

General Points

1. In his letter of 16 February the Independent Reviewer of ASA Adjudications stated:

I said that I was minded to conclude that while its verdicts on the Points concerned did not appear necessarily to me to be substantially flawed I was not satisfied that the arguments in relation to the evidence you had presented had been adequately represented in the adjudication; that there were minor flaws in the rationale for some of the assessments; and it was wrong that the ASA had not examined and assessed the publication "Halloween Science". The ASA Chairman has told me that in the light of my preliminary conclusions he has decided to reopen the ASA's investigation into the aspects of the case which I have described above. A different ASA Executive from the one who conducted the original investigation will carry out this further investigation, under my supervision. You will be consulted about the findings from this further work, as indeed will be the complainants, before any report is presented to the ASA Council.

2. We note that in the course of this new investigation the ASA has sought expert advice from Professor Hylands on two documents: the Commons Science and Technology Committee's *Evidence Check 2: Homeopathy* and the Swiss Health Technology Assessment, as published in *Homeopathy In Healthcare*.
3. We are concerned that this Draft Recommendation has not addressed points made in our Appeal to the Independent Reviewer or issues repeatedly raised in our correspondence with the ASA since November 2010.
4. We are particularly concerned that the ASA's case now relies heavily not on primary evidence or even secondary evidence about homeopathy, but on the reports of Professor Hylands. We wish to re-emphasise that the CAP Code 2.1 states that

Substantiation will be assessed on the basis of the available scientific knowledge.

5. In a separate correspondence we have pointed out that there are serious errors and omissions in these reports by Professor Hylands, and so they cannot be regarded as proper assessments of "the available scientific knowledge". H:MC21 also is concerned that some of the errors are so obvious, that it is difficult to understand how the ASA failed to notice them, especially in the context of a potential conflict of interest.
6. The ASA sets out clear demands for expertise in CAP Code 12.2:

Health professionals will be deemed suitably qualified only if they can provide suitable credentials; for example, evidence of: relevant professional expertise or qualifications; ...

7. We note that Professor Hylands is a pharmacist with extensive experience in conventional pharmacology. We note that he has been closely involved in the development of pharmaceuticals from plants, and in the application of pharmaceutical knowledge to traditional Chinese herbal medicine (TCM). However, there is a considerable difference between the perspective of conventional pharmacy or herbalism and that of homeopathy, and we have not identified any evidence that he has "relevant professional expertise or qualifications" in respect of homeopathy.
8. In the light the serious problems we have identified in his reports, H:MC21 is led to wonder if Professor Hylands may not have had the necessary expertise and understanding to appreciate the importance of some of issues raised by the *Evidence Check 2: Homeopathy* and the Swiss HTA. We presume that the ASA requires marketers to ensure that experts are able to show "suitable credentials; for example, evidence of: relevant professional expertise or qualifications" precisely so as to avoid this sort of mistake.

9. As a result, H:MC21 suggests that the ASA may be in serious conflict with its values, as stated on the ASA website, if it continues to rely on these reports:

Our values

Our shared values are to be:

- Consistent and proportionate
- Reliable and ethical
- Fair and respectful to all
- Accessible and helpful
- Intelligent and thorough, but also timely and proportionate
- Open and accountable, acting with integrity and never being afraid to admit when we're wrong
- An excellent team, inspiring excellence in each other

Our external stakeholders will also find us:

- Independent in administering the Advertising Codes
- Evidence-based, targeted and consistent
- Reflective of society, not a social engineer

10. Specifically the ASA appears to be in breach of its commitments to being “consistent”, “reliable and ethical”, “fair and respectful”, “intelligent and thorough”, “independent in administering the Advertising Codes”, and “evidence-based, targeted and consistent”.
11. In our very first submission we made the point that there is a need to recognise that opposition to homeopathy is rooted in commercial and ideological interests, not in “the available science”. There is no serious conflict between the theoretical position of homeopathy and what is known about biology and medicine. There is, however, a serious conflict between the theoretical position of homeopathy and that of conventional pharmacology, and this conflict has enormous financial implications.
12. For this reason, H:MC21 considers that the ASA’s assessment of this case needs to be scrupulously founded on “the available science”, and that any experts employed by the ASA should have the necessary qualifications and expertise to understand both conventional methods of assessing medical treatments and the complications of applying these to the theory and practice of homeopathy. H:MC21 has consistently sought to provide evidence from those with this combination of knowledge and expertise.

Evidence of efficacy

13. As we stated in our very first submission, the available science does not support the position that evidence of efficacy out-ranks all other evidence, but specifically rejects this position.¹
- 13.1. We have provided evidence that even in conventional medicine nearly 50% of RCTs are inconclusive,² which is one of the reasons why trials of efficacy are recognised to be of limited value. This evidence has been ignored by the ASA.
- 13.2. Another reason why trials of efficacy are recognised to be of limited value is that positive outcomes in such trials may be invalidated by clinical practice. For example, the Shang et al. meta-analysis of RCTs included conventional medical trials in which positive outcomes were achieved, but
- Shang et al made the choice to disregard safety. This decreased the relevance of the comparison of effects of homeopathy and conventional medicine. Some conventional treatments in this analysis are not available because of serious adverse effects.³
- 13.3. For this reason treatments are monitored for their effectiveness in practice, such as through the MHRA Yellow Card Scheme. If evidence of efficacy were reliable, no such scheme would be necessary.

¹ H:MC21’s response to the Notification of the Complaints, 8 December 2010, paras 3.-3.7., pp. 2-4.

² Sent with the formal appeal and identified as ‘El Dib.pdf’.

