

Therapeutic Products Advertising Complaints COMPLAINTS RESOLUTION PANEL

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Complaints Register

Date:	16/09/10						
Code:	2010-06-018						
Product:	Power Balance Wrist Bands						
Complainant:	Dr Ken Harvey						
Respondent:	Power Balance Australia Pty Ltd						
Finding:	Justified						
Sections Found Justified:	Act section 42DL(1)(g), Code sections 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c)						
Sections Found Not Justified:	Act section 41FN						
Action:	Publication of retraction, Withdraw advertisement; withdraw representations						
Panel Determination:	<p>COMPLAINTS RESOLUTION PANEL DETERMINATION</p> <p>Complaint 2010-06-018 Power Balance Wrist Bands</p> <p>Meeting held 16 September 2010</p> <p>Complaint summary</p> <hr/> <table> <tr> <td>Complainant</td> <td>Dr Ken Harvey</td> </tr> <tr> <td>Advertiser</td> <td>Power Balance Australia Pty Ltd</td> </tr> <tr> <td>Subject matter of complaint</td> <td>Website advertisement</td> </tr> </table>	Complainant	Dr Ken Harvey	Advertiser	Power Balance Australia Pty Ltd	Subject matter of complaint	Website advertisement
Complainant	Dr Ken Harvey						
Advertiser	Power Balance Australia Pty Ltd						
Subject matter of complaint	Website advertisement						

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)
Sections of the Code, Regulations or Act found <u>not to have been breached</u> *	Act section 41FN
Sanctions	Withdrawal of representations Withdrawal of advertisement Publication of a retraction
<p>* 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)</p> <hr/> <ol style="list-style-type: none"> 1. The complaint concerned internet advertisements published at the websites <i>powerbalance.com.au</i>, <i>crazysales.com.au</i>, <i>completehealth.com.au</i>, and <i>completefitnessaustralia.com.au</i>. 2. The advertisement at <i>powerbalance.com.au</i> stated that “everyone’s body is essentially a complex set of electro-chemical processes, a series of organic chemicals generating electro-magnetic energy”, and that “even on a molecular level... your body is generating an electric field.” It stated that “hundreds of recent and historical medical and scientific studies have documented the electrical forces at work within the body and the influence internal and external factors have on the 	

efficient transference of electro-chemical exchanges”, together with many other similar claims regarding the “electro-chemical” nature of the human body.

3. In relation to the advertised product, it stated that “you can restore balance & harmonic equilibrium... with a new ‘switch’”, “Power Balance, after years of research and development, has produced a system to safely restore and optimise the electro-magnetic balance within the human body... IMMEDIATELY”, “Power Balance’s Mylar Holographic Disk (the same substance used to keep static electricity from damaging electrical components) has been imbedded with an electrical frequency that restores your body’s electrical balance, promoting a free exchange of positive and negative ions and align your body’s energy pathways”, “the high density Disk acts much like a switch, resonating within your system and turning on your energy field while it clears the pathways so the electro-chemical exchange functions like the well-tuned generator it was meant to be”, “RESULTS ARE ALMOST IMMEDIATE... & TRULY PHENOMENAL”, “unlike many other ionic electro-magnetic devices, the Power Balance Holographic Disks begin to work almost instantly, restoring optimal electro-magnetic balance and promoting free flowing energy pathways... NO PROMISES, JUST RESULTS”, and “the benefits are clear: faster synaptic response (brain function), enhanced muscle response (in both fast and slow twitch tissues), increased stamina (better oxygen uptake and recovery), more flexibility (faster recovery), and vastly improved gravitational balance.”
4. The other advertisements were less extensive but made similar representations in relation to such benefits as “faster synaptic response (brain function)”, “enhanced muscle response (in both fast and slow twitch tissues)”, “increased stamina (better oxygen uptake and recovery)”, “improved flexibility (faster recovery)”, and “vastly improved gravitational balance.”
5. An excerpt of the advertisement can be viewed in the relevant Appendix to this determination.

