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Please Quote: A10-139800/JN

17 May 2011

Dear Mr Alderson

Thank you for your letter of 6 April.

We consider that the Draft Recommendation makes clear the salient points of your response and the evidence supplied and that although we have made some minor changes to the Draft Recommendation, our assessments are sound. However, we will respond to points you have made to explain our reasoning for the wording and presentation of the Draft Recommendation.

General points

1- 6.

We understand that the theoretical basis of homeopathy has been drawn from orthodox medical texts. We have not included this in the response section of the Draft Recommendation because we do not consider that there is a consensus within the medical community that the theory referred to in these texts can be used to demonstrate that homeopathy can be used to treat disease and medical conditions. Where there is no scientific consensus, the levels of evidence expected to substantiate claims that may have been fully accepted by those who support homeopathy (including those who also work with orthodox medicine) are high because they are claims which are not universally agreed and for which the ASA has yet to see convincing evidence.

The CAP Advice Online entry titled 'Therapies: Homeopathy' states "Despite its popularity, CAP understands that no scientific rationale exists for assuming that remedies lacking in pharmacologically active molecules can produce clinical effects and is unaware of robust evidence that proves it does. Some homeopaths seem to be medically qualified and therefore regulated by the General Medical Council. Those who are medically qualified may make claims about treating conditions but only if it is clear that the efficacy is due to conventional treatments. Those practitioners who are not medically qualified

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should not make claims about the efficacy of their treatments and should not refer to serious medical conditions”.

The CAP advice is based on existing adjudications. Although it is not binding on the ASA Council, it will be made aware of the CAP position on homeopathy as part of this investigation.

The Draft Recommendation is not the appropriate place for repeating the arguments for and against the evidence for homeopathy. It is clear that at the present time the theories behind claims for how and why homeopathy can have a physiological effect not been universally accepted. In those circumstances you would have made advertising claims that reflected the controversy rather than presenting your view point as ‘fact’.

We note your comments that the Evidence Check report recommendations were rejected. However, we consider that this does not mean that the overall content of the report was incorrect in its concerns about the evidence for homeopathy and as such maintain that it is the largest and most recent independent review of the evidence for homeopathy. We understand that homeopaths were invited to contribute to the consultation alongside orthodox medical practitioners.

7. We note your comments and concerns. However, the investigation process is fluid and interpretation and reasoning does sometimes change as we consider the most likely interpretation by the reader of the publication.

8. The CAP Code does not specifically define a marketer. However, if H:MC21 has any doubts about whether the ad falls under the remit of the CAP Code, we would like to draw your attention to the remit section which refers to the types of ads that are considered to be in remit, and those that are not.

CAP is the industry facing side of the ASA and as such advertisers should be aware of its position as outlined in the various AdviceOnline entries and Help Notes.

We note your comment that H:MC21 has not specifically stated the EBM is the wrong paradigm for examining evidence for homeopathy and have made a minor alternation the introduction to the Assessment section of the Draft Recommendation.

As you requested, we wrote to the complainants and asked them to confirm their position. Although four complainants confirmed that they were ‘cynical’ members of the public, two of the complainants have confirmed that since the

ad appeared they have become part of the Nightingale Collaboration and although they were not members at the time the ad appeared, they have agreed for the organisation to be named in the Draft Recommendation.

Responses

1. (These comments mirror those in the response to your general issues). We understand that the theoretical basis of homeopathy has been drawn from orthodox medical texts. We have not included this in the response section of the Draft Recommendation because we do not consider that there is a consensus within the medical community that this theory referred to in these texts can be used in practice to demonstrate that homeopathy can be used in practice to treat disease and medical conditions. Where there is no scientific consensus, the levels of evidence expected to substantiate claims that may have been fully accepted by those who support homeopathy (including those who also work with orthodox medicine) are much higher because they are considered to be “new” or “breakthrough” claims. The CAP Advice Online entry titled ‘Therapies: Homeopathy’ states “Despite its popularity, CAP understands that no scientific rationale exists for assuming that remedies lacking in pharmacologically active molecules can produce clinical effects and is unaware of robust evidence that proves it does. Some homeopaths seem to be medically qualified and therefore regulated by the General Medical Council. Those who are medically qualified may make claims about treating conditions but only if it is clear that the efficacy is due to conventional treatments. Those practitioners who are not medically qualified should not make claims about the efficacy of their treatments and should not refer to serious medical conditions”.

