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**14 December 2004**

**Per electronic mail, fax and registered mail**

**Advertising Standards Authority (ASA)**

**Complaints Division**

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**Complaint submitted by Vuyani Jacobs on behalf of the Treatment Action Campaign regarding an advertisement in Mail & Guardian newspaper on 26 November 2004 against:**

- 1 'Dr Rath Health Foundation Africa'. The Hague 'Zurich Tower', Muzenstraat 89 and The Terraces 34 Bree Street Cape Town; and**
- 2. 'Treatment Information Group'. Care of Rath Health Foundation Africa, The Terraces, 34 Bree Street, Cape Town**

1. My name is Vuyani Jacobs. I live with HIV. I use antiretroviral medicines (“ARVs”) including the drugs lopinavir/ritonavir, didanosine and tenofovir.
2. I am the People With HIV/AIDS representative on the South African National AIDS Council as well as an executive member. I work for an organisation that produces treatment literacy videos on HIV/AIDS. I am also a member of the Treatment Action Campaign.
3. I am lodging a complaint with the Advertising Standards Authority (“ASA”) of South Africa regarding an advertisement (“the advert”) that appeared in the Mail and Guardian newspaper on 26 November 2004. The advert appears to have been placed by the “Dr. Rath Health Foundation Africa” {“the foundation”) and the “Treatment Information Group” (“the group”).
4. I am submitting this complaint in both my personal capacity and after duly being authorised to do so, by the secretariat of the Treatment Action Campaign.
5. For the sake of convenience, a copy of the advert is attached marked “ASA 1”.
6. Before I began taking antiretrovirals, I had AIDS. I constantly had opportunistic infections. I suffered from weight-loss, diarrhea and memory-loss. My CD4 count, a measure of the strength of my immune system was 175 and my viral load was 11 million, indicating that I was in the advanced stages of HIV-disease. Since taking antiretrovirals, my viral load has become undetectable and my CD4 count at last check was 375. My memory has returned and I have had no opportunistic infections. My weight has risen to 65kg from 55kg. My skin has also improved. I still have HIV and will have to take ARVs everyday for life, but my quality of life and fitness has improved substantially. All of this is in accordance with current medical science.

### **Nature of the complaint**

7. The Code of Advertising Practice issues by the Advertising Standards Authority of South Africa (ASASA) (“Code”)<sup>1</sup> provides that *“[a]dvertising is a service to the public and, as such, should be informative, factual, honest, decent and its content should not violate any of the laws of the country. All entities bound by the Code shall neither prepare nor accept any advertising which conflicts with the Code and shall withdraw any advertising which has subsequently been deemed to be unacceptable by the ASA Directorate, Advertising Standards Committee, Advertising Industry Tribunal or Appeal Committee”*.
8. The advert constitutes “advertising” for purposes of the Code. The word “advertisement” applies to published advertising wherever it may appear.
9. Clause 2 of Section i of the Code divides adverts into four categories: (1) commercial, (2) non-commercial, (3) political and (4) advocacy.
10. The advert constitutes commercial advertising as is understood by the Code. The Code specifies that its primary object is the “regulation of commercial advertising”. The Code applies to “all advertisements for the supply of goods or services or the provision of facilities by way of trade, and also to advertisements other than those for specific products which are placed in the course of trade by or on behalf of any trader”. I submit that the advert constitutes an advert for the supply and sale of particular medicines and as such the Code is applicable. In any event, the Code also applies to non-commercial advertising, by providing that the “Code applies, so far as is appropriate, to advertisements by government departments and agencies and to those by other non-commercial organisations and individuals”.
11. The advert breaches the Code in the following respects:
  - 11.1. It exaggerates the efficacy of multivitamins in “treating” AIDS.

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<sup>1</sup> As appears from [www.asasa.org.za](http://www.asasa.org.za), last accessed 8 December 2004. I note that the Health Products Association of Southern Africa and the [Self-Medication Manufacturers' Association of South Africa](#) subscribe to the ASASA Code. The Code binds the advertiser, the advertising practitioner and the medium involved in publication of the advertiser's message to the public.

