

Poppyseed Cottage, High Street, Stoke Ferry, Norfolk PE 33 9SF

Guy Parker
Chief Executive
Advertising Standards Authority
Mid City Place
71 High Holborn
London WC1V 6QT

16 May 2011

Dear Mr Parker

We are writing to formally complain about the way the ASA investigation team is handling complaints made about an advertisement published by us in a Care supplement of the *New Statesman* in the autumn 2010 (reference: A10-139800/JN).

Our concern is that the investigation team

- Appears to have conducted this investigation on the basis of predetermined views of what the outcome should be.
- Appears to have failed to consider the context in which the complaints have been made, and what pressures this puts on the independence of the ASA.
- Appears to have failed to take into account the purpose of the advertisement and of the organisation publishing it, and the nature of the readership.
- Appears to have shown a serious lack of awareness of the relevant scientific and medical principles.

At the same time the investigation team

- Has made disproportionate demands on our organisation for evidence in support of our statements;
- Has been seriously inconsistent and arbitrary in its treatment of the issues;
- Has been unreliable and inaccurate in presenting our arguments in the drafts of its recommendations;
- Has been unethical in its approach to the process as a whole; and
- Has taken an inequitable position as regards the time permitted for responses.

We present a selection of examples below, but we wish to emphasize that these do not constitute a comprehensive list of examples.

Pre-determined views

Evidence for the pre-determined nature of the investigation team's views can be seen in their proposal that seven of the complaints would not be investigated if we agreed to not repeat those statements in the future (original complaints 6, 8, 9, 10, 11, 12, 13). Given that six of these were complaints about statements of fact, we considered it impossible to accept such a proposal. Curiously, the only one of the seven complaints which was actually about a statement of opinion ("Opposition to homeopathy is based on propaganda" – original complaint 11) was subsequently withdrawn by the investigation team after we had responded, rather than being "upheld" or "not upheld". One consequence of the withdrawal of this complaint is that all the evidence we supplied in response to it was suppressed and so would not be made available to the ASA Council even in a summarised version.

The motives of the complainants

The significance of this lies in the fact that there has been an organised campaign against homeopathy over the last five or six years. The charity Sense About Science explicitly acknowledged its role in this campaign in evidence to the House of Commons Science and Technology Committee in November 2009. In this context, it is essential that the ASA should be clear about the motives of complainants, what precisely is being investigated and what the scientific bases are for any arguments. The investigation team has failed to be thorough on these issues.

The ASA's *Non-broadcast Complaint Handling Procedures* states that

In some circumstances public complainants might be asked for a formal, written assurance that they have no commercial or other interest in registering their complaints.

The investigation team did not seek such written assurances until we raised the issue, and it then found that one third of the complainants admitted to not being able to give such an assurance. We have no knowledge as to whether or not the other complainants are being honest about their positions, but consideration of the similarity of the complaints might provide information as to their degree of independence. We do know that one person published on the internet the full complaint which he alleged he was making to the ASA as an encouragement to others to complain. In this context, the ASA should have seriously considered the possibility that these complaints were not genuine but malicious and frivolous.

The nature of the advertisement and its readership

The investigation team also appears to be confused about what precisely it is investigating. The placing of the advertisement in a Care supplement of the *New Statesman* clearly indicated that it was directed at educated professionals in the health and care field. The advertisement also explicitly stated that:

H:MC21 believes that the NHS should increase the integration of homeopathic practitioners into front-line healthcare whilst monitoring both clinical and cost benefits.

H:MC21 believes that, by sharing clinical experience and skills in this way, homeopathic and conventional practitioners can provide the safest, most economic and most effective service to patients.

H:MC21 believes that this will allow the NHS to confirm the benefits of homeopathy in the real world of clinical practice.

As such, the advertisement was clearly intended to encourage an increase in the existing use of homeopathy by the NHS, and in arguing this case it presented information which we considered had not been widely enough publicised.

