House of Commons

Science and Technology Committee

Evidence Check 2: Homeopathy

Fourth Report of Session 2009–10

HC 45

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Report, together with formal minutes, oral and written evidence

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1 Introduction

Evidence Check inquiries

1. Since the Science and Technology Committee was reformed in October 2009, we have been running a novel programme of work that we have called "Evidence Check". The purpose of Evidence Check is to examine how the Government uses evidence to formulate and review its policies. We have focussed on narrow policy areas and asked the Government to answer two questions: (1) what is the policy? and (2) on what evidence is the policy based? In December 2009 we published our first Evidence Check on Early Literacy Interventions.[1]

2. This is the second Evidence Check report. It examines the Government's policies on the provision of homeopathy through the National Health Service (NHS) and the licensing of homeopathic products by the Medicines and Healthcare products Regulatory Agency (MHRA). We selected this topic following the Government's responses in September 2009 to questions we asked about the evidence base underpinning several different policies. The Government's response on homeopathy indicated that scientific evidence was not used to formulate the licensing regime operated by the MHRA.[2] We were surprised by this response and decided to broaden the inquiry to include consideration of the evidence base underpinning the Government's policy regarding the funding of homeopathy on the NHS.

The inquiry

3. This inquiry had a dual focus on the NHS and the MHRA. In October 2009 we issued a call for written evidence on:

- Government policy on licensing of homeopathic products;
- Government policy on the funding of homeopathy through the NHS; and
- the evidence base on homeopathic products and services.[3]

4. This inquiry was an examination of the evidence behind government policies on homeopathy, not an inquiry into homeopathy. We do not challenge the intentions of those homeopaths who strive to cure patients, nor do we question that many people feel they have benefited from it. Our task was to determine whether scientific evidence supports government policies that allow the funding and provision of homeopathy through the NHS and the licensing of homeopathic products by the MHRA.

5. We received around 60 written submissions. Because we had received a response from the Government on MHRA licensing prior to calling for written submissions,[4] the

1 Science and Technology Committee, Second Report of Session 2009–10, *Evidence Check 1: Early Literacy Interventions*, HC 44

2 Ev 60

3 "New Inquiry, Evidence Check: Homeopathy", House of Commons Science and Technology Committee press notice No. 11, Session 2008–09

4 Ev 60

Government's response on that aspect of the inquiry was available for interested parties to read and comment on in their written submissions. Additionally, some were received after the oral evidence sessions had concluded and some of these commented on the oral evidence.[5] We also received many background papers relating to the inquiry.

6. On 25 November 2009 we took oral evidence from two panels; one focused on NHS funding and provision of homeopathy and the other on MHRA licensing. The expertise of the witnesses on each panel spread across both topics and there was overlap on the issues discussed, particularly in relation to the evidence base. On 30 November 2009 we took oral evidence from Mike O'Brien QC MP, Minister for Health Services, Professor David Harper, Chief Scientist at the Department of Health (DH), and Professor Kent Woods, Chief Executive of the MHRA, on the Government's policies.

7. We carefully considered all the background documents, written submissions and oral evidence in drawing up our conclusions and recommendations. We would like to put on record our thanks to all those who made submissions and gave evidence to the inquiry.

Structure of the report

8. This report is in two parts. Chapter 2 addresses the evidence base for the provision of homeopathy on the NHS. Chapter 3 examines the evidence base for the MHRA's licensing regime for homeopathic products. In each chapter we have adopted the approach we followed in the first Evidence Check inquiry: we have outlined the Government's policy, summarised what we would expect of a good evidence base and then evaluated whether the Government's policy is sufficiently evidence-based (the Evidence Check).

5 *For example*, Ev 189–194

2 NHS funding and provision

What is homeopathy?

9. Homeopathy is a 200-year old system of medicine that seeks to treat patients with highly diluted substances that are administered orally. Homeopathy is based on two principles: "like-cures-like" whereby a substance that causes a symptom is used in diluted form to treat the same symptom in illness[6] and "ultra-dilution" whereby the more dilute a substance the more potent it is (this is aided by a specific method of shaking the solutions, termed "succussion").[7] It is claimed that homeopathy works by stimulating the body's self-healing mechanisms.[8]

10. Homeopathic products should not be confused with herbal remedies. Some homeopathic products are derived from herbal active ingredients, but the important distinction is that homeopathic products are extremely diluted and administered according to specific principles.

The policy

11. The Department of Health (DH) told us that it "does not maintain a position" on any complementary or alternative treatment, including homeopathy.[9] Decisions on the use of homeopathy are left to the National Health Service (NHS).[10] Primary Care Trusts (PCTs) are responsible for commissioning care services[11] and are thus currently free to fund homeopathy.

12. Homeopathy was introduced into Britain in the 1830s and has been funded and provided on the NHS since its inception in 1948.[12] There are four homeopathic hospitals in the UK, located in London, Bristol, Liverpool and Glasgow. These hospitals fall under the jurisdiction of their respective PCTs. A homeopathic hospital in Tunbridge Wells was closed in 2009 following a drop in referrals to the hospital and a review by the West Kent PCT on the commissioning of homeopathy.[13]

13. The Government was unable to tell us how much money the NHS spends on homeopathy as "data on spending in the area of homeopathy on the National Health Service has never been routinely collected".[14] When he gave oral evidence Mike O'Brien, Minister for Health Services at the DH, was, however, able to say that:

6 We examine the issue of "like-cures-like" in more detail at paragraph 50 and following.

7 "How does homeopathy work?", *British Homeopathic Association*, www.britishhomeopathic.org

8 "What is homeopathy?", *The Society of Homeopaths*, www.homeopathy-soh.org

9 Ev 61, para 7

10 *As above*

11 Ev 61, para 11

12 Ev 174, para 2.1

13 Ev 61, para 9; see also paragraph 83 and following.

14 Ev 62, para 18

> In terms of drugs it is £152,000 a year which comes from a budget of £11 billion. It is approximately 0.001 per cent, we calculated, of the drugs budget. In terms of overall funding it is very difficult to know. We have done some work to see if we can find out what it is. We have four hospitals—one in Glasgow, three in England—which provide homeopathic assistance to people and we do provide some NHS funding for those, so it would run into several million on that basis, so probably less than 12—I think I saw that in *The Guardian* as a quote—so probably less than that but not too much less.[15]

14. In June 2009 the Guardian reported that the NHS had spent £12 million on homeopathy in the period 2005–08.[16] According to the Society of Homeopaths, the NHS spends £4 million on homeopathy annually.[17] It appears that these figures do not include maintenance and running costs of the homeopathic hospitals or the £20 million spent on refurbishing the Royal London Homeopathic Hospital between 2002 and 2005.[18]

15. When we asked Dr Mathie of the British Homeopathic Association (BHA) whether money spent by the NHS on homeopathy could be usefully redirected elsewhere, he replied that "there is a need for cost-effectiveness evaluation of homeopathy. There is almost none".[19] It is impossible to evaluate the overall cost-effectiveness of homeopathy provided by the NHS if the cost is unknown. **We recommend that the Government determine the total amount of money spent by the NHS on homeopathy annually over the past 10 years, differentiating homeopathic products, patient referrals and maintenance and refurbishment of homeopathic hospitals, and publish the figures.**

Our expectations of the evidence base

16. The NHS Constitution, which outlines patient rights, states:

> You have the right to expect local decisions on funding of [...] drugs and treatments to be made rationally following a proper consideration of the evidence.[20]

17. This statement summarises our own expectations. NHS funding of treatments is expensive and of high societal importance, and therefore it is crucial that decisions are made on the best available evidence. We would expect the Government's policy on NHS funding and provision of homeopathy to be evidence-based. We outline below our views on the different types of evidence and their individual importance as a component of the overall evidence base.

15 Q 244

16 "Critics find NHS's £12m spend on homeopathy hard to swallow", *The Guardian*, 10 June 2009

17 Ev 141, para 8.3

18 "New developments: Royal London Homeopathic Hospital redevelopment", University College London Hospitals press release, 16 June 2005

19 Q 128

20 Department of Health, *"The NHS Constitution for England"*, January 2009

Scientific plausibility

18. Medical interventions are usually supported by explanations for how they work and the same is true of homeopathy. Scientific explanations for a mechanism of action are important because they can lead to refinements of medicines: for example, new vaccines for viruses based on the known mechanisms of immunisation. Understanding a mechanism of action can also enable the development of entirely new medicines: for example, the persistent threat of resistance means that new anti-malarial drugs with novel mechanisms of action are continually required.[21] Our expectation of an explanation for a mechanism of action is that it is both scientifically plausible and demonstrable. We should, however, add that, while we comment on explanations for how homeopathy works, it is not a key part of our Evidence Check. Historically, some medical interventions were demonstrably effective before anyone understood their modes of action. For example, after 150 years of use, there is still debate about precisely how anaesthetics work.[22] It is more important to know *whether* a treatment works—its efficacy—than *how* it works.

Evidence of efficacy

Randomised controlled trials (RCTs)

19. Randomised Controlled Trials (RCTs) are the best way of determining whether a cause-effect relationship exists between a treatment and an outcome.[23] Well designed RCTs have the following important features:

- randomisation: patients should be randomly allocated to placebo (dummy treatment)[24] or treatment groups—this ensures that there are no systematic differences between patient groups that may affect the outcome;
- controlled conditions: aside from the treatment given, all patients should be treated identically, whether in placebo or treatment groups—this excludes other factors from influencing the outcome;
- intention to treat analysis: patients are analysed within their allocated group even if they did not experience the intervention—this maintains the advantages of randomisation which may be lost if patients withdraw or fail to comply;
- double blinding: patients and clinicians should remain unaware of which patients received placebo or treatment until the study is completed—this eliminates the possibility of preconceived views of patients and clinicians affecting the outcome; and
- placebo controlled: if there is no appropriate alternative treatment against which to compare the test treatment, the intervention under consideration is tested against a dummy treatment to see if the intervention has any benefit or side effects.

21 T Wells, P Alonso and W Gutteridge, "New medicines to improve control and contribute to the eradication of malaria", *Nature Reviews*, November 2009, vol 8: 879

22 "Anaesthesia", *BBC Medical Notes,* 2 May 2006, news.bbc.co.uk

23 "Understanding controlled trials: Why are randomised controlled trials important?", *BMJ*,1998, vol 316, p 201

24 Placebos and the placebo effect are considered at paragraph 30 and following.

20. In clinical research, it is widely accepted that RCTs are the best way to evaluate the efficacy of different treatments and distinguish them from placebos. However, some supporters of homeopathy claim that RCTs are not an appropriate way to test homeopathy because "they are far less suitable when studying the overall effects of a holistic therapy in a complex organism with multiple problems".[25] We do not agree. If homeopathic products—or any medicinal product—are more than placebos, and all other elements of the "holistic" care package are the same (controlled), it should be possible to see differential results between the test substance and the placebo. **We consider that conclusions about the evidence on the efficacy of homeopathy should be derived from well designed and rigorous randomised controlled trials (RCTs).**

Meta-analyses and systematic reviews

21. There may be variation in the results produced by different RCTs, particularly if there are many trials with low statistical power, that is, small trials with low numbers of participants. When trials produce varying results, proponents of both sides of an argument can "cherry-pick" data to support whichever side of the argument they like. This is a situation we wish to avoid. We can do so by turning to two types of analysis of clinical trials to help us appraise the evidence: meta-analyses and systematic reviews.

22. Meta-analyses combine the results of trials, increasing the sample size and statistical power of the data. Meta-analyses may reveal statistically significant trends that were not apparent by studying the trials individually. When pooling data, it is important to ensure that the data are comparable. It is preferable that a meta-analysis only include well designed trials, since these trials produce the most rigorous data. When meta-analyses are conducted on less well-designed trials, the design flaws should be recognised and the diminished power of the data acknowledged.

23. Systematic reviews refer to the process of collecting, reviewing and presenting all the available evidence, for example, by selecting trials listed in the PubMed database[26] that meet pre-defined criteria. Systematic reviews often, but not always, include a meta-analysis.[27]

24. Properly conducted systematic reviews have the following important features:

- the prior determination and explanation of eligibility criteria (which will allow or disallow inclusion of published studies) for the systematic review;
- a literature search looking for all potentially relevant published studies;
- examination of the methodology of all potential candidate studies to ensure that they fit the eligibility criteria; this includes clear rules about the design and methodology of such studies.
- assembly of the most complete dataset feasible;

25 Ev 135 [Dr Eames], para 3.1

26 "PubMed", *National Centre for Biotechnology Information*, www.ncbi.nlm.nih.gov/pubmed

27 "An introduction to meta-analysis", *The Cochrane Collaboration*, www.cochrane-net.org

- analysis of the results of included studies, with statistical analysis (meta-analysis) if appropriate; and
- a critical summary of the systematic review, including identification of the "confidence intervals"[28] and "statistical significance"[29] of any findings.

25. **We expect the conclusions on the evidence for the efficacy of homeopathy to give particular weight to properly conducted meta-analyses and systematic reviews of RCTs.**

The distinction between efficacy and effectiveness

26. It has been suggested that it is useful to draw a distinction between efficacy and effectiveness.[30] Dr Peter Fisher, Director of the Royal London Homeopathic Hospital, explained the difference:

> In simple terms the distinction is between ideal conditions and real world conditions—efficacy being ideal conditions and effectiveness being real world conditions.[31]

27. Professor Edzard Ernst, Director of the Peninsula Medical School, gave the following example:

> Efficacy tests whether treatment works under ideal conditions; for instance, a hypertensive agent may well be effective under ideal conditions and then will not work in the real world because people experience side-effects.[32]

28. The opposite might also occur: a product might not work in "ideal" conditions, but may appear effective in "the real world". In the case of homeopathy, arguments have predominantly centred around whether or not it is a placebo treatment. If homeopathy was better than a placebo treatment, one would expect tests of efficacy to show that it is efficacious; and "real world" tests of effectiveness to show that it may or may not be effective. If homeopathy was a placebo treatment, it would fail tests of efficacy, but with tests of effectiveness it would appear to be effective for some conditions and some patients, but not for others.

A summary of the logical outcomes depending on whether homeopathy is or is not a placebo

	Efficacy	Effectiveness
Homeopathy is not a placebo	PASS	EITHER PASS OR FAIL
Homeopathy is a placebo	FAIL	

29. The answer to why a medicine can be effective without being efficacious lies with a phenomenon known as the placebo effect.

28 A confidence interval helps assess the likelihood of a result occurring by chance. A confidence interval represents a range of values that is believed to encompass the "true" value with high probability (usually 95%).

29 A result is defined as statistically significant if it is unlikely to have occurred by chance, typically when the probability of obtaining that result by chance is less than 5%.

30 Ev 162 [Dr Relton]

31 Q 116

32 *As above*

Placebos and the placebo effect

30. There is extensive scientific literature on placebos and the placebo effect.[33]

31. The most frequently quoted definition of a placebo came from Arthur Shapiro, a psychiatrist, who in 1964 described a placebo as "any therapeutic procedure which has an effect on a patient, symptom, syndrome or disease, but which is objectively without specific activity for the condition being treated".[34]

32. Shapiro then described the placebo effect as "the psychological or psychophysiological effect produced by placebos".[35] However, this is rather simplistic and therefore we are attracted to the definition produced by Dr Howard Brody, Director of the Institute of Medical Humanities at the University of Texas Medical Branch, who defined the placebo effect as "a change in a patient's illness attributable to the symbolic import of a treatment rather than a specific pharmacologic or physiologic property".[36] According to this definition, the placebo effect does not necessarily require a dummy treatment.[37] It is important to remember that when patients receive an efficacious treatment, they may benefit from a placebo (non-specific) effect as well as the specific effect of the treatment. Brody's definition also allows for a wider range of non-specific effects, such as the doctor-patient relationship, to be relevant to the placebo effect.

33. To complete the picture, it is worth mentioning that the impact of the placebo effect may be positive or negative. In common usage, "placebo effect" refers to a positive response. When there is a negative outcome, it is often referred to as the "nocebo effect".[33]

34. The placebo effect should not be confused with other phenomena. Sometimes patients just get better and sometimes symptoms fluctuate in severity. If a patient seeks the advice of a homeopath, GP or any other health specialist, when he or she is feeling most ill with a condition that would get better of its own accord, for example a common cold, it is statistically likely that he or she will begin recovery soon after the consultation anyway (the natural course of a disease). If a patient seeks advice when he or she is suffering badly from a symptom that fluctuates in severity, for example the pain of osteoarthritis, it is statistically likely that he or she will experience alleviation of the symptoms soon after the consultation anyway (regression to the mean). The effects of the natural course of a disease and regression to the mean should be distinguished from the placebo effect.[38]

35. The precise mechanisms of the placebo effect are not well understood. However, studies have shown the following:

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33 J M Anton de Craen, Ted J Kaptchuk, Jan G P Tijssen and J Kleijen, "Placebos and placebo effects in medicine: historical overview", *Journal of the Royal Society of Medicine*, vol 92 (1999), pp 511–515

34 A K Shapiro, "Factors contributing to the placebo effect. Their implications for psychotherapy", *American Journal of Psychotherapy,* vol 18 (1964), pp 73–88

35 *As above*

36 Brody H. "Placebos and the Philosophy of Medicine. Clinical, Conceptual and Ethical Issues", *University of Chicago Press*, 1980

37 de Craen *et al*, *as above*

38 E Ernst and K L Resch, "Concept of true and perceived placebo effects", *BMJ*, 1995, vol 311, pp 551–553

- The placebo effect can be powerful but is usually only effective for relatively minor ailments.[39]

- The placebo effect is unpredictable. It is not possible to characterise who will be a "placebo responder" (someone who reacts well to placebo treatment).[40] Nor has it been possible to establish conclusively how many patients experience a placebo effect.

- The placebo effect is culturally specific. Colours affect the perceived action of a drug and seem to influence the effectiveness of a drug. For example red, yellow, and orange are associated with a stimulant effect, while blue and green are related to a tranquillising effect.[41] The route of administration also has an effect. For example, one study showed that subcutaneous (injected) placebos were more effective than oral placebos in the treatment of migraine.[42]

36. Professor Ernst summarised the problem with prescribing placebos in the NHS:

> I would argue it is unnecessary, unreliable and unethical to prescribe placebos through the NHS; unnecessary because if you do it well then an active treatment will also generate a placebo effect. If I give my patient an aspirin for his or her headache and I do it with empathy, time and understanding this patient will benefit from the pharmacological effect of the aspirin and she will also benefit from the placebo effect through the encounter with her clinician. It is unreliable and there is lots of data to show that placebo effects are notoriously unreliable; somebody who responds today may not respond tomorrow; responses are not large in effect size and they are not usually long-lasting. Foremost, it is unethical.[43]

37. Despite the power of the placebo effect, there are a number of reasons why pure placebos are not used routinely (officially) in the medical profession. First, as outlined above, the placebo effect is unpredictable and highly susceptible to individual patient expectations and therefore not a reliable treatment on its own. Second, there is a placebo effect included in the delivery of efficacious treatment so it is not necessary to deliver a placebo effect in isolation. Third, to maximise the impact of placebos, doctors need to deceive their patients by, for example, telling them that the placebo pills they are receiving are in fact a "proper" drug. To a certain extent, the greater the deception the stronger the placebo effect. The nature of deception can vary between:

- unintentional deception: where the practitioner prescribes a placebo, sincerely believing that it is efficacious;

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39 Ev 1 [RPSGB], para 3.08

40 A K Shapiro, "Factors contributing to the placebo effect. Their implications for psychotherapy", *American Journal of Psychotherapy,* vol 18 (1964), pp 73–88

41 A J de Craen, P J Roos, S Leonard de Vrie, J Kleijnen, "Effect of colour of drugs: systematic review of perceived effect of drugs and of their effectiveness", *BMJ*,1996 Dec 21–28, vol 313 (7072) pp 1624–6.

42 A J de Craen, J G P Tijssen, J de Gans and J Kleijnen, "Placebo effect in the acute treatment of migraine: subcutaneous placebos are better than oral placebos", *J Neurol,* 2000, vol 247: pp 83–188

43 Q 126

- paternalistic deception: where the practitioner prescribes a placebo, knowing it is not efficacious but believing that it may be beneficial to the patient; and
- dishonest deception: where the practitioner prescribes a placebo, knowing it is not efficacious, without acting in the patient's best interest (for example, if they have a vested interest in the placebo product or merely wish to send the patient away).

38. Deception arguably abuses the doctor-patient relationship and may undermine trust. It also removes informed patient choice, because the patient is being asked to make decisions under false pretences. It represents a reversal of the welcome and recent approach to treating patients as equals who have the right to make fully informed decisions about treatment options. One could also argue that using placebos is not good medical practice: placebos treat symptoms, not causes, and doctors should be tackling the causes of disease wherever possible. Even where only symptomatic relief is required, doctors should rely on evidence-based, efficacious medicines. Some doctors have argued that they administer placebos to demonstrate to a patient that the condition is psychological,[44] but this misunderstands the power of the placebo effect which can make a patient feel better even when there is a serious underlying condition. (We examine the ethical issues further at paragraph 93 and following.)