³ From ‘Rutten.pdf’, p. 175.

14. We have submitted further evidence in the form of Andrew James Turner’s PhD thesis on *Evidence Based Medicine, ‘Placebos’ and the Homeopathy Controversy* (2012).⁴ This thesis makes it clear that the argument that RCT evidence is the only possible evidence of whether or not homeopathy is efficacious, the ‘Categorical Interpretation’, is not scientific but ideological, as we have always maintained.

14.1. Turner notes that

The work here does not challenge the view that randomised trials often provide the best evidential support for medical claims. It does challenge the naïve view that they always and only do so.⁵

and that

An evaluation of the evidence-base for homeopathy must be a critical appraisal of the total evidence. As a result, and contrary to the STC [Commons Science and Technology Committee], it would appear to be less obvious that the best evidence for whether or not homeopathic treatment is a placebo comes solely from placebo-controlled trials.⁶

- 14.2. Turner also points out that good observational studies are better than bad randomised trials or meta-analyses:

Grossman and Mackenzie as well as Bluhm have identified this, seemingly trivial, point; noting that other authors have made exactly the mistake of ignoring it. Contrary to the Categorical Interpretation [of evidence based medicine] they point out that no one ought to hold the view that a badly implemented randomised study will always provide good support, and more support, for a hypothesis than an excellent observational study would.⁷

- 14.3. In the face of this evidence, the continued assumption by the ASA that evidence of efficacy is the only reliable evidence is both mistaken and a threat to the health and safety of the public. We have made this point consistently from our very first submission onwards.⁸ The failure of the ASA to take account of this issue is a failure to assess the evidence on the basis of “the available science”.

Established nature of homeopathy

15. We have submitted evidence about the history of homeopathy, and this is acknowledged in the Draft Recommendation:

The ASA noted there was a large amount of data and numerous case studies on homeopathy that dated back hundreds of years and understood that there was significant support for the use of homeopathy in the treatment of chronic illnesses. We noted H:MC21’s belief that there was significant evidence to support the basic science upon which homeopathy was based and to support more specific claims for successful treatment of chronic disease and illness.⁹

16. Homeopathy has been practised in the UK for nearly 200 years, and it has been part of the NHS for some 65 years. In this context homeopathy is clearly an established medical approach.

⁴ Sent with the comments on the Hylands reports and identified as ‘Turner.pdf’. It should be noted that this is not evidence necessary to support the statements made by H:MC21 in its advertisement, but evidence necessary to correct the mistakes in the ASA’s arguments, and to bring those arguments in line with the available science.

⁵ Turner.pdf, p. 157.

⁶ ‘Turner.pdf’, p. 157.

⁷ From ‘Turner.pdf’, pp. 137-138.

⁸ H:MC21’s response to the Notification of the Complaints, 8 December 2010, para. 3.3.7, p. 4.

⁹ H:MC21 still objects profoundly to the ASA’s use of ‘slanted’ language in its assessments, such as the use of the term “belief” in this passage. While investigators and the ASA Council may know what is meant by this jargon, the general public will tend to assume, when reading published adjudications, that the words are being used in their conventional sense, and so be misled about the relationship to the actual evidence of the ASA’s opinions and those of marketers.

16.1. One of the H:MC21 trustees worked for the British Postgraduate Medical Foundation (BPMF) in the 1980s and reports that the demand from GPs for training in homeopathy at that time exceeded the capacity of the BPMF to provide courses. This example of the restriction of the availability of homeopathic training for GPs would explain the growth in private practice of homeopathy, since it is unreasonable to expect that most people would access a paying service were it readily available without additional payment.

17. As regards controversy about homeopathy, we note that

the ASA had considered very few complaints relating to Homeopathy before the extension of our remit in 2011 to online marketing communications.¹⁰

18. The level of complaints was quantified by the ASA in subsequent correspondence as follows.

18.1. 29 closed complaints, of which: 7 were resolved on an informal basis; 4 were out of the ASA's remit; and the remainder were not investigated. These complaints date back to 2007.

18.2. Another search showed 1,400 complaints in the Product Category of 'alternative therapies'. Only around 120-170 of these cases involved formal procedures, of which only 3 relate to homeopathy.¹¹ It would appear from this that controversy about homeopathy has been minimal in the experience of the ASA.

19. In correspondence with the ASA, H:MC21 was informed that

... the IE will often attach one or two similar cases for Council's information. The two cases attached to this investigation have been attached to this email - they are both from 2006.¹²

20. An aspect of one of these two cases is of particular interest (ref. 116411, 12 July 2006).

20.1. The ASA "challenged whether the TV ad suggested: 4. that there were no side-effects from the treatments". The advertiser responded, according to the ASA with the statement that "there were no side-effects from homeopathic treatment", which is a known fact about homeopathy. The ASA upheld its complaint on the grounds that all medicines produce side-effects, which is a known fact about conventional medicine:

The CAP (Broadcast) TV Advertising Standards Code states that "No advertisement for a medicinal product may suggest that it has no side effects". We considered the claim 'no side effects' breached the Code."

21. This example is important for two reasons:

21.1. Firstly, it indicates that the ASA, after 43 years, was so unfamiliar with homeopathy that it was not aware that whilst all conventional medicines produce side-effects, homeopathic treatment does not. Clearly, controversy about homeopathy was minimal over this period with the result that the ASA did not acquire the relevant knowledge.

21.2. Secondly, the ASA did not check whether the advertiser's statement was correct, but based its decision on a statement only relevant to conventional medicine and not relevant to homeopathy.

