

Re: Slim Herbaqua / Dr HA Steinman / 1757

Thank you for asking me to act as a credible independent expert in terms of substantiating your request for arbitration with the Advertising Standards Authority (ASA), with reference to the above product.

I note that in a recent appeal ruling, dated 8 January, 2007, my credentials were accepted by the ASA.

I understand that in terms of Clause 4-1 of Section ii of the Code, I am required to comment on this matter in my own capacity, or at the very least confirm, in writing, that I have read your submissions and believe that the conclusions reached verify your submissions.

I intend both to comment in terms of Clause 4-1 of Section ii of the Advertising Code, as well as to confirm that I have read your submission requesting arbitration. I will state my conclusions in the final part of this document.

Firstly let me say that I fully support your request for arbitration. I hope to demonstrate in this document certain major deficiencies in the substantiation provided by the respondent, as well as to verify the statements made by yourself in requesting arbitration.

I have been sent copies of correspondence between yourself and the ASA, as well as copies of correspondence from the respondent, including a substantiating report from Dr R C Sandell, the respondent's credible independent expert. I have also consulted the websites: www.herbaqua.com and www.porceval.co.za and labels of the actual product. It is important to note that the list of ingredients and strengths of the mother tincture, forwarded to the respondent by the manufacturer "Parceval (Pty) Ltd", and then forwarded to yourself as the complainant, is barely legible both in electronic fax format and hard copy fax.

According to Clause 4.1, please note some initial comments inserted where relevant:

4.1 Substantiation

4.1.1 Before advertising is published, advertisers shall hold in their possession documentary evidence as set out in Clause 4.1, to support all claims, whether direct or implied, that are capable of objective substantiation.

As the words "before" and "shall" appear in this clause, I can only assume that the ASA has already requested and obtained such *a priori* documentary evidence, which can be shown to have been in the respondent's possession prior to the advertising being published. I have not had access to such documentary evidence, however, and cannot comment on it. If no such documentation is available, then I have to also assume that the respondent is already in breach of the Code of Advertising Practice.

4.1.2 Documentary evidence, whether in the form of survey data or any other documentation, shall be up to date and current, and shall have market relevance.

I intend to focus primarily on this part of Clause 4.1 below.

4.1.3 Survey data

Survey data are not provided and would not be appropriate for a product of this nature.

4.1.4 Documentary evidence, other than survey data, shall emanate from or be evaluated by a person/entity, which is independent, credible, and an expert in the particular field to which the claims relate and be acceptable to the ASA.

This letter forms “my” documentary evidence.

4.1.5

Clause 4.1.5 applies to the respondent, and has already been fulfilled.

4.1.6 Claims based on research conducted by publications must clearly state the source in advertising.

I find this clause somewhat difficult to apply, as I am not aware of “publications doing research” in the field of weight loss products. Perhaps this form of research is suitable for substantiating claims of other kinds of products.

Documentary evidence

1. Dr Steinman has primarily complained about the claims made that Slim Herb Aqua is an effective aid to weight loss. He refers to claims made on the website. I can confirm that prominently featured on the homepage and all relevant linked pages making up this site, the following statement is made:

“Welcome to Slim Herb Aqua”

and below that:

“A range of flavoured sparkling mineral waters infused with herbal weight loss formula.” (emphasis added)

and below this:

“the great taste of slimming” (emphasis added)

2. It is quite clear that the product is primarily making weight loss claims.

3. Further claims made on the home page include:

“**SLIM HERB AQUA** is a consumer convenient product that provides rehydration in a pleasant fashion.” (emphasis added)

and

“**SLIM HERB AQUA** is proving to be hugely popular, in line with a growing worldwide trend towards the use of natural herbal products to enhance vitality and maintain health.” (emphasis added)

Four further information boxes appear on the home page. Three have headings as follows:

- “I want to be slim without the hassle”
- “A great new way to slim for summer”
- “Fat is not fun”

(emphasis added in each)

Each of these three boxes has a link with the words “Click for more” leading to the same page: www.herbaqua.com/slim.php . The first two boxes each have a picture of a beautiful white woman as well as a picture of the container (bottle) and label of the product. The third encourages “fat” women as follows: “So come on girls - lose that excess weight and get a fuller social life.”

The fourth information box is much smaller than the others, has no picture and no links and simply states: "To achieve and maintain your goal weight with this product it is recommended that you follow a healthy diet and exercise programme."

4. Therefore, from a perusal of the home page (www.herbaqua.com) it can be clearly seen that the following claims are made or implied:

- the product is a weight loss product
- the product is a slimming product
- the product helps overweight women ("Fat is not fun")
- the product provides rehydration
- the product enhances vitality and maintains health
- by using the product and losing weight, a fuller social life can be anticipated

It is also clear that the advertising could be said to exploit women – the most vulnerable group in terms of societal norms relate to appearance, and vulnerable in terms of self-esteem related to appearance.