39. **We have set out the issue of efficacy and effectiveness at some length to illustrate that a non-efficacious medicine might, in some situations, be effective (patients feel better) because of the placebo effect. That is why we put more weight on evidence of efficacy than of effectiveness.**

40. The placebo effect may manifest when any medical intervention is given and therefore the placebo effect is important in understanding why medical interventions work. **We would expect the Government to have a proper understanding of the power and complexities of the placebo effect and the ethical issues surrounding its use in a clinical setting; otherwise it cannot hope to make good decisions relating to patients and public health.**

Patient satisfaction

41. We received submissions from patients and practitioners testifying to the benefits of homeopathy as well as written submissions citing observational patient studies. We also received requests to take oral evidence from patients who had benefited from homeopathy. These submissions and requests led us to consider carefully what kind of evidence reports of patient satisfaction constituted and whether taking oral evidence from patients was necessary or appropriate.

42. Our key consideration was whether evidence of patient satisfaction would add any insight into whether homeopathy works beyond placebo. This is an issue that the House of Lords Science and Technology Committee considered in detail during its 1999–2000 inquiry on complementary and alternative medicines (CAM). It reported:

44 House of Lords, *Complementary and Alternative Medicine*, Sixth Report of the Select Committee on Science and Technology, Session 1999–2000, HL Paper 123, para 3.21

> We have heard many conflicting opinions on the idea that high levels of patient satisfaction could be used as evidence for a therapy's efficacy. It has been argued by some that such satisfaction is very important […] because much of CAM emphasises patients' participation in the therapy and evaluation of its effects. Many other witnesses have asserted that although patient satisfaction has its place it is not sufficient to justify accepting that a therapy works so that objective rather than subjective evidence is needed. The Academy of Medical Sciences explained why this may be: "It needs to be emphasised that patient satisfaction is not in itself a sufficient estimate of clinical benefit. While it is very important that patients be satisfied with the efforts made on their behalf, it is at least equally important that they should obtain objective benefit. The two do not always go together. For example, patients with peripheral vascular disease, if they go to a practitioner who allows them to continue smoking will show a high patient satisfaction although their outcome will be poor. In contrast, if they are made to stop smoking they are likely to be dissatisfied but their outcome will be much better".[45]

43. Another example of how patient satisfaction may not correlate to the medical intervention might be if a patient seeks treatment for a common cold. The patient's perception of the quality of the consultation and whether a course of treatment has been prescribed may contribute to patient satisfaction, irrespective of whether the treatment itself is effective; the patient would have become better anyway. The House of Lords Committee concluded:

> patient satisfaction has its place as part of the evidence base for CAM but its position is complicated, as Sir Michael Rawlins [Chairman of NICE], explained: "The difficulty, of course, is that very often the anecdotal evidence relates to conditions where there is fluctuation in the clinical course and people who start an intervention at a time when there is a natural resolution of the disease, very understandably, are likely to attribute cause and effect when it may not be. But, on the other hand, there are some anecdotes that are quite clearly important." Therefore, ideally studies should include patient satisfaction as one of a number of measures in evaluating a treatment, but it alone cannot be taken as a proof or otherwise of a treatment's efficacy or as evidence to justify provision.[46]

44. We have already outlined that treatments may seem effective irrespective of whether they are efficacious. Patient satisfaction therefore, does not help us to distinguish between efficacious and placebo treatments; on that basis, it is of less relevance to resolving this issue than randomised controlled trials, and meta-analyses and systematic reviews of RCTs. We agree that patient satisfaction may be relevant to the consideration of the effectiveness of treatments in the real world, rather than efficacy, but its main contribution would be to identify that research may be needed to establish whether there is a real effect.

45 HL Paper (1999–2000) 123, paras 4.21–4.27

46 HL Paper (1999–2000) 123, para 4.27

Homeopathic provings

45. A homeopathic "proving" is the method by which homeopaths determine what symptoms or diseases a product could be used to treat. A proving records the effects of substances, either at concentrated doses or in ultra-dilutions, when given to healthy individuals. Homeopaths use the symptom profiles of substances to prescribe homeopathic remedies to patients on the like-cures-like principle. For example, a proving may demonstrate that coffee keeps people awake and so coffee is used to make a homeopathic remedy to treat insomnia.[47]

46. Provings are not designed to provide evidence of efficacy and homeopaths do not claim that they do.

Summary

47. **Our expectations of the evidence base relevant to government policies on the provision of homeopathy are straightforward. We would expect the Government to have a view on the efficacy of homeopathy so as to inform its policy on the NHS funding and provision of homeopathy. Such a view should be based on the best available evidence, that is, rigorous randomised controlled trials and meta-analyses and systematic reviews of RCTs. If the effects of homeopathy can be primarily attributed to the placebo effect, we would expect the Government to have a view on the ethics of prescribing placebos.**

The evidence check

Scientific plausibility for a mode of action

48. Both critics and supporters of homeopathy have questioned the scientific plausibility of any direct physiological mode of action. For example, the Royal Pharmaceutical Society of Great Britain (RPSGB), which is firmly in the "critic" camp,[48] argues that "no plausible scientific reason has yet been proposed as to why it should work".[49] The Prince's Foundation for Integrated Health, which is more supportive of homeopathy,[50] also notes: "any specific mechanism of action based on extreme dilution is implausible and regarded as unsupportable by the majority of scientists working in this field".[51]

49. There appear to be two main concerns. The first is the principle of like-cures-like and the second is about how ultra-dilutions could retain characteristics of the active ingredient. We deal with each in turn.

47 "What is homeopathy?", *The Society of Homeopaths*, www.homeopathy-soh.org

48 Ev 5, para 3.10

49 Ev 3, para 3.01

50 Ev 179, para 11

51 Ev 179, para 10

Like-cures-like principle

50. The principle of like-cures-like was described by Dr Peter Fisher as analogous to the principle of toxicology hormesis.[52] Professor Edward Calabrese, a toxicology expert from the University of Massachusetts, has described hormesis as "a dose-response relationship phenomenon characterized by low-dose stimulation and high-dose inhibition".[53] In other words, the impact of toxins on physiology depends on dose: substances that are toxic in high doses may be beneficial in low doses. For example, "as the dose of a carcinogen decreases, it reaches a point where the agent actually may reduce the risk of cancer below that of the control group".[54] And this has been likened to the like-cures-like principle central to homeopathy,[55] whereby a substance that causes a particular symptom will cure that symptom if administered at a low dose.

51. There are two aspects of the argument that the like-cures-like principle is based on hormesis that concern us.

a) Over-extrapolation: it is not good scientific practice to conclude that because some substances are harmful at high doses and beneficial at low doses, that all substances behave in the same way; and

b) Provings using ultra-dilutions: the similarity with hormesis breaks down further if provings are carried out using ultra-dilutions. Hormesis is a dose-response: it provides no rationale for expecting an ultra-dilution to cause symptoms in "healthy" people and the same ultra-dilution to cure those symptoms in "unwell" people.

52. We have a further concern about the like-cures-like principle. It is not reasonable to lump "symptoms" into categories independent of physiological causation. For example, there are many different kinds of stimulants—caffeine, nicotine, amphetamines—but the metabolic pathways they use to cause stimulation differ. The principle of like-cures-like overlooks this complication, by holding that any kind of stimulant could, at low enough doses, counteract insomnia. But insomnia is caused by different things, such as pain, hormonal changes, psychological disorders or jet lag as well as the use of stimulants. Treating the symptoms and ignoring the causes is simply not good medical practice.

53. Finally, there are examples of practice. We are concerned by some homeopathic products. For example, it is possible to buy homeopathic products made from body parts such as hip joints and colons, animals such as iguana and dragonfly, and different kinds of sunlight. We are doubly concerned that it is also possible to buy products derived from precious archaeological features such as the Great Wall of China and Stonehenge.[56] We do not understand what symptoms could be induced (and therefore be treated) by these products under the like-cures-like principle.

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52 Ev 22, para 10

53 Edward J Calabrese and Linda A Baldwin, "HORMESIS: The Dose-Response Revolution", *Annual Review of Pharmacology and Toxicology,* April 2003, 43, 175–197

54 Edward J Calabrese, "Hormesis: a revolution in toxicology, risk assessment and medicine", *European Molecular Biology Organization*, Vol 5 (2004), pp S37–S40

55 "What is homeopathy?", *The Society of Homeopaths,* www.homeopathy-soh.org

56 "Helios remedy list 21/1/2010", *Helios Homeopathy Ltd.*, www.helios.co.uk

54. **We conclude that the principle of like-cures-like is theoretically weak. It fails to provide a credible physiological mode of action for homeopathic products. We note that this is the settled view of medical science.**[57]

Ultra-dilutions

55. Under the homeopathic principles, "the greater the dilution, the more potent the medicine".[58] Dr Peter Fisher, Director of the Royal London Homeopathic Hospital, described how homeopathic dilutions are made:

> [They] are prepared by a process of sequential dilution with vigorous shaking at each stage of dilution, known as succussion. Dilution is usually in steps of 1:10 or 1:100, referred to as x or d (decimal) or c (centesimal) respectively.[59]

56. For example, a 30C dilution indicates that the solution has been diluted in the ratio of 1:100, thirty times successively; one drop of the original solution would be diluted with 100 drops of water and the resulting solution would be diluted again, and so on until 30 dilutions had taken place. According to the Prince's Foundation for Integrated Health, in some homeopathic products "not even a single molecule of the original substance remains in the diluted medicine prescribed to the patient".[60]

57. Dr Fisher stated that the process of "shaking is important"[61] but was unable to say how much shaking was required. He said "that has not been fully investigated"[62] but did tell us that "You have to shake it vigorously [...] if you just stir it gently, it does not work".[63]

58. A number of theories have been proposed to explain how water that does not contain a single molecule of the active ingredient can retain the properties of that ingredient and have a physiological action on the patient. The most frequently mentioned in the written evidence is the theory of "molecular memory", which proposes that water can retain some imprint of substances previously dissolved in it. Some of the explanations for how water might remember substances dissolved in it cite electromagnetic properties,[64] frequency imprinting,[65] quantum physics[66] and supra-molecular behaviour of water (that is, large-scale interactions).[67]

59. There are enormous difficulties presented by the notion that water can "remember" substances that have previously been dissolved in it. When substances are dissolved in

57 *For example* Ev 91, para 3.3 [Professor Colquhoun], Ev 117, para 13–14 [Dr Lewis] and Ev 131, para 7 [Professor Marks]

58 "About homeopathy", *British Homeopathic Association*, www.britishhomeopathic.org

59 Ev 21, para 4

60 Ev 179, para 8

61 Q 155

62 Q 157

63 Q 158

64 Ev 128 [Ms Waters]

65 Ev 103 [Mr Smith]

66 "What is homeopathy?", *The Society of Homeopaths,* www.homeopathy-soh.org

67 Ev 96 [Dr Milgrom], para 5.6

water, the water molecules will form structures around the solute molecules; but the hydrogen bonds between water molecules are far too weak and short-lived to hold that structure once the solute has been removed. It is not surprising that experiments that claim to have demonstrated the memory of water have failed to be reproducible.[68] The notion that water could hold imprints of solutions previously dissolved in it is so far removed from current scientific understanding that, as Professor David Colquhoun, Professor of Pharmacology at UCL, put it: "If homeopathy worked the whole of chemistry and physics would have to be overturned".[69] Professor Jayne Lawrence, Chief Scientific Adviser to the RPSGB, put it a little less dramatically:

> I think it probably would be revolutionary if homeopathy was proved to be right, because it does go against a lot of fundamental understanding of science as it stands at the moment.[70]

60. Even if water could retain a memory of previously dissolved substances we know of no explanation for why the sugar-based homeopathic pills routinely dispensed would retain such a memory.

61. **We consider the notion that ultra-dilutions can maintain an imprint of substances previously dissolved in them to be scientifically implausible.**

62. When we asked Professor David Harper, Chief Scientist at the DH, about the scientific plausibility of homeopathy, he agreed with our assessment that there was "a lack of scientific plausibility in how homeopathic remedies might work".[71] However, he added "that is not to say there should not be research into like cures like or molecular memory. I think that is a different thing."[72]

63. We would challenge Professor Harper's comment that research funding should be directed towards exploring theories that are not scientifically plausible. **Research funding is limited and highly competitive. The Government should continue its policy of funding the highest quality applications for important scientific research determined on the basis of peer review.**

64. The Government Chief Scientific Adviser, Professor John Beddington, has told us in unequivocal terms that he is of the view that there is no evidence base for homeopathy.[73] **We recommend that the Government Chief Scientific Adviser and Professor Harper, Chief Scientist at the DH, get together to see if they can reach an agreed position on the question of whether there is any merit in research funding being directed towards the claimed modes of action of homeopathy.**

68 "Could water really have a memory?", *BBC News*, 25 July 2008, www.news.bbc.co.uk

69 Ev 92, para 3.3

70 Q 104

71 Q 200

72 Q 200; we examine the question of research at paragraph 74 and following.

73 Oral evidence taken before the Innovation, Universities, Science and Skills Committee on 5 November 2008, HC (2007–08) 999–iii, Q297

Evidence of efficacy

65. Lack of scientific plausibility is disappointing, but does not necessarily mean that a treatment does not work. What is important is how a treatment performs when tested fairly against a placebo treatment or other treatments. We consider that the best evidence is provided by randomised controlled trials, meta-analyses and systematic reviews of RCTs.

66. We received conflicting opinions on whether homeopathic products are efficacious (that is, whether they work better than a placebo treatment). The British Homeopathic Association (BHA) told us that:

> Four out of five comprehensive systematic reviews of RCTs in homeopathy have reached the qualified conclusion that homeopathy differs from placebo.[74]

67. Professor Edzard Ernst, Director of the Complementary Medicine Group at the Peninsula Medical School, disputed this summary of the evidence in detail. The systematic reviews to which the BHA refers are: Kleijnen *et al*, 1991;[75] Boissel *et al*, 1996;[76] Cucherat *et al*, 2000;[77] Linde *et al*, 1997;[78] and Shang *et al*, 2005.[79] Professor Ernst pointed out that:

> 1. The Kleijnen review is now 18 years old and thus outdated.
>
> 2. Boissel *et al* merely combined p-values[80] of the included studies. This article is now also outdated. Furthermore it is not unambiguously positive.
>
> 3. Cucherat *et al* is the publication of the Boissel document which was a EU-sponsored report. [The authors themselves noted that "there is some evidence that homeopathic treatments are more effective than placebo; however, the strength of this evidence is low because of the low methodological quality of the trials."[81]]
>
> 4. Linde *et al* has been re-analysed by various authors, including Linde himself, and all of the 6 re-analyses (none of which were cited in the BHA's submission) have come out negative.
>
> 5. Shang *et al* very clearly arrived at a devastatingly negative overall conclusion.[82]

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74 Ev 37, para 2.1

75 J Kleijnen, P Knipschild, G Ter Riet, "Clinical trials of homoeopathy", *BMJ, vol 302 (*1991), pp 316–332

76 JP Boissel, M Cucherat, M Haugh, E Gauthier, "Critical literature review on the effectiveness of homoeopathy: overview of the homoeopathic medicine trials*", Homoeopathic Medicine Research Group, Report of the Commission of the European Communities, Directorate-General XII–Science, Research and Development E–RTD Actions: Life Sciences and Technologies–Medical Research,* Brussels, Belgium, 1996

77 M Cucherat, M C Haugh, M Gooch, J P Boissel, "Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials", *European Journal of Clinical Pharmacology*, vol 56 (2000), pp 27–33

78 K Linde, N Clausius,G Ramirez, D Melchart, F Eitel, L V Hedges *et al*., "Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials", *Lancet* 1997, vol 350, pp 834–843

79 A Shang, K Huwiler-Muntener, L Nartey, P Juni, S Dorig, J A Sterne *et al*., "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy", *Lancet* 2005, vol 366, pp 726–732

80 P-values represent the probability that an observed or greater difference occurred by chance, if it is assumed that there is in fact no real difference between the effects of the interventions. If this probability is less than 1/20 (which is when the P value is less than 0.05), then the result is conventionally regarded as being statistically significant.

81 M Cucherat *et al., as above*

82 Ev 51, para 2

68. Professor Ernst also commented on the BHA's claims about reviews that offered positive reviews for allergies,[83] upper respiratory tract infections[84] and rheumatic diseases[85] were equally flawed: the "review" on allergies was a lecture series, not a systematic review; the "reviews" on upper respiratory tract infections were health technology assessments, not systematic reviews, and mostly contained uncontrolled data; and the "review" on rheumatic diseases was not conclusive.[86] Finally, he pointed out that the BHA had omitted several systematic reviews and meta-analyses, each of which "must have been known to the BHA" and "all of them arrived at negative conclusions".[87]

69. The review which we consider the most comprehensive to date is that by Shang *et al*.[88] The review compared 110 placebo-controlled trials of homeopathy matched according to disorder and type of outcome to trials of conventional medicine. The study only included trials that were controlled, included randomised assignment to treatment or placebo groups and were accompanied by sufficient data for odds ratio calculations.[89] The authors concluded that "when analyses were restricted to large trials of higher quality there was no convincing evidence that homeopathy was superior to placebo".[90]

70. **In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos.** The Government shares our interpretation of the evidence. We asked the Minister, Mike O'Brien, whether the Government had any credible evidence that homeopathy works beyond the placebo effect and he responded: "the straight answer is no".[91]

71. We were troubled that the Chief Scientist at the DH seemed to be out of step with the accepted scientific consensus on the question of efficacy. Unlike the Minister,[92] he did not agree that there was no credible evidence that homeopathy worked beyond the placebo effect. He stated that "the majority of independent scientists feel that the evidence is weak or absent"[93] and that there are "real difficulties" in drawing conclusions on efficacy because of a "lack of agreement between experts working in the field".[94] However, we could find no

83 P Bellavite, R Ortolaini, F Pontarolo *et al*, "Immunology and homeopathy. 4. Clinical studies–Part 2", *eCAM,* vol 3 (2006), pp 397–409

84 G Bornhöft, U Wolf, K von Ammon, M Righetti, S Maxion-Bergemann, S Baumgartner *et al*, "Effectiveness, safety and cost-effectiveness of homeopathy in general practice–summarised health technology assessment", *Forsch Komplementmed*, vol 13 (Suppl 2), 2006, pp 19–29; and P Bellavite, R Ortolaini, F Pontarolo *et al*, "Immunology and homeopathy. 4. Clinical studies–Part 1", *eCAM*, vol 3 (2006), pp 397–409

85 W B Jonas, K Linde,G Ramirez, "Homeopathy and rheumatic disease", *Rheum Dis Clin North Am*, vol 26 (2000), pp 117–123

86 Ev 53, para 4

87 Ev 53, para 5

88 A Shang, K Huwiler-Muntener, L Nartey, P Juni, S Dorig, J A Sterne *et al*. "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy", *Lancet,* vol 366 (2005), pp 726–732

89 An odds ratio indicates how likely it is that an event will occur compared to likelihood that the event will not happen. This can be used to show the strength of a relationship between treatment and outcome.

90 Shang A *et al*, *as above*

91 Q 175

92 Qq 174–75

93 Q 176

94 Q 177

support from independent experts for the idea that there is good evidence for the efficacy of homeopathy.

72. The Government Chief Scientific Adviser, Professor John Beddington, was publicly unequivocal about the evidence base for homeopathy when he appeared before us in 2008,[95] but the Chief Scientist at the DH appeared to take a different position. **We recommend that the Government Chief Scientific Adviser and Professor Harper get together to see if they can reach an agreed position on the question of whether there is any good evidence for the efficacy of homeopathy and whether there is a genuine scientific controversy over the efficacy of homeopathy and publish this.**

73. **We regret that advocates of homeopathy, including in their submissions to our inquiry, choose to rely on, and promulgate, selective approaches to the treatment of the evidence base as this risks confusing or misleading the public, the media and policy-makers.**

More research?