22. In the current case, H:MC21 suspected that the ASA might not be aware of the history and nature of homeopathy, the relevant "available science", or the evidence in support of this medical system. As a result, our original submission contained considerable referenced background material in order that the ASA could be made aware of the important issues and pit-falls. In addition to supplying the evidence which we directly referred to in the advertisement, H:MC21 has directed the ASA to other evidence supporting homeopathy,

¹⁰ Email from Gerald Blee, 7 January 2013.

¹¹ Email from Gerald Blee, 10 January 2013.

¹² Email from Gerald Blee, 7 January 2013.

including: replicated RCTs showing homeopathy to be efficacious in the treatment of fibromyalgia, osteoarthritis, seasonal allergic rhinitis, sinusitis, vertigo, chronic fatigue syndrome, premenstrual syndrome, upper respiratory tract infections and allergic reactions;^{13,14} systematic reviews; pre-clinical studies (in basic science, on plants and animals, and on human tissues); and a major study of homeopathy, the Swiss Health Technology Assessment.

23. H:MC21 has provided clear evidence in support of its statements and considerable further evidence of the validity of homeopathy as a medical system, yet the ASA has dismissed this evidence in the following terms

... we noted many of the studies which reported positive outcomes were based on patient self-assessments only, whereas a substantial review of over 100 placebo controlled trials showed no convincing evidence that homeopathy was superior to placebo.

24. For a whole system of medicine to be dismissed on the basis of a single study is scientifically unacceptable. Moreover, the ASA has acknowledged that this is not a reference to the actual study but only to a report of the study in the *Evidence Check 2: Homeopathy*.¹⁵
- 24.1. Had the ASA looked at the original study (Shang et al.),¹⁶ it would have found that the conclusion was based on an unexplained and arbitrary choice of only eight trials of homeopathy, rather than on “over 100” trials.
- 24.2. Had the ASA read the evidence we have submitted,¹⁷ it would have further found that this study has been thoroughly discredited by experts in the field.
- 24.3. In the light of the ASA’s continued reliance on the Shang et al. meta-analysis, we attach further criticisms of this study.¹⁸
25. We are concerned that the ASA continues to fail to pay proper attention to the evidence supplied by H:MC21; that it has stated that it is unable to assess the research evidence supplied; that it is relying on a single discredited study; and that it is further relying on ‘expert’ reports which are seriously inadequate. We have co-operated with the ASA for over two years, pursuing all the appropriate avenues to a proper resolution of the issues, but we consider that the latest Draft Recommendation is still in breach of the rules and standards governing the ASA’s activity.

Assessment

Introductory points

26. We note that the first paragraph of introductory remarks is identical with the opening sentences of the original adjudication. We refer the ASA to our Appeal (paras 4.1.3.-4.1.4.) for criticism of these statements.
27. We note that the subsequent paragraphs are written on the basis of the report on the Commons Science and Technology Committee *Evidence Check 2: Homeopathy* prepared for the ASA by Professor Hylands (‘Hylands EC2 Report’). We refer the ASA to our comments on this report for relevant criticism of these statements, and we wish these comments to be included in full as part of this response to the Draft Recommendation.

¹³ Faculty of Homeopathy website.

¹⁴ Rutten, p. 173. See also the Swiss HTA: *Homeopathy in Healthcare*, chapter 10.

¹⁵ Email from Gerald Blee, 10 January 2013.

¹⁶ A. Shang, K. Huwiler-Müntener, L. Nartey, P. Jüni, S. Dörig, J.A.C. Sterne, D. Pewsner and M. Egger, ‘Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy’, *Lancet*, 366 (2005), 726-732. Attached as ‘Shang.pdf’

¹⁷ ‘Rutten.pdf’ and *Homeopathy in Healthcare*.

¹⁸ Attached as ‘Dantas on Shang.webarchive’, ‘Fisher on Shang.webarchive’, ‘Linde on Shang.webarchive’ and ‘Luedtke on Shang.pdf’,

28. In addition to these comments on the Hylands EC2 Report, we wish to point out that the *Evidence Check 2: Homeopathy* appears to have been carefully structured so as to devalue (and ignore) evidence from pre-clinical trials; to belittle evidence from clinical practice; to minimise discussion of RCTs; and give precedence to systematic reviews and meta-analyses. In particular the committee relied on the uncritical use of the single study Shang et al. (2005), despite the fact that this study had been discredited by experts in the field (see General Points above).
29. We also note that the organisation Sense About Science has informed us that (our emphasis)
- You say that only three MPs voted for the Commons Science and Technology Evidence Check report out of 14, implying that the majority disagreed with it. It is not a scientific report, so not one that Sense About Science relies upon, but rather it is concerned with use of evidence in policy.¹⁹
- 29.1. The ASA currently rejects our claim that Sense About Science does not base its criticisms of homeopathy on the available science or relevant expertise, and the ASA has indicated that it considers this organisation has scientific credibility (Assessment 8).
- 29.2. If the ASA considers that Sense About Science is a reliable source of information about science, then there is a need to explain why the ASA considers that the *Evidence Check 2: Homeopathy* is a scientific report when Sense About Science categorically states that it is not.
- 29.3. If the ASA considers that the *Evidence Check 2: Homeopathy* is a scientific report, then it needs to explain why it considers Sense About Science to be scientifically reliable when this organisation categorically states that the report is not scientific.