5. No evidence is given, nor references provided, for the average consumer to validate any of these claims made on the homepage.

6. In the letter to the ASA Dispute Resolution Consultant, dated 12 December, 2006, Ms Peiser quotes from the abstract of a University of North Carolina study. However if the full article is accessed and read, the following paragraph is included:

Clearly this paper is just a small step forward in our efforts to understand more about water intake patterns and their relationship with overall diet. There are so many questions linked to the relationship and impact of water use on consumption not only of other beverages, particularly the caloric beverages, but also of overall diets. Longitudinal research is the major need from an epidemiological perspective. At the same time, it is clear that many questions that relate water use to the overall selection of foods and beverages require clinical trials.¹ (emphasis added)

7. In the above-quoted letter, the following statement is made:

"Herbex Slim Aqua, being a sparkling mineral water infused with the Herbex Slimmers formula, benefits the consumer through both the herbal content and increased water intake."

8. Purported benefits of the Herbex Slimmers formula have not been proven.

9. No evidence is provided that a consumer would in fact increase their water intake through the purchase of this product. The product is relatively expensive compared to other forms of bottled water, and it is just as possible that, in order to buy the product, the consumer buys less bottled water than normal – thus decreasing their water intake.

10. The very study from which Herbex have prematurely extrapolated their conclusion, recommends longitudinal epidemiological research (the study published and quoted was a cross-sectional study), as well as a clinical trial.

11. Furthermore, the study was only conducted in the United States and cannot be generalised to a South African population.

12. Clearly this study cannot be used to substantiate the claims made for the product. Dr Sandell, the respondent's independent credible expert, makes no reference to this study in his substantiation.

13. I agree with Dr Steinman's analysis of the ingredients, and his interpretation of their (lack of) efficacy for weight loss, as outlined in the Natural Medicines Comprehensive Database and the other references consulted.

14. I agree with Dr Steinman's assertion that the dosage of the "tincture" used to "infuse" the mineral water is miniscule, and unlikely to have any effect at all on weight loss or appetite suppression. From the barely legible list of ingredients supplied by Parceval (Pty) Ltd, it appears that less than 1 ml of the tincture is to "be used per 500 ml of Herbex Slim Aqua Water" and less than 1 ml of the tincture is to "be used per 250 ml of Herbex Slim Ice Tea".

15. From a simple calculation, assuming that the tincture was in fact 1 ml, the amount of herbal formulation within Herbex Slim Aqua Water is 0.2 % of the product (in other words 2 ml per 1000 ml).

16. Although the names and strengths of the 33 herbs forming the tincture are essentially illegible, 34 ingredients are in fact listed. It appears as if 3 of these are possibly not herbs at all, but water and two different concentrations of alcohol. If this is so, then there are in fact only 31 herbs in the tincture, and the advertising becomes factually incorrect. (This would need verification by the arbitrator using a legible list of ingredients.) The product label does not list the herbs but merely states that there are 33 herbs in the product. Dr Sandell does list 33 herbs, but does not include the alcohol and (?)water contained in the Parceval list.)

17. It appears as if the combined water and alcohol amounts may form at least half the total amount of the tincture.

18. Assuming that the herbal components form half of the tincture, and that the amount of each of the herbs is equal (although clearly they are not), it would mean that in 500 ml of the product, each of 31 herbs contributes about 0.00323 % – which truly is, as Dr Steinman stated, miniscule.

19. There is no evidence that this is a homeopathic product, prepared according to homeopathic principles. According to Dr JP Prinsloo:

Homoeopathy is a system of medical practice based on three principles ; 1) Drugs are tested on healthy human subjects, 2) The Law of Similars, 3) The Individual Disease Picture. It is not necessary that the dilution of the medicine be infinitely diluted. However, what is important in every individual case, is the homoeopathicity of the prescription. Homoeopathicity meaning that the medicine or remedy prescribed should be in accordance with the Homoeopathic principle of similimum (individualised to the condition as presented in the patient).²

A commercial product such as Slim Herb Aqua cannot claim to be "individualised to the condition as presented in the patient".

20. On the webpage www.herbaqua.com/slim.php under the heading "Formulation" – the following statement is made:

"**Slim Herb Aqua** contains a powerful herbal formula with a nine-fold action that will reduce appetite, boost metabolism and improve digestion."

The word "powerful" in this context is highly questionable and probably misleading, as there is no evidence that the herbal formula has any effect at all.

21. It is not clarified how the three overall effects mentioned above are achieved by this “nine-fold action”. Listed below this statement, under the heading “Herbs and their effects”, are 12 different purported effects of the 33 herbs. Dr Sandell lists ten different “health benefits” and then adds “while rehydrating the body and thereby assisting energy levels.”