74. Robert Wilson, Chairman of the British Association of Homeopathic Manufacturers (BAHM), acknowledged the robust criticisms of the evidence for the efficacy of homeopathy. He told us that there is a "need to have more research into homeopathy; research that can stand up to some of the criticisms that have been placed at it".[96] Dr Robert Mathie, Research Development Adviser for the BHA, shared this view:

> The British Homeopathic Association strongly supports patient choice for treatments that are evidence-based and would propose the development of much greater research in order to secure that evidence base.[97]

75. When asked whether there was room for research using public money on the efficacy of homeopathy, the Minister said:

> Is it worth researching into? I think there is an argument for doing that, yes, given there is NHS money being spent on it and has been over a considerable period of time, so the straight answer to your question is yes.[98]

Professor David Harper, in contrast, told us that:

> If you are talking about randomised clinical trials, I personally do not think that it is an issue of conducting more randomised clinical trials because there are a whole lot that have been done and meta-analyses.[99]

76. Dr Ben Goldacre, a medical doctor and journalist, also disagreed:

95 Oral evidence taken before the Innovation, Universities, Science and Skills Committee on 5 November 2008, HC (2007–08) 999–iii, Q297

96 Q 111

97 Q 162

98 Q 199

99 Q 201

> There have now been around 200 trials of homeopathy against placebo sugar pills and, taken collectively, they show that there is no evidence that homeopathy pills are any better than a placebo. […] it is not worth doing any more placebo controlled trials because you would be throwing good money after bad and you would have to have a huge number of very strongly positive trials to outweigh all of the negative ones.[100]

77. **There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious. Competition for research funding is fierce and we cannot see how further research on the efficacy of homeopathy is justified in the face of competing priorities.**

78. **It is also unethical to enter patients into trials to answer questions that have been settled already. Given the different position on this important question between the Minister and his Chief Scientist, we recommend that the Government Chief Scientific Adviser, Professor John Beddington, investigate whether ministers are receiving effective advice and publish his own advice on this question.**

Effectiveness

79. We proceed on the basis that homeopathy is not supported by evidence of efficacy and is therefore no more than a placebo treatment, albeit a popular one. But before we discuss government policy in relation to the evidence, it is important to consider what evidence there is on the effectiveness of homeopathy.

Patient satisfaction

80. One aspect of effectiveness is patient satisfaction. The popularity of homeopathy indicates that many patients are satisfied. Dr Hugh Nielson, Consultant at the Department of Homeopathic Medicine at the Old Swan Health Centre, highlighted several patient outcome surveys including:

- An observational survey of over 6,500 patients over a 6-year period conducted by Bristol Homeopathic Hospital. 70% of follow-up patients reported improved health, 50% reported a major improvement.[101]

- A survey of 500 patients at the Royal London Homeopathic Hospital showing that many patients were able to reduce or stop conventional medication following homeopathic treatment. For example, 72% of patients reported being able to stop or reduce their conventional medication.[102]

81. Although these surveys show that homeopathy makes some people feel better, it does not, as we have explained, mean that homeopathy is efficacious. The high levels of patient satisfaction could be attributed to the placebo effect, particularly enhanced by three factors:

100 Q 87

101 Ev 158, para 3.1

102 Ev 158, para 3.2

a) Homeopaths treat the kinds of illnesses that clear up on their own (self-limiting) or are susceptible to placebo responses;

b) Individuals who have been treated by homeopaths usually chose homeopathy as a treatment; in other words, they have invested in the process of undergoing homeopathic treatment, probably because they already know that they like it. That means that it is a self-selecting group; and

c) Homeopathic consultations are long and empathetic.[103] In 2001, a systematic review found that that "physicians who adopt a warm, friendly, and reassuring manner are more effective than those who keep consultations formal and do not offer reassurance".[104] Homeopathic consultations may therefore have a positive impact on patients' perception of the intervention and result in a more powerful placebo effect.

82. **We do not doubt that homeopathy makes some patients feel better. However, patient satisfaction can occur through a placebo effect alone and therefore does not prove the efficacy of homeopathic interventions.**

Cost-effectiveness

83. Patient satisfaction alone may not be sufficient to warrant the expenditure of public money on homeopathy. What is important is how the costs and benefits of particular treatments stack up against each other. At a national level it is not possible to evaluate the cost-effectiveness of homeopathy as the cost has not been determined.[105] However, one Primary Care Trust (PCT) has assessed the cost-effectiveness of homeopathy at a local level. In 2007, the NHS West Kent Primary Health Care Trust (PCT), which was responsible for a homeopathic hospital, initiated a review to assess whether the commissioning of homeopathy represented value for money. The consultation process included:

- a systematic review of the high quality evidence base;
- production of a consultation document and related questionnaire—sent to a random sample of 1000 of the PCT's registered patient population in addition to those who requested it directly or received a copy through their personal connection with homeopathy or the Tunbridge Wells Homeopathic Hospital (TWHH);
- a series of public meetings; and
- an audit of all GPs in West Kent.[106]

84. The original public consultation process was challenged in the courts and found to be sufficient. NHS West Kent explained to us that the review "was not about whether homeopathy works but rather whether the NHS, in light of competing priorities, should

103 Q 116 [Professor Ernst]

104 Z di Blasi, E Harkness, E Ernst, A Georgiou, J Kleijnen, "Influence of context effects on health outcomes: a systematic review", *Lancet*., vol 357, no. 9258 (Mar 10, 2001), pp 757–62.

105 See paragraph 13.

106 Ev 35, para 1.6

fund it".[107] The PCT concluded that homeopathy did not represent value for money and took the decision to cease funding for TWHH. It now operates a policy "not to fund routine homeopathy treatment".[108]

85. We asked Dr James Thallon, Medical Director of NHS West Kent, whether the review could be replicated by other PCTs. He considered that:

> our process in terms of its quality and the way that it is done with scrutiny is a good roadmap for other organisations to adopt, and we would be very happy to act as a guide to other commissioning organisations that wish to follow this path.[109]

We then asked Dr Thallon whether the DH should circulate the review to other PCTs. He responded:

> I certainly do not think the issue of the decommissioning of non-evidence based practice should be beneath the Department of Health to help commissioning organisations with. Yes, I would have thought there could well be a role for the Department of Health in helping other organisations get to the point we have got to should they choose to do so.[110]

Dr Thallon did, however, distinguish between PCTs with homeopathic hospitals and those without:

> We are in a particular circumstance because there is a homeopathic hospital within our geographical locality and that is why we had to go to the lengths we did in order to prove the case, […] to do this in every locality would be a diversion of otherwise scarce resources.[111]

86. We were impressed with NHS West Kent's review of the commissioning of homeopathy and consider that it provides a good model for other commissioning organisations, particularly those that fund homeopathic hospitals. **We recommend that the Department of Health circulate NHS West Kent's review of the commissioning of homeopathy to those PCTs with homeopathic hospitals within their areas. It should recommend that they also conduct reviews as a matter of urgency, to determine whether spending money on homeopathy is cost effective in the context of competing priorities.**

Should NICE evaluate homeopathy?

87. Another approach to aiding PCTs would be to have the National Institute of Health and Clinical Excellence (NICE) evaluate homeopathy and produce guidance on whether it

107 Ev 34, para 1.4

108 Ev 37, para 7.1

109 Q 146

110 Q 147

111 Q 146

should be commissioned. We heard several calls for NICE to evaluate homeopathy, including from the British Medical Association[112] and the RPSGB.[113] NICE told us that:

> Topics for guidance development are referred to NICE by the Secretary of State for Health, in line with national priorities established for the NHS—for example; policy importance (i.e. whether the topic falls within a government priority area) and whether there is inappropriate variation in practice across the country.[114]

88. We consider the issue of NICE evaluation important because it ensures patient safety and evidence-based practice. Additionally there is variation in practice across the country with some PCTs funding homeopathy and others not.

89. We asked the Minister whether homeopathy should be evaluated by NICE and he responded:

> I have no objection to NICE evaluating this but they do have a couple of problems with it. Firstly, they have a large queue of drugs that they need to evaluate and there are greater priorities. Secondly, there is a somewhat limited evidential base and before evaluating things NICE want to see an evidential base, and for the reasons we have already discussed it simply is not there at the moment.[115]

90. NICE takes the approach that if there is no good evidence for the efficacy or cost effectiveness of a treatment then the NHS should not use it. This is based in part on the fact that scarce NHS resources should be directed at those treatments that have been shown to work in a cost-effective manner. **We accept that NICE has a large queue of drugs to evaluate and that it may have greater priorities than evaluating homeopathy. However, we cannot understand why the lack of an evidence base for homeopathy might prevent NICE evaluating it but not prevent the NHS spending money on it. This position is not logical.**

Homeopathy on the NHS

91. Discussions about patient satisfaction, cost-benefit analyses and NICE's responsibilities do not resolve what we consider to be the central issue. We have already concluded that homeopathy acts as a placebo and we now consider whether the NHS should be funding placebo treatments.

92. The Government is clearly of the view that the NHS should be free to fund the use of placebo treatments like homeopathy. The Minister told us that:

> [D]octors can, if they feel that there is an ethical and efficacious reason for doing so, prescribe a placebo. It may well be their view that that would assist a particular

112 Ev 194

113 Ev 3, para 2.04

114 Ev 187

115 Q 251

> patient. I think they would have to think carefully about doing it, but I suspect they could probably justify that.[116]

93. In paragraph 38, we laid out a series of reasons why we might consider the use of placebos to be generally unethical. We shall consider each in turn.

Integrity of the doctor-patient relationship

94. In order to maximise the impact of a placebo treatment, the doctor must deceive the patient, telling the patient that he or she is receiving a real treatment. The temptation to do so may be strong, as Dr Goldacre told us:

> [C]ircumstances might occur in which it could arguably be desirable to have the option of prescribing a placebo. There are often situations where an individual may want treatment, for example, but where medicine has little to offer—lots of back pain, stress at work, medically unexplained fatigue, and most common colds, to give just a few examples. Going through a 'theatre' of medical treatment, and trying every medication in the book, will only risk side-effects. A harmless sugar pill in these circumstances may seem to be the sensible option.[117]

95. It was the Minster who most succinctly voiced our concerns about such a practice:

> I would not be happy to be misled and I suspect most patients would not. However, that was not the question you asked me. What you were asking me […] was whether it would be unethical for a doctor ever to prescribe a placebo. […] I thought about it and I took the view that there might be circumstances, but would you generally do it? Of course you would not.[118]

96. We asked Dr Thallon his opinion and he told us:

> I struggle with the notion that it is ethical to prescribe placebos. I am not saying that it does not happen; I think that a number of the ways in which people behave or prescribe could be described as prescribing placebos but, in principle, if you prescribe a drug which you know to have no clinical efficacy on a basis which is essentially dishonest with a patient, I personally feel that that is unethical behaviour.[119]

97. **When doctors prescribe placebos, they risk damaging the trust that exists between them and their patients.**

Patient choice

98. Patient choice is an important concept in modern medicine. Medical practice used to be highly paternalistic, whereby the doctors would know what was best for patients and

116 Q 190

117 Ev 9

118 Q 193

119 Q 120

would prescribe whatever treatments they felt best. Today, doctors are trained to communicate with patients about their treatments and, while providing advice and guidance, ultimately enable patients to make informed choices, where possible, over treatment options and more control over the management of their conditions.

99. Indeed, patient choice was repeatedly cited in written submissions as a reason why homeopathy should be provided on the NHS.[120] The Minister stated:

> I think there is an illiberality in saying that personal choice in an area of significant medical controversy should be completely denied, and I think the Government should be cautious about constraining that illiberality, or interfering with it. We should not take the view that patients should not be able to have homeopathic medicine when they want it.[121]

100. However, patient choice is not simply about patients being able to pick whatever treatments they like. They must understand the implications of their decisions, which means that patient choice must be informed choice. As Professor Ernst put it: "patient choice that is not guided by evidence is not choice but arbitrariness".[122] The RPSGB echoed this view:

> It is essential […] that the patient is given the appropriate information to make these informed choices and as a consequence it should be clear to the patient that there is no scientific evidence for homeopathy.[123]

101. We agree with Professor Ernst and the RPSGB. **For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo—that is, homeopathy—may be diminished. We argue that the provision of homeopathy on the NHS, in effect, diminishes, not increases, informed patient choice.**

Personal health budgets

102. In this context, we raised the issue of the DH's announcement in 2009 of a pilot to test personal health budgets as a way of giving people greater control over the services they use.[124] As part of this scheme, patients might be able to use their personal health budget to spend NHS money on complementary therapies such as homeopathy.[125]

103. We asked whether, through personal health budgets, the Government would be encouraging people to spend NHS money on homeopathy, the Minister replied:

120 *For example*, Ev 140 [Society of Homeopaths] and Ev 151 [Alliance of Registered Homeopaths], para 4

121 Q 248

122 Q 161

123 Ev 3, para 1.11

124 "Personal Health Budgets", *Department of Health,* www.dh.gov.uk

125 "Personal budgets to allow patients to buy homeopathy and acupuncture", *Pulse*, 30 October 2009

> It would depend to some extent on two factors. First, there has to be an agreement on the health package with a GP. Let us say, for the sake of your argument, there was a GP who believed in homeopathy and, therefore, thought this was the right thing to do. Secondly, there would have to be a PCT who was prepared to fund that. There would have to be the agreement of three parties, in effect: the patient, the doctor (the GP) and the PCT. All would have to agree that that funding would be forthcoming for homeopathy. In theory it is possible. Is it going to happen in the next few years? No. Is it possible it could happen in the long term? Theoretically yes, but you would have to get the three to agree.[126]

104. As we understand it, to get homeopathy on the NHS today, the agreement of patient, GP and PCT is already necessary. We fail to see how this arrangement would change with the introduction of personal health budgets: the PCT will continue to have a veto over provision of homeopathy. In our view, the Government should prohibit access to non-evidence-based treatments if it introduces personal health budgets. We see no convincing reason to allow patients to spend public money on placebos such as homeopathy. We also recognise the problem that allowing NHS funding to be spent on non-efficacious and non-cost effective treatments means that NHS money cannot be spent on efficacious and cost-effective treatments. **We recommend that if personal health budgets proceed beyond the pilot stage the Government should not allow patients to buy non-evidence-based treatments such as homeopathy with public money.**

Risk of harm to patients

105. The central aim of medicine is making people better. While placebos may be effective at relieving symptoms (for example, pain), they cannot treat the underlying cause of symptoms (for example, broken bones). There is a risk that a patient whose symptoms improve following homeopathic treatment (because of a placebo effect or because the symptom would have diminished unaided) may delay seeking proper medical diagnosis for future symptoms that may or may not be for a serious underlying condition. Tracey Brown, Managing Director of Sense About Science, pointed out that:

> there is the issue that even minor conditions can sometimes betray a more serious condition. For example, constipation. It sounds harmless to be taking sugar pills for constipation, but actually sometimes that is a symptom of a more serious condition and diagnosis is necessary. So there is the possibility of delayed diagnosis or people believing that they are seeking effective treatment when they are not.[127]

106. We are aware that large numbers of the public may not be aware what homeopathy really is. Sense About Science, which is a charity promoting science and evidence for the public, has monitored public perceptions of homeopathy. In their written submission they told us:

> In 2006 we reviewed discussion about homeopathy and made two observations:

126 Qq 215–16

127 Q 27

a) That it was believed to contain an active ingredient, and was often confused with herbal medicine (and, related to this, that people were often unaware of the mystical belief in water memory and in 'like cures like' on which it is based).

b) That because it was supplied on the National Health Service, it was assumed that it 'must be effective' and 'there must be something in it'.[128]

The charity added that it had come across clinicians and researchers who reported that it was "hard to argue against something that was supplied through the NHS and that appeared to be officially endorsed".[129]

107. We find this worrying. Patients who do not seek medical advice from properly qualified doctors run the risk of missing serious underlying conditions while they have their symptoms treated with a placebo.

108. These are not merely hypothetical concerns. Professor John McLachlan, Professor of Medical Education at the University of Durham, highlighted in his written submission several cases where children had died as a result of their parents rejecting conventional treatments, including for treatable conditions like diabetes.[130] He alerted us to a case in Australia, where a homeopath and his wife were charged with manslaughter by gross criminal negligence when their baby daughter died after they continually treated her with homeopathic remedies instead of conventional medicine. The baby died from eczema which, when left insufficiently treated, depleted her immune system.[131] In the UK, the General Medical Council found a doctor guilty of professional misconduct after he advised a patient to use only homeopathic remedies. The patient subsequently died.[132]

109. **When the NHS funds homeopathy, it endorses it. Since the NHS Constitution explicitly gives people the right to expect that decisions on the funding of drugs and treatments are made "following a proper consideration of the evidence", patients may reasonably form the view that homeopathy is an evidence-based treatment.**

Conclusions

110. The Government's position on homeopathy is confused. On the one hand, it accepts that homeopathy is a placebo treatment. This is an evidence-based view. On the other hand, it funds homeopathy on the NHS without taking a view on the ethics of providing placebo treatments. We argue that this undermines the relationship between NHS doctors and their patients, reduces real patient choice and puts patients' health at risk. **The Government should stop allowing the funding of homeopathy on the NHS.**

111. **We conclude that placebos should not be routinely prescribed on the NHS. The funding of homeopathic hospitals—hospitals that specialise in the administration of**

128 Ev 6, para 2.1

129 Ev 7, para 2.3

130 Ev 101, para 8

131 "Parents guilty of manslaughter over daughter's eczema death", *The Sydney Morning Herald*, 5 June 2009

132 "Alternative cure doctor suspended", *BBC News*, 29 June 2007

placebos—should not continue, and NHS doctors should not refer patients to homeopaths.

3 MHRA licensing

112. Our inquiry also looked at the Medicines and Healthcare products Regulatory Agency (MHRA) licensing regimes for homeopathic products.

The policy

113. We started with the MHRA's purpose. It declares boldly on its website: "What we regulate: Medicines."[133] It continues:

> Whether it's a medicine you buy, or one prescribed for you as part of a course of treatment, it's reassuring to know that all medicines available in the UK are subject to rigorous scrutiny by the MHRA before they can be used by patients. This ensures that medicines meet acceptable standards on safety, quality and efficacy.[133]

114. Normally, medicines are licensed by the MHRA as follows:

- To begin the process, companies and/or researchers must apply to the MHRA for permission to test drugs through clinical trials, if these trials are to be conducted in the UK;
- All the test results from these trials on how well the medicine works and its side effects, plus details of what the medicine contains, how it works in the body, and who it is meant to treat, are then sent to the MHRA for detailed assessment; and
- Once the MHRA is satisfied that the medicine works as it should, and that it is acceptably safe, it is given a marketing authorisation or product licence.[134]

115. Homeopathic products are not subject to this process. As we explained in the previous chapter, homeopathy has a long tradition of use in the UK and homeopathic products were available before a comprehensive regulatory system was introduced. There are currently three licensing regimes in operation for which the MHRA has varying degrees of responsibility. First, the Medicines Act 1968, which required medicines to be licensed before being allowed onto the UK market, led to Product Licences of Right (PLRs) being automatically issued to all products already on the market when the Act was implemented in 1971.[135] Products with PLRs were allowed to stay on the market with their medical indications attached to them.[136]

116. Second, in 1992, the Simplified Scheme for homeopathic medicinal products was introduced under European Directive 92/73/EC. There is no requirement in the Directive (and therefore in the Simplified Scheme) for data to demonstrate clinical efficacy of the product. The scheme is regarded as simplified because its purpose is to ensure the safety

133 "What we regulate: Medicines", *Medicines and Healthcare Products Regulatory Agency*, www.mhra.gov.uk

134 "Medicines and Medical Devices Regulation: What you need to know", *Medicines and Healthcare Products Regulatory Agency*, April 2008, pp 5–6

135 Ev 60 [DH]; Q 210 [Professor Woods]

136 Q 210 [Professor Woods]

and quality of products, not efficacy. Products certified under the Simplified Scheme are not permitted to make medical claims.[137]

117. Third, in 2006, the MHRA sought to address inconsistencies in homeopathic product licensing, where products with PLRs could make medical claims and products certified under the Simplified Scheme could not.[138] Following a public consultation (MLX 312), the MRHA introduced the National Rules Scheme (NRS), the purpose of which, according to the MHRA website,

> is to enable homeopathic medicinal products to be registered with indications for the relief or treatment of minor symptoms and conditions (those that can ordinarily be relieved or treated without the supervision or intervention of a doctor). Applications under the National Rules Scheme must be supported by a dossier of data on quality, safety and efficacy, together with appropriate product labelling and product literature.[139]

Our expectations of the evidence base

118. On the basis of these licensing arrangements for homeopathic products it is clear to us that the "rigorous scrutiny" on safety, quality and efficacy applied by the MHRA before medicines can be used by patients does not apply to homeopathic products. Indeed, in its response to our evidence check questions the Government stated that the "three elements of the licensing regime probably lie outside the scope of [the] Inquiry, because government consideration of scientific evidence was not the basis for their establishment".[140] It explained:

> Firstly, the Product Licences of Right were granted to all existing marketed medicines in 1971, under the provisions of the Medicines Act 1968.
>
> Secondly, the Simplified Scheme derives from European Directive 92/73/EC, so probably lies outside the scope of the Inquiry; and
>
> Thirdly, no scientific evidence was examined in drawing up the National Rules Scheme, which also derives from a European Directive. Definitions of 'product safety' and 'product quality' are commonly understood and did not need to be embedded in the scheme itself. Therefore, the onus to provide supportive scientific evidence is on each individual product that manufacturers put through the scheme—to demonstrate that the product is used as a homeopathic medicine, that it is safe, and that it is of suitable quality.[141]

119. We cannot accept this approach. First, the MHRA, as a regulatory agency, has a responsibility to scrutinise the safety and quality of the medicines and healthcare products that it licenses, and to scrutinise the efficacy of products which make any medical claims

137 "Homoeopathic Medicines", *Medicines and Healthcare products Regulatory Agency*, www.mhra.gov.uk

138 *As above*

139 *As above*

140 Ev 60

141 *As above*

(medical indications). Where there is no evidence of efficacy, or scrutiny of efficacy, we question whether products should make claims or indeed be subject to any MHRA processes or endorsement.[142] Second, there are three licensing regimes—the old PLR, the NRS and normal medicinal licensing—which permit or have permitted medical claims. When the MHRA allows claims to be made we would expect all their licensing approaches to be based on the process outlined in paragraph 114, that is, the same process (requiring evidence of efficacy) that medicines permitted to make medical indications would undergo. Both of these issues feed through to the labelling of homeopathic products, which enable informed choice. Third, the NRS process places an "onus to provide supportive scientific evidence […] on each individual product that manufacturers put through the scheme", which creates the expectation that the MHRA will review the basis of this evidence.