The product(s)

6. The advertisement promoted the Power Balance Wrist Band.

The advertiser(s)

7. The advertiser in relation to the www.powerbalance.com.au website was Power Balance Australia Pty Ltd.

8. The advertiser in relation to the *www.crazysales.com.au* website was Auspac Sources Australia Pty Ltd.
9. The advertiser in relation to the *www.completehealth.com.au* website was Evelyn Faye Nutrition.
10. The advertiser in relation to the *www.powerbalance.com.au* website was Complete Fitness.

The complaint

11. The complainant was Dr Ken Harvey.
12. The complainant argued that the benefits claimed for the product were “biologically implausible”.
13. He argued that the advertised product fell within the definition of “therapeutic goods” found within the Act, and that the advertisement therefore breached section 42DL(1)(g) of the Act.
14. The complainant alleged that the advertisements breached sections 4(1)(a), 4(1)(b), 4(2)(a), and 4(2)(c) of the Code because of the benefits claimed for the product.
15. The complainant also alleged that the advertisements breached section 41FN of the Act.

Power Balance Australia Pty Ltd’s response to the complaint

16. Power Balance Australia Pty Ltd (“Power Balance”), the product sponsor and the advertiser in relation to the *powerbalance.com.au* advertisement, stated that they would respond to the complaint on their own behalf and on behalf of Evelyn Fay Nutrition and Auspac Sources Australia Pty Ltd. Power Balance responded through legal counsel.
17. Power Balance provided background information in relation to the advertisement, essentially stating that they were the exclusive Australian distributor of an international product, and had “unfortunately and without admission”, published advertisements and disseminated marketing material that had not been “subjected to any legal review or approval.”
18. They stated that, in late May 2010, “official, uniform Power Balance messaging” had been adopted and had

been “legally approved” by the international supplier of the product.

19. Power Balance stated that, at the time of the complaint, they were “already in the process of replacing” the claims noted in the complaint.
20. Power Balance stated that they accepted “full responsibility for the publication of the Complaint Claims on [their] authorised resellers websites.”
21. In relation to the alleged breach of section 41FN of the Act, Power Balance argued that, as the advertised product is not included in the Register, 41FN could not apply.
22. In relation to the alleged breach of section 42DL(1)(g) of the Act, Power Balance stated that, “without admission... [they accepted] that given the definition of ‘therapeutic use’ under the [Act], it is possible that the Specific Complaint Claims may have resulted in a reasonable consumer viewing the Power Balance wristbands as influencing or modifying a physiological process in persons and therefore likely to be taken to be for therapeutic use”. Power Balance restated that, since the time of the complaint, the relevant claims had been removed from the website.
23. In relation to the alleged breaches of sections 4(1)(a), 4(1)(b), 4(2)(a), and 4(2)(c) of the Code, Power Balance acknowledged that, should the Panel find that the advertisements were advertisements for therapeutic goods, then they had as a result breached these sections of the Code.

The other advertisers’ response to the complaint

24. Evelyn Fay Nutrition (in relation to the *completehealth.com.au* advertisement) and Auspasc Sources Australia Pty Ltd (in relation to the *crazysales.com.au* advertisement) stated that they would rely upon the response provided by Power Balance Australia Pty Ltd.
25. Complete Fitness (in relation to the *completefitnessaustralia.com.au* advertisement) did not provide a response in relation to the complaint.

Findings of the Panel

26. Both Power Balance and the complainant made reference to an article appearing in the Sunday Age newspaper in June 2010. The Panel noted, as a preliminary matter, that this article did not appear to contain any matter which

would influence the Panel's deliberations or decision in relation to the complaint.

