The authors were Conrado and Munin. The advertiser stated that, during the preparation of their response, they had learned that the article had been accepted for publication with the citation Conrado LA, Munin E “Reduction in body measurements after use of a garment made with synthetic fibers embedded with ceramic nanoparticles” *J Cosmet Dermatol*. 2011 Mar;10(1):30-35.
32. Supporting item two was an abstract of the published version of supporting item one. A full copy of the article was subsequently provided by the advertiser (referred to herein as “supporting item six”).
33. Supporting item three was the curriculum vitae of Dr Luis Augusto Lupato Conrado, the lead author for supporting items one and two.
34. Supporting item four was an article entitled “Evaluation of fabric effectiveness in the physical performance of athletes” which had been published on the author's website but appeared not to have been published in a peer reviewed scientific journal.
35. Supporting item five was an article entitled “Biological activities caused by far-infrared radiation”, authored by Shojiro Inoue and Morihiro Kabaya, and published in the *International Journal of Biometeorology* in 1989.
36. Supporting items four and five did not appear to be of high relevance to the advertisements or the complaint. Supporting item four related to shorts and shirts worn by athletes during exertion. It did not appear to give any consideration to FIRRs, biocrystals, or other features represented to be central to the benefits of the advertised products. Supporting item five did relate to FIRRs, but concerned “far infrared radiator disks embedded in bedclothes” and primarily involved subjective measures. It did not involve any measures of outcomes connected with weight loss, measurement reduction, clothing size reduction, or other such effects. The Panel noted that, to the extent that items four and five could be regarded as a general body of evidence despite being relatively irrelevant to the advertisement and complaint, they could not be regarded as a very substantial or persuasive body of evidence. On this point, the Panel also noted that the advertiser did not provide any material to the Panel to illustrate a wider body of evidence relating to far infrared radiation generally.
37. Supporting items one, two, three, and six (the published version of item one which had been provided separately) were, in a sense, all facets of a single item of evidence. The Panel regarded the published version of the article (item six) as meriting the closest consideration, but also reviewed the unpublished version (item one). The Panel noted that the unpublished and published versions of the study were in fact quite different. The published version involved 42 subjects over 30 days, while the unpublished version was said to involve 50 subjects and included results measured over 120 days.
38. In relation to two previous complaints, the Panel found that the unpublished version of the study “was of an extremely limited nature – essentially, a single unpublished study involving fifty subjects. The Panel was satisfied that the evidence was by no means of a type, scope, or quality that could appropriately support claims made in advertisements directed to consumers, and that it did not support the representations about the mode of action or benefits of the advertised products.” The Panel remained of this view in the context of the present complaint.
39. The published version of the article described a trial involving 42 female subjects. It appeared to be single-blind trial. It involved several measures of hip, waist, and thigh circumference after 30 days of wearing either a placebo garment or a garment containing a ceramic powder, described as a “piece of clothing made with ceramic-impregnated polyamide and elastane fibers”. The advertiser did not provide evidence that the advertised products were the same as those used in the study, but the Panel assumed, in favour of the advertiser, that this was the case for the purposes of determining the complaint. This assumption was supported by some text in the unpublished version of the study. The

Panel noted, however, that little information was reported about the fabric in the article; for example, the total ceramic content of the garments was not reported. The reported results were to some degree positive and the authors stated that it showed that “clothing made of ceramic-impregnated fabric does interact with the human body through light radiation and promotes measurable effects on body circumferences at diverse anatomical positions and on the body mass.”

40. It was, however, a single study, was not double-blinded, and involved only a small number of subjects. It involved measures of body mass and hip, waist, and thigh circumference, but did not involve any measures that could be directly correlated to body fat levels, or fat reduction, and did not measure whether effects continued for a meaningful period after the garments were no longer worn. The study did not disclose whether the placebo garments were otherwise identical to the garments infused with ceramic powder and did not show whether subject blinding was effective. Measurements of areas of the body where the garments were not worn were not reported in the published study, but could have shed some light on the effects of the product and in particular shown whether any measured effects were local to the area on which the garment was worn, or more general. Neither version of the study appeared to distinguish between ordinary warming effects of the garments and effects caused by their ceramic content. This was important as the Panel was satisfied that the advertisements conveyed that the effects of the advertised products were not merely the ordinary effects of warming or retention of body warmth.
41. The Panel was satisfied that, taken as a whole, the evidence provided by the advertiser supported only a view that products such as those advertised could merit further study, and did not support any claims of specific product effects or benefits in advertisements directed to consumers.