- 11.2. It deliberately misleads consumers about zidovudine (AZT). AZT is approved as both safe and effective by the Medicines Control Council of South Africa ("MCC") for treating HIV/AIDS and preventing mother-to-child transmission of HIV under certain conditions, in combination with other antiretrovirals.
- 11.3. It deliberately misleads consumers about nevirapine (NVP). NVP is approved as both safe and effective by the MCC for treating HIV/AIDS and preventing mother-to-child transmission of HIV under certain conditions, in combination with other antiretrovirals.
- 11.4. It deliberately misleads the public about the MCC by falsely claiming that the MCC has proposed new regulations that will "effectively prevent free access to life-saving vitamin therapy and information about it."
- 11.5. It deliberately misleads the public about the MCC by implying that the MCC's registration of AZT for pregnant HIV-positive women is irresponsible because it endangers infants.

## **Treatment of HIV /AIDS**

12. Below I explain the current science of treating HIV/AIDS.
13. First, scientific evidence indicates that some vitamins (which are taken as supplements) slow the progression to AIDS for some people in certain circumstances. However, for nearly all people, the evidence suggests that they will develop AIDS even if they are using the most optimal nutrition and vitamin supplements.
14. Where a person develops AIDS, or more accurately, when a person's CD4 count (a measure of immune system strength) is below a certain point (below 200 is the figure used by the National Department of Health ("NDOH") in its antiretroviral programme in the public sector), ARV treatment is necessary to prolong life. To date, there is no evidence that multivitamins increase life-expectancy once a patient commences ARV treatment.

15. In this respect, a recent decision by the office of the Public Protector is relevant. *The "REPORT OF THE PUBLIC PROTECTOR ON AN INVESTIGATION INTO ALLEGATIONS OF IMPROPRIETY IN CONNECTION WITH THE APPROVAL BY THE CABINET OF AN OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA, DESIGNED BY THE NATIONAL DEPARTMENT OF HEALTH"* is available online at:  
<http://www.tac.org.za/Documents/Public%20Protector%20report%20Anita%20Allen.doc>.
16. The report dismissed a complaint lodged by Ms Anita Allen who complained that the adoption of the *Operation Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* by Cabinet was unconstitutional because (1) HIV does not cause AIDS and (2) ARV medicines are toxic.

### **The advert breaches the ASA Code of Advertising Practice**

17. The advert breaches numerous clauses of the Code, including Clause 11 of the Preface and Clause 1.1 of the Preamble to the Introduction. This is because the advert is factually incorrect and dishonest for the following reasons.
18. With regard to multivitamins:
  - 18.1. The advert uses a quotation from the New York Times to claim that a study published in the New England Journal of Medicine (NEJM) found that 'daily doses of multivitamins slow down the disease and cut the risk of developing AIDS in half.' However, the study in the NEJM (2004 Jul 1; 351(1):23-32) is selectively cited and did not purport to make such findings.
  - 18.2. The NEJM study did however find that a multivitamin supplement containing vitamins B, C and E delayed the onset to AIDS in pregnant women in Tanzania. 24.7% of the study group taking the vitamins developed AIDS compared to 31.1%

of the study group who despite taking a placebo also developed AIDS. It did not cut the risk of developing AIDS in half; though it did *delay* the onset of AIDS in approximately 21% of the sample group. There is no evidence that it *reduces* the risk of developing AIDS – and certainly not by half.

- 18.3. Furthermore, it is premature to project the result of the NEJM study which was conducted on Tanzanian pregnant women. It is not clear that a result for this cohort is applicable to other populations or to the South African population.
- 18.4. At most, the particular multivitamin supplement of vitamin's B, C and E might have some effect in delaying the onset of AIDS. Once a person develops AIDS however, ARV treatment is clinically indicated. The conclusion of the NEJM study itself is: "Multivitamin supplements delay the progression of HIV disease and provide an effective, low-cost means of delaying the initiation of antiretroviral therapy in HIV-infected women." We would not object to an advertisement that makes such a claim, but the advert that is the subject of this complaint goes much further than this.
- 18.5. The tone and style of the advert conveys the impression that multivitamins are a much more effective treatment of HIV/AIDS than they actually are. For example, the advert states "The Treatment Information Group and the Dr. Rath Health Foundation have launched a public education programme to break the silence about the natural answer to AIDS." This statement is misleading because there is no proven, safe and effective 'natural health' answer to AIDS."
- 18.6. The advert further states that the NEJM study found that "inexpensive multivitamin treatment is more effective in staving off disease among HIV-positive women than any toxic AIDS drug." This statement is misleading and false. There are a range of ARV medicines, including AZT, which have been shown to be effective in suppressing HIV. As stated previously, the most generous possible interpretation of