We have also requested, but not received, clarification of what exactly the ASA means by the terms “marketer” and “product”. At no point did we promote a new product, a new medical treatment or the introduction of a new medical therapy. Nor did we make any recommendations to individuals about their personal healthcare choices. However, the investigation team has treated many of the statements we made as though they were promotions of specific new treatments or intended to influence readers against use of other treatments or of the NHS.

Ignorance of scientific and medical principles

In preparing our initial response to the complaints, we were aware that the investigation team might not be aware of certain information fundamental to understanding medical issues, especially the relationship

of science to medicine. As a result, we provided detailed information supported by relevant documents, many of which were conventional medical texts. Included in our outline of these issues was a specific warning about the requirements of the empirical ‘evidence based medicine’ paradigm (EBM). Because this is not a scientific approach, but is intended to fill a gap in current scientific knowledge, it is imperative that those using this paradigm resist the temptation to assume that certain elements are important and that other elements are not. Despite our warning, the investigation team failed to resist this temptation, and has asserted explicitly and by implication that evidence of efficacy is the only evidence which has any real validity.

The importance of this failure is that it indicates that the investigation team has bowed to the pressure of those opposed to homeopathy. The following fallacies are central to the arguments of those campaigning against homeopathy

- **Evidence of efficacy:** The claim that evidence of efficacy is the only evidence which has any real validity is not only scientifically and medically indefensible, but is dangerous to the health of the public because it seriously devalues the importance of clinical practice in the process of monitoring and evaluating the full effects of drugs when used in the real world.
- **Objective evidence:** The claim that the only valid evidence of illness is “objective” evidence (‘signs’ as opposed to ‘symptoms’) is also not only scientifically and medically indefensible, but is dangerous to the health of the public, since it encourages doctors not to take medical action until pathological change has already taken place.
- **Proven theories:** The claim that evidence is only valid if there is proof of an explanatory theory is scientifically and medically indefensible. The purpose of science is not to reject unexplained evidence, but to find explanations for it, so this is a rejection of the scientific method. At the same time, the purpose of the EBM paradigm is to assess evidence in the absence of a scientific theory of medicine, so this is a rejection of EBM. As a result this is also harmful to the health of the public because it creates a barrier to the development of any new treatments, by rejecting the use of all beneficial, but currently inexplicable treatments.

A disproportionate approach

The failure of the investigation team to understand or be clear about these basic issues has led to unacceptable behaviour in the conduct of the investigation. One effect has been to make disproportionate demands for evidence. For example, in complaint 2 the investigation team has required evidence of improvement in signs to “substantiate” evidence of improvement in symptoms, when there is no direct correlation between signs and symptoms. In complaint 4 the investigation team noted that “evidence had not been supplied to demonstrate that the homeopathic medicine referred to in the report had been shown to be efficacious against Leptospirosis under clinical conditions”, when there is no direct correlation between evidence of efficacy and evidence of effectiveness (a primary principle in EBM).

Another example of a disproportionate demand for evidence is seen in complaint 6. We stated in the advertisement that

according to the *British Medical Journal*, of the 2,500 most commonly used treatments in the NHS, 51% have unknown effectiveness, and only 11% have been shown to be beneficial.

In response to the complaint we provided the webpage and URL, thus verifying that this reputable journal had made these statements. However, against all normal academic practice and against common sense, the investigation team has repeatedly required H:MC21 to provide “evidence to substantiate the quoted figures”, as if they were our own figures.

Furthermore, we are not aware that any of the complainants has made a complaint to the ASA alleging that the *British Medical Journal (BMJ)* cannot substantiate these figures, is misleading the public, and is

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acting irresponsibly. The information is updated regularly on the *BMJ* website and is part of the promotion of a *BMJ* publication, so it is open to complaint through the ASA. If those who have complained about our reference to the figures have not also complained about the *BMJ*'s publication of them, this is prima facie evidence that their complaints are motivated by some interest in attacking H:MC21. We are not aware that the investigation team has addressed this issue.

