



Dr Jacqueline Mulhallen
Chair

Homeopathy: Medicine for the 21st Century

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Ref:A10-139800/GB

10 May 2013
By email

Dear Dr Mulhallen

Re-opened investigation into the marketing of Homeopathy: Medicine for the 21st Century (HM21C)

We have considered your comments on the revised DR, and on the expert reports by Professor Hylands. We have also considered the various documents that you submitted subsequent to receiving the revised DR.

Following HM21C's request for an independent review, the Independent Reviewer (IR), in his letter to you of February 2012, stated that whilst he did not believe the ASA's verdicts on the various Points of the Complaint were substantially flawed, he was not satisfied that the arguments in relation to the evidence you had presented had been adequately represented in the adjudication. He also said there were minor flaws in the rationale for some of the assessments and that the ASA should have read the publication *Halloween Science*.

The case was re-opened in order for these points to be corrected. As explained by the IR, when that work was completed the case was to be re-submitted to the ASA Council, along with a revised DR and a report from the IR, including any views put to the IR about the terms of the DR.

I wrote to you on 11 December 2012 with the revised DR; it had been amended to reflect the areas of concern raised by the IR in light of your submission. A general concern raised in your submission to the IR, was that the ASA had acknowledged the need for an expert but had not found one. This has since been rectified; we have received an expert report on

the Science and Technology Committee's (STC) report *Evidence Check 2: Homeopathy* (EC2). The expert report on EC2 confirms that it was a robust and fair examination of the available evidence and came to reasonable conclusions. We also read *Halloween Science* and amended the relevant section of the Assessment at Point (9). Minor flaws were amended and a number of typographical errors were corrected.

Although not specifically required under the terms of the re-opened investigation, we also read *Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety, Costs* and sought expert advice on this publication. This led to additions to the original DR, which featured in the revised DR sent to you in December 2012.

In response to the revised DR you submitted a number of documents. One document contained criticisms of Professor Hylands' report on EC2: you said the report did not explore the analysis in EC2 or tackle what you considered to be serious questions about its reliability. We are satisfied with the expert report, which fulfilled its brief to summarise EC2 and consider whether it came to appropriate conclusions, based on current scientific standards.

You also submitted objections to Professor Hylands' report on *Homeopathy in Healthcare*. Professor Hylands has amended the report following your comments and comments from the complainants. He has removed an erroneous reference to phytotherapy and also any implication that the publication was part of a Swiss government Healthcare Technology Assessment. These changes have been reflected in the revised DR. We are content with the expert report referring to the reanalysis of Shang et al as providing the "main conclusion" of the publication. We also agree with the expert that the reanalysis was based on considering a different set of data, though the writers give various reasons why this was done.

Homeopathy in Healthcare poses questions about the validity of RCTs and the EBM approach to assessing homeopathy, as does another document you submitted, the thesis *Evidence Based Medicine, 'Placebos' and the Homeopathy Controversy*, by Turner. However, whilst the arguments presented in these documents are at points interesting, they do not move the case forward in terms of providing supporting evidence of the efficacy of homeopathy. At this point I would remind you that the CAP Code places the burden of proof on marketers to substantiate their claims. We will uphold complaints about objective claims if marketers cannot provide adequate evidence – we do not require complainants, experts or other parties to provide evidence proving that the claims are false.

As stated above, it was not required of the ASA when this case was re-opened to consider these further submissions. But we have done so and find that none of them provide any positive evidence for the efficacy of homeopathy. The article titled 'Cuba BMJ', dated November 2012, acknowledges that there is no published or peer-reviewed research from that experience: it therefore only serves as confirmation that the type of evidence we expect to see in support of those claims is not available, or has not been submitted. Likewise, the several responses to Shang et al do not provide any supporting evidence for the claims under investigation.

On a similar note, the anecdotal account that you provided along with some extracts from *The Political Economy of Health* by Hart et al is interesting but does not provide the type and level of evidence that we require in support of efficacy claims.

I understand that you are challenging the emphasis the ASA places on objective scientific observation, especially in the form of RCTs. However, in response to this I must reiterate that the requirements of the CAP Code are clear and, as acknowledged by the IR in his interim report, the ASA is not flawed for expecting marketers to provide evidence in line with those requirements.

I can advise that should a marketer provide a robust examination of our current expectations and a detailed suggestion for a robust alternative methodology for substantiating objective claims, CAP will be willing to consider this. If CAP were convinced to change the requirements of the Code, the ASA would be able to investigate these sorts of cases under a different framework. We would of course still require marketers to hold robust documentary evidence in support of their claims. No such submission has yet been made to CAP.

In summary, we have addressed the specific issues raised by the IR when the investigation was re-opened, and have made appropriate changes to the DR. We have not altered any of our recommendations with regards to the actual verdicts made by the ASA Council. Although it was beyond what was specifically required of us in the re-opening of the investigation, we have also carefully considered the additional evidence that has been submitted. We have concluded that those submissions did not provide any positive evidence in support of the claims under investigation that merited altering our recommendations to Council.

The case is now ready to be presented to the ASA Council, along with the IR's report. This will take place at the next opportunity, which will be the June Council meeting. We are no longer accepting additional evidence so please do not send us any. We will write to you again once the Council has reconsidered the case, to inform you of the outcome.

Yours sincerely,

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