120. The continuation of the PLR scheme is problematic as it allows medical claims to be made. When consulting on whether to introduce the NRS in 2006, the MHRA explained that:

> It was intended to review PLRs against current standards of quality safety and efficacy. In 1973, the UK joined the EU, European legislation came into force and the review of PLRs became mandatory.
>
> By the time of the Review it became obvious that proof of efficacy for homeopathic products would be difficult if clinical trials were required and homeopathics were therefore, exempted from the review and PLRs remain in force. Currently almost 3,000 PLRs are extant.[143]

The Government has told us that PLR licences are next due for review in September 2013 as legislation requires PLRs to be reviewed over a seven-year-period from 1 September 2006 (following the introduction of the NRS).[144]

121. **We are concerned that homeopathic products were, and continued to be, exempted from the requirement for evidence of efficacy and have been allowed to continue holding Product Licences of Right. We recommend that no PLRs for homeopathic products are renewed beyond 2013.**

User-testing of labels for homeopathic products

122. As we outlined in the previous chapter, patient choice is not real choice unless it is informed. The DH, in its written submission to this inquiry, stated that:

> The Government takes the view that consumers who choose to use homeopathic medicines should be fully informed about their purpose.[145]

142 In this Evidence Check the safety and quality of homeopathic products are not examined as (1) it is unlikely that water and sugar pills can be directly unsafe and (2) efficacy is the primary consideration of our Evidence check.

143 "Consultation Document MLX 312; Licensing of homeopathics: Proposals for a new National Rules Scheme and for a review of Product Licences of Right", *Medicines and Healthcare products Regulatory Agency,* 20 June 2005

144 Innovation, Universities, Science and Skills Committee, Ninth report of Session 2008–09, *Putting Science and Engineering at the Heart of Government Policy: Government Response to the Innovation, Universities, Science and Skills Committee's Eighth Report of Session 2008–09*, HC 1036, p 4

Our expectation is that being "fully informed" requires the consumer to have an understanding of the content and efficacy of the homeopathic product and, moreover, not to be misled by the label. Therefore we would expect user-testing of labels for homeopathic products to test whether the participants could determine from the label that:

- the product did not contain any active ingredient (or contained only a few molecules); and
- the product was not proven to be efficacious in the treatment of any medical complaint.

The Evidence Check

Evidence of efficacy

123. In Chapter 2 we reached the conclusion that homeopathy was not efficacious and any perceived effectiveness was in fact solely due to the placebo effect. When we took oral evidence from Professor Woods, Chief Executive of the MHRA, we asked his view on the efficacy of homeopathy and he responded:

> One has to look at the totality of the evidence and in my view there is no single piece of evidence that gives that reassurance. […] In aggregate I do not think there is anything there that one would take as robust evidence of an effect over and above the placebo effect.[146]

124. Professor Woods claimed that the MHRA does not seek evidence of efficacy under the NRS[147] yet the MHRA's guidance on the NRS states:

> The applicant must submit data on the efficacy of the product which is the subject of the application.[148]

The guidance continues:

> It should be noted that results of clinical trials are not required to support applications for marketing authorizations under the National Rules Scheme. However, the applicant must provide one or more of the following:
>
> • Study reports in relation to the product which is the subject of the application;
>
> • Published scientific literature;
>
> • Homeopathic provings.[149]

125. The RPSGB expressed concern that "homeopathic literature can be used as evidence for medical claims despite the fact that it may not have been subjected to the same level

145 Ev 63, para 31

146 Q 182

147 Qq 227–28

148 "The Homeopathic National Rules Scheme: Brief Guidance for Manufacturers and Suppliers", *Medicines and Healthcare products Regulatory Agency*, 2006

149 *As above*

peer review as more main stream scientific literature".[150] It added that "the reliance on such evidence for homeopathic preparations is in stark contrast to the stringent tests that conventional medicines must undergo prior to obtaining a licence".[151] We share the RPSGB's concerns about the evidence that the MHRA accepts in assessing homeopathic products under the NRS. As we made clear in the preceding chapter, homeopathic provings do not provide a sound evidence base for efficacy. Indeed, when we asked Robert Wilson, Chairman of the British Association of Homeopathic Manufacturers (BAHM), whether homeopathic provings represented good evidence, he replied: "No, a homeopathic proving is a technical term for when homeopathic medicines are assessed. It is not a way of doing a trial."[152]

126. We asked Professor Woods why the MHRA accepted provings as evidence. He responded:

> They are not accepted as evidence of efficacy: they are accepted as evidence that this is a product used by homeopaths within the homeopathic tradition for that indication. It does not mean to say we endorse that indication; it is simply a marker that that product is used within the homeopathic community for the purpose for which the homeopath wishes to use it.[153]

127. On the basis of Professor Woods' evidence, we found the reference in the NRS's guidance to efficacy misconceived and confusing. In our view the juxtaposition of efficacy with provings could establish an implication that homeopathic provings are acceptable as evidence of efficacy, which is unsupported by the evidence. The MHRA subjects neither homeopathic products nor provings to the analysis it applies to conventional medicines. Given that homeopathic products are pills that consist of sugar and water we cannot see how the MHRA could apply credible scientific assessments of efficacy that showed any result other than the placebo effect.

128. The absence of a requirement to show evidence of efficacy means that the MHRA's current arrangements would allow a person to seek, for example, a licence for a confectionary product as long as he or she persuaded a number of people that it was a homeopathic product with therapeutic effects. Such a development would, rightly, bring the licensing arrangements into disrepute. We are concerned that the lack of rigour in the MHRA's licensing processes by, for example, allowing the use of provings is allowing homeopathic products to build medical claims unsupported by any evidence. **We conclude that the MHRA should seek evidence of efficacy to the same standard for all the products examined for licensing which make medical claims and we recommend that the MHRA remove all references to homeopathic provings from its guidance other than to make it clear that they are not evidence of efficacy.**

150 Ev 2, para 1.06

151 *As above*

152 Q 36

153 Q 212

The purpose of the National Rules Scheme

129. Given that the NRS is not based on evaluating or assuring the efficacy of homeopathic treatments we probed what purpose the NRS served. In 2006, the MHRA recommended to Government the introduction of the NRS in response to European Directive 2001/83. Ms Brown from Sense About Science explained that:

> the EC Directive makes provision for national agencies to introduce their own national rules. Under the EC Directive it would have been perfectly acceptable to require homeopathic products to go through the same licensing procedures as other products if they wanted to make medicinal claims, so it was not the only option.[154]

130. The MHRA held a public consultation (MLX 312) prior to introducing the scheme. The MHRA invited responses to their basic proposals for the NRS as well as the four possible options for handling existing PLRs:

- Option 1: Do nothing;
- Option 2: Revoke all PLRs, forcing products to apply for licences under the Simplified Scheme or new NRS;
- Option 3: Revoke all PLRs and force products to apply for licences under the new NRS; and
- Option 4: Renew and keep PLRs (reviewing those for more serious conditions), while encouraging companies to consider applying for new licences instead.[155]

131. Ms Brown told us:

> from a public health point of view none of these options has a rationale in terms of public health, they all have a rationale in terms of the industry, […] So that is why they preferred option four—it allowed indications and levelled the playing field for the industry; there was no other justification.[156]

132. We noted that some consultation respondents (including those classed by the MHRA as supportive of the scheme) were concerned about the lack of evidence behind homeopathy and the introduction of a scheme that would permit medical indications.[157] In response to this concern the MHRA stated:

> The National Rules scheme does not endorse clinical efficacy of homeopathic products, as clinical efficacy is understood in the context of conventional pharmaceutical medicines.[158]

133. The MLX 312 consultation document explained that:

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154 Q 46

155 "Consultation Document MLX 312; Licensing of homeopathics: Proposals for a new National Rules Scheme and for a review of Product Licences of Right", *Medicines and Healthcare products Regulatory Agency,* 20 June 2005

156 Q 50

157 Ev 77–89

158 *As above*

> Our proposals will benefit both the general public, by strengthening the public health protection of users of homeopathic medicinal products and the homeopathic industry by levelling the playing field and increasing the range of products that can be marketed. The associated increase in costs for MHRA and the homeopathic industry are offset against the benefits outlined above.
>
> The risk of leaving things is that the expansion of the homeopathic industry will be inhibited by the prevention of the development of new products with indications.[159]

134. Yet when we asked Professor Woods whether the NRS was introduced to facilitate the growth of the homeopathic industry, he responded:

> No, and, if it were, it has failed because since the National Rule Scheme was introduced we have exactly one product registered under it since 2006.[160]

135. We have two concerns about the consultation (MLX 312) which led to the introduction of the NRS. First, although derived from an EC Directive, the MHRA had some freedom to design the regulatory regime. It could have pursued the logical route of requiring evidence of efficacy for products whose labelling could make medical claims, or what would be perceived by the public to be medical claims, to be in line with the requirement for medical products. Second, respondents' concerns about lack of evidence behind homeopathy were largely brushed aside. Having looked at the evidence we fail to understand why the MHRA threw away the opportunity, when formulating the NRS for homeopathic products, to make efficacy supported by clinical evidence a requirement before medical claims were allowed. **We consider that the MHRA's consultation, which led to the introduction of the NRS, was flawed and we remain unconvinced that the NRS was designed with a public health rationale.**

Labelling of homeopathic products

136. The MHRA licensing regime regulates what can be written on the label of a homeopathic product. Dr Goldacre considered that:

> The MHRA approved label on homeopathy sugar pills is misleading. A great deal of effort has gone into making patient literature, leaflets, and labels more easily understood, explaining the benefits and risks of treatments clearly, so it seems perverse and anomalous that the MHRA have settled on a plainly misleading convention for labelling these homeopathic sugar pills. The MHRA may deploy sophistry, or invoke technical readings of the statements, but the public read these labels as saying that the homeopathic sugar pills are effective for the conditions listed.[161]

159 "Consultation Document MLX 312; Licensing of homeopathics: Proposals for a new National Rules Scheme and for a review of Product Licences of Right", *Medicines and Healthcare products Regulatory Agency,* 20 June 2005

160 Q 210

161 Ev 9

137. Currently, under the Simplified Scheme, homeopathic product labels must include the phrase "Homeopathic medicinal product without approved therapeutic indications".[162] We asked Professor Woods about the labelling on Arnica Montana 30C, the only product currently granted a licence under the NRS. Professor Woods explained that:

> The descriptor on the packet says […]: 'A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches, bruising and swelling'. That is what we wish to confirm and this is used within the homeopathic tradition for that purpose. It is not the same as us accepting it as evidence.[163]

138. We have two concerns about this label. First, the mere use of a product in the homeopathic tradition, without any actual evidence of efficacy, does not provide any information as to whether a product actually works, and therefore is a poor basis for allowing medical indications on a product label. Second, we are concerned about how the public would interpret the label. We asked Professor Woods whether the average person would conclude from the labelling that the product worked for symptomatic relief of the listed minor conditions or whether they would realise there was no evidence of efficacy. He replied:

> [B]y law all packaging and patient information leaflets are subjected to user testing to ensure that they are comprehensible to the man in the street, and indeed that seems to be a very straightforward statement of the reality. This is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising or swelling after contusions. That is what it says and the user testing is part of the approval of that leaflet, has the labelling been tested on the average man in the street.[164]

139. We were not reassured by this answer and so we requested further information on the MHRA's user testing of the Arnica Montana 30C product label. The MHRA explained in a supplementary memorandum that as part of the label testing on Arnica, they carried out three rounds of user tests, in each round asking 10 participants a set of questions.[165] The questions included the following:

a) What does the label say that this medicine is for?

b) What does the label say is the active ingredient in this medicine?

c) This medicine contains Arnica Montana 30C. What are the other ingredients in this medicine?

140. In our view, these questions are problematic. Question a) implies that the product can be used to treat the ailment in question. Questions b) and c) imply to participants that there is an active ingredient. On the evidence of these questions it appears to us that the

162 "UK Homeopathic Registration and National Rules Scheme Guidance Notes: note on labelling requirements for homeopathic products", *Medicines and Healthcare products Regulatory Agency*, 2009

163 Q 227

164 Q 229

165 Ev 90

MHRA is encouraging participants in the survey to come to the conclusion that the product contains an active ingredient that can be used to provide relief of sprains, muscular aches and bruising or swelling after contusions, which is contrary to what Professor Woods told us was the intention and effect of the label. On the assumption that this is what most of the participants concluded **we fail to see why the label test design should be acceptable to the MHRA given that, first, it considers that homeopathic products have no effect beyond placebo and, second, Arnica Montana 30C contains no active ingredient and there is no scientific evidence that it has been demonstrated to be efficacious. We conclude that the user-testing of the Arnica Montana 30C label was poorly designed with parts of the test actively misleading participants. In our view the MHRA's testing of the public's understanding of the labelling of homeopathic products is defective.**

141. As a Committee we are strong advocates of evidence-based decision-making and we are firmly of the view that members of the public should have the opportunity to make evidence-based decisions about their health. It follows that all patients should be informed about the lack of evidence of efficacy for homeopathic products, most crucially at the point of sale, so that they can make an informed choice. The current labelling arrangements fail to provide patients with the information to make informed choices about homeopathic products. **If the MHRA is to continue to regulate the labelling of homeopathic products, which we do not support, we recommend that the tests are redesigned to ensure and demonstrate through user testing that participants clearly understand that the products contain no active ingredients and are unsupported by evidence of efficacy, and the labelling should not mention symptoms, unless the same standard of evidence of efficacy used to assess conventional medicines has been met.**

The role of pharmacies

142. Homeopathic products are available to buy over-the-counter in pharmacies, which provide advice to many enquiring about homeopathic products. Pharmacists are required to provide advice on complementary therapies and medicines, in accordance with guidance from the RPSGB, particularly the Professional Standards and Guidance for the Sale and Supply of Medicines, which advises pharmacists:

> You must ensure that you are competent in any area in which you offer advice on treatment or medicines. If you sell or supply homeopathic or herbal medicines, or other complementary therapies, you must:
>
> 1) assist patients in making informed decisions by providing them with necessary and relevant information
>
> 2) ensure any stock is obtained from a reputable source
>
> 3) recommend a remedy only where you can be satisfied of its safety and quality, taking into account the Medicines and Healthcare products Regulatory Agency registration schemes for homeopathic and herbal remedies.[166]

166 "Professional Standards and Guidance for the Sale and Supply of Medicines", *Royal Pharmaceutical Society of Great Britain*, April 2009, para 8

143. Boots is the leading pharmacy chain in the UK and is a well recognised retailer and brand. The pharmacy section of Boots sells a range of complementary and alternative medicines, including homeopathic products. We asked Paul Bennett, Professional Standards Director at Boots, why they sold homeopathic products. Mr Bennett replied:

> It is about consumer choice for us. A large number of our consumers actually do believe they are efficacious, but they are licensed medicinal products and, therefore, we believe it is right to make them available.[167]

144. Beyond the issue of consumer choice, Professor Lawrence, Chief Scientific Adviser for the RPSGB, considered there were reasons why pharmacies should continue to sell homeopathic products:

> We would contest it is better for the patient for pharmacists to be present […] because they are able, if appropriate, to offer advice to that patient, and there are two things that are important. It is important that patients should realise there is not any evidence for the particular preparations and, also, it gives the pharmacist an opportunity to ensure that the patient is not actually taking something unnecessary.[168]

We found this response unsatisfactory. As the RPSGB takes the view that "there is no scientific or clinical evidence to support homeopathy"[169] the only advice pharmacists could give is that the products are placebos. Pharmacists should ensure that patients with symptoms that may require further medical investigation and treatment are not led to believe that a homeopathic remedy is effective beyond the placebo effect. The RPSGB itself has described pharmacists as "scientists in the high street"[170] and therefore has a particular responsibility to ensure that pharmacists provide scientifically accurate advice to patients.

145. The RPSGB had concerns about the possibly legitimisation of homeopathy caused by the sale of products through pharmacies. It pointed out in its written submission that:

> the current Government policy of allowing indications for homeopathic preparations intended for over the counter sale, may be seen to legitimising the practice of homeopathy and may prompt some patients to use, for example, homeopathic preparations for malaria prophylaxis, treatment of HIV, TB, influenza, childhood diarrhoea or in place of immunisation.[171]

146. Although the availability of homeopathic products in pharmacies could be interpreted by patients as an endorsement of efficacy, in our view it would be pointless to seek to remove homeopathic products from sale in pharmacies. Many pharmacies sell ranges of non-evidence-based products and homeopathic products are easily available over the internet in any case. **We consider that the way to deal with the sale of homeopathic**

167 Q 5

168 Q 60

169 Ev 5, para 3.10

170 For example, "Scientist in the High Street campaign: factsheets", *Royal Pharmaceutical Society of Great Britain*, www.rpsgb.org

171 Ev 3, para 1.12

products is to remove any medical claim and any implied endorsement of efficacy by the MHRA—other than where its evidential standards used to assess conventional medicines have been met—and for the labelling to make it explicit that there is no scientific evidence that homeopathic products work beyond the placebo effect.

Enforcement of the RPSGB's guidelines

147. We asked Professor Lawrence how the RPSGB became aware of breaches of Professional Standards and Guidance for the Sale and Supply of Medicines. She explained that:

> One of them is through the Society's inspectorate which visits the shops on an occasional basis, and one of their roles is to check that the pharmacists are adhering to ethical guidelines.[172]
>
> The other way is from complaints from perhaps a member of the public.[173]

148. We also asked Professor Lawrence how pharmacies breaching the RPSGB's guidelines were disciplined. In 2006, a BBC Newsnight investigation revealed that some homeopathic pharmacies were claiming that their products could treat malaria, in place of conventional anti-malarial drugs.[174] Professor Lawrence was not able to tell us whether this investigation had concluded.[175] We are concerned that the investigation of a case that began in 2006 is taking so long to resolve.

149. Concerns were raised that these were not isolated cases. Dr Andy Lewis told us, in his written evidence, that:

> Homeopathic pharmacies are full of products with direct and implied claims. […] Visiting a homeopathic pharmacy website will show many products with implied indications. […] The remedy lists of Ainsworths show products for each Influenza strain going back 20 years. You will find homeopathic replacements for Measles vaccine, Parotitis vaccine (mumps) and Rubella. You find homeopathic sugar pills for all forms of Hepatitis, strains of TB, and Typhoid.[176]

150. We asked Professor Lawrence if she could assure us that pharmacies are not selling homeopathic anti-malarial prophylaxis[177] in the absence of conventional evidence-based prophylaxis and she replied:

> Obviously I cannot assure you that every pharmacy is not, but I can assure you that the pharmaceutical society has made it very clear to its members that it is completely inappropriate to use homeopathy for the treatment of malaria.[178]

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172 Q 63

173 Q 64

174 "Malaria advice 'risks lives'", *BBC Newsnight*, 13 July 2006

175 Qq 69–70

176 Ev 118, para 9

177 Prophylaxis is preventative medicine.

178 Q 71

151. **Although it goes wider than the scope of this Evidence Check inquiry we must put on record our concern about the length of time the RPSGB appears to be taking to investigate and reach conclusions on cases where it has been alleged that its guidelines on the sale of homeopathic products have been breached. We recommend that the Government enquires into whether the RPSGB, and from the 2010 handover, the General Pharmaceutical Council, is doing an adequate job in respect of the time taken to pursue complaints.**

Conclusions on the licensing regimes

152. The MHRA, with commendable frankness, told our inquiry that it does not consider that homeopathic medicines have efficacy beyond placebo. The evidence we received during this inquiry supports that conclusion. On that basis, the tests that the MHRA uses to assess non-homeopathic medical products would mean that no homeopathic products would be licensed by the MHRA. Instead of introducing a blanket requirement for evidence of efficacy, the MHRA operates three licensing regimes for homeopathic products, in part, for historical reasons and, in part, it appears, to support the homeopathic industry. **It is unacceptable for the MHRA to license placebo products—in this case sugar pills—conferring upon them some of the status of medicines. Even if medical claims on labels are prohibited, the MHRA's licensing itself lends direct credibility to a product. Licensing paves the way for retail in pharmacies and consequently the patient's view of the credibility of homeopathy may be further enhanced. We conclude that it is time to break this chain and, as the licensing regimes operated by the MHRA fail the Evidence Check, the MHRA should withdraw its discrete licensing schemes for homeopathic products.**

4 Conclusions

153. This second Evidence Check has been an interesting exercise, and quite different to Evidence Check 1: Early Literacy Interventions. By conducting this inquiry we have attracted a great deal more public interest and controversy and have found that views on homeopathy are more polarised.