representations that had not been verified, were not correct and balanced, etc

42. 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”.
43. The Panel considered (a) whether the study provided by the advertiser could be regarded as sufficient evidence to support the claims of product effects made in the advertisement, such that the advertisement would comply with these provisions, and (b) whether the study could support the claims that the product effects were scientifically or clinically proven or demonstrated, such that the advertisement would comply with these provisions.
44. The Panel was satisfied that, even if the evidence provided by the advertiser had offered general support for the claims of product effects made in the advertisements, it could not provide adequate support for the representations that such effects were scientifically or clinically proven or demonstrated.
45. In reaching this view, the Panel noted that, in an advertisement directed to consumers, representations that a particular benefit had been clinically or scientifically demonstrated or proven are highly unlikely to be adequately supported when only one published study is relied upon. This is particularly so when, as in the present case, that single study involves only a small number of subjects, and is not highly methodologically rigorous. A substantial body of evidence of high methodological quality, with independently repeated results involving a large number of subjects, ought to be available before such claims are made in advertisements directed to consumers. No such body of evidence was before the Panel in the present matter.

46. The Panel was therefore satisfied that the representations that the benefits described in the advertisement were clinically or scientifically proven or demonstrated had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.
47. The Panel was also satisfied that the evidence provided by the advertiser did not support representations about the mode of action of the advertised products described in the advertisements. The Panel noted that the advertisements referred to the advertised products using words such as “fat-blaster” and “fat-buster”, and clearly conveyed that they worked to reduce body measurements, clothing size, the appearance of cellulite, etc, by affecting fat tissue with FIRRs. The Panel was satisfied that the evidence provided by the advertiser did not adequately support any representations that the advertised products would have any effect on fat tissue at all. Moreover, the evidence supplied by the advertiser did not, in the Panel’s view, support representations that the products’ effects were caused by the “biocrystals” or ceramic powder content of the garments, or FIRRs emitted by them, as distinct from the ordinary warming or warmth-retaining effects of the garments. The Panel was therefore satisfied that these representations had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.
48. The Panel noted that the single study provided by the advertiser did offer some support for the representations about measurement reduction made in the advertisements. As noted, these representations were misleading because they were misleadingly associated in the advertisements with a mode of action that had not been established by the evidence.
49. In any case, however, the Panel was satisfied that, while the study could perhaps be regarded as preliminary evidence that could prompt further investigation, it was not on its own (or in the context of the other material provided by the advertiser) sufficient evidence to support claims made in advertising directed to consumers, and could not be regarded as supporting the representations about product benefits made in the advertisement. The Panel was therefore satisfied that the representations about product benefits generally had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.
50. The Panel also noted that, even if the single study were to be regarded as sufficient to support representations in advertisements directed to consumers (and the Panel did not so regard it), it did not support some of the specific representations made in the advertisement, such as representations that images showed “the incredible BioPromise effect visible after just one hour!”, “effective even after you have taken it off”, “fat-buster”, “deliver the most impressive results in body shapewear ever achieved”, “melt fat away”, “reduce the signs of cellulite”, “reduce the appearance of cellulite”, “getting rid of those embarrassing lumps and bumps”, “fat busting Brazilian Undies”, “the only affordable and scientifically proven alternative to messy and wasteful creams that get washed down the drain every day, and risky and expensive surgery”, “helps to reduce the drop in skin temperature that occurs during exercise”, and “the fabric contains ‘active biocrystals’ to stimulate blood flow”. The Panel was therefore satisfied that these representations had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.
51. The advertisement also contained representations about results achieved after 120 days. The published version of the study provided by the advertiser clearly could not, in itself, support any such representations because it involved only a 30-day study period. The unpublished version of the study did include measured results over a 120-day period. For similar reasons to those already noted, the Panel was satisfied that the representations about the 120-day study were not adequately supported by evidence, such as the representations that “82% of women who wore Scala BioPromise saw a

significant improvement in the appearance of their bodies and also the appearance of their skin after only 30 days, with the Improvements continuing over the course of the 120-day study” and “best results are seen when BioPromise is worn for a minimum of six hours daily [on this point the Panel noted that the study referred in any case to wear for 8 hours daily], for at least 30 days - but studies show that continuous improvements can be seen for at least 120 days, so the longer you wear it the better.” Given that only one clinical trial was provided by the advertiser, it was also clear that reference to “clinical trials” in the advertisements was also unsupported. The Panel was therefore satisfied that these representations had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.

abusing the trust and exploiting the lack of knowledge of consumers

52. 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.”
53. Because of the unverified and misleading representations already noted, the Panel was satisfied that the advertisements abused the trust or exploit the lack of knowledge of consumers. This aspect of the complaint was therefore justified.