Issue 1

30. We note that the combined first and final paragraphs are identical with the original adjudication. We refer the ASA to our Appeal (paras 4.2.-4.2.4.) for criticism of these statements.
31. We note that the intervening paragraphs are written on the basis of the report on the Swiss Health Technology Assessment prepared for the ASA by Professor Hylands ('Hylands HTA Report'). We refer the ASA to our comments on this report for relevant criticism of these statements, and we wish these comments to be included in full as part of this response to the Draft Recommendation.
32. H:MC21 takes this opportunity to inform the ASA that in the event of the ASA continuing to use the Hylands HTA Report, we will have no option but to immediately send both the report and our comments on it to the authors of the Swiss HTA and *Homeopathy in Healthcare*, as they may wish to make representations or even take legal action in respect of some of the statements it contains. H:MC21 trustees will take this action because they consider they are duty-bound to protect H:MC21 from the risk of any legal action based on allegations of H:MC21 complicity in the publication of the views expressed in this report.
33. In addition to these comments, we wish to point out that the ASA has referred to the alleged views of others rather than to those of H:MC21 itself :

We noted that proponents of the homeopathic approach often objected to conventional medicine's focus on RCTs as the gold standard for assessing efficacy, and instead they favoured other forms of measurement in their assessment, such as patient self-analysis and outcome studies.

- 33.1. H:MC21 has been consistent and very precise about its views on the validity of RCTs, and has directed the ASA to cases of replicated RCTs showing the success of homeopathy

¹⁹ Letter to H:MC21 from Síle Lane, Director of Campaigns, Sense About Science, 1 August 2012. Attached as 'SAS Letter.pdf'.

in treating fibromyalgia, osteoarthritis, seasonal allergic rhinitis, sinusitis, vertigo, chronic fatigue syndrome, premenstrual syndrome, and upper respiratory tract infections.

33.2. H:MC21 has also pointed out the potential weaknesses of RCTs, in that they can fail to test homeopathy if not properly designed, and so has supported this evidence by a range of other types of evidence, a position endorsed by other researchers.

33.2.1. The authors of the Swiss HTA discussed these issues in detail, and reached their conclusions as regards efficacy and effectiveness on the basis of studies of pre-clinical research, RCTs of upper respiratory tract infections and allergic reactions, and analysis of systematic reviews.

34. In the light of the ASA's concluding remarks that "H:MC21 had not supplied sufficient evidence to substantiate the claim and noted there was a lack of evidence to support claims for its efficacy", we require the ASA to explain precisely why the substantial amounts and varied types of evidence H:MC21 has supplied in support of homeopathy are insufficient.

34.1. The H:MC21 advertisement did not make statements of efficacy, so it is inappropriate to apply standards appropriate to trials of efficacy to these statements.

34.2. The H:MC21 advertisement did make statements explicitly about the results of homeopathy in clinical use, about its effectiveness. The evidence supplied was appropriate since it was derived from this type of study. H:MC21's supporting evidence for these statements was of the same type, and so was also appropriate.

34.3. The H:MC21 advertisement did not promote any new use of homeopathy, any new homeopathic medicine, or any new mechanism of delivery of homeopathic treatment, but only an increase in expenditure on existing services within the NHS.

34.4. In this context the demand for proof of efficacy of homeopathy by ASA is effectively a statement that no promotion of the practice of homeopathy, even existing and established practice, will be permitted by the ASA unless such promotion can be supported by specific proof of the efficacy of homeopathy. H:MC21 considers that this is an unreasonable position for the ASA to take, especially since the ASA has admitted that it lacks the necessary competence to assess the evidence, as pointed out in our appeal.

35. Evidence of efficacy is very narrowly defined. It is evidence that a specific medicine will produce specific benefits in a certain percentage of people exhibiting a specific condition with particular defined signs, symptoms and aetiology.²⁰ It is a conventional pharmaceutical model relating to individual drugs, and it is not used, for example, to assess conventional medicine as a system.

36. Since the ASA is choosing to apply this model to homeopathy as a system, it is essential that the ASA demonstrate rigour in its approach. Such rigour is lacking in the face of the evidence H:MC21 has supplied.

36.1. There is RCT evidence that homeopathy is efficacious in a number of conditions, such as fibromyalgia, osteoarthritis, seasonal allergic rhinitis, sinusitis, vertigo, chronic fatigue syndrome, premenstrual syndrome, and upper respiratory tract infections. This is *prima facie* evidence that the system is valid.

36.2. The pattern of positive, negative and inconclusive outcomes of RCTs of homeopathy is almost identical with that of conventional medical RCTs, and research indicates that homeopathic RCTs are of higher quality than conventional medical RCTs.

36.3. There is evidence that homeopathic medicines are not inert and can have biological effects.

²⁰ The specificity of evidence of efficacy was even stressed by the ASA's 'expert', Professor Hylands.

36.4. There is evidence from clinical practice that homeopathy has significant effects inconsistent with the placebo effect, both in respect of the type of conditions affected and the duration of the benefits.

37. The ASA's rejection of this evidence is dependent on the claim that

a substantial review of over 100 placebo controlled trials showed no convincing evidence that homeopathy was superior to placebo.

37.1. This "substantial review" was the Shang et al. meta-analysis, and its claim to assess the relationship of homeopathy to placebo has been invalidated by experts in the field:

A review of data provided after publication of Shang et al's analysis did not support the conclusion that homeopathy is a placebo effect. There was intermingling of comparison of quality and comparison of effects, and thus matching was lost. The comparison of effects was also flawed by subjective choices and heterogeneity. The result in the subgroup from which the conclusion was drawn was further influenced by the choice of cut-off value for 'larger' trials. If we confine ourselves to the predefined hypotheses and the part of this analysis that is consistent with the comparative design, the only legitimate conclusion is that quality of homeopathy trials is better than of conventional trials, for all trials ($p = 0.03$) as well as for smaller trials with $n < 100$ ($p = 0.003$).²¹

38. In conclusion, the balance of evidence, according to the available science, is that homeopathy as a system is efficacious, and there is no conclusive evidence that homeopathy as a system is not efficacious. In the context of homeopathy's established position in the NHS, there is no justification for the ASA's extreme demands for evidence. The demands, in fact, appear to be ideological rather than scientific.