154. We welcome the Government's acknowledgement that there is no credible evidence of efficacy for homeopathy, which is an evidence-based view. However, the Government's view has not translated into evidence-based policies.

155. The NHS funds homeopathy and has done so since 1948. We were disappointed that, in light of its view on evidence for homeopathy, the Government has no appetite to review its policies in favour of an evidence-based approach. The Government was reluctant to address the issues of informed patient choice or the appropriateness and ethics of prescribing placebos to patients.

156. The MHRA licenses homeopathic products under three different licensing schemes. These arrangements in part arose through a historical legacy inherited by the MHRA. We were concerned, however, that in introducing the National Rules Scheme in 2006, the MHRA chose not to take a rigorous, evidence-based approach to licensing of homeopathic products. The MHRA's justification for introducing a scheme permitting products to make medical indications—that the product labelling was stringently tested to ensure patients would understand the purpose of the product—was not evidence-based.

157. **By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy. Homeopathy should not be funded on the NHS and the MHRA should stop licensing homeopathic products.**

Conclusions and recommendations

The policy on NHS funding and provision of homeopathy

1. We recommend that the Government determine the total amount of money spent by the NHS on homeopathy annually over the past 10 years, differentiating homeopathic products, patient referrals and maintenance and refurbishment of homeopathic hospitals, and publish the figures. (Paragraph 15)

Our expectations of the evidence base

2. We consider that conclusions about the evidence on the efficacy of homeopathy should be derived from well designed and rigorous randomised controlled trials (RCTs). (Paragraph 20)

3. We expect the conclusions on the evidence for the efficacy of homeopathy to give particular weight to properly conducted meta-analyses and systematic reviews of RCTs. (Paragraph 25)

4. We have set out the issue of efficacy and effectiveness at some length to illustrate that a non-efficacious medicine might, in some situations, be effective (patients feel better) because of the placebo effect. That is why we put more weight on evidence of efficacy than of effectiveness. (Paragraph 39)

5. We would expect the Government to have a proper understanding of the power and complexities of the placebo effect and the ethical issues surrounding its use in a clinical setting; otherwise it cannot hope to make good decisions relating to patients and public health. (Paragraph 40)

6. Our expectations of the evidence base relevant to government policies on the provision of homeopathy are straightforward. We would expect the Government to have a view on the efficacy of homeopathy so as to inform its policy on the NHS funding and provision of homeopathy. Such a view should be based on the best available evidence, that is, rigorous randomised controlled trials and meta-analyses and systematic reviews of RCTs. If the effects of homeopathy can be primarily attributed to the placebo effect, we would expect the Government to have a view on the ethics of prescribing placebos. (Paragraph 47)

The evidence check: NHS funding and provision

7. We conclude that the principle of like-cures-like is theoretically weak. It fails to provide a credible physiological mode of action for homeopathic products. We note that this is the settled view of medical science. (Paragraph 54)

8. We consider the notion that ultra-dilutions can maintain an imprint of substances previously dissolved in them to be scientifically implausible. (Paragraph 61)

9. Research funding is limited and highly competitive. The Government should continue its policy of funding the highest quality applications for important scientific research determined on the basis of peer review. (Paragraph 63)

10. We recommend that the Government Chief Scientific Adviser and Professor Harper, Chief Scientist at the DH, get together to see if they can reach an agreed position on the question of whether there is any merit in research funding being directed towards the claimed modes of action of homeopathy. (Paragraph 64)

11. In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos. (Paragraph 70)

12. We recommend that the Government Chief Scientific Adviser and Professor Harper get together to see if they can reach an agreed position on the question of whether there is any good evidence for the efficacy of homeopathy and whether there is a genuine scientific controversy over the efficacy of homeopathy and publish this. (Paragraph 72)

13. We regret that advocates of homeopathy, including in their submissions to our inquiry, choose to rely on, and promulgate, selective approaches to the treatment of the evidence base as this risks confusing or misleading the public, the media and policy-makers. (Paragraph 73)

14. There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious. Competition for research funding is fierce and we cannot see how further research on the efficacy of homeopathy is justified in the face of competing priorities. (Paragraph 77)

15. It is also unethical to enter patients into trials to answer questions that have been settled already. Given the different position on this important question between the Minister and his Chief Scientist, we recommend that the Government Chief Scientific Adviser, Professor John Beddington, investigate whether ministers are receiving effective advice and publish his own advice on this question. (Paragraph 78)

16. We do not doubt that homeopathy makes some patients feel better. However, patient satisfaction can occur through a placebo effect alone and therefore does not prove the efficacy of homeopathic interventions. (Paragraph 82)

17. We recommend that the Department of Health circulate NHS West Kent's review of the commissioning of homeopathy to those PCTs with homeopathic hospitals within their areas. It should recommend that they also conduct reviews as a matter of urgency, to determine whether spending money on homeopathy is cost effective in the context of competing priorities. (Paragraph 86)

Should NICE evaluate homeopathy?

18. We accept that NICE has a large queue of drugs to evaluate and that it may have greater priorities than evaluating homeopathy. However, we cannot understand why the lack of an evidence base for homeopathy might prevent NICE evaluating it but

not prevent the NHS spending money on it. This position is not logical. (Paragraph 90)

Homeopathy on the NHS

19. When doctors prescribe placebos, they risk damaging the trust that exists between them and their patients. (Paragraph 97)

20. For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo—that is, homeopathy—may be diminished. We argue that the provision of homeopathy on the NHS, in effect, diminishes, not increases, informed patient choice. (Paragraph 101)

21. We recommend that if personal health budgets proceed beyond the pilot stage the Government should not allow patients to buy non-evidence-based treatments such as homeopathy with public money. (Paragraph 104)

22. When the NHS funds homeopathy, it endorses it. Since the NHS Constitution explicitly gives people the right to expect that decisions on the funding of drugs and treatments are made "following a proper consideration of the evidence", patients may reasonably form the view that homeopathy is an evidence-based treatment. (Paragraph 109)

23. The Government should stop allowing the funding of homeopathy on the NHS. (Paragraph 110)

24. We conclude that placebos should not be routinely prescribed on the NHS. The funding of homeopathic hospitals—hospitals that specialise in the administration of placebos—should not continue, and NHS doctors should not refer patients to homeopaths. (Paragraph 111)

Product Licences of Right

25. We are concerned that homeopathic products were, and continued to be, exempted from the requirement for evidence of efficacy and have been allowed to continue holding Product Licences of Right. We recommend that no PLRs for homeopathic products are renewed beyond 2013. (Paragraph 121)

The evidence check: licensing

26. We conclude that the MHRA should seek evidence of efficacy to the same standard for all the products examined for licensing which make medical claims and we recommend that the MHRA remove all references to homeopathic provings from its guidance other than to make it clear that they are not evidence of efficacy. (Paragraph 128)

27. We consider that the MHRA's consultation, which led to the introduction of the NRS, was flawed and we remain unconvinced that the NRS was designed with a public health rationale. (Paragraph 135)

28. We fail to see why the label test design should be acceptable to the MHRA given that, first, it considers that homeopathic products have no effect beyond placebo and, second, Arnica Montana 30C contains no active ingredient and there is no scientific evidence that it has been demonstrated to be efficacious. We conclude that the user-testing of the Arnica Montana 30C label was poorly designed with parts of the test actively misleading participants. In our view the MHRA's testing of the public's understanding of the labelling of homeopathic products is defective. (Paragraph 140)

29. If the MHRA is to continue to regulate the labelling of homeopathic products, which we do not support, we recommend that the tests are redesigned to ensure and demonstrate through user testing that participants clearly understand that the products contain no active ingredients and are unsupported by evidence of efficacy, and the labelling should not mention symptoms, unless the same standard of evidence of efficacy used to assess conventional medicines has been met. (Paragraph 141)

The role of pharmacies

30. We consider that the way to deal with the sale of homeopathic products is to remove any medical claim and any implied endorsement of efficacy by the MHRA—other than where its evidential standards used to assess conventional medicines have been met—and for the labelling to make it explicit that there is no scientific evidence that homeopathic products work beyond the placebo effect. (Paragraph 146)

31. Although it goes wider than the scope of this Evidence Check inquiry we must put on record our concern about the length of time the RPSGB appears to be taking to investigate and reach conclusions on cases where it has been alleged that its guidelines on the sale of homeopathic products have been breached. We recommend that the Government enquires into whether the RPSGB, and from the 2010 handover, the General Pharmaceutical Council, is doing an adequate job in respect of the time taken to pursue complaints. (Paragraph 151)

Conclusions on the licensing regimes

32. It is unacceptable for the MHRA to license placebo products—in this case sugar pills—conferring upon them some of the status of medicines. Even if medical claims on labels are prohibited, the MHRA's licensing itself lends direct credibility to a product. Licensing paves the way for retail in pharmacies and consequently the patient's view of the credibility of homeopathy may be further enhanced. We conclude that it is time to break this chain and, as the licensing regimes operated by the MHRA fail the Evidence Check, the MHRA should withdraw its discrete licensing schemes for homeopathic products. (Paragraph 152)

Overall conclusion

33. By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy. Homeopathy should not be funded on the NHS and the MHRA should stop licensing homeopathic products. (Paragraph 157)

Formal Minutes

Monday 8 February 2010

Members present:

Mr Phil Willis, in the Chair

Mr Tim Boswell
Mr Ian Cawsey
Dr Evan Harris
Dr Doug Naysmith
Ian Stewart

1. Evidence Check 2: Homeopathy

The Committee considered this matter.

Draft Report (*Evidence Check 2: Homeopathy*), proposed by the Chairman, brought up and read.

Motion made, and Question proposed, That the draft Report be read a second time, paragraph by paragraph.

Amendment proposed, to leave out from "That" to the end of the question and add "this Committee declines to read the report a second time because it contains an evaluation of homeopathy which is outside the terms of reference of the inquiry as published by the Committee on 20 October 2009 and instead decides to write to the Government to call on it to fund a rigorous research programme into homeopathy." instead thereof.—(*Ian Stewart.*)

Question put, That the Amendment be made.

The Committee divided.

Ayes, 1
Ian Stewart

Noes, 3
Mr Ian Cawsey
Dr Evan Harris
Dr Doug Naysmith

Main Question put and agreed to.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 76 read and agreed to.

Paragraph 77 read.

Question put That the paragraph stand part of the Report.

The Committee divided.

Ayes, 3
Mr Ian Cawsey
Dr Evan Harris
Dr Doug Naysmith

Noes, 1
Ian Stewart

Paragraph agreed to.

Paragraphs 78 to 157 read and agreed to.

Summary brought up and read as follows:

This inquiry, our second Evidence Check, asks whether the Government's policies on the provision of homeopathy through the NHS and the licensing of homeopathic products by the MHRA are evidence-based. It is not an evaluation of homeopathy itself.

The Government does not consider that there is any credible evidence of efficacy for homeopathy, which, we found, to be an evidence-based view. That there is no plausible evidence to show that homeopathy is efficacious but there is a body of opinion that it is effective, means homeopathy fits the profile of a placebo, or dummy, treatment. While acknowledging the lack of evidence, the Government has not, however, based its policies on homeopathy being a placebo. Indeed, the Government is content to fence homeopathy off within the NHS and to place a "keep out" notice on the gate. We cannot accept this approach to the formulation or scrutiny of policy. Either homeopathy is an evidence-based treatment subject to the same tests as conventional treatments or it is a placebo and should therefore be subject to NHS policy on placebos.

The problem is, however, that it appears the NHS has no policy on placebos. The placebo effect is unreliable and addresses symptoms not the causes of illness. The use of placebos also poses serious ethical issues as it partly relies on deception of patients. Speaking personally, the Minister for Health Services considered the use of placebo treatments to be "unethical". We share his misgivings, as would most patients if they knew that the evidence showed, and the Government considered, homeopathy to be a placebo treatment. We conclude that homeopathy should therefore no longer be available on the NHS.

Similar considerations applied when we examined the licensing of homeopathic products by the MHRA. Homeopathic products are regulated through three licensing schemes, none of which require evidence of clinical efficacy, yet two of the schemes permit medical indications on the label. The product labelling fails to inform the public that homeopathic products are sugar pills containing no active ingredients. The licensing regimes and deficient labelling lend a spurious medical legitimacy to homeopathic products. We call for the MHRA to cease licensing homeopathic products.

We conclude that the Government's policies on the provision of homeopathy through the NHS and licensing of homeopathic products are not evidence-based. Indeed the policies run counter to the evidence.

Question put That the summary be added to the Report.

The Committee divided.

Ayes, 1	Noes, 3
Ian Stewart	Mr Ian Cawsey
	Dr Evan Harris
	Dr Doug Naysmith

Summary disagreed to.

Motion made, and Question put, That the Report be the Fourth Report of the Committee to the House.

The Committee divided.

Ayes, 3	Noes, 1
Mr Ian Cawsey	Ian Stewart
Dr Evan Harris	
Dr Doug Naysmith	

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

[Adjourned till Wednesday 10 February at 9.00 am

Witnesses

Wednesday 25 November 2009

Page

Monday 30 November 2009

List of written evidence

List of unprinted evidence

The following memoranda have been reported to the House, but to save printing costs they have not been printed and copies have been placed in the House of Commons Library, where they may be inspected by Members. Other copies are in the Parliamentary Archives, and are available to the public for inspection. Requests for inspection should be addressed to The Parliamentary Archives, Houses of Parliament, London SW1A 0PW (tel. 020 7219 3074). Opening hours are from 9.30 am to 5.00 pm on Mondays to Fridays.

HO 38a Judith Ford (supplementary)

HO 57a and HO 57b Carol Boyce

List of Reports from the Committee during the current Parliament

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2009–10

First Report	The work of the Committee in 2008–09	HC 103
Second Report	Evidence Check 1: Early Literacy Interventions	HC 44
Third Report	The Government's review of the principles applying to the treatment of independent scientific advice provided to government	HC 158-I
Fourth Report	Evidence Check 2: Homeopathy	HC 45

Session 2008–09

First Report	Re-skilling for recovery: After Leitch, implementing skills and training policies	HC 48–I (HC 365)
Second Report	The Work of the Committee 2007–08	HC 49
Third Report	DIUS's Departmental Report 2008	HC 51–I (HC 383)
Fourth Report	Engineering: turning ideas into reality	HC 50–I (HC 759)
Fifth Report	Pre-appointment hearing with the Chair-elect of the Economic and Social Research Council, Dr Alan Gillespie CBE	HC 505
Sixth Report	Pre-appointment hearing with the Chair-elect of the Biotechnology and Biological Sciences Research Council, Professor Sir Tom Blundell	HC 506
Seventh Report	Spend, spend, spend? – The mismanagement of the Learning and Skills Council's capital programme in further education colleges	HC 530 (HC 989)
Eighth Report	Putting Science and Engineering at the Heart of Government Policy	HC 168–I (HC 1036)
Ninth Report	Pre-appointment hearing with the Chair-elect of the Science and Technology Facilities Council, Professor Michael Sterling	HC 887
Tenth Report	Sites of Special Scientific Interest	HC 717 (HC 990)
Eleventh Report	Students and Universities	HC 170–I (HC 991)

Session 2007–08

First Report	UK Centre for Medical Research and Innovation	HC 185 (HC 459)
Second Report	The work and operation of the Copyright Tribunal	HC 245 (HC 637)
Third Report	Withdrawal of funding for equivalent or lower level qualifications (ELQs)	HC 187–I (HC 638)
Fourth Report	Science Budget Allocations	HC 215 (HC 639)
Fifth Report	Renewable electricity-generation technologies	HC 216–I (HC 1063)
Sixth Report	Biosecurity in UK research laboratories	HC 360–I (HC 1111)
Seventh Report	Pre-legislative Scrutiny of the Draft Apprenticeships Bill	HC 1062–I (HC (2008–09)262)
First Special Report	The Funding of Science and Discovery Centres: Government Response to the Eleventh Report from the Science and Technology Committee, Session 2006–07	HC 214

Session 2007–08 (Continued)

Second Special Report	The Last Report: Government Response to the Thirteenth Report from the Science and Technology Committee, Session 2006–07	HC 244
Fourth Special Report	Investigating the Oceans: Government Response to the Science and Technology Committee's Tenth Report of Session 2006–07	HC 506 [incorporating HC 469–i]

Oral evidence

Taken before the Science and Technology Committee,

(Science and Technology Sub-Committee)

on Wednesday 25 November 2009

Members present

Mr Phil Willis, in the Chair

Mr Tim Boswell
Dr Evan Harris
Dr Brian Iddon
Ian Stewart
Graham Stringer

Memorandum submitted by Royal Pharmaceutical Society of Great Britain (HO 37)

PREAMBLE

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional body for pharmacists and the regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper *Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century*, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

The Society welcomes the opportunity to respond to the invitation of the House of Commons Science and Technology Committee to submit evidence to their enquiry on homeopathy. In this document the Royal Pharmaceutical Society has provided responses to the three issues highlighted by the Committee.

SUMMARY OF RECOMMENDATIONS

Recommendation 1: research needs to be undertaken to develop alternative and robust methodology to assess clinical interventions involving homeopathic treatments.

Recommendation 2: unless or until such a time as efficacy of a homeopathic product can be proven using appropriate methodology (as for conventional medicines) claims of efficacy should be removed from the label of a homeopathic product. This recommendation includes any homeopathic products with PLR when they come up for review by the MHRA in the near future.

Recommendation 3: Unless or until such a time as efficacy of a homeopathic product can be proven using appropriate methodology (as for conventional medicines) labelling on the homeopathic product should make it very clear that the efficacy of the homeopathic preparation has not be proven.

Recommendation 4: Patients are made aware of the fact that there is no scientific basis for the use of homeopathy.

Recommendation 5: research should urgently be undertaken to determine how effective homeopathic remedies are and whether it is the whole package of care provided by homeopathic treatment that is beneficial for the patient rather than the product *per se*.

Recommendation 6: homeopathic remedies should be reviewed by NICE if they are to be used within the NHS to ensure that they give value for money and to ensure that the funding of conventional medicines is not compromised by their use.

Recommendation 7: the cost-benefit ratio for homeopathic interventions should be established.

Recommendation 8: if homeopathy continues to be made available on the NHS all homeopaths *must* be registered with an appropriate body and governed by a Code of Ethics.

RESPONSE

1. *Government policy on licensing homeopathic products*

1.01 Between 1971 and 2006 it was not possible to make a claim about effectiveness of a new homeopathic product, product registration was made solely on the basis of quality and safety.

1.02 The introduction of UK National Rules in September 2006 (as permissible under European legislation) allowed limited medical claims such as "for the relief of…." for new homeopathic preparations provided there is "suitable evidence that the product has been used as a homeopathic treatment in the indications sought. Information provided should be in the form of provings, excerpts from homeopathic material medica or other bibliographic data and should be sufficient to demonstrate that homeopathic practitioners would accept the efficacy of the products for those indications".

1.03 It should be noted that products registered under the UK National Rules are intended for over-the-counter sale and are indicated for the relief of self-limiting minor symptoms and minor conditions. For these purposes, minor symptoms are defined by the MHRA as those, which can ordinarily and with reasonable safety, be relieved or treated without the supervision or intervention of a doctor. Serious conditions such as diabetes, epilepsy, cancer and prevention and treatment of malaria are excluded from the scheme.

1.04 Significantly the UK National Rules go against the findings of the 2000 UK Parliamentary Select Committee on Science and Technology on complementary and alternative medicine in reported that "any therapy that makes specific claims for being able to treat specific conditions should have evidence of being able to do this above and beyond the placebo effect".

1.05 One consequence of the 2006 UK National Rules is that there is no requirement for rigorous clinical data to demonstrate efficacy of a new homeopathic medicine as is understood in the context of conventional pharmaceutical medicines where clinical efficacy is demonstrated using pre-clinical tests and clinical trials.

1.06 Homeopathic provings (ie where healthy volunteers are given the potential homeopathic substance to elicit the same symptoms as the illness that is to be treated) can now be used as evidence for medical claims despite the fact that they do not prove efficacy. Furthermore the homeopathic literature can also be used as evidence for medical claims despite the fact that it may not have been subjected to the same level peer review as more main stream scientific literature. The reliance on such evidence for homeopathic preparations is in stark contrast to the stringent tests that conventional medicines must undergo prior to obtaining a licence.

1.07 When the UK joined the European Community in 1973, a review of all products covered by Product Licences of Right (PLR) awarded under the 1968 Medicines Act became mandatory. Many homeopathic products had been awarded Product Licences of Right (PLR) and were able to claim efficacy if the product had been previously used for this purpose. However, it was recognised by the regulatory authorities that providing proof of efficacy for homeopathic products would pose a difficulty, and as a consequence homeopathic medicines were exempted from the review and many PLRs remain in place. The MHRA has however stated that it will review all PLR by 2013 and remove "any unsuitable indications", although under current UK National Rules it is unlikely that many homeopathic preparations will not be granted licences.