22. Dr Sandell prefaces his list with the statement that it is in his *opinion* that the doses will be therapeutically effective in providing the health benefits. Nothing beyond his “opinion” is given to support the efficacy of the combination formula for weight loss and the other advertising claims made. This surely does not constitute “substantiation”.

23. In terms of the category “Nervines”, it is not clear which of the purported herbs provide sedative effects or stimulant effects, and what correlation this has with weight loss, if any. However, one of the ingredients, milk thistle, (also listed under “Liver Tonics / Protectors), contains a substance, silymarin – which is a Schedule 3 Substance in terms of the Medicines and Related Substances Act. This is referred to as *Silybum marianum* (*Carduus marianus*) by Dr Sandell. Schedule 3 substances require a prescription, may not be sold in a supermarket or health shop, and may not be advertised to the general public.

24. In the category “Metabolic Enhancers”, guarana (referred to as *Paullinia sorbilis* by Dr Sandell) is listed on the webpage. Guarana contains a substance, theophylline – which is a Schedule 2 substance in terms of the Medicines and Related Substances Act.

25. In the category “Metabolic Enhancers”, kelp (referred to as *Fucus vesiculosus* by Dr Sandell) is listed. In a recent arbitration related to a product containing kelp (also known as bladderwrack), the arbitrators stated:

“Theoretically, thyroid stimulation from bladderwrack may increase metabolism and cause weight loss. However safety and effectiveness have not been studied in humans (Grade C - Unclear Scientific Evidence for this use) (NIH, 2005).”

There is no evidence that kelp will assist in weight loss.

26. I agree with Dr Steinman’s challenge that Dr Sandell has not provided any evidence of “synergy” between these ingredients. In fact, in pharmacodynamic terms Dr Sandell seems to have ignored that apart from possible synergistic effects between ingredients in a “combination formulation”, additive effects and antagonistic effects are also possible. Usually in determining the synergistic/additive/antagonistic effects of the ingredients within a combination formulation, one would require information concerning the absorption, distribution, metabolism and excretion of the ingredients individually and in combination. No such evidence has been provided.

27. In contrast, Dr Steinman’s analysis of the ingredients shows conflicting evidence for the presumed effects of the individual ingredients on weight loss and appetite, particularly in terms of those which purportedly stimulate the appetite as opposed to the claimed appetite suppression.

28. In considering the webpage “Technical Information” (www.herbaqua.com/tech.php), the following statement is made: Each product contains a blend of different herbs. These are all well known clinically tested herbs and have been approved for human consumption by the South African Medicines Control Council.

29. No information validating that the herbs are “well known clinically tested herbs” has been provided. The phrase “clinically tested” implies that the tests have been done in humans under clinically controlled conditions.

30. This product was developed in 2003. I have been a member of the Medicines Control Council (MCC) since July 2002. The MCC does not approve herbs for “human consumption” as stated here, and I am personally unaware of such an approval ever having been given to any product. The MCC registers medicines on the basis of quality, safety and efficacy.

31. The manufacturers of this product may have submitted information to the MCC as part of the February 2002 “call-up” of complementary medicines. This most certainly does not provide any explicit or implicit “approval”. The call-up merely provided for manufacturers to partially fulfill the requirements for full registration, and was regarded as a “first step” towards registration.

32. Although the respondent has submitted a copy of a valid and current certificate of Good Manufacturing Practice for Parceval, it must be noted that according to the respondent’s website, the tincture is transported from Parceval’s Wellington site to the respondent’s Franschoek bottling site. There is no evidence that the water quality is consistent nor that no contamination of the tincture occurs before or during the process of “infusing” it into the mineral water.

In summary:

33. In my opinion Dr Steinman’s request for arbitration is reasonable and should be granted.

34. No evidence has been provided to show that the claims made for this product are valid. Some of the claims may actually be misleading.

35. Dr Steinman’s conclusions concerning the lack of evidence, and conflicting evidence in terms of weight loss, appetite and other purported therapeutic effects appear to be correct.

Recommendations:

36. Certificates of analysis of all the components (ingredients) of the product, as well as for randomly selected batches of the product should be made available to the arbitrator.

Conclusion:

37. Dr Steinman has provided sufficient reason for requesting arbitration. Additional reasons for arbitration and for consideration by an arbitrator, have been provided by myself.

Signed:

References:

1. POPKIN BM, BARCLAY DV, NIELSEN SJ. Water and food consumption patterns in U.S. adults from 1999 to 2001. *Obes Res.* 2005; 13:2146 –2152.
2. Prinsloo JP. Homeopathy in Perspective. http://www.homeopathy.org.za/hom_in_per.htm (accessed 14 March 2007)