Issue 2

39. We note that this assessment is identical with the original adjudication. We refer the ASA to our Appeal (paras 4.3.-4.3.6.) for criticism of these statements.

40. We also refer the ASA to the statements above about evidence of the efficacy of homeopathy.

41. We wish to re-emphasise the following points in addition to those made in the Appeal:

41.1. The statement that "there was no in-depth objective clinical assessment of patients' observable conditions following the introduction of homeopathic treatment" is incorrect, since the study clearly stated that (our emphasis)

At the first consultation the current state of health and the nature and severity of each patient's symptoms were evaluated and recorded in detail. These details provided the baseline from which treatment was commenced.²²

and (our emphasis)

Objective parameters were incorporated in the assessment whenever possible (e.g., alteration in conventional medication, changes in forced expiratory volume, measurable changes in mobility or exercise tolerance, or changes in results of investigations).²³

41.2. Furthermore, these were qualified doctors working within the NHS and having a duty of care backed by full complaints procedures. We consider that the suggestion that they are not telling the truth when stating that they took all proper steps to assess the health of their patients is potentially defamatory.

²¹ 'Rutten.pdf' p. 175.

²² 'Spence.pdf', p. 794.

²³ 'Spence.pdf', p. 794.

- 41.3. This study was explicitly presented by H:MC21 as an outcome study, and it meets all reasonable demands of such a study in supporting its conclusions.

Issue 3

42. We note that this assessment is identical with the original adjudication. We refer the ASA to our Appeal (paras 4.4.-4.4.2.) for criticism of these statements.

43. We note that the ASA has completely ignored the evidence supplied with our Appeal concerning the reliability of RCTs ('El Dib.pdf'). This evidence showed that 49% of RCTs across medicine as a whole were inconclusive.

- 43.1. The ASA's position as regards trials of homeopathy is based on the argument that

the 49% of inconclusive results was a significant piece of information and should have been included in the ad because it indicated that under RCT conditions, inconclusive results had occurred more often than positive results.

- 43.2. For this argument to be valid, the ASA needs to show that this information was not just significant but significant with respect to homeopathy as opposed to other medical approaches. In fact, it appears to be a general rule in medicine that, under RCT conditions, inconclusive results occur more often than positive results. The information is, therefore, not significant in respect of RCTs of homeopathy, and need not be included.

- 43.3. The argument presented by the ASA is also circular and, therefore, self-fulfilling. The suggestion 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 homeopathy was substantiated because more "positive" than "negative" results were achieved

depends on those readers holding the view (as the ASA appears to) that RCTs are the only way of proving efficacy. In this case, it is the stress on the significance of such trials which leads to this interpretation of the figures, and within that view the interpretation is valid, since the results for RCTs of homeopathy are similar to those for trials of conventional medicine. As a result the statement is not misleading.

- 43.4. For any reader who does not put such stress on the significance of RCTs, the statement is simply one of fact without any implications, and so it is again not misleading.

Issue 4

44. We note that this assessment is identical with the original adjudication, except for the removal of the passage referring to the need for clinical evidence to demonstrate how the remedy acted upon the disease within the body. We refer the ASA to our Appeal (paras 4.5.-4.5.2.) for criticism of the statements here.

45. We would like to add that the ideological adherence to the premise that 'the only valid evidence is an RCT' is not true to "the available science". Turner points out that there has never been an RCT of the efficacy of parachutes, but this does not provide reasonable grounds for claiming that parachutes are not "effective at preventing death and severe trauma after freefall":

Recognising the problem of Dramatic Effects, Howick calls this the 'paradox of effectiveness'. He states: 'what we take to be our most effective therapies, ranging from the Heimlich manoeuvre to unblock an airway to eating to reverse the effects of starvation, have never been tested in randomised trials ... it seems to follow that [on the Categorical Interpretation] our most effective therapies are not

supported by “best” (randomised) evidence’. Contrary to the Categorical Interpretation, these dramatic effects seem to show that one may have good evidence without having top-tier evidence.²⁴

46. In the case of the Cuba study, the sheer magnitude of the numbers involved (2.3 million treated and 8 million not treated) and the scale and duration of the difference (as measured against four separate parameters) makes this an example of ‘dramatic effects’. Whilst an RCT may provide ‘better’ evidence, in an abstract sense, in a practical sense it is not necessary.

47. We would also refer the ASA to discussion in the Comment section of the BMJ website. The following points were made there:

1) The authors of the Cuban homeopathic leptospirosis trial were not homeopaths. They were veteran conventional medical researchers and scientists who had been manufacturing, testing and implementing the use of conventional vaccinations for decades. They were highly respected in the vaccine world. Their work had previously been published in many of the major vaccine journals such as, *Vaccine*, *Human Vaccines*, *Expert Review of Vaccines*, etc. They were and are in fact, amongst the world’s leading experts on leptospirosis vaccination – with the trivalent Vax-spiral (the only conventional leptospirosis vaccine made anywhere in the world) designed and manufactured in their own facilities (the Finlay Institute – a WHO-designated research center). In sum, they were not homeopathic apologists. Prior to the leptospirosis study, they had no ‘skin in the game’ whatsoever, and no reason at all to defend or advocate for homeopathy.