the study is that it is possible that multivitamins (vitamins B, C and E to be precise) are slightly effective in delaying the onset of AIDS for the general population.

18.7. The NEJM study referenced above states “The benefits with respect to immunologic and virologic outcomes in our study were small relative to the benefits of triple antiretroviral therapy.”

18.8. The advert also refers to a study conducted in 1990 that an optimal dose of vitamin C can block replication of HIV by 99% (Proceedings of the National Academy of Sciences of the United States of America 1990 Sep; 87(18):7245-9). The study was not conducted on humans and has no validity as a claim for the efficacy of multivitamins as a treatment for HIV/AIDS. It is therefore a misleading reference.

19. With regard to AZT and NVP:

19.1. It should be noted that AZT and NVP are registered with the MCC for the treatment of HIV, as well as for the reduction of mother-to-child transmission of HIV, when used in combination with other ARV medicines. They do have certain side effects and in rare circumstances these can be fatal. It is recognised however that the benefits of appropriately using ARVs far outweigh the risk of not using them.

19.2. According to the NDOH, 5.6 million people are living with HIV/AIDS in South Africa. Of these, approximately 300,000 to 500,000 have AIDS and need access to ARV treatment immediately. Both AZT and NVP are used widely in the public and private health care sector to treat and prevent HIV/AIDS. Both drugs appear on the NDoH's ARV procurement list for use in the public sector.

19.3. Both AZT and NVP constitute critical components of resolving the public health crisis created by the HIV epidemic. Attempts to undermine public confidence in them is dangerous and life-threatening because it could adversely affect patient adherence, which is a critical component of treatment success. It could also lead to people who need ARVs refusing to take them, resulting in their premature death.

The heading of the advert “Why should South Africans continue to be poisoned with AZT?” is particularly misleading.

- 19.4. The advert also contains a photo of a bottle of AZT with a ‘toxic warning’ label on it. Accompanying the photo is the text “this is a 25mg bottle of AZT supplied by Sigma-Aldrich for use in research laboratories. The label speaks for itself. GlaxoSmithKline (GSK) recommends between 500 and 1500 mg of AZT daily - twenty and sixty times the quantity that Sigma-Aldrich warns research workers could kill or severely injure them- alleging that ‘AZT has extended and improved the quality of life of millions of people living with HIV/AIDS around the globe’. Also that ‘GlaxoWellcome [now GSK] are a reputable company. We do not lie to people.’ ”
- 19.5. The bottle used in the photograph is for use in Sigma-Aldrich's laboratories. It is a research bottle and not intended for human use. But the labeling is clearly meant for the employees and contractors of Sigma-Aldrich, not for the general public. It has no relevance to the safety and efficacy of AZT when used for the indications registered by the MCC. It is therefore misleading.
- 19.6. The advert also states:
  - 19.6.1. “Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system”;
  - 19.6.2. “Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases, and early death”;
  - 19.6.3. “Do you want to continue being misled by the pharmaceutical and its front organisations to believe that exorbitantly expensive and highly toxic drugs like AZT and nevirapine are the answer to AIDS?”;