The investigation team has also been disproportionate in its approach to interpreting the claims. For example, in complaint 3 the team stated that

H:MC21 had intended this claim to demonstrate that RCT's were unreliable as a source of evidence.

This is not only an extreme claim, but it is untrue and clearly at odds with the text of the advertisement. Similarly, in complaint 10 the investigation team argued that

the claim would be interpreted by most readers to mean that homeopathy was a viable alternative to conventional medicine.

The team then recommended upholding the complaint not because we had failed to substantiate our statements, but because we had not substantiated a claim we had not even made.

An arbitrary and inconsistent approach

The investigation team has, in addition, been arbitrary and inconsistent in its approach to the alleged claims made in the advertisement. For example, in the case of complaint 8, the team stated that

most readers would interpret this statement to mean that Sense About Science was wholly funded by the pharmaceutical industry (18/2/11)

However, after this was challenged the team claimed that most readers

would understand the statement to mean that because the charity was partially funded by the pharmaceutical industry, its findings were biased and unreliable (21/3/11)

These are radically different interpretations, yet they are both equally authoritatively asserted to have been the response of "most readers". A more extreme case of the same arbitrariness occurs in complaint 2. In one and the same paragraph the investigation team states categorically that

the statement was likely to be interpreted by the average reader as a claim that randomised controlled trials on homeopathy demonstrated that the science behind the medicine was substantiated... (21/3/11)

and equally categorically that

without clarification, the average reader was likely to find the claim ambiguous. (21/3/11)

How a statement can be simultaneously unambiguous and ambiguous is beyond us.

In complaint 11 a wholly invalid argument has been turned on its head to create another equally invalid argument. Initially the investigation team presented the argument that Professor Ernst's general qualifications conferred specific expertise in homeopathy:

Because we understood Professor Ernst was had [sic] an MD, PhD and was Professor of Complementary Medicine at Exeter University, we considered that he was likely to be qualified to comment on homeopathy. Because the ad implied he was not sufficiently qualified to, we concluded the claim was denigratory. (18/2/11)

When we challenged this, the team claimed that our identifying a specific lack of qualifications implied a claim of general lack of knowledge and expertise:

Although we [sic] H:MC21's comment that Professor Ernst did not have a specific qualification in homeopathy, we considered that it had failed to demonstrate why he was not sufficiently qualified to comment on the scientific evidence for homeopathy. Because the ad discredited Professor Ernst's scientific knowledge and expertise, we concluded the claim was denigratory. (21/3/11)

The only common factor in these arguments is that H:MC21 is accused of being denigratory.

The inconsistency of the investigation team is seen in other ways too. In complaint 2 the team maintained that we had not substantiated our statement, and yet it simultaneously claimed that we had been misleading because we had not included more information from the same source.

The summary of our arguments

As regards the investigation team's summary of our arguments, there have been two main problems. The first problem is that the team has repeatedly failed to understand what we have written, even when it was basic arithmetic (see complaint 7) or our views on randomised controlled trials (see complaint 3). The second problem is that the team has frequently misrepresented our arguments in various ways. In the case of complaint 9, for example, we initially pointed out that

At no point do the authors of *Trick or Treatment?* supply a definition of disease or explain that orthodox medicine and homeopathy disagree over the definition. (8/12/10, para. 8.9.1.2)

The failure to define terms is a serious issue in a discussion of scientific validity, but this was transformed by the investigation team into a communications problem when it claimed that

H:MC21 believed *Trick or Treatment* failed to explain the differences between orthodox medicine and homeopathy (21/3/11)

In the case of complaint 12, the summary of our argument is still wildly inaccurate. Thus we initially pointed out that

Given the profound changes demanded by this report, it is not irresponsible to make the public aware of the very low number of MPs who actually voted for it (3 out of 14). (8/12/10, para. 8.13.1)

This statement, based on the attendance records in the Committee's published minutes, has been mutated by the investigation team into the statement that

They [H:MC21] also supplied the formal minutes of a document which examined the Science and Technology Committee report and stated that these minutes concluded that it was not irresponsible for the public to be made aware that only three out of 14 MP's actually voted for it. (21/3/11)

This is not only inaccurate but bizarrely so.