2) The authors implemented the use of the homeopathic leptospirosis prophylaxis as a last ditch effort in 2007, when the island was overwhelmed by a record hurricane season and there were insufficient resources/time to produce enough of the conventional vaccine. They tried homeopathy in light of having no other options.

3) Unlike the conventional vaccine, the homeopathic product could be produced in less than 2 weeks (compared to 6 months), cost 2% of the conventional vaccine, and was far more easily stored and administered.

4) The results of using the homeopathic product in 2007 were far more successful than any previous use of the conventional vaccine, despite what was objectively one of the worst Atlantic hurricane seasons in modern history. Within 2 weeks of administering the homeopathic product, they observed a 90% decrease in incidence of leptospirosis in the intervention region (comprising 2.1 million persons), while in the low-risk areas which did not receive any intervention (either homeopathic or conventional) incidence of the disease continued to rise – a set of facts that would have been drastically reversed if the homeopathic product had no efficacy.

5) The homeopathic prophylaxis was then, in the ensuing years, administered to the entire Cuban population (11 million persons), to the effect of near eradication of the disease on the island – a result not achieved with use of the conventional vaccine product.

6) Despite the fact that the researchers had for decades published papers in the leading vaccine journals, none of these journals were willing to publish this groundbreaking trial – by all accounts, one of the largest ever conducted in medicine. What happened? Were the researchers no longer ‘experts?’ Did they forget how to conduct a proper trial? Was the trial of insufficient quality? No legitimate criticism has been registered to date and none was given by the journals. I’ll leave it to readers to make up their own minds, but will provide some historical context: from the beginning of homeopathy the conventional medical community has repeatedly sabotaged homeopathic research. Throughout the 19th century, on numerous occasions, conventional medical authorities simply confiscated and destroyed the records of successful homeopathic trials. Of course, we know the scientific world is much more ‘civilized’ now, right?

7) Despite all this, the researchers and scientists involved with the study still advocate for and use conventional vaccination in many diseases. Unlike homeopathic ‘skeptics,’ these people are actually committed to science – i.e. unbiased and objective observation. They care only about what works and are not blinded by dogma and ideology.

²⁴ ‘Turner.pdf’, p. 139.

8) Based on the results achieved with leptospirosis, the Cuban Ministry of Health began using homeopathic prophylaxis and treatment for other infectious epidemics, including dengue fever, ‘swine’ flu, hepatitis A and conjunctivitis – all with similar success.²⁵

48. We consider that the ASA is adopting an indefensible ideological position in rejecting the evidence provided and failing to recognise “the available science”.

Issue 7

49. We note that this assessment is identical with the original adjudication. We refer the ASA to our Appeal (paras 4.6.-4.6.4.6.) for criticism of the statements here.

50. Further information about the potential cost-savings from using homeopathy were available in the Swiss HTA, and we note that none of this information has been taken into account.

51. We note that the ASA’s position is that no amount of objective evidence of cost-savings is valid in support of an argument about potential cost-savings unless H:MC21 provides evidence which is satisfactory to the ASA of the efficacy of homeopathy. We dispute this confusion of different types of evidence on the grounds that it is unscientific. Whether or not the ASA believes that homeopathy is efficacious, the existence of evidence that it is cost-effective (which means that it has dealt with problems at less cost) is sufficient basis on which to suggest that it could lead to further savings.

52. We have dealt above with the issue of evidence of the efficacy of homeopathy.

Issue 8

53. We note that this assessment is identical with the original adjudication. We refer the ASA to our Appeal (paras 4.7.-4.7.2.5.) for criticism of the statements here. We still consider it unacceptable to create a new complaint seven months after the process has begun, when there is a three month deadline on making complaints. We are surprised that this has not been challenged by the Independent Reviewer.

54. The complaint, as it stands at present, involves three specific issues concerning Sense About Science: its source of income; its use of scientific research; and the nature of its activities. We draw the ASA’s attention to the facts about these issues.

54.1. Income: during 2012 H:MC21 received a letter from Sense About Science criticising our statements about the organisation and its income from organisations connected with the pharmaceutical industry, and making the following claim which is particularly relevant to this ASA investigation:

In the financial year ending April 2009 the proportion reduced to 12%, in April 2010 it was 1%
...²⁶

54.2. H:MC21 responded to this letter by re-investigating the issues in detail, and our reply is attached.²⁷ In this reply we documented in detail that over 42% of Sense About Science’s total income for the years 2004-2010 came from organisations supporting the pharmaceutical industry. Our conclusion was as follows:

Sense About Science appears to have received an average of 42.3% of its total income between 2004 and 2010 from pharmaceutical companies or organisations clearly linked to the pharmaceutical industry. In 2006, the year *Sense About Homeopathy* was published, there was a huge leap in such funding, from £37,300 (36.9% of total income) to £102,165 (51.2% of total income).

²⁵ Available at <<http://www.bmj.com/content/345/bmj.e6184/rr/616928>>, and attached as ‘Cuba BMJ.webarchive’.

²⁶ Letter to H:MC21 from Sile Lane, Director of Campaigns, Sense About Science, 1 August 2012, attached as ‘SAS Letter.pdf’.

²⁷ Attached as ‘HMC21 Reply to SAS.pdf’.