1.08 The RPSGB is concerned that, under the current UK National Rules, the patient will not realise that the regulatory regime for homeopathic products is not the same as that for conventional pharmaceutical medicines and may understand the phrase "for the relief of or treatment of….." on the label to imply an endorsement of efficacy (by the MHRA) where none has actually been proven. Indeed while it is acknowledged that homeopathic manufacturers are advised under National Rules to include a statement on all labels and product literature along the lines that "A homeopathic medicinal product used within the homeopathic tradition for the relief of or treatment of …." and a statement advising the consumer to consult a medical practitioner if symptoms persist, our concern is that this is not a clear enough message to the patient.

1.09 The RPSGB believes that any medicinal claim for a product must be based on sound scientific and clinical evidence and that it is the duty of the regulatory authorities to ensure that no claims for efficacy for any form of a medicine (homeopathic or otherwise) are made unless there is good scientific and clinical evidence for doing so.

1.10 It has long been claimed by the homeopathic community that current randomised controlled clinical trial methodology is inappropriate for assessing any benefit arising from a homeopathic intervention (*Weatherley et al Homeopathy (2004) 93, 186–189; Chanda and Furnham Focus on Alternative and Complementary Therapies (2008) 13, 157–167*).

Recommendation 1: research needs to be undertaken to develop alternative and robust methodology to assess clinical interventions involving homeopathic treatments

Recommendation 2: unless or until such a time as efficacy of a homeopathic product can be proven using appropriate methodology (as for conventional medicines) claims of efficacy should be removed from the label of a homeopathic product. This recommendation includes any homeopathic products with PLR when they come up for review by the MHRA in the near future

Recommendation 3: Unless or until such a time as efficacy of a homeopathic product can be proven using appropriate methodology (as for conventional medicines) labelling on the homeopathic product should make it very clear that the efficacy of the homeopathic preparation has not be proven

1.11 The RPSGB recognises the UK Government view that consumers should be free to make informed choices that involve non-conventional approaches to the relief of certain symptoms or conditions. It is essential therefore that the patient is given the appropriate information to make these informed choices and as a consequence it should be clear to the patient that there is no scientific evidence for homeopathy (contrary to what is sometimes stated on homeopathic web-sites) and that the claims of efficacy made for homeopathic medicines (on their labels) are not made on the same stringent basis as conventional medicines.

1.12 The RPSGB is concerned that the current Government policy of allowing indications for homeopathic preparations intended for over the counter sale, may be seen to legitimising the practice of homeopathy and may prompt some patients to use, for example, homeopathic preparations for malaria prophylaxis, treatment of HIV, TB, influenza, childhood diarrhoea or in place of immunisation, practices which have been condemned earlier this year by the WHO (*British Medical Journal (2009) 339, 479*).

Recommendation 4: Patients are made aware of the fact that there is no scientific basis for the use of homeopathy

2. *Government policy on funding homeopathy through the NHS*

2.01 The NHS currently supports 4 homeopathic hospitals in Bristol, London, Liverpool and Glasgow. Until March 2009 NHS patients could be referred to the homeopathic hospital in Tunbridge Wells. It is reported that the four NHS homeopathic hospitals currently treat 55,000 patients per year referred by GPs, PCTs and NHS specialists. In addition there are over 400 GP's practising homeopathy and who are regulated by the GMC and are members of the Faculty of Homeopathy. They treat 200,000 NHS patients a year with homeopathy. GPs are able to refer NHS patients to qualified and regulated homeopaths. However, it is not clear what the cost of homeopathy currently is to the NHS.

2.02 Although there is no scientific or definitive clinical trial evidence for the benefit of homeopathy, there is anecdotal evidence of patients gaining benefit from such treatment. For example an analysis of 23,000 out-patient consultations at the Bristol Homeopathic Hospital from 1997 to 2003, suggested that over 70% of patients followed up reported positive health changes following homeopathic treatment (*Spence et al* Journal of Alternative and Complementary Medicine (2005) 11, 793–798). Furthermore there are instances after treatment using homeopathy that for some illnesses patients no longer required conventional treatment. For example the London homeopathic hospital report that "specific projects on childhood asthma and eczema showed a decrease in the use of steroid inhalers as well as the use of topical steroids in 60% of the children" (*London Homeopathic Hospital web-site, http://www.uclh.nhs.uk/GPs+healthcare+professionals/Clinical+services/Homeopathy+%28Royal+London+Homoeopathic+Hospital%29/Homeopathy+-+Childrens+Clinic/accessed 9 November 2009*).

2.03 Homeopathy involves a holistic approach to the treatment of patients, which requires an assessment of the physical, mental and emotional state of the patient as well as the symptoms they present with. Whether the benefits patients gain when taking homepathic preparations is due to a counselling effect ie someone just giving the time to listen to a patients problems and talk them through as many experts believe (a typical initial homeopathic consultations takes about 45–60 minutes, follow up ones slightly less), a psychological effect due to the belief by the patient they will get better, or the actual homeopathic remedy itself, is not clear.

2.04 It must be also realised that homeopathic treatment on the NHS rarely means solely homeopathic remedies as it usually used in conjunction with conventional medicine and sometimes other complimentary medicines. Indeed homeopaths frequently state that homeopathy should not be used instead of conventional medical treatment, but that it should be used in conjunction with it.

Recommendation 5: research should urgently be undertaken to determine how effective homeopathic remedies are and whether it is the whole package of care provided by homeopathic treatment that is beneficial for the patient rather than the product *per se*

Recommendation 6: homeopathic remedies should be reviewed by NICE if they are to be used within the NHS to ensure that they give value for money and to ensure that the funding of conventional medicines is not compromised by their use

Recommendation 7: the cost-benefit ratio for homeopathic interventions should be established

Recommendation 8: if homeopathy continues to be made available on the NHS all homeopaths *must* be registered with an appropriate body and governed by a Code of Ethics

3. *The evidence on homeopathic products and services*

3.01 Homeopathy has been used in Britain for about 150 years, and has always been available through the NHS since its inception in 1948 although it has gained increasing prominence with the general public over the last 20 years, mainly because it is generally viewed as being safe (being prepared from plant, mineral or animal), not producing serious adverse reactions (other than aggravations, ie an initial worsening of symptoms following administration of the homeopathic remedy, or in individuals who have a lactose sensitivity when lactose is used as diluent), and not interacting with conventional medicines. (It is worth commenting that homeopathic and herbal medicines are often confused in the Public's mind.) Despite the

longevity of homeopathy no plausible scientific reason has yet been proposed as to why it should work. Further, as yet no unambiguous clinical trial data has been presented as evidence for the effectiveness of a homeopathic preparation.

3.02 Homeopathy is proposed to work on the principle of "treating like with like" and uses extremely dilute amounts of the homeopathic substance to treat an illness with symptoms that large doses of the same substance would actually cause in healthy patients. The philosophy of homeopathy that a substance becomes more potent as it is diluted goes against the conventional theory of the pharmacological action of compounds in the body, which increase in activity with concentration. Homeopathic preparations are made by repeated diluting and vigorous shaking (succusion) of a stock until there is little, *if indeed any*, of the original substance left. Successive succusion and dilution steps are required to potentise the preparation.

3.03 Such is the extent of dilution used in homeopathy that even the most concentrated homeopathic preparation generally used (ie a 6C preparation) contains only one picogram of homeopathic substance. (Conventional medicines are usually administered in milligram or microgram, ie 10_6 or 10_3 higher amounts.) The most commonly used preparation (a 30C preparation) is diluted to such an extent that only one molecule of the homeopathic substance would be present in a sphere the size of the orbit of the planet Neptune. As a consequence of their extreme dilution, most high dilution/potency homeopathic remedies do not contain a single active molecule. The administration of a preparation containing substance at such large dilutions leads to a RPSGB view that such preparations will not produce clinical effects.

3.04 To explain the activity of the homeopathic preparation, homeopaths state that the homeopathic substance leaves a molecular "imprint" in the preparation that triggers your body's healing mechanisms, that the dilution and succusion steps are essential to the efficacy of the remedy, and that the more dilute the preparation, the more effective it becomes. However there is no robust scientific evidence to suggest that differences can be detected between ultra dilute homeopathic remedies and the diluent used to prepare the remedy in terms of their physical properties and behaviour.

3.05 In 1986, an RPSGB Council Statement on homeopathic products stated that with regard to homeopathic remedies, there was no scientific evidence for their efficacy, only anecdotal or subjective reports. A 2006 Law and Ethics bulletin reported that there was no scientific proof that homeopathic remedies were effective in preventing malaria.

3.06 In 1999, the RPSGB submitted a report on complementary and alternative medicine to the House of Lords Science and Technology Committee. In the report, a literature review of the efficacy of homeopathic medicines was presented which considered two recent meta-analyses. In summarising the available evidence, it was noted "the equivocal outcome of these two meta-analyses, which represent the best cumulative evidence on homeopathic remedies to date, together with the absence of a scientific basis for efficacy, implies that there is no scientific basis for the use of homeopathy to treat any specific clinical condition. However, a non-pharmacological therapeutic benefit from the administration of a homeopathic remedy in an individual patient can not be ruled out."

3.07 An Information Sheet produced on Homeopathy, which forms part of the "Pharmacists—the scientists in the high street" series was commissioned by the RPSGB's Science Committee, the most recent update of which was produced in June 2007. In reviewing the research on homeopathic remedies, it stated "there is no sound pharmacological or scientific basis for their activity. Conversely, there are many anecdotal accounts of effectiveness."

3.08 A literature review of the evidence to date for homeopathy carried out in 2009 for RPSGB's Science Committee came to a very similar conclusion (*see Appendix 1*). The main points that came out of this summary were

(1) Relatively few randomised, controlled clinical trials (RCTs) have been carried out in the field of homeopathy.

(2) Of the many systematic reviews and meta-analyses of homeopathy RCTs, the majority showed that either there was no convincing evidence that homeopathy was superior to placebo, or that there was not enough evidence to draw conclusions.

(3) A recent Cochrane review reports preliminary data to support the use of specific homeopathic preparations to treat adverse effects of cancer treatments. Meta-analyses of homeopathy RCTs suggest that homeopathy may also be of some benefit in postoperative ileus and acute pollinosis, and possibly in childhood diarrhoea.[1]

(4) High quality RCTs tend to show that the effects of homeopathy are similar to placebo; lower quality trials tend to show an effect for homeopathy superior to placebo.

(5) Arguments regarding the design and methodology used for RCTs are made by both proponents and opponents of homeopathy.

(6) The placebo effect can be powerful and should not be underestimated, but is only effective for relatively minor ailments.

[1] Since this document was produced in May 2009, further examination of the references cited in the Cochrane review suggest that although the Calendula product showing benefit in the treatment of the adverse effects of cancer was produced according to a homeopathic pharmacopoeia, its characteristics were more akin to a herbal preparation.

(7) There is evidence that patients receiving individualised homeopathic treatment report clinical improvements.

(8) More high quality research in homeopathy is required to increase the knowledge base. This includes RCT's covering the treatment of specific clinical conditions, as well as the effects of specific remedies. Furthermore, methodologies that encompass the holistic or individualised care approach of homeopathy need to be developed.

3.09 However as homeopathy is a whole person treatment it does not lend itself well to testing through the placebo-controlled randomised trial since significant components of the treatment may be the interaction and trust building with patients that may be compromised if the patient has a chance of receiving a placebo. The classic homeopathic approach of one treatment per one person contrasts with the conventional approach of one or more therapies per disease, which may make many of the randomised controlled study designs inappropriate for homeopathic research. Despite this, most trials of homeopathic medicines do not individualise treatments for patients. Interestingly results from meta analyses suggest that in cases of individualised treatment, homeopathy may have an effect over placebo.

3.10 While there is no sound pharmacological or scientific basis for the activity of homeopathic remedies, there are many anecdotal accounts of effectiveness. In this context the placebo effect can be powerful and should not be underestimated, but is only effective for relatively minor ailments.

In conclusion there is no scientific or clinical evidence to support homeopathy, although in spite of this, patients still report beneficial effects, especially from individualised patient treatments.

November 2009

Memorandum submitted by the British Association of Homeopathic Manufacturers (HO30)

1. The British Association of Homeopathic Manufacturers (BAHM) welcomes the opportunity to submit evidence to the Science and Technology Select Committee's evidence check for homeopathy. As the trade association for the manufacturing industry, we act as the focus point for discussions between the Medicines and Healthcare Products Regulatory Agency (MHRA) and industry, ensuring that homeopathic products are produced to the highest quality and safety standards.

2. We provide evidence below on the following issues:

— Government policy on licensing of homeopathic products

— Government policy on the funding of homeopathy through the NHS

— The evidence base on homeopathic products and services

About the British Association of Homeopathic Manufacturers

3. The British Association of Homeopathic Manufacturers was founded in 1992 to act as a central point for discussions between UK licensed homeopathic manufacturing industry and the (then) Medicines Control Agency (MCA) in the run-up to the introduction of the EU Homeopathic Directive in 2001. BAHM's founder members were UK homeopathic manufacturing companies who held Product Licences of Right for a wide range of medicinal products. Since the adoption of the EU Homeopathic Directive, two further UK manufacturers have obtained product registrations and have joined the BAHM. Today, BAHM continues to act as the focus point for discussions between the Medicines and Healthcare Products Regulatory Agency (MHRA) and the industry.

4. BAHM and its individual company members recognise the need for effective regulation of medicinal products in the UK and throughout the EU. As a responsible industry, BAHM members operate within this regulatory framework to ensure that consumers, patients and practitioners have access to high quality homeopathic medicinal products as part of an integrated approach to healthcare in the UK.

5. BAHM member companies are:

— Ainsworths Ltd., 36 New Cavendish Street, London W1G 8UF

— A. Nelson and Co. Ltd., 83 Parkside, Wimbledon, London SW19 5LP

— Helios Homoeopathy Ltd., 89–97 Camden Road, Tunbridge Wells, Kent TN1 2QR

— Seven Seas Ltd., Hedon Road, Marfleet, Hull HU9 5NJ

— Weleda (UK) Ltd., Heanor Road, Ilkeston, Derbyshire DE7 8DR

6. Together, these companies represent 95% of UK homeopathic production.

Government Policy on Licensing of Homeopathic Products

7. Homeopathic medicinal products in the UK are authorised or registered in accordance with the legislation for medicinal products. They may have:

— Product Licences of Right (PLR) granted MHRA, or

— Homeopathic Registration Certificates, granted by MHRA in accordance with the requirements of Directive 92/73/EC, or

— Homeopathic Registration Certificates, granted by MHRA under the National Rules scheme, in accordance with the requirements of Directive 200l/83/EC.

8. The primary purpose of the MHRA licensing process is to guarantee patient and consumer safety. As the Department of Health noted in its submission to the committee's broader evidence check in the summer,

> "*only products which are indicated for the relief of minor symptoms and minor conditions in humans are eligible for a homeopathic marketing authorisation under this scheme. For these purposes, minor symptoms are those which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.*"

9. Patients themselves can make decisions on Over the Counter product purchase in the full knowledge that the homeopathic medicines they are purchasing are safe. Health professionals, particularly GPs and pharmacists, are also in a strong position to advise on when complementary products and services can provide a solution, and when conventional medicines are more appropriate and can prescribe homeopathic medicines accordingly.

Government Policy on the Funding of Homeopathy through the NHS

10. The Department of Health determines and authorises those homeopathic medicines that can be obtained via NHS prescription. It is up to Primary Care Trusts to determine the flow of funds in each particular area are available within the National Health Service, and to direct funds accordingly.

11. As Department of Health Minister Phil Hope MP said in a written answer on 5 February 2009:

> "The Government considers that it is the responsibility of the National Health Service to make decisions on what treatments are most appropriate for their patients, including complementary and alternative medicine treatments and referrals to homeopathic hospitals. In some cases complementary and alternative medicine treatments may be appropriate and a general practitioner would make a decision to refer taking into account safety, clinical and cost effectiveness as well as the availability of suitably qualified and regulated practitioners." (*Official Report*, 5 February 2009, column WA 1501)

12. The situation in other European countries is radically different to the UK. For example, in France, 25% of prescriptions are homeopathic. The situation in Germany is similar. Whilst we are aware that the reimbursement system is different in France and Germany, it is nevertheless significant that medical practitioners see a role for homeopathic medicines and are willing to direct prescribing decisions accordingly.

The Evidence Base on Homeopathic Products and Services

13. The authorisation/registration legislation for homeopathic medicinal products primarily relates to assurance of safety and quality as we describe above. Comment on homeopathic "services" is outside the scope of activity of the BAHM.

14. There is a place for homeopathic medicine in any system based on patient outcomes and patient demand, and the Faculty of Homeopathy has separately studied the evidence base in detail.

15. As indicated above, patients themselves make decisions on product purchase in the full knowledge that the homeopathic medicines they are purchasing are safe, often under the guidance of GPs and pharmacists. Such professionals are in a strong place to advise when homeopathic medicines present a cost-effective, quality solution to specific health conditions.

November 2009

Memorandum submitted by Sense About Science (HO36)

1. Background

Sense About Science is a UK registered charity that works to equip people to make sense of science and evidence. We work with over 4,000 scientists, from Nobel prize winners to our Voice of Young Science network of postdoctoral researchers, to help civic groups including community organisations, media and commentators to weigh up claims about evidence.

2.1 *Public perception of homeopathy*

We monitor public discussions, together with our own log of requests for help and concerns raised by scientists, to identify frequently occurring misconceptions or misleading information. In 2006 we reviewed discussion about homeopathy and made two observations:

(a) That it was believed to contain an active ingredient, and was often confused with herbal medicine (and, related to this, that people were often unaware of the mystical belief in water memory and in "like cures like" on which it is based).

(b) That because it was supplied on the National Health Service, it was assumed that it "must be effective" and "there must be something in it".

2.2 We also noted regular reports of homeopathic remedies being marketed for serious diseases, notably at that time anti-malarial prophylaxis. We assessed this to be in part a consequence of the assumptions (a) and (b) above.

2.3 We noted, through discussions held with clinicians and researchers, that there was an atmosphere of resigned frustration about the possibility of addressing the misconception that homeopathic products contain active ingredients and the misconception that there was reliable evidence of efficacy beyond the placebo effect. In particular they found it hard to argue against something that was supplied through the NHS and that appeared to be officially endorsed. We also noted their frustration about the acclaimed "holistic" approach of homeopathy despite its inability to diagnose disease and the potentially dangerous consequences of that. Furthermore, if the use of some unproven and unlikely remedies is officially flattered and endorsed, then this affects our ability to reason through debates about the suitability or provision of any other remedy. In other words, one cannot demand that people accept the evidence regarding the provision of drugs for Alzheimer's yet overlook it regarding the provision of homeopathy.

2.4 Scientists' resignation to public misconceptions is anathema to Sense About Science's mission of equipping the public to make sense of science and evidence. It disenfranchises the public by removing scientific reasoning to senior common rooms and private clubs.

3. Challenging Perceptions

We supported and encouraged medical scientists to make themselves plain in public discussions about homeopathy in the following ways:

3.1 In May 2006, a group of medical specialists, led by cancer surgeon Professor Mike Baum, writing to the medical directors and directors of public health at NHS trusts to draw attention to the provision of homeopathy and the lack of evidence in support of its efficacy. In particular they raised concern about: overt promotion of homeopathy for general use in the NHS, including on the NHS Direct website; a government-funded patient guide, prepared by the Foundation for Integrated Health; and the Smallwood report commissioned by the Prince of Wales to make a case for increasing NHS provision of homeopathy. They pointed out that over a dozen systemic reviews had failed to provide convincing evidence of effectiveness. This letter was followed one year later with a letter led by Professor Gus Born, enclosing a copy of an evidence review by a London NHS trust.

3.2 From this time, a group of clinical researchers and journalists gathering information on the extent of provision of homeopathy by NHS trusts, a summary of which has been supplied to you separately.

3.3 In July 2006, working with experts in malaria and tropical diseases to warn the public that homeopathic medicines offer no protection against malaria or other serious tropical diseases. This followed a short investigation by Sense About Science, which showed that the first ten homeopathic clinics and pharmacies selected from an internet search and consulted were willing to break public health protocols by providing unproven homeopathic pills to protect against malaria and other tropical diseases such as typhoid, dengue fever and yellow fever. In widely report comments, the malaria experts called on the Government to ensure that the safety of the travelling public was not put at risk by such prescriptions. Subsequent action was brought by the Royal Pharmaceutical Society of Great Britain (the pharmacy registration body at that time) against two of the pharmacies investigated. This is ongoing.

3.4 In September 2006 producing a short public leaflet, Sense About Homeopathy, describing homeopathy in a scientific context and exploring why some people think it works (http://www.senseaboutscience.org.uk/pdf/SenseAboutHomeopathy.pdf).