- 19.6.4. “Read poisoning our Children: AZT and nevirapine in pregnancy on the Treatment Information Group website.”
- 19.7. All of the above statements are misleading and constitute ‘puffery’ as defined by the Code.
- 19.8. With regard to the MCC, the advert states:
- 19.8.1. “Incredibly, two weeks after the publication of the Harvard study [the NEJM study referred to], the Medicines Control Council proposed new regulations that will effectively prevent free access to life-saving vitamin therapy and information about it, and recommended that HIV-positive women take AZT during their pregnancies.”
- 19.9. However, the MCC has registered both AZT and NVP as appropriate medicines to be used in the treatment of HIV and for use in mother-to-child transmission prevention of HIV/AIDS. The MCC has registered these medicines on the basis of a number of studies submitted to the MCC. The MCC has been extremely cautious in its registration of AZT and NVP for mother-to-child transmission prevention and the package inserts of both medicines are a reflection of the conditions associated with their use. In this respect, ASASA must consult with the MCC.
- 19.10. Furthermore, vitamin supplements, which have for a long time been thought to have some benefit to people with HIV are available at many public sector health clinics. It is government policy to supply these supplements. The implication that there is a conspiratorial state cover-up against the use of vitamins is therefore unsupported by the facts.

19.11. New regulations regarding the registration of traditional and complementary medicines and proposed by the MCC will not have any effect on the general availability of vitamins. Instead, it will ensure that information that is more accurate is filtered through to the public by prohibiting and punishing false claims made about any medicine or substance.

### **Breach of the Code**

20. The advert breaches Clause 2 of Section ii of the Code in that it abuses the trust of the consumer and exploits his lack of experience, knowledge and credulity. Many people with HIV do not have the skills or resources at hand to determine that the claims made in the advert are false.
21. The advert breaches Clause 4.1.1 of Section ii of the Code in that the advertisers do not hold in their possession scientific documentary evidence as set out in Clause 4.1, to support the claim that multivitamins are a substitute for ARVs. They do not hold such documentary evidence because such evidence does not exist.
22. The advert breaches Clause 4.2.1 of Section ii in that it contains statements and visual presentations which, directly, by omission, ambiguity, and exaggerated claim, are likely to mislead the consumer about multivitamins, AZT and nevirapine.
23. The advert breaches Clause 4.2.2 of Section ii in that the advert commits puffery, that it is not clear that an opinion is being expressed and that there is likelihood of the opinion or the way it is expressed, misleading consumers about multi-vitamins on the one hand and AZT, Nevirapine and the MCC on the other.
24. The advert breaches Clause 4.2.3 of Section ii in that it contains hyperbolic claims that are not obvious to readers.
25. The advert breaches Clause 4.2.4 of Section ii in that it contains what is purported to be informed opinion in support of multivitamin use so exaggerated that it is unsupported by independent evidence.

26. The advert breaches Clause 4.2.5 of Section ii in that it misuses research results or quotations from technical and scientific literature. It gives greater validity to the efficacy of multivitamins than is the case and ignores the weight of scientific evidence which has found that the benefits of AZT and nevirapine outweigh their risks.
27. The advert breaches Clause 4.2.6 of Section ii in that its headline is misleading, stating that South Africans are being poisoned with AZT and that “natural” remedies are an answer to AIDS.
28. The advert breaches Clause 6.1 of Section ii because it disparages other products, i.e. AZT and nevirapine, as well as the MCC. It does so using false allegations and against the public interest.
29. The advert breaches various comparative advertising clauses including 7.1.2, 7.1.3, 7.1.4, 7.1.6, 7.1.7, 7.1.9, 7.1.10, 7.2, 7.3 and 7.4 of Section ii in that it makes false, exaggerated and misleading claims about AZT and nevirapine.
30. The advert breaches Clause 13 of Section ii in that it promotes a dangerous practice that is unsafe and likely to lead to premature death, i.e. using multivitamins instead of antiretroviral treatment where the latter is indicated.
31. The advert infringes appendix H to the Code which specifically prohibits advertising that contains “improper, alarming or misleading claims of a recovery”. Further, appendix H states that in respect of comparisons  
”22. All descriptions, claims and comparisons to be used, must be based on fact and have been approved by the MCC”.<sup>2</sup>

### **The advert falls under the scope of commercial advertising in ASA's code**

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<sup>2</sup> The appendices are determined by the various member organisations or negotiated with governmental institutions. All such codes conform to the general principles laid down by the ASA Code and differ only in detail where individual needs are to be met. The provisions of the Code are mostly broadly framed, but special rules covered by the appendices apply to particular audiences and to certain categories of products and services. Appendix H deals with the advertising of over the counter medicines and was determined by the Self Medication Manufacturers Association of South Africa.