- 54.3. Clearly Sense About Science is funded to a significant extent by the pharmaceutical industry and its supporters.
- 54.4. Scientific research: Despite receiving funding totalling £1,283,945 between 2004 and 2010, and despite the fact that it has made a deliberate decision to address the subject of homeopathy, Sense About Science does not appear to have conducted any scientific research during this time in the area of homeopathy. It does not even appear to have conducted a formal survey, or any other market research, to support and quantify its assertions about widespread concern among scientists over homeopathy.
- 54.5. Its principle document on homeopathy refers to only a single piece of homeopathic research, and that is the discredited Shang et al. meta-analysis.
- 54.6. We are struggling to see how Sense About Science could be described as relying on scientific research.
- 54.7. Activities: Sense About Science has itself summarised its activities in respect of homeopathy, as we have documented. All these activities have involved influencing the media, political bodies and the public against homeopathy. None of the members of Sense About Science playing a primary role in this process up to 2010 have supplied any evidence of relevant expertise in the field of medicine, let alone of homeopathy. All have had experience in lobbying, risk-management or the media. As pointed out, none of this work has been based on scientific research.
- 54.8. We also note that while Sense About Science published its letter to H:MC21 on its website, it has still not published our reply some five months after receiving it. This does not indicate a commitment to presenting fair and unbiased information to the public.
- 54.9. Clearly Sense About Science has pursued activities which are aimed at changing attitudes to ones favourable to those organisations contributing a high proportion of its financial support without providing objective grounds for this activity. We would suggest that this falls under a reasonable definition of propaganda.
55. Within the field of homeopathy, the only area of Sense About Science's activity H:MC21 has commented on, the evidence indicates that this organisation is as described in our advertisement.

Issue 9

56. We note that the ASA has now read both *Trick or Treatment? Alternative Medicine On Trial and Halloween Science*.
57. We draw the ASA's attention to the following statement in *Trick or Treatment?*:

In particular, we will answer the fundamental question: 'Is alternative medicine effective for treating disease?' Although a short and simple question, when unpacked it becomes somewhat complicated and has many answers depending on three key issues. First, which alternative therapy are we talking about? Second, which disease are we applying it to? Third, what is meant by effective?²⁸

- 57.1. It is clear that the authors believe that their book can only reach valid scientific conclusions if there is a clear objective definition of each of these terms:
- 'alternative medicine' and 'not alternative medicine',
 - 'disease', and
 - 'effective'.
- 57.2. H:MC21 fully concurs with this belief, and we feel sure that the ASA, which assesses claims on the basis of "the available science" will also concur. Without any definition of the basic terms being used, there can be no scientific debate.

²⁸ *Trick or Treatment?*, p. 3.

- 57.3. If the ASA cannot identify where in *Trick or Treatment?* these terms are objectively defined, then, according to the authors' own stated views, there is no basis for claiming that the book is scientifically reliable.
- 57.4. *Halloween Science* not only claims that these terms are not defined in *Trick or Treatment?*, but points out that the term 'alternative medicine' is defined four times, and that each definition is both subjective and incompatible with the other definitions. Furthermore, the fourth version of the definition of 'alternative medicine' in *Trick or Treatment?* is absolutely dependent on the term "effective", which has not been defined by the authors.
- 57.5. H:MC21 concludes that the failure to define these basic terms is alone objective evidence that *Trick or Treatment?* is not scientifically reliable.
58. *Halloween Science* detailed a considerable number of other objective inaccuracies and contradictions in *Trick or Treatment?*, and H:MC21 considers that these too demonstrate a general lack of reliability. H:MC21 considers it unnecessary to repeat every example within this response to the Draft Recommendation, but it expects the ASA to take note of all the examples in *Halloween Science* and of their collective impact on an assessment of the reliability of *Trick or Treatment?*. Many examples were given in previous submissions.²⁹
59. The failure of the authors of *Trick or Treatment?* to supply references has been a widespread criticism, to which they responded by starting to provide them online. However, while references for two chapters appeared by July 2009, none have been provided since then.³⁰ H:MC21 is left wondering whether the authors can actually substantiate many of the claims made in their book.
- 59.1. We draw the ASA's attention to the fact that these online references have validated at least one criticism of the authors' reliability made in *Halloween Science*. The alleged "major study" cited in the quotation from *Trick or Treatment?* below was indeed two studies,³¹ as *Halloween Science* claimed. To make inaccurate claims about research is to be scientifically unreliable.

The third example concerns criticism of "scare stories" in the news about mercury fillings in teeth. Ernst and Singh note that

In fact, a major study in 2006 confirmed numerous previous investigations showing that fears over mercury fillings were groundless. Researchers monitored the health of 1,000 children who had received either mercury fillings or mercury-free fillings. Over the course of several years there was no significant difference between the two groups in terms of their kidney function, memory, coordination, IQ and other qualities. (p. 265)

It is unfortunate that there is no reference for this research, as we have not been able to find any evidence of it. On the other hand we have found that in 2006 there were two separate studies published, one conducted over 5 years in New England, USA, and the other over 7 years in Lisbon, Portugal, involving respectively 534 children of ages 6 to 10 years old and 507 children of ages 8 to 10 years old.^{32,33} If these studies are combined, they closely resemble the

²⁹ For example, in H:MC21's response to the ASA Draft Recommendation version 2, 30 March 2011, paras 16-16.3.5.2, pp. 5-9.

³⁰ References for *Trick or Treatment?* are available at <<http://www.trickortreatment.com/references.html>>. They are also attached as 'References.webarchive', 'References Ch 5.webarchive' and 'References Ch 6.webarchive'.