inappropriate or excessive use

54. Section 4(2)(f) of the Code prohibits representations that “encourage inappropriate or excessive use” of therapeutic goods. The Panel was, as noted above, satisfied that the representations about the effects of the products were misleading and unverified. The Panel was therefore satisfied that encouraging their use for purposes such as weight loss or measurement reduction through the effects of FIRRs encouraged inappropriate use of them. Moreover, it was inappropriate to encourage therapeutic use of the products when they were not included in the Register. This aspect of the complaint was therefore justified.

scientific information

55. Section 4(4) of the Code requires scientific information to be “presented in a manner that is accurate, balanced and not misleading”, and requires that publication of scientific research results should “identify the researcher and financial sponsor of the research.” For the reasons already noted, the Panel was satisfied that scientific information in the advertisements was presented in a manner that was not accurate, was not balanced, and was misleading. Moreover, representations such as “82% of women who wore Scala BioPromise saw a significant improvement in the appearance of their bodies and also the appearance of their skin after only 30 days, with the Improvements continuing over the course of the 120-day study” constituted the publication of scientific research results, and were not accompanied by information identifying the researcher and financial sponsor of the research. This aspect of the complaint was therefore justified.

comparisons

56. 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.” The advertisements contained representations such as “Scala BioPromise is the only affordable and scientifically proven alternative to messy and wasteful creams that get washed down the drain every day, and risky and expensive surgery”. The Panel was satisfied that this comparison was not balanced and misleading for several reasons,

including that the advertised products are not in fact “scientifically proven”. The Panel therefore found this aspect of the complaint justified.

endorsement by healthcare professionals

57. Section 4(6)(b) of the Code prohibits representations that therapeutic goods are endorsed by healthcare professionals. The Panel was satisfied that the advertisement at www.scalabipromise.com.au represented the advertised goods to be endorsed by Dr Tim Nielsen, and that an ordinary and reasonable consumer would infer that Dr Nielsen was a healthcare professional. This aspect of the complaint was therefore justified.

testimonials

58. 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 advertisements contained a range of testimonial material including text and photographic “before” and “after” images.

59. In response to this aspect of the complaint, the advertiser argued that the photographic images included in the advertisements were “in fact typical” and referred to supporting item one, which contained the same images. The advertiser did not respond specifically in relation to the written testimonials, such as “the revolutionary bottom wear that actually works to fight cellulite, as opposed to just concealing it... I’m only five days into the trial and so far I’m really liking the way the tights feel and how they shape my lower half”, “the fat-busting underwear range from Brazil”, “the fabric contains ‘active biocrystals’ to stimulate blood flow”, “the front of my thighs appear smoother and slightly firmer, and the dimpling on my buttocks appears to be less obvious”.

60. The Panel was satisfied, as noted above, that the representations about the products’ benefits had not been verified and were misleading. The Panel was satisfied that the unpublished study, supporting item one, was not an appropriate type or quality of evidence to support representations made in advertisements to consumers, including representations in testimonial form. The Panel was also satisfied that the results referred to in the testimonials could not be regarded as typical in the absence of an extensive and robust body of evidence showing that such results could typically be expected by an ordinary consumer using the advertised products in typical real-world circumstances.

61. This aspect of the complaint was therefore justified.

advertisements making weight management claims

62. Section 7(3) of the Code requires that advertisements making weight management claims must have an appropriate balance between those claims and references to healthy energy-controlled diet and physical activity. This section defines “weight management” to include weight loss, measurement reduction, clothing size loss and weight control/maintenance. The advertisements clearly fell within the scope of section 7(3). They did not convey the required balance, and indeed stated that consumers could achieve weight loss, measurement reduction, clothing size loss simply by wearing the advertised garments. The Panel therefore found this aspect of the complaint justified.

63. 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. Because of the breaches already noted, this aspect of the complaint was justified.

sanctions

64. In relation to sanctions, the advertiser argued that “in light of the fact that: 1) we have rapidly responded to previous complaints and immediately made serious and documented efforts to address concerns and bring our advertising into line with the regulations; 2) we do have what we consider good evidence to support all the claims made in our advertising; and 3) we have never made claims that our products can be used to treat or cure any ailment or disease; we feel that the complainant’s request that the CRP ‘... impose a corrective advertising order, to be placed in each print and web page promoting these products’ is manifestly excessive.”
65. The Panel was satisfied that, while past conduct of an advertiser could in some circumstances be relevant to its decisions about sanctions, the primary concern in this area was the protection of consumers from misleading information. The Panel was satisfied that it was appropriate and necessary that consumers be provided with information correcting the misleading and unverified information contained in the advertisements, and decided to request that the advertiser publish retractions.