32. The advert falls under the first category: commercial advertising. It constitutes commercial advertising for the following reasons:
- 32.1. The Foundation is inextricably linked to the personality of its operator, Dr. Matthias Rath. First, the organisation is named after him. Second, the organisation's websites <http://www4.dr-rath-foundation.org.za/> and <http://www.dr-rath-foundation.org/> make it clear that the views propounded are those of Dr. Rath and that he is the leader of this organisation.
  - 32.2. The websites prominently and falsely describe Dr. Rath as “the physician and scientist who led the breakthrough discoveries in the natural control of cancer, cardiovascular disease and other chronic health conditions.”
  - 32.3. His speeches and papers are also linked on these websites.
  - 32.4. Dr. Rath is also the proprietor of products sold at <http://www.drrathvitamins.com/index.html>.
  - 32.5. I invite the ASA to examine this website and note its similar style and content to websites referred to above, except that this particular website sells a whole range of products many of which are multivitamin supplements. See [http://www.drrathvitamins.com/sales/main/sales\\_main.html](http://www.drrathvitamins.com/sales/main/sales_main.html) (last accessed 14 December 2004) for a list of products and prices. See also “ASA 2”.
  - 32.6. Although the advert is critical of the pharmaceutical industry, Dr. Rath, is also the proprietor of a pharmaceutical company selling synthesized vitamins and amino acid supplements. Dr. Rath markets his supplements under a series of programmes trademarked as “Dr. Rath's Cellular Health”.

- 32.7. The British Advertising Standards Authority has forced Dr. Rath to remove his advertising for treatments as they were unsupported by evidence and misled the public. See:  
[http://www.asa.org.uk/adjudications/show\\_adjudication.asp?adjudication\\_id=30238&from\\_index=by\\_sector&dates\\_of\\_adjudications\\_id=all](http://www.asa.org.uk/adjudications/show_adjudication.asp?adjudication_id=30238&from_index=by_sector&dates_of_adjudications_id=all)
- 32.8. The Swiss Study Group for Complementary and Alternative Methods in Cancer (SKAK) and the Swiss Cancer League (SCL) has issued warnings against the theories and products of Dr. Rath. See: <http://www.quackwatch.org/11Ind/rath.html>
- 32.9. The US Food and Drug Administration (FDA) has issued a warning against Dr. Rath for his online advertisements because he claims his products have health benefits but he has provided the FDA with no safety or efficacy information. See: <http://www.fda.gov/cder/warn/cyber/2002/CFSANvitacor.htm>
- 32.10. In the advert, it is stated, “non-patentable natural therapies have very low profit margins, whereas patented synthetic pharmaceutical AIDS drugs are a multi-billion dollar business.”
- 32.11. However, Dr Rath himself holds the following patents on uses of various vitamins and amino acids in the United States: US patent nos: 6,693,129; 6,686,340; 5,650,418; 5,278,189 and 5,230,996.
- 32.12. Dr. Rath claims that Vitacor Plus (TM) “is the foundation product for Dr. Rath's Cellular Health™ Programs, this multivitamin contains the essential nutrients that provide support for the integrity of the cells of the body.” See:  
[http://www.drrathvitamins.com/products/main/pdvitacor\\_main.html](http://www.drrathvitamins.com/products/main/pdvitacor_main.html)
- 32.13. The components of Dr. Rath's Vitacor cost a few cents to produce, but Dr Rath sells them at \$29.95 for 90 tablets, a much higher price than many similar multivitamin brands.