3.5 In autumn 2006, challenging the Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006. The new regulations permitted homeopathic products to make medical claims but exempted them from providing scientific evidence that they are effective. This was the first time in its history that the regulation of medicines moved away from science and from clear, meaningful information for the public. What is more, it happened without parliamentary time or public debate. In October 2009, Sense About Science summarised for parliament hundreds of responses protesting the introduction of the regulations, including many from scientific and medical bodies. These were instrumental in pressing for the debate that was held in the House of Lords on 26 October 2006. The serious concerns of the scientific and medical community were raised by Lord Taverne (Chairman of Sense About Science), Lord Rees of Ludlow (President of the Royal Society), Lord Turnberg, Lord Jenkin of Roding, Lord McColl of Dulwich and Baroness O'Neill of Bengarve. A summary of our objection at that time was:

> "*The regulations*
>
> The mission of the UK's licensing body, the Medicine and Healthcare products Regulatory Agency (MHRA), is to ensure "that medicines and medical devices work, and are acceptably safe". However, with the introduction of the new rules for homeopathy, it now accepts homeopathic provings as evidence of efficacy. A "proving" is the method homeopaths use to determine the symptoms a substance causes (with a view to treating diseases with similar symptoms). Provings are not carried out on the finished product and are nothing to do with efficacy.

> The regulations also mean that, for the first time in more than 30 years, homeopathic products will be able to make medical claims such as "For the relief of…". Such claims, however worded, imply efficacy where none has been proven.
>
> The MHRA did not have to change the regulations in this way. It was not required to do so by EC Directive 2001/83. The MHRA set out four options to government, including doing nothing. It chose to eliminate the old, stricter licences in order to facilitate the "expansion of the homeopathic industry" through new products.
>
> The MHRA has designed the regulations to respond to pressure from the homeopathic industry, which wants to expand (see impact assessment right)."

3.6 In June 2009 working with Voice of Young Science to urge the World Health Organisation to respond to the promotion of homeopathy in developing countries for infant diarrhoea, influenza, HIV, tuberculosis and TB. A note from Julia Wilson of VoYS is appended.

1. *Summary*

A group of young researchers have received comments from directors of WHO disease programmes stating that they do not recommend homeopathy for the treatment of HIV, influenza, TB, Malaria and Infant diarrhoea. These comments have been sent to all health minsters in the world and provide a guideline for governments and health care workers dealing with these issues.

2. *Background*

Voice of Young Science (VoYS) is a network of over 600 early career researchers set up by Sense About Science. Sense About Science is a charity that equips people to make sense of science and evidence. VoYS became aware of a conference[2] promoting the use of homeopathy in developing countries and discovered that homeopaths are setting up clinics in these countries and claiming to treat HIV, malaria, TB, influenza and infant diarrhoea. Medics working with the most rural and impoverished people of the world already struggle to deliver the medical help that is needed. The promotion of homeopathy for serious diseases puts lives at risk. On 1 June 2009 25 early career researchers and medics from the UK and Africa sent an open letter to the World Health Organisation (WHO) calling on the body to condemn the promotion of homeopathy for treating life threatening diseases. Their letter available at http://www.senseaboutscience.org.uk/index.php/site/project/331/had the support of leading international experts in malaria, HIV and other serious diseases.

3. *Response*

VoYS received supportive comments from the Stop TB Department, the TB Strategy and Health Systems, the HIV/AIDS Department, the Global Malaria Programme and the Department of Child and Adolescent Health and Development stating that they do not recommend homeopathy for serious diseases. These comments are available at http://www.senseaboutscience.org.uk/index.php/site/project/392/. The Director General's office confirmed that these "clearly express the WHO position".

4. *Impact*

VoYS released the WHO response on 21 August 2009. It was sent to the health ministers of all countries to highlight the WHO's position on homeopathy and to call on governments to combat its promotion for serious diseases. The WHO response was covered widely in UK and international media including African, Indian and South American news. VoYS were contacted by a number of researchers and medics in Africa and India, organisations such as the Centre for Inquiry in Nigeria and several South African journalists, concerned about the promotion of homeopathy in their countries and pleased to have this support.

November 2009

Memorandum submitted by Dr Ben Goldacre (HO 40)

BACKGROUND

Sugar pills which have been prepared in accordance with the principles or rituals of homeopaths are physically indistinguishable from untreated or "placebo" sugar pills, and these homeopathy pills have overall been shown, repeatedly, in summaries of fair clinical trials, to perform no better than dummy placebo sugar pills. Any claims to the contrary rely on cherry picking the evidence to selectively reference only positive findings, to reference poorer quality studies which are not "fair tests" of the pills, and so on. Almost any ineffective medical treatment could be made to appear effective using these strategies: they simply reflect misleading and partisan scholarship. These sugar pills are not physically harmful, nor do they physically

[2] Homeopathy for Developing Countries, An International Conference in Amersfoort, the Netherlands, 6–7 June 2009. The programme can be found here: www.homeopathycommunity.com/upload/HomeopathySeminar.pdf

confer benefit on patients. Where there are benefits (and indeed harms) from these sugar pills, it is only in how they are presented. I assume that this basic territory will be covered by others, and confine my submission to issues that interest me particularly.

Licensing of Homeopathic Pills

The Medicines and Healthcare Regulatory Agency (MHRA) approved label on homeopathy sugar pills is misleading. A great deal of effort has gone into making patient literature, leaflets, and labels more easily understood, explaining the benefits and risks of treatments clearly, so it seems perverse and anomalous that the MHRA have settled on a plainly misleading convention for labelling these homeopathic sugar pills. The MHRA may deploy sophistry, or invoke technical readings of the statements, but the public read these labels as saying that the homeopathic sugar pills are effective for the conditions listed. They are not effective, and the MHRA know they are not. The confused wording of the labels is compounded by the fact that the government medicines regulator is giving licenses to pills sold in pharmacies which have not been shown to be effective, something few would expect a government regulator to do, so this unusual state of affairs requires even more explicit clarity than normal. As things stand, this labelling system is misleading, ignores the evidence on best practise in communicating risks and benefits to the public, and should be changed.

The MHRA approval reinforces an unwelcome situation in which pharmacists are misleading patients. Patients and doctors should be entitled to trust pharmacists as a valuable source of evidence-based information on the treatments they deal in. Pharmacists hold themselves out as a valuable community resource in this regard, for example in the Royal Pharmaceutical Society of Great Britain's (RPSGB) "Scientist In The High Street" campaign. Now they are selling placebo sugar pills to sick people by misleading them. Each profession should be free to make its own decisions, but it may be worth ensuring that the public are told that pharmacists have abandoned their previous principles, so that they are not trusted in error.

Homeopathy on the NHS

The obvious argument is that homeopathy, since it works no better than placebo, should not be funded by the NHS. Although homeopathy is certainly not the biggest example of resources being wasted on an ineffective treatment, a recession should be a time for rational disinvestment, homeopathy is a clear example, and the NHS should be scanning its activities for other good candidates.

Although it is clear that homeopathy works no better than placebo, I do however accept that circumstances might occur in which it could arguably be desirable to have the option of prescribing a placebo. There are often situations where an individual may want treatment, for example, but where medicine has little to offer—lots of back pain, stress at work, medically unexplained fatigue, and most common colds, to give just a few examples. Going through a "theatre" of medical treatment, and trying every medication in the book, will only risk side-effects. A harmless sugar pill in these circumstances may seem to be the sensible option.

However the limited benefits must be weighed up against the risks:

1. Prescribing a placebo requires that a healthcare practitioner misleads their patient, which is unethical, paternalistic, and undermines the current emphasis on shared decision making in medicine. It also undermines the credibility of healthcare professionals' utterances, when it is widely known that doctors and others will lie to you about a treatment.
2. Even if we accepted that it was desirable and cost effective to prescribe a placebo, and responsible healthcare practitioners could be found who were willing to work around the ethical issues and do so, homeopathy may not be the best model for delivering placeboes, for a number of reasons:
   (a) It is routine marketing practice for homeopaths to denigrate mainstream medicine, for example campaigning against vaccination programmes, advising against medical treatments, undermining treatments such as chemotherapy which are distressing—but overall confer benefit—by overstating the side effects, and so on. One study found that more than half of all homeopaths approached advised a client against the MMR vaccine for their child. A BBC Newsnight investigation found that almost all the homeopaths approached recommended ineffective homeopathic pills to protect against malaria, and advised against medical malaria prophylactics, while not even giving basic advice on bite prevention.
   (b) Homeopaths who are not medically qualified can miss fatal diagnoses, actively disregard them, advise patients to avoid beneficial medications, and so on.
   (c) Senior and respected homeopaths, and homeopathic membership groups, promote irresponsible and extreme quackery. One example of many is the Society of Homeopaths' symposium on the treatment of Aids, featuring the work of Peter Chappell (a man who claims to have found a homeopathic solution to the Aids epidemic involving homeopathic remedies which are broadcast over the radio). The state should not be encouraging the public to trust people and organisations which go anywhere near such plainly foolish ideas.

(d) The endorsement of these sugar pills by the NHS is used by homeopaths as evidence that they work, and this further misleads the public. There are also more specific examples. Visitors to everyday NHS medicine clinics which happen to be held in the building of the Royal London Homeopathic Hospital in Queen's Square, walk past adverts proclaiming that homeopathy sugar pills are effective for a range of childhood and adult conditions, in an NHS setting. This is misleading and an abuse of the good faith that people have in the NHS.

(e) Homeopaths—and the marketing activity around homeopathy—mislead the public by sending out false messages on evidence in the name of marketing their pills, for example making prominent arguments in popular media claiming incorrectly that fair trials of homeopathy sugar pills cannot be done, or that systematic reviews of the literature are biased. This is corrosive. Ideally we would be encouraging patients to have a greater understanding of evidence based medicine, of how we know what is good for us and bad for us, to improve engagement in shared decision making with doctors, and to encourage participation in clinical trials.

(f) Homeopaths have cut themselves off from normal academic discourse on evidence based medicine by threatening critics with legal action to silence them, failing to engage with criticisms adequately in their literature, and shrouding their university teaching in secrecy. I can find no evidence that any of the plain criticisms I have outlined above with regard to the practise of homeopathy are seriously discussed by homeopaths. This would be unusual in other healthcare professions.

Conclusions

1. It is my view that the MHRA labelling system is misleading, not evidence based, and should be overhauled so that it unambiguously and explicitly states that homeopathy sugar pills have not been shown to be effective.

2. If the government believes that prescribing placebo sugar pills is a cost-effective strategy to manage a sub-population of treatment-resistant patients, then they should specify the characteristics of this population and commission a pragmatic cost-effectiveness analysis, comparing "GP treatment-as-usual" against "GP treatment-as-usual plus homeopathy". There is no need for any further trials comparing homeopathy sugar pills against untreated "placebo" sugar pills, as we already know the answer to that question, and we know that homeopaths ignore the results, so any further trials of that design are wasteful and uninformative.

Dr Ben Goldacre

November 2009

Witnesses: **Mr Paul Bennett**, Professional Standards Director and Superintendent Pharmacist, Boots, **Ms Tracey Brown**, Managing Director, Sense About Science, **Mr Ben Goldacre**, Journalist, **Professor Jayne Lawrence**, Chief Scientific Adviser, Royal Pharmaceutical Society of Great Britain, and **Mr Robert Wilson**, Chairman, British Association of Homeopathic Manufacturers (BAHM), gave evidence.

Q1 Chairman: Good morning everyone. This is a one-off evidence check session on homeopathy. It is part of a series of evidence checks we are doing as the Science and Technology Committee looking across government at whether there is evidence to support Government policy or, indeed, what evidence there is to actually scrutinise the effectiveness of Government policy. In a public call for topics homeopathy was one of the issues that was raised, and we are very happy to have this session. We welcome for our first panel Paul Bennett, Professional Standards Director and Superintendent Pharmacist Boots—welcome to you, Paul, and thank you very much for coming; Tracey Brown, the Managing Director for Sense About Science—welcome to you, Tracey; Dr Ben Goldacre, a journalist from *The Guardian*—welcome to you, Ben, this morning; Professor Jayne Lawrence, the Chief Scientific Adviser for the Royal Pharmaceutical Society of Great Britain—welcome to you; and, last but by no means least, Robert Wilson, the Chairman of the British Association of Homeopathic Manufacturers (BAHM)—welcome and thank you very much indeed for coming. I wonder if I could start with you, Paul, this morning. You actually manufacture and sell homeopathic remedies. Do they work beyond the placebo effect, very briefly?
Mr Bennett: First, I need to correct you actually, I am afraid. We do not manufacture products.

Q2 Chairman: You sell them though?
Mr Bennett: We do sell them.

Q3 Chairman: So you sell them?
Mr Bennett: We do indeed sell them and there is certainly a consumer demand for those products.

Q4 Chairman: I did not ask you that question. I said do they work beyond the placebo effect?
Mr Bennett: I have no evidence before me to suggest that they are efficacious, and we look very much for the evidence to support that, and so I am unable to give you a yes or no answer to that question.

Q5 Chairman: You sell them but you do not believe they are efficacious?
Mr Bennett: It is about consumer choice for us. A large number of our consumers actually do believe they are efficacious, but they are licensed medicinal products and, therefore, we believe it is right to make them available.

Q6 Chairman: But as a company you do not believe that they necessarily are?
Mr Bennett: We do not disbelieve either. It is an evidence issue.

Q7 Chairman: Robert, what is your position? You do manufacture.
Mr Wilson: We do manufacture, yes, and I represent 95 per cent of the manufacturers in the UK. Definitely we believe there is a strong case for the efficaciousness of homeopathic medicines. This is an industry that has been growing strongly. It has been around for 200 years and I think it is worth saying that in France it is a 400 million euro business and in Germany it is the same.

Q8 Chairman: So is prostitution. It does not mean to say it is right, does it? My question to you, Robert, is does it work outside the placebo effect?
Mr Wilson: It definitely does work outside the placebo effect.

Q9 Chairman: It definitely does. You have cast-iron evidence to support that?
Mr Wilson: We have many trials that show a strong efficaciousness for homeopathic medicines.

Q10 Chairman: Why do you not supply that to Boots then?
Mr Wilson: We do supply that to Boots.

Q11 Chairman: So why do they not believe you?
Mr Wilson: They do believe us.

Q12 Chairman: He has just said they do not.
Mr Wilson: No.

Q13 Chairman: He said he neither believes you or he does not believe you.
Mr Wilson: He has not asked us specifically about the efficaciousness of homeopathic medicines. Boots are a very important retailer; they sell a great deal of these products. You have also got to ask the question, if these products did not work beyond the placebo effect, why do people keep buying them? Leaving that aside, there is a trial out which was literally published in the last—

Q14 Chairman: That was not a serious point, was it? Was that a serious point you were making?
Mr Wilson: Yes, I believe, certainly, that people continue to buy products because they work for them.

Q15 Chairman: Because they work for them?
Mr Wilson: Yes.

Q16 Chairman: Even though there is no evidence.
Mr Wilson: There is a lot of evidence.

Q17 Chairman: Will you give me just one product where you say there is clear evidence that one of the things that you manufacture as a homeopathic remedy actually works?
Mr Wilson: Arnica, which is for bruising, and is extremely useful in post-operative care. There was a major trial done on arnica and, indeed, there is one that has just been published, the Witt Trial, which was done by the Charité Hospital in Berlin. It was a large trial—3,700 patients involved—and that has shown clearly that there is a strong benefit in homeopathic use to these patients with long-term chronic conditions. One of the subjects of that trial was arnica.

Q18 Chairman: Professor Lawrence, from the Royal Pharmaceutical Society, do you believe that homeopathic remedies work beyond the placebo effect?
Professor Lawrence: No, we do not believe there is any scientific or clinical evidence, using standard clinical trials, that there is—

Q19 Chairman: Even for arnica?
Professor Lawrence: I have not seen this latest trial, but certainly up until recently we reviewed all the evidence and we believe there is not any clinical or scientific evidence supporting their use.

Q20 Ian Stewart: Does that mean they do not work at all? Are you very definite that they do not work at all?
Professor Lawrence: Some patients, a lot of patients in fact, claim to have benefited, if they are asked afterwards, from the therapies.

Q21 Ian Stewart: That is a different issue.
Professor Lawrence: There is no evidence that we can see that supports—

Q22 Ian Stewart: It is only that there is no evidence. You are not saying that that does not mean that they work in some cases?
Professor Lawrence: There is no scientific basis for their being effective. There is no reason why they would be effective scientifically.

Q23 Chairman: Dr Goldacre, what is your view? Is there any effect beyond the placebo effect?
Dr Goldacre: No. The placebo effect is undoubtedly very powerful, and that is one reason why they are very attractive to people, but if you look at all of the trials in the whole, collectively, what you see when you look at the best quality trials is that homeopathy pills work no better than placebo pills. You can select individual trials and say: we have got this individual trial, or even ten individual trials, which show that it works, but if you cherry-pick your

literature and pick out only the positive results and ignore the unfavourable results, you can make any treatment work, including ones that are known to be ineffective or even dangerous. That is just bad scholarship.

Q24 Chairman: Do you believe that they are harmful though?
Dr Goldacre: I do not think they are physically harmful, in the same way that they are not physically beneficial. I think that they can have other harms. For example, I think pharmacists selling homeopathic sugar pills on the high street to patients and to the public is very harmful to the public reputation of pharmacists. The RPSGB describes pharmacists on the high street as being the "scientist in the high street", and I think it is sad that the public are now having to realise that, in fact, what should be a trustworthy resource for information on healthcare is, in fact, somebody who is, as a business person, selling them sugar pills.

Q25 Ian Stewart: Can we be clear as to what you have said there. It is harmful to pharmacists; you are not saying it is harmful to patients.
Dr Goldacre: That was one example of non-physical harm. I think they are culturally harmful. I think it is harmful, for example, to tell people that a sugar pill is an effective treatment when it is not; I think you undermine the credibility of the doctor, the healthcare worker, the pharmacist; I think you undermine the credibility of the MHRA. When you drive people into the hands of alternative therapists who may not be adequately medically trained by giving them credibility through MHRA approval, as it is perceived, then you drive people into the hands of people who may not be able to spot serious diagnoses. I think there are a number of harms that come, but none of them, you are absolutely correct to say, are direct physical harms. I do not believe that sugar pills are physically harmful; nor are they beneficial to people physically.

Q26 Chairman: I want to try and move on. Beyond the placebo effect, no justification?
Ms Brown: No, I am of a similar mind to Ben and Jayne Lawrence.

Q27 Chairman: But they are not harmful?
Ms Brown: Actually, I think there is the issue that even minor conditions can sometimes betray a more serious condition. For example, constipation. It sounds harmless to be taking sugar pills for constipation, but actually sometimes that is a symptom of a more serious condition and diagnosis is necessary. So there is the possibility of delayed diagnosis or people believing that they are seeking effective treatment when they are not. There is also a broader harm to the public, I think. If you think about the rows that have happened around things like the prescription of Alzheimer's drugs on the NHS, on the one hand, you are expecting people to look at the evidence to understand why certain drugs are available for people with a condition and certain are not and, on the other, you throw the evidence up in the air and say that if people want it they should have it. We just lose, as a society, the dividing line, the ability to talk to people about the evidence behind their medicines, and I think that is a serious public health issue.

Q28 Chairman: So we should sell nothing unless it has got clear evidence to support the claims of what it does?
Ms Brown: I think the point at issue is that we should flatter nothing with official endorsement. If people want to make potions and lotions and sell them to one another, I do not have a very strong view about that, but when that has official endorsement, for example a medicines licence, then I think we have a problem, because that does give people the message that some judgment has been made about its use and the treatment of that condition.

Q29 Chairman: So you think that homeopathic products should be licensed before they can be sold?
Ms Brown: There was always previously what is called the Simplified Scheme, which is about manufacturing safety, quality and cleanliness, and I think there is no problem with reviewing that kind of quality over medicine, but any suggestion that they should have indications that they are effective in the treatment of certain conditions, I think that becomes a problem, and that is the situation we are in at the moment.

Q30 Dr Harris: Can I first declare an interest that I have worked with Sense About Science on a number of issues and I have personally argued a lot with Ben Goldacre over the years. I want to ask Mr Wilson, while we are on declarations of interests, you and your members make money out of selling this and, obviously, if they can have medical indications on them they might sell better and then you might make more money. Is that accurate?
Mr Wilson: I represent the manufacturers. There is one thing I would like to say on the scientific evidence, if I may. I think it is important to say that a number of the trials that are put forward about discrediting homeopathy are with very, very small sample groups.

Q31 Dr Harris: I was going to come on to that. I just wanted to give you the chance to put your interest on the record.
Mr Wilson: Yes, I represent the manufacturers.

Q32 Dr Harris: Let me ask you a question then, and I will ask you about evidence. You heard Dr Goldacre say that the best way of looking at the evidence is to look at all the evidence, positive and negative, look at, for example, systematic reviews or meta-analyses as the best way of looking at published data, so that you are looking at the best trials, selecting the best trials and discarding those that are flawed and then using that. Do you accept

that as the best way of doing it, or do you think that picking a trial that other people may not have seen that has just been published is a better way?
Mr Wilson: No; absolutely. I think the important thing is the homeopathic industry is extremely pro research and pro trials. What we say is there have to be good trials. In *The Lancet* article there was the Langer experiment where they compared 100 trials. In each of those trials the median number of people involved was 65. Now 65 people in any trial is not statistically relevant. If you look at a number of the experts in trials, they will always say size is the only thing that matters. When you talk about a trial, the second question you should ask is how big was the sample? Any sample of fewer than 500 is not going to be statistically relevant.