27. As a further preliminary matter, the Panel noted the willingness of Power Balance to take "full responsibility" for the advertisements of two of the other advertisers, Evelyn Faye Nutrition and Auspac Sources Australia Pty Ltd (and apparently did not do so in relation to Complete Fitness). The Panel noted, however, that while it was reasonable to regard the response from Power Balance as applying to the *completehealth.com.au* and *crazysales.com.au* websites, as well as to the *powerbalance.com.au* website, this did not mean that Evelyn Faye Nutrition and Auspac Sources Australia Pty Ltd were not in fact responsible for the advertisements which they published. On the contrary, the Panel was satisfied that each of the advertisers (including Complete Fitness) was responsible for the advertisement published on their own website.
28. In reaching this conclusion, the Panel noted that the claims made in the advertisements were extraordinary to such a degree that no reasonable retailer could publish them on the basis of assurances from the product sponsor, without requesting evidence that such claims could lawfully be made about the product.
29. Therapeutic goods are defined in the Act to include goods that are represented in any way to be for therapeutic use. Therapeutic use is defined to include use in or in connection with influencing, inhibiting, or modifying a physiological process in persons.
30. It was clear that the advertisements represented the advertised Power Balance Wrist Bands to be for therapeutic use, and indeed made very strong claims of therapeutic benefits from using the product, such as the claims of "faster synaptic response (brain function)", "enhanced muscle response (in both fast and slow twitch tissues)", "increased stamina (better oxygen uptake and recovery)", "improved flexibility (faster recovery)", and "vastly improved gravitational balance."
31. The Panel was therefore satisfied that the advertisements therefore constituted advertisements for therapeutic goods.
32. Section 42DL(1)(g) of the Act prohibits the publication of advertisements for therapeutic goods that are not included in the Register. The advertiser acknowledged that the wrist band product is not included in the Register and the Panel was of the view that the product was promoted for therapeutic use. The advertisements therefore breached section 42DL(1)(g) of the Act and the Panel found this aspect of the complaint justified.
33. 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”.

34. It was clear that the claims made about therapeutic benefits from the advertised product had not been verified, were misleading, and were likely to arouse unwarranted expectations regarding its effectiveness. The Panel noted that Power Balance had provided no evidence in support of the claims, and no indication that such evidence existed.
35. The Panel was satisfied that the advertisements breached sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code, and these aspects of the complaint were therefore justified.
36. 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. Section 4(1)(a) is therefore breached if any section of the Code, Regulations, or Act is breached. This aspect of the complaint was therefore justified on the basis of the breaches noted above.
37. Section 41FN(5) of the Code imposes a condition upon sponsors of medical devices that are included on the Register. It does not apply to goods that are not included on the Register. The Panel therefore gave no consideration to this aspect of the complaint.
38. The Panel noted, without making any formal finding, that the advertisements appeared likely to breach section 4(2)(i) of the Code by representing the advertised product to be safe without qualification.
39. Please note that the Panel has considered the advertisement with regard to the matters raised by the complainant. The advertiser should not assume that these are the only breaches in the advertisement. The advertiser should therefore familiarise themselves with all the relevant requirements prior to re-publication of the advertisement.

Sanctions

40. The Panel requests Power Balance Australia Pty Ltd, Auspac Sources Australia Pty Ltd, Evelyn Faye Nutrition, and Complete Fitness, in accordance with subregulation 42ZCAI(1) of the *Therapeutic Goods Regulations 1990*:

- a) to withdraw their respective advertisements from further publication;

- b) to withdraw any representations that the advertised product can restore balance and equilibrium, has effects on the “electro-magnetic balance within the human body”, restores the body’s “electrical balance”, has effects on ion exchange within the body, causes faster synaptic response, affects brain function, causes enhanced muscle response, increases stamina, improves oxygen uptake, improves recovery, improves flexibility, or improves “gravitational balance”, together with any other representations that the advertised product is for therapeutic use;
- c) 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;
- e) to arrange for publication on their respective websites of retractions in the form of, and in accordance with, the conditions set out in the attachment to this determination; and,
- f) within 14 days of being notified of this request, to provide evidence to the Panel of its compliance, including a response in writing that they will comply with the Panel’s sanctions, and where appropriate, supporting material such as copies of instructions to advertising agents or publishers, or correspondence with retailers and other third party advertisers.

41. 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 12 November 2010

For the Panel

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).

**Under regulation 42ZCA1 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: Retraction

An advertisement is to appear on the websites www.powerbalance.com.au, www.crazysales.com.au, www.completehealth.com.au, and www.completefitnessaustralia.com.au at the earliest opportunity.

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

RETRACTION

Advertisement Copy:

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