The unethical use of justifications

All the examples given here and all those others not mentioned have one major factor in common: no matter what changes the investigation team has made to its arguments or allegations, and no matter how contradictory these changes might be, its recommendations have remained the same. This seems to us to be confirmation that the purpose of the formal investigation is not to impartially assess the evidence and the complaints, but to find a way to justify predetermined conclusions. If this is truly the case, it constitutes a seriously unethical approach.

In this context it is important to address another issue which emerged in the last draft of the investigation team's recommendations. According to CAP Code 12.1 the ASA investigation relies on "available science". According to the investigation team the ASA investigation relies on the paradigm of EBM (Letter, 21/3/11, para. 2). However, the investigation team has begun to support its assessments on the basis of the conclusions of the House of Commons Science and Technology Committee's *Evidence Check 2: Homeopathy* (February 2010). This creates a serious ethical issue.

To start with, this report was a report by MPs, not a scientific report, and so it does not meet the standards of "available science". At the same time it implicitly rejected the principles of EBM by asserting that the only valid evidence was evidence of efficacy. As such, the report fails to accord with either of the grounds on which the investigation team has claimed to base its assessments. The report has also been seriously criticised for distorting and manipulating the evidence and arguments, and it was rejected by the government. In addition it failed to address all the evidence submitted to it. Furthermore, of the three MPs who voted for it, two had close connections with interests opposed to homeopathy, and only one actually attended the hearings of evidence in November 2009, whilst one was not even a member of the committee until January 2010. As such, there are serious questions as to the reliability and impartiality of the report. Finally, the report's conclusions were profoundly opposed to the use of homeopathy, to research into homeopathy, and to the recognition of any therapeutic value in the medicines used by homeopaths. We can see no ethical basis for the ASA investigation team to use these conclusions in any shape or form.

An unethical approach to homeopathy

The issue of the Science and Technology Committee report is significant because it raises another ethical issue. The practice of homeopathy is legally recognised in the UK to such an extent that it was incorporated by an elected government in the NHS on its foundation some 60 years ago and continues to be practised in the NHS. This status was re-confirmed by government in 2010.

The ASA is a self-regulatory body of the advertising industry. It has no mechanisms of democratic accountability to the public, and is recognised as having a limited advisory role. It has no inherent expertise in the fields of science, conventional medicine or homeopathy, and is part of no academic or research structure investigating these fields. As such it has no mandate or justification for independently establishing definitions of what is scientifically valid or invalid in those fields, but should confine itself to applying the principles used by those fields themselves, and requiring advertisers to conform to those principles.

In the light of this, it is profoundly unethical for the investigation team to attempt to take rules and guidance developed by those in the field of conventional medicine and specifically intended for particular use in the field of conventional medicine and apply these rules uncritically to the separate and distinct field of homeopathy. Furthermore, it is profoundly unethical for the investigation team to then use these inappropriate rules and guidance in order to inhibit the legally recognised and existing rights of those working in the field of homeopathy.

Finally, we have shown earlier that the investigation team has not even applied the accepted (if unproven) principles of conventional medicine to homeopathy, but has applied a debased version of these principles. As a result the action of the investigation team is not only unethical but dangerous.

Inequitable demands

The investigation team has also exercised its power inequitably. As the calendar of events below shows, the deadlines set by the investigation team mean that our unpaid volunteers have been allocated a total of

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between 19 and 24 working days to provide information to the ASA, whereas the paid investigation team has currently allocated itself some 95 working days.