- 32.14. A British Medical Journal article BMJ 1998;317:1069-1071(17 October ) reviewed what seems to be a similar product, Vitacor, sold by Dr. Rath. The title of the paper was "Validity of advertising claims for multivitamin preparation Vitacor 20/90 on the internet". The article stated: "New electronic media such as the internet are used by companies to distribute drugs uncontrollably. We examined the scientific validity of advertising statements for Vitacor, a multivitamin preparation being heavily advertised on the Internet. ... In the references used to support advertising statements, we found no proper evidence for the claimed beneficial effects on morbidity, mortality, and quality of life associated with coronary heart disease, heart insufficiency, high blood pressure, arrhythmia, and diabetes. Testing of the components of the preparation was not sufficient, and no general reduction of cardiovascular risks could be demonstrated even for standard substances such as vitamin E, beta-carotene, and vitamin A. The advertising statements would raise hopes in patients that cannot be justified from the data currently available".
- 32.15. I am not aware of any scientific studies published since 1998 that offer any reason to doubt the conclusions reached in the above article.
- 32.16. Dr. Rath until recently treated a young boy with cancer named Dominik. He claimed that his multivitamin products including Vitacor would cure Dominik. Dominik subsequently died of cancer. See:  
<http://www.sat1.de/tvmagazine/fruehstuecksfernsehen/themen/02211/>.
- 32.17. The above demonstrates that Dr. Rath promotes his products by unethical means. He uses his foundation to act as an advocacy voice for his company, which sells scientifically untested and unproven products. Furthermore, by telling people not to use proven medical methods with a high probability of success, and instead use supplements promoted by him, he endangers lives which, contributes to a public health crisis. Clearly, the advert falls within the ambit of the Code.

32.18. The Foundation is a front for a commercial venture. Whereas the Group has aligned itself with the Dr. Rath Health Foundation Africa. By co-advertising, Dr Rath's products are promoted. Dr. Rath also features prominently on the Group's website. See: [www.tig.org.za](http://www.tig.org.za).

## **Sanctions**

33. The Dr Rath Health Foundation Africa and the Treatment Information Group are endangering public health. The advert undermines the response to the most urgent and serious health epidemic facing our country. The advert itself endangers lives.
34. Although, a finding against the Foundation and Group constitutes a first offence in this jurisdiction, it will not be the first from similarly constituted bodies established in other countries. The Foundation has both judgments and cautions issued by regulatory authorities in the US and UK, as explained above. There is a pattern of Dr. Rath moving to different jurisdictions to run the same types of adverts.
35. The following sanctions under the Code are appropriate in the circumstances:
  - 35.1. Pursuant to Clause 14.1 of Procedures and Relief in the Code, the advert must be ordered to be withdrawn in its entirety and current format;
  - 35.2. Pursuant to Clause 14.2, the Foundation and the Group must submit any proposed amendment, as well as the original advertisement and relevant ASA ruling to the ACA Advisory Service for pre-publication advice;
  - 35.3. Under Clause 14.4, publicise the names of the Foundation and the Group;
  - 35.4. Under Clause 14.5 order the Foundation and the Group to publish a summarised version of the ruling, at their own expense, in the Mail & Guardian newspaper;

## **Why the ASA?**

36. No attempt has been made to resolve this matter with the Foundation and the Group.

There are several reasons for this:

36.1. The head of the Foundation, Dr Rath, has an international record of rulings and warnings against him by regulatory authorities in the US and UK. This has however not deterred him from continuing to place misleading advertisements in other countries such as SA;

36.2. The advert endangers public health; and

36.3. It is my view that Dr. Rath is aware that the advert is misleading and is unlikely to be swayed by a request from me to stop placing such adverts.

37. Please note that this complaint is endorsed in its entirety by the Rural Doctors Association of South Africa. In this respect please refer to the respective letters of endorsement, marked "ASA 3"..

38. Please also note a letter, attached as "ASA 4", submitted by the South African Medical Association to the Mail & Guardian, the content of which adds further weight to this complaint.

39. Kindly note that if you require any further information I can be reached on 021 788 9163, 021 448 5328 and [vuyani@beatit.co.za](mailto:vuyani@beatit.co.za). Faxes can be sent for my attention to 021 788 3726. Correspondence can be posted to Vuyani Jacobs, c/o Treatment Action Campaign, 34 Main Road Muizenberg, 7945. I look forward to hearing the outcome of the complaint as a matter of urgency.

Signed at .....

Date.....

Full name and identity number.....