Sanctions

66. The Panel requests Brazcom Imports , 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 have effects because of their “biocrystal” or ceramic powder content, as opposed to ordinary warming or warmth-retention effects;
 - c) to withdraw any representations that the advertised products can cause weight loss or reduction, fat loss or reduction, or cellulite loss or reduction;
 - d) to withdraw any representations that the advertised products can cause body measurement reduction or clothing size reduction, or can affect the appearance of the skin, body, or body shape, except where such representations are explicitly and exclusively attributed to physical compression effects of wearing the garments;
 - e) to withdraw any representations that the benefits of the advertised products have been scientifically or clinically demonstrated or proven;
 - f) to withdraw any representations that the advertised products are endorsed by any healthcare professional or any person likely to be taken by a reasonable consumer to be a healthcare professional;
 - g) to withdraw any representations conveyed by the comparisons or testimonials in the advertisements; and,
 - h) to withdraw any representations that the advertised products are for any therapeutic use, including any use the effects of which are attributed to the “biocrystal” or ceramic powder content of the products or associated FIRR emissions, and any other use that would reasonably be taken to be influencing, inhibiting, or modifying a physiological process in the wearer, such as the physiological process by which fat or other tissue is stored, altered, retained, or eliminated within the body, or physiological processes such as circulation of fluids in the body.
 - i) not to use the representations in paragraphs (b) to (h) above in any other advertisement*;
 - j) 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;

k) to arrange for publication on the websites *www.brazcom.com.au* and *www.scalabiopromise.com.au* of a retraction in the form of, and in accordance with, the conditions set out in the attachment to this determination; and,

l) 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.

67. 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 18 July 2013

For the Panel

A handwritten signature in blue ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

Jason Korke
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 42ZCA1 of the Regulations, the Panel may request that a person apparently responsible for an advertisement withdraw a particular claim or representation, and give the Panel a written undertaking not to use the claim or representation in any other advertisement unless the person 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: Retraction

An advertisement is to appear on the homepages of the websites *www.brazcom.com.au* and *www.scalabiopromise.com.au* at the earliest opportunity.

A copy of the retraction advertisements, and the pages on which they will be published, are to be provided to the Complaints Resolution Panel for approval before publication.

RETRACTION

Advertisements for **Scala BioPromise and BioFir garments**, which we published at the websites *www.brazcom.com.au* and *www.scalabiopromise.com.au*, and in magazines, should not have been published.

In the advertisements we unlawfully made claims that “Active BioCrystals” in the advertised products caused them to be effective in fat reduction, cellulite reduction, reducing body measurements, and reducing clothing size.

We also claimed that these effects had been “scientifically proven” and “clinically proven.”

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. We were unable to provide sufficient evidence 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.

The Panel therefore requested that Brazcom Imports Pty Ltd 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 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.

Appendix C: Excerpt of the Advertisements

So, how do these "miracle Brazilian undies" work? what's the big secret?

Through modern science, researchers have developed a patented technology exclusive to Scala called Active BioCrystals™, which emit a type of energy called Far Infra Red Rays (FIRRs). These FIRRs have been clinically proven to kick-start what is known as the *BioPromise Effect*, which leads to a dramatic improvement in the appearance of your silhouette and skin while getting rid of those embarrassing lumps and bumps.



Thermal imaging showing the incredible *BioPromise Effect*, visible after just one hour!!

Little wonder BioPromise is known as "The Fat-Busting Brazilian Undies"!!!

Dr Tim Nielsen, Scala representative in Australia, describes the incredible results of the clinical trials evaluating BioPromise:

"82% of women who wore Scala BioPromise for six hours a day saw a significant improvement in the appearance of their bodies and also the appearance of their skin after only 30 days, with the improvements continuing over the course of the 120-day study".

How do I use BioPromise to get results?

The amazing thing about BioPromise is that ALL YOU HAVE TO DO IS WEAR IT!!

Best results are seen when BioPromise is worn for a minimum of six hours daily, for at least 30 days - but studies show that continuous improvements can be seen for at least 120 days, so the longer you wear it, the better!

Scala BioPromise is the *only* affordable and scientifically proven alternative to messy and wasteful creams that get washed down the drain every day, and risky and expensive surgery.



SCALA BIOPROMISE SHAPEWEAR HAS BEEN FULLY EVALUATED ACCORDING TO OEKO-TEX STANDARD 100 AND SHOWN TO MEET THE REQUIREMENTS OF THE STANDARD FOR PRODUCTS WITH DIRECT SKIN CONTACT (certificate 3330CIT).



[CLICK HERE TO SEE THE FULL PRODUCT RANGE!](#)

<http://www.scalabiopromise.com.au/how-it-works>