The CAP advice is based on previous ASA adjudications. Although it is not binding on the ASA Council, Council will be made aware of the CAP position on homeopathy as part of this investigation.

3. We consider that the Draft Recommendation makes clear that the RCT evidence had been assessed by various professional and orthodox organisations. We do not consider that the additional information is therefore necessary within the Draft Recommendation. However, please be assured we have noted your comments.

I am sorry if we had misunderstood your argument about the intention of the claim about the RCTs. We will amend accordingly. However, we will be summarising your argument as we do not consider this is the appropriate forum to discuss the arguments for and against the most appropriate designs of trials to test how, why and to what extent, homeopathy can be used to treat chronic medical conditions and disease. We note your comments that good quality

RCTs in terms of pharmacological testing standards may be inconclusive or negative because it has failed to comply with the theoretical framework on homeopathy. We now understand that you had not referred to the inconclusive results because you believed that they were not themselves evidence for the ineffectiveness of homeopathy and as such, including those figures in the ad would be likely to mislead as to the true meanings of the outcomes of the trials. However, CAP and the ASA considers that any health and beauty claims must be supported by, and considered under, the same testing framework and that if health/beauty claims were made for any other product which contained a significant number of negative or inconclusive results, it is likely that we would consider that the claim had not been substantiated and was therefore misleading. We appreciate that you may disagree with our position: however we believe that the paradigm used at present is not likely meet with consumers' expectations.

We consider that the inconclusive results were a significant piece of information that should have been included in the ad. We note your comments that readers of New Statesmen would know to question the remaining results, but we consider that this does not prevent the claim itself from being misleading through omission.

4.

We have amended the Response section to make clear that all people in the high risk areas received treatment through the programme.

We note the various differences in infection rates. Although we will alter the Draft Recommendation slightly to indicate that the infection rates of disease in high risk areas were lower than that of the rest of Cuba following treatment, we will not be presenting all of the data as the Draft Recommendation is intended to summarise your responses and our assessments.

6. We note your comments but we will not be making any further changes to the Draft Recommendation. We note readers of the New Statesman are likely to know of the British Medical Journal. However, this does not negate your responsibility under the CAP Code to provide documentary evidence to support claims being made in your advertising.

7. We note your comments on the figures and will make the changes to the response section of the Draft Recommendation. We will also add your comments about the Scottish Parliament. However, please note that the claim in the ad is one that is likely to be interpreted as a claim that homeopathy has been proven to reduce symptoms of disease/medical conditions and, as such, increased spending would result in a reduction in conventional medicines. We

understand that you believe the statement from the Scottish Parliament is sufficient to substantiate the claim in the ad. However, as I have previously explained in relation to claims that have, in effect, been inherited from other sources, we would need to see the evidence upon which that statement was made.

8. We understand that you consider the ASA has changed its approach on this point. Please note this is not the case. We had received responses from complainants who had expressed concerns that their complaints about this element of the ad had to be correctly addressed as the concern was about the implication of the sentence as a whole. We apologise for any confusion on this matter. However, you should also be aware that we have since noted that the evidence for the financial backing for the charity ends in April 2009 and that you have not demonstrated that it is currently being partially funded by the industry or was supported by the industry at the time at which the ad appeared.

9. We understand that Halloween Science was peer-reviewed prior to publication. We also note it was written by the Chairman of H:MC21. We consider that the ad does not make clear that this is the opinion of the author and therefore we do not consider that this is sufficient to substantiate the claim that "Trick or Treatment? has **been shown to be** scientifically unreliable". Although we will add a statement to reflect your comments about the book being peer reviewed, we do not intend to enter into argument the discussions about whether Trick or Treatment? is scientifically flawed, as our investigation is into whether the claim that the publication **has been proven** to be scientifically flawed can be substantiated.

10. We note your comments. We have added your statement that the cost of treating the side effects of the NHS is already in the public domain. We consider that this is sufficient to represent your responses on this point.

11. We note your comments. However, we consider that the specific comments which may have been made by Professor Ernst in his interview are not sufficient to substantiate the implied claim in the ad that Professor Ernst is not adequately qualified to criticize the evidence for homeopathy.