³¹ The two references given online are as follows, and are the same as those supplied by *Halloween Science*:

Page 320: Neurobehavioral Effects of Dental Amalgam in Children DeRouen et al JAMA. 2006;295:1784-1792

Page 320: Neuropsychological and Renal Effects of Dental Amalgam in Children David C. Bellinger et al JAMA. 2006;295:1775-1783.

³² David C. Bellinger et al., 'Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial', *JAMA*, 295 (2006), 1775-1783 at <<http://jama.ama-assn.org/cgi/content/full/295/15/1775>>, accessed 23 February 2009.

authors' single "major study" in terms of numbers and results, though both reported a significantly higher mean urinary mercury level in children with mercury fillings, which Ernst and Singh do not mention.³⁴

60. We note that the ASA has produced a new argument that "the ad implied there was a general scientific consensus that the arguments contained in *Trick or Treatment* were fundamentally scientifically flawed". If the advert genuinely implied this, we would have expected to see this argument in the first Draft Recommendation, whereas the ASA has taken more than two years and six versions of the Recommendations to 'discover' it.

60.1. We note, too, that the ASA is basing its conclusions on this new implication rather than on the evidence supplied.

60.2. In this context, we should point out that others have criticised the reliability of *Trick or Treatment?* We attach a review from the *British Journal of General Practice*, which makes some significant points.³⁵ We draw the ASA's attention to the following passages in particular:

The authors set great store by the pursuit of truth and knowledge, and the role of science in that enterprise. The book is explicitly dedicated to the pursuit of truth, and claims a balanced presentation of the facts in pursuit of the truth of the matter, in this case the validity of CAM as a contribution to health care. I applaud that aim. Truthfulness is an essential attribute of a therapeutic relationship and an essential attribute of the scholarship that informs clinical practice. But it is in this regard that I am critical of '*Trick or Treatment? Alternative Medicine on Trial*'. It is full of data about CAM, but it does little to advance our knowledge of medicine, particularly our knowledge of its role in human healing. That is disappointing. And although I don't doubt the authors' desire for truth, I do doubt their hold on truth. They display great certainty in their pronouncements, but there is a difference between truth and certainty. Both are precarious, but those engaged in the pursuit of truth know it. Those possessed of certainty often don't. It takes wisdom and discernment to tell the difference, and on those counts I find this book lacking.

... But a recurring lack of truthfulness is the lack of the perspective that would have been provided by relating these to comparable problems in conventional medicine. For example, risk is an ever-present concern in all medicine, and Ernst and Singh rightly highlight the risks of CAM. Unfortunately they do not present those risks in relation to the risks of conventional medicine; nor discuss the rarity of the CAM disasters they cite. Medical risk is direct (harm caused by the intervention), or indirect (harm resulting from neglect of some more necessary or appropriate intervention). In conventional medicine the predominant risk is direct — adverse, for example, drug reactions, anaesthetic or surgical errors. But indirect risk also occurs. A simple example is inappropriately prescribing an antibiotic for a self-limiting viral infection rather than explaining the condition and encouraging an expectant and self-sufficient attitude; compounded by the direct risk of an adverse reaction and the further indirect risk of developing antibiotic resistance. Iatrogenic harm from direct risk in conventional medicine is regrettably frequent, and can be fatal. In CAM it is very rare. Indirect risk in CAM is a more serious problem and comparable to indirect risk in conventional practice.

This is one example of a lack of truthfulness and balance in the book. If CAM lacks compelling evidence of specific efficacy, patients may legitimately prefer it to a treatment of proven efficacy that carries a greater degree of direct risk. More so if the training of the practitioner guards against indirect risk; increasingly the case in the best established therapies.

This use of the word 'efficacy' points up another evasion. Throughout, the word 'effectiveness' is used in discussing the lack of positive evidence from formal trials of CAM. Formal trials usually test efficacy, the ability of an intervention to do what is intended in ideal

³³ Timothy A DeRouen et al., 'Neurobehavioral Effects of Dental Amalgam in Children: A Randomized Clinical Trial' *JAMA*, 295 (2006), 1784-1792 at <<http://jama.ama-assn.org/cgi/content/short/295/15/1784>>, accessed 23 February 2009.

³⁴ *Halloween Science*, pp. 106-107.

³⁵ Jeremy Swayne, 'Book review: *Trick or Treatment? Alternative Medicine on Trial*', *British Journal of General Practice*, 58 (2008), 738-739, available at doi:10.3399/bjgp08X342525. Attached as 'Swayne.webarchive'.

test conditions. Effectiveness is what happens in an actual clinical context. ‘Efficacy’ tests narrowly defined specific effects. Effectiveness is more relevant to what happens in the real world and really more interesting. *Trick or Treatment? Alternative Medicine on Trial* is generally challenging efficacy, not effectiveness.

- 60.3. H:MC21 considers that the argument about consensus is not a response to the advertisement at all, but an attempt to devalue the detailed and valid criticisms in *Halloween Science* by suggesting that however accurate those criticisms may be, they need to have won a “general scientific consensus” before they will be regarded as facts by the ASA.
- 60.4. We remind the ASA that its values state that it is “not a social engineer”, and that the process of achieving a “general scientific consensus” requires the broadcasting of the facts. We do not consider that the ASA has any right to prevent publication of the facts on the grounds of an alleged lack of consensus.
- 60.5. We also remind the ASA that there is no detailed critique of *Trick or Treatment?* other than *Halloween Science*, and that none of the facts or criticisms presented in *Halloween Science* have been refuted by the authors of *Trick or Treatment?*, the ASA or anyone else in the four years since *Halloween Science* was published.