24/11/10 We were first informed of the complaints, and we were given until 1/12/10 to decide whether we would respond to complaint ‘Option One’ or ‘Option Two’. We were also informed that “Regardless of which option you choose, the full response including any substantiation, should be supplied within five working days (8 December)”

H:MC21: in total ten working days.

8-9/12/10 Our response was submitted with technical problems arising from the volume of material submitted.

9/2/11 The investigation team reports the lack of a document, and requests that it be sent by 14/2/11. The H:MC21 office was closed at this time.

15/2/11 The investigation team reports the lack of two further documents. The H:MC21 office was still closed.

18/2/11 The investigation team sent its first draft of its recommendations, acknowledging that four documents had not been received.

ASA: forty-eight working days.

We were given until 1/3/11 to respond.

H:MC21: seven working days.

1/3/11 Our response was submitted.

21/3/11 The investigation team sent its second draft of its recommendations.

ASA: fourteen working days.

We were given until 29/3/11 to respond. We asked for an extension of one day.

H:MC21: in total seven working days.

30/3/11 Our response was submitted.

12/4/11 The investigation team informed us that they were expecting to respond by 15/4/11 (twelve working days). This did not happen.

3/5/11 The investigation team informed us that they were expecting to respond by 11/5/11, but they had not responded by 13/5/11.

ASA: thirty-three working days.

In addition, whilst we have been required to provide documentary evidence for our statements, the investigation team does not appear to have read this evidence, and it has been free to make its own claims without any regard to whether it has evidence to support them. Furthermore, whilst we can not afford to make any mistakes in our submissions, the investigation team can make mistake after mistake in the knowledge that the responsibility for identifying these mistakes lies with us. There is no way in which this can be described as a fair allocation of burdens.

The investigation team has also threatened to exercise its power to curtail the investigation despite the demonstrable existence of material and factual errors in its summary of our arguments and in its own assessments of the complaints. Given that the ASA Council will assume that the formal investigation has been thorough and that the recommendations are accurate, to submit these recommendations before they meet this standard is to deliberately mislead the Council and to compromise and invalidate any decision the Council makes.

The investigation team has offered H:MC21 the opportunity to submit an additional report to the Council of up to two sides of A4 paper, but this is unacceptable. If the investigation team has been unable to prepare a reliable and thorough report of its investigations after six months, it cannot be supposed that the ASA Council will be able to make a sound decision on the basis of an inaccurate report and an additional brief submission from H:MC21 which will automatically be deemed prejudiced. This present document,

which is not comprehensive, but outlines the issues we have with the investigation is nearly four times the length of the document we would be allowed to submit to the Council.

Conclusion

On all the grounds outlined above, we consider the handling of this complaint to be unacceptable. The current recommendations of the investigation team, if confirmed by the ASA Council, would seriously curtail our organisation's ability to publish facts, even facts already in the public domain. This is not just a restriction of free speech, but a restriction of free access to legitimate information. As a result we are concerned that the ASA is threatening our ability to pursue our legally sanctioned business. We have taken preliminary legal advice, as we told the investigation team we would, and we are aware that the issues which concern us are serious. We believe that the ASA should have the opportunity to deal with this matter internally, and that it has the means to do so through this formal complaints process, but we reserve the right to take legal action in the future.

We recognise that the ASA plays an invaluable role in protecting the public from misleading advertisements and in acting on genuine complaints from the public. However, for the last five or six years a campaign has been organised against homeopathy, most recently manifested in the Nightingale Campaign. The climate this has created is encouraging a small number of detractors of homeopathy to abuse the ASA complaints procedures to further their own overt aims to discredit homeopaths and homeopathy, at no cost to themselves, but at considerable cost to the ASA. We urge you, as the Chief Executive of the ASA to consider carefully the purpose, conduct and value of this particular investigation.

Yours faithfully

Paul Burnett

On behalf of the Trustees of Homeopathy: Medicine for the 21st Century
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