12. We note your comments and have made some minor changes.

Assessments

1.

We note your points. However, we consider that this is not a new argument and that this is the position that has been held by CAP and the ASA for some

time and is clear from the CAP AdviceOnline entry on Therapies: Homeopathy. Because the ASA/CAP has yet to see convincing substantiation that the rationale behind homeopathy has a proven result, any claims for efficacy are considered to be breakthrough or new, under the CAP Code(s). We consider that you have been given ample opportunity to respond to this point of complaint and will not be considering any further information in response to this point of complaint.

2. We note your comments. However we maintain that self assessments by patients are not sufficient to establish the suitability of the removal of, or reduction in conventional medicines for the purpose of establishing claims for the efficacy of homeopathy for treating chronic conditions. We note the study stated that the objective measurements were the alteration in conventional medicines, changes in forced expiratory volume, measurable changes in mobility or exercise tolerance or changes in the result of investigations. However, we consider that there is nothing within the trial that demonstrates that any changes (self reported or otherwise) occurred as a result of the introduction of homeopathy and that therefore any reported reductions in symptoms (for those conditions such as migraine and IBS) and any subsequent reduction in conventional treatments have not been shown to be directly attributed to homeopathy. We consider that claims that introducing homeopathy could result in a reduction in symptoms and reduction in conventional medicines for diseases like IBS, Asthma, Eczema, Arthritis and Cancer are breakthrough claims and as such must be tested very robustly. We do not consider the trial, to be sufficiently robust to support such significant claims and therefore do not consider that the Bristol study in its entirety can be used to support the claim that “.....6,500 patients with chronic condition benefited from homeopathic treatment and had reduced need for conventional medicine”. The problem with the study is that it does not include any measure for ensuring the results are due to homeopathic treatment. In order to do that, it would need some kind of control group.

3. We understand the intentions of this claim. However, we must make our recommendations based on how we believe the ad will be interpreted by the readers, and we believe they would interpret the text as a claim that evidence shows that RCT's on homeopathy are more positive than negative and therefore as a claim that evidence showed that homeopathy was efficacious. We consider that under this interpretation, the “non-conclusive” results are significant as they alter the way in which the consumer will view the overall results on the use of RCT's to test the efficacy of homeopathy. We have answered your other points in the response section on point 3.

6. We understand you based this claim on the information from the BMJ website and that it is a prestigious publication. However, this does not negate your responsibility under the CAP Code to provide documentary evidence to support claims being made in your advertising. You would need to demonstrate on what basis the statement on the BMJ website was made and that it could be extrapolated to substantiate the claim in the ad.

We consider that, without any further evidence or explanation, the claim could result in individuals not trusting any conventional medicine (because they could not be aware which medicine fell into this 51%) and therefore not obtaining the treatment they may need. We understand some readers of the New Statesman may investigate their options before making any decision to seek medical advice. However, the intention of the ad is to market homeopathy and this particular statement is to tell readers that 51% of conventional medicine has an 'unknown effectiveness'. In this context we consider that some readers may be discouraged from seeking conventional medical treatment.

We note the ad was intended to promote an increase in the use of homeopathy in the NHS and note one of the claims specifically refers to what you believe will result from an increased funding in homeopathy. However, we consider that most readers would interpret the ad overall as a claim that conventional medicine has been shown to either be ineffective, costly or to have side-effects, whereas homeopathy had been shown to be efficacious in treating medical conditions, cost-effective and without side effects and that this is the stronger message in the ad. We therefore consider that readers with serious medical conditions who understood that conventional medicine may not be effective, may not seek the opinion of a GP. We understand there are no guarantees in conventional diagnosis and treatment. However, the Code states that ads should not discourage essential (conventional) medical treatment and we consider the claim in the ad may do this.

We note your statement about the experience of Roger Daltry's son. However, I am sure you can appreciate that an article relating to the experience of one individual is not sufficient to substantiate the claim that 51% of conventional medicine has been shown to be ineffective.

7.

As I have already explained, we consider that because, as yet, CAP and the ASA has yet to see convincing evidence for the principle of homeopathy, any claims for the effectiveness of homeopathy need to be accompanied by robust levels of substantiation. This is not a new position and the ASA and CAP have been clear on this. We note your comments that the reliance on efficacy is unjustifiable under EBM and that we should be looking at effectiveness when

considering the claims and the evidence. We note your concerns about the ASA's reliance on clinical data to substantiate claims for the effectiveness (or efficacy) of homeopathy in the real world. However, if homeopaths claim to treat medical conditions and diseases there should be in-depth clinical trials to demonstrate that. We appreciate that you do not agree with our position and that you have provided details and extracts of many publications in which the theories surrounding homeopathy are explored and discussed and have provided details of a large number of trials which have reported positive results. However, we understand that the theory behind homeopathy is not generally accepted and as such advertising claims which make references to the efficacy of homeopathy are likely to be a problem under the CAP Code. The broader discussion about real world effectiveness and trials of efficacy is not something we can engage in relation to an advertising complaint.

8. We note your comments. In the same way in which aspects of the Draft Recommendation have changed as a result of comments you have made, we have also received comments from some of the complainants (who have the right to response to the Draft Recommendation). They stated that the ASA had not fully understood their initial complaint and that they were not merely challenging the quoted figures, but how that was likely to be interpreted in the context of the text that followed. We understand that has meant that the response to this challenge has changed slightly, and we apologise for this, but we consider that you have been given an opportunity to respond to this assessment on this point. We do not think this is an imaginary complaint and we consider that most readers will interpret the ad as a claim that Sense About Science is funded by the pharmaceutical companies and is therefore biased, because the full sentence reads "The leading organisation opposing homeopathy, Sense About Science, is funded by pharmaceutical companies and relies on a strategy of propaganda stunts rather than scientific research".

9. We note you consider that the Draft Recommendation over simplifies the issue. However, this is not the appropriate forum for you to raise all of your concern about the book *Trick or Treatment?* and we consider that the Draft Recommendation is adequate. This is especially the case because we are not investigating whether you can show that you believe the publication to be scientifically flawed, but whether the ad makes clear that this is the opinion of H:MC21 and not established fact. We note Halloween Science pointed out these flaws. However, because this was written by the Chairman of H:MC21, we consider that this is not independent evidence that the publication is flawed. We consider that reading Halloween Science is not necessary to determine whether the claim is misleading. We consider that the claim is the opinion of H:MC21 (which is laid out in Halloween Science) but that this is not made clear in the ad and for this reason it is misleading.

10.

As we have already explained, we consider any efficacy claims for homeopathy to treat medical conditions and disease to be claims for which we have not yet seen robust scientific evidence.

We accept that homeopathy has no side effects. However, we consider that readers would interpret the claim within the context of the ad as a whole which refers to the use of homeopathy to treat disease and medical conditions and would therefore consider the claim to be a direct comparison between conventional medicine and homeopathy in that context. In the same way in which the claim about conventional medicines being ineffective may prevent some readers from seeking 'conventional' medical treatment, we consider that the reference to the extent of spending on adverse side effects could, with no further qualification, result in readers not wishing to partake in conventional medicines and may therefore not seek medical advice from their GP.

11.

We note your points that the assessment on this point has changed. However, both versions of the Draft considered whether the claim was denigratory because the way in which the information was presented, appears to discredit Professor Ernst's qualifications. We note your comments that he has admitted that he is not qualified in homeopathic training and his qualification in training in homeopathy is not factually being disputed. However, we consider the ad implies that in order to criticize homeopathy, Professor Ernst should have a qualification in homeopathy and because he does not, he is not sufficiently qualified to criticize it. Because you have not shown that Professor Ernst is not qualified to criticize homeopathy, we consider that the claim as a whole discredits Professor Ernst and the scientific expertise he does have. We will therefore not be changing the Draft Recommendation on this point.

12. We note your comments but will not be making any changes to our recommendation on this point.

We consider that this Draft Recommendation is an accurate reflection of your responses and that your assessments are sound. We will not be making any further changes to the Draft Recommendation and will therefore be submitting the case to the ASA Council for its decision.

In my letter of 22 March, we invited you to write a direct submission to Council to consider during the decision making process. This offer is still open to you provided it is provided by 27 May and is no longer than two A4 pages in length.

Yours sincerely

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