Q33 Dr Harris: Hang on a second, because this was not my question. Firstly, I think we can all agree, but I will stand to be corrected, that whether the sample size is statistically significant depends on the frequency of the outcome you are measuring. So for rare outcomes you would clearly need to power up the sample, but that was not my question. My question to you, which I would urge you to answer, is do you accept the assertion that has been made that the best way to consider the evidence is to look at systematic reviews, including meta-analyses which combine sample sizes from a number of studies in a scientifically valid way, and judge the outcome, the conclusions of those systematic reviews which discard the flawed trials? It does not matter how many patients you have in a flawed trial if it its flawed. Do you accept that that is better than, to quote Dr Goldacre, cherry-picking from either side of the argument individual trials? That is a straightforward question.
Mr Wilson: The danger of meta-analysis is that all it does is compare a number of trials. If those trials are not good, it is still comparing bad trials. So if you have got a series of small groups of, say, 20 patients in a trial, and then you compare that with a series of others, you are still getting a skewed result.

Q34 Dr Harris: You are repeating yourself. I am asking a different question. Systematic reviews discard flawed trials, they do not count them at all, and they aggregate the results of a number of trials—large ones, small ones—which are well-designed. That is what they do. Do you accept—and I will ask you this for the third time—that that is a better way of judging the whole of the evidence than cherry-picking, on either side of the argument, individual trials?
Mr Wilson: I think the key question is—

Q35 Dr Harris: Yes or no. You are not asking me a question.
Mr Wilson: You have used the phrase "well-designed" a number of times. It does not matter how well designed a trial is if it is only 20 patients.

Q36 Dr Harris: I am talking about systematic reviews. Are you saying some systematic reviews are good and some are bad? I am not making progress there, so I will change my question. When you were asked about the evidence, you did not suggest, as far as I can recall, homeopathic provings as being good evidence. Do you think, compared to cherry-picked trials or systematic reviews, homeopathic provings represent good evidence of effectiveness?
Mr Wilson: No, a homeopathic proving is a technical term for when homeopathic medicines are assessed. It is not a way of doing a trial, proving.

Q37 Dr Harris: But it is the provings that are relied on by the MHRA. That is a condition, under the new scheme, the new National Rules, for the MHRA allowing indications to be given, claims to be given for the alleviation of minor illnesses. That is right, is it not?
Mr Wilson: The proving is part of the bibliographical traditional evidence for a homeopathic remedy.

Q38 Dr Harris: I would just like to ask Paul Bennett if he has any qualms at all about making money, as you do—it is your right to do that—out of selling products which you do not believe are effective but which have, on the basis of homeopathic provings (which even the homeopaths do not think is the best evidence of effectiveness) a stamp from the MHRA saying you are allowed to say this is effective, or can be effective, in constipation. Do you have any qualms about that?
Mr Bennett: I think actually at the root of this is that these are regulated products which are safe, and it is actually really important that we are able to support the very large number of our consumers who believe they are efficacious through their own experience and through recommendations from others. I think to deny somebody access to a product of that nature where they strongly believe it is efficacious would be wrong for us to do.

Q39 Dr Harris: If someone believed that paracetamol was efficacious in preventing heart disease and the paracetamol said on it "this can be used to prevent heart disease" you would not be happy and I am sure Jayne Lawrence would not be happy with that. So what is it about homeopathy which does not give you qualms when they make claims which you say you do not believe stand up? No-one is saying you should not sell them and you should not sell them as certified as safe and well-manufactured and the box says what is in it, which is nothing—that is fine—but do you not have qualms about selling things that have assertions on about clinical effectiveness that do not have evidence behind them and evidence that you do not believe?
Mr Bennett: Again, our key requirement here is for greater clinical evidence. If that were available to us as retailers and to the consumer, I think that would be extremely helpful.

Dr Harris: How would it be helpful? There has been a series of systematic reviews which demonstrate in homeopathy—I am not talking about the herbal stuff that is around—that there is no effectiveness beyond placebo. Yet you are not selling them as placebos, you are selling some of these products with indications. Do you not feel that if you were a manufacturer of something that had gone through clinical trials to treat these minor ailments—
Chairman: I think he has got the point.
Dr Harris: There has been all this evidence.

Q40 Chairman: He has got the point. I am sure he will give us an answer.
Mr Bennett: The point is that the products that we retail clearly have a label on them which states "a homeopathic medicinal product without approved therapeutic indications", because we cannot draw upon any further information to give that therapeutic assurance.

Q41 Dr Harris: Some of them now will have under the National Rules this claim?
Mr Bennett: They will under the National Rules.

Q42 Dr Harris: Indeed, some of them have from the old PLR.
Mr Bennett: But the products that we have available which are manufactured by Nelsons on behalf of Boots would be of that type, the type that does not have a therapeutic indication.
Chairman: I am going to call a halt there and bring in Brian Iddon.

Q43 Dr Iddon: I have a problem with the interpretation of EC Directive 2001/83 through the National Rules Scheme. I turn to you first, Paul. When you are selling vitamins and minerals on your shelves you are not allowed (and neither are other manufacturers or wholesalers or retailers) to advertise any medicinal value for those products unless there is clear scientific and clinical evidence for the medicinal claims, but the way that the MHRA in this country have interpreted that EC Directive through the National Rules Scheme allows you to sell homeopathic products with medicinal claims without the evidence. Surely that is a serious contradiction in this country?
Mr Bennett: I am happy to respond. I am concerned I am going to sound a little bit like a broken record in my response. I actually think that question would be a good one for the MHRA, who, I believe, are attending this Committee at another session.

Q44 Dr Iddon: We will put it to them.
Mr Bennett: I am sure you will. From a community pharmacy retail point of view, we rely very heavily on the regulatory process to indicate to us which products are approved and safe for sale. If the regulatory process is inadequate, then I would suggest that is something that does need to be taken up with the MHRA. We would respond accordingly to that, but at the moment we are operating within the regulatory framework that exists.

Q45 Dr Iddon: I turn to Robert Wilson at the other end of the table and put a similar question to you, Robert. Has not the National Rules Scheme been written deliberately to allow the interpretation of this EC Directive so that the homeopathic industry can expand?
Mr Wilson: The National Rules Scheme is the implementation of an EU Directive; so it comes from Europe. The homeopathic market in Europe is £1.5 billion. One in four prescriptions in France is homeopathic, so this is a sizeable European business. In this country the market is very small by comparison—about £30 million. So these are rules that have come from Brussels that is used to homeopathy as part of their mainstream healthcare offering. All the MHRA has done is implement a series of Directives that have been pushed from Europe and the National Rules Scheme is embodying clause 16.2 of that Directive which allows indications for minor complaints. By minor complaints we mean things that are not going to require the intervention of a doctor or medical practitioner. All that the UK MHRA is doing is implementing an EU Directive. There are a number of examples of EU Directives in herbal medicine, in traditional use medicine, where a system of medicine has been around for hundreds of years that they will allow bibliographical evidence to uphold a medical claim in a self-limiting or minor symptomatic area.

Q46 Dr Iddon: I will put to the rest of the panel now another question. Why should the MHRA have an interest in supporting the homeopathic industry when so many people believe there is no clinical evidence for the efficacy of the products?
Ms Brown: That sits really uneasily with the mission of the MHRA, which is to tell the public what works. I think it is very difficult to see how they identified a public health interest in putting forward these National Rules. Can I just clarify that it is a National Rules Scheme, that the EC Directive makes provision for national agencies to introduce their own national rules. Under the EC Directive it would have been perfectly acceptable to require homeopathic products to go through the same licensing procedures as other products if they wanted to make medicinal claims, so it was not the only option. It was not simply reading off from the European Directive straight into UK law.

Q47 Dr Iddon: Perhaps, for the record, you would give us the other options that MHRA gave to Government when they chose to go forward with the National Rules Scheme?
Ms Brown: The other options were to do nothing, and the problem that was identified prior to the 1968 Medicines Act was that there were a number of homeopathic products which were granted a product licence of right, and they continued to be sold on that basis, and then other products coming onto the market had had to use the Simplified Scheme, which had been introduced particularly after 1971 and the European Community requirements. The only reason for not doing nothing

(and this is the description given by a MHRA to Government) was that sections of the homeopathic industry were unhappy with what they saw as not a level playing field, where the PLRs could make claims and the new products could not make claims. Another version of doing nothing would have been option two, which is to revoke the PLRs and require the medicine simply to go through the Simplified Scheme. That would mean that they would not be able to make medicinal claims. Again, that would have been perfectly acceptable.

Q48 Dr Iddon: Without the evidence?
Ms Brown: Without the evidence. They could either go through the full application for a licence, in which case they would have to bring the same quality of information about efficacy as any other medicine, or they could register under the Simplified Scheme, which was simply, as we have talked about, manufacturing safety.

Q49 Dr Iddon: That would have levelled the playing field between the various homeopathic products?
Ms Brown: It would have done, but, clearly, the manufacturers of those products which were being sold with medicinal claims would not have been very happy at having to lose the ability to make those medicinal claims on their products. So that section, in effect, would have lost out of the homeopathic industry.

Q50 Dr Iddon: But the other section of the industry, who sell vitamins and minerals, will be put under that pressure. It seems a contradiction that the homeopathic industry is not put under the same pressure.
Ms Brown: Yes, it certainly does. Options three and four are not that dissimilar. Option three was to introduce National Rules and option four similarly; there are just some differences between the requirements. I find it very difficult to make sense of these options, because from a public health point of view none of these options has a rationale in terms of public health, they all have a rationale in terms of the industry, and, in fact, that becomes much clearer when you look at the rationale that was given to government. The only rationale for government intervention given by the MHRA was "although the development of National Rules by Member States under Directive 2001/83 is optional"—just to make that point clear—"failing to introduce a scheme would inhibit the expansion of the homeopathic industry by the prevention of the development of new products with indications". So that is why they preferred option four—it allowed indications and levelled the playing field for the industry; there was no other justification.

Q51 Dr Iddon: Robert, it just seems to me, and possibly other members of the Committee, that the National Rules Scheme was produced by the MHRA to allow your industry to expand. What is the evidence since the National Rules Scheme was introduced? Have your product lists grown and have you expanded?
Mr Wilson: Again, I think this is something that needs to be made clear. Currently under the National Rules Scheme there is one licence that has gone through that process since 2006. We submitted a dossier for arnica in 2007 and it was granted to us in March 2009, so you are talking about one product in the whole of the UK homeopathic industry. The National Rules Scheme is implemented by the UK but there are clear understandings from Europe that indications on products for homeopathic use which have been around since the start of the various Medical Acts in all the countries need to be regularised, and this was a way of bringing products that had been on the market for over 30 years into a standard way that could come across Europe. The homeopathic industry has been in quite serious decline because there has been a huge amount of negative PR about homeopathy built on a lot of spurious trials and the homeopathic voice has not been allowed to be heard. If I could make one point, in 2005 the NHS prescriptions for homeopathics was 500,000; in 2007 it was 320,000.

Q52 Chairman: I want to come on to that separately; so please do not take us down that road. Ben Goldacre, in terms of responding to Brian Iddon's point, if, in fact, in France a significant amount of "homeopathic medicines" are being prescribed, the French do not seem to be dying in droves as a result of it. Why on earth should we bother? Why do we not just say perhaps they have got something that is going which we should have?
Dr Goldacre: I agree. I do not think it is the most important issue in the world. I do not think people taking homeopathic pills is very important, but I think the MHRA endorsing them is extremely problematic. In answer to Dr Iddon's question why they would be interested, the MHRA is the regulator of the pharmaceutical industry but it gets, as I understand it, 90 per cent of its income from the pharmaceutical industry and much of that income comes in the form of product licence applications, and so on—the fees that they charge for processing them—and when they say that they are passing a new regulation to enable the expansion of the homeopathic industry, I think, unfortunately, that sends out a clear message that this is a £1.5 billion European industry that is able to influence the activities of an industry regulator, and that is problematic.
Chairman: That is very cynical.

Q53 Graham Stringer: Is the definition of homeopathy in France exactly the same as it is in this country?
Dr Goldacre: Yes, it is sugar pills that have been treated ceremonially, if you like, but I do not believe that Robert Wilson, who is a manufacturer of homeopathic pills, could tell the difference between one of his arnica pills and one of his arsenic pills; they are simply sugar pills.

Q54 Ian Stewart: Is that the formal definition in the UK and in France? The question you were asked was: is the definition the same? You gave what appeared to me to be a personal definition. That was not the question you were asked.
Dr Goldacre: I would imagine that there would be a huge number of different definitions in France and in England.

Q55 Ian Stewart: That is a very different answer than you gave to Graham Stringer before.
Dr Goldacre: There is no substantively different understanding of the meaning of the word "homeopathic" between France and England.

Q56 Chairman: Professor Lawrence, in terms of the Pharmaceutical Society, I presume there is an equivalent of the Royal Pharmaceutical Society in France?
Professor Lawrence: Yes, there is.

Q57 Chairman: Why are they not jumping up and down, or are you just so much better?
Professor Lawrence: I am sorry?

Q58 Chairman: Is yours so much more a professional organisation in the UK? Are they a little bit backward in France?
Professor Lawrence: No, the organisations are actually quite different. Although they are national societies, I think the Pharmaceutical Society is rather unique in being, up until recently, or presently, both the regulator and a professional body. So there is a difference between the societies across Europe.
Chairman: Can I move on then to Tim Boswell.

Q59 Mr Boswell: Some questions about the role of pharmacists in this, and I am talking about pharmacists as pharmacists rather than as retailers. Could I invite the panel to go straight down the line and give me a one word or one sentence answer to this question, starting with Paul and proceeding: should pharmacists sell homeopathic products?
Mr Bennett: Yes.
Ms Brown: No.
Dr Goldacre: Yes, but they should not say they are effective.
Professor Lawrence: Yes, but they should not say they are effective.
Mr Wilson: Yes.

Q60 Mr Boswell: Following on from that, perhaps I could ask Professor Lawrence to lead and others to feel they can join in. Questions about the role of pharmacists specifically. Can you explain to us how pharmacists assist patients in making informed decisions, as they would do in relation to other medicines, by providing them with the necessary relevant information about homeopathy?
Professor Lawrence: I think the first thing to realise is that the homeopathic preparations sold in pharmacies are over-the-counter products. So it is possible for a patient to just walk up, take a product off the shelf and buy it. We would contest it is better for the patient for pharmacists to be present when that happens, because they are able, if appropriate, to offer advice to that patient, and there are two things that are important. It is important that patients should realise there is not any evidence for the particular preparations and, also, it gives the pharmacist an opportunity to ensure that the patient is not actually taking something unnecessarily. Somebody mentioned before about taking inappropriate medicine. If they come into a pharmacy, they can have a consultation and the pharmacist can check it is not inappropriate.

Q61 Mr Boswell: So if you present with a particular condition, say, as it has been mentioned, constipation, for the sake of argument, there is no sort of implied either financial or other pressure which the pharmacist would feel to steer them towards a homeopathic product?
Professor Lawrence: No.

Q62 Mr Boswell: Or to make claims for the efficacy of that product which would not otherwise be scientifically justified?
Professor Lawrence: No, that would go against the pharmacists' Code of Ethics.

Q63 Mr Boswell: Would anyone else like to comment on that specific line of questioning? If there is not, could I ask this. Often the difficulty arises in delivery, however well the Royal Society has set out its stall, and you have, as you have rightly said, drawn up ethical guidelines. How can you ensure as a Royal Society that pharmacists selling homeopathic remedies are adhering to those guidelines? Can you discipline people? Is there any evidence of disciplining where people have gone outside the rules?
Professor Lawrence: There are two ways a pharmacist might be disciplined. One of them is through the Society's inspectorate which visits the shops on an occasional basis, and one of their roles is to check that the pharmacists are adhering to ethical guidelines. So it might be picked up there and, if it is, it might just initially be a warning, but if that is not complied with, it would go to—

Q64 Mr Boswell: There have actually been cases where there has been a warning in relation to homeopathic products that you are aware of?
Professor Lawrence: Not from the inspectorate, but the other way is from complaints from perhaps a member of the public, and they would be investigated, and there has been a case recently where it did go to a fitness to practise case.

Q65 Mr Boswell: Do you want to comment on that, Paul, from the point of view of a large pharmaceutical retailer?
Mr Bennett: Talking in general terms, clearly pharmacists are trained healthcare professionals, they are members of the Royal Pharmaceutical Society, which is a regulated profession, and clearly aspire to very high professional standards. Internally

within our own business we would supplement that with standard operating procedures and provide training material and facilitate the development of professional capability of our individual pharmacists. It is really very important that pharmacists adhere to the professional code at all times and, if I can, I would just like to quote from some guidance from the Royal Pharmaceutical Society which I think is succinct but very relevant to this point. That guidance states: "Pharmacists providing homeopathic therapies have a professional responsibility only to offer advice if they have undertaken suitable training or have specialised knowledge," and further (and my last point): "Pharmacists should consider whether any symptoms described by the patient and for which they are taking a homeopathic preparation could be associated with a serious or life-threatening underlying condition. If in doubt, refer the patient to a general practitioner."

Q66 Mr Boswell: I have two questions arising from that, if I may. The first one is: do you have operational experience if a particular employee of yours who is a pharmacist is "pushing" homeopathic remedies or might be inclined to disregard some of the small print of the code? Do you actually have cases where you have had to discipline or retrain people where this has happened that you are aware of?
Mr Bennett: Not at all. Our pharmacists take their responsibility very, very seriously. I have not, as Superintendent Pharmacist within Boots UK, encountered that circumstance at all.

Q67 Mr Boswell: Did you want to say something, Tracey?
Ms Brown: I did want to say that, whilst Boots' experience may be that (and it is an on-going situation that I cannot give you details of), there is a situation that has arisen where we discovered one large high street pharmacist was selling homeopathic anti-malarial prophylaxis prevention.

Q68 Mr Boswell: Without scientific evidence.
Ms Brown: Certainly so, and that, in fact, in one case was making appointments for a homeopathic travel clinic providing anti-malarial prophylaxis. That is something that the RPSGB is looking into.

Q69 Dr Harris: Is looking into! I am amazed, because this was July 2006. Pharmacists, on television—I saw this programme—said, yes, if you want to avoid malaria, you have a malaria-sized hole in your aura, take this homeopathic remedy—no advice on bed mosquito nets or proper malarial prophylaxis—and Dr Brown has just said that you are still looking at that. I would have thought that is an emergency, is it not? I think there were ten pharmacists doing that.
Professor Lawrence: I really cannot comment on the disciplinary procedure, unfortunately.

Q70 Mr Boswell: But it is on-going. Just to confirm, it is not resolved or you are not aware of it.
Professor Lawrence: I cannot comment.

Q71 Dr Harris: Wait a minute. Forget those cases. Can you give me the assurance that the people you regulate on behalf of the public are not selling homeopathic anti-malarial prophylaxis in the absence of conventional evidence-based prophylaxis and advice on bed nets?
Professor Lawrence: Obviously I cannot assure you that every pharmacy is not, but I can assure you that the pharmaceutical society has made it very clear to its members that it is completely inappropriate to use homeopathy for the treatment of malaria.

Q72 Dr Harris: They should be struck off if they do.
Professor Lawrence: Yes.[1]

Q73 Mr Boswell: That is helpful. To come back to Paul Bennett, presumably, statistically within a large organisation some of your pharmacists will themselves be interested in homeopathic remedies for self-medication, as it were. Is there any evidence at all, that you are aware of, of the individual who might be pushing a homeopathic solution because they are, as it were, committed to it?
Mr Bennett: I would have no evidence to support that assertion at all.

Q74 Chairman: Yes, Ben?
Dr Goldacre: I just want to say very briefly that I think very widespread anecdotal evidence is that if you ask a pharmacist, including in Boots, for advice and you say that you are interested in homeopathic pills then you will get advice that is certainly not in keeping with the evidence. I know that Professor David Colquhoun recently went into six pharmacies and said: "I've got a five-year old who has had three days of diarrhoea and I would like an alternative treatment", and in all but one case—and I think these were Boots pharmacies—he was told about a homeopathic pill.

Q75 Mr Boswell: Can I just be clear because I may have misheard you. You are suggesting that the potential patient or customer has self-declared an interest in homeopathic medicine before this is prescribed? You are not saying that if I walk in, not having made any commitment and just say: "I have a problem; my child is ill" that it will be "pushed" to you? I just want to be clear of the difference.
Dr Goldacre: They have expressed an interest but they are not getting accurate and impartial information.

Q76 Mr Boswell: Can I just round up and ask Robert Wilson a couple of questions. You chair the BAHM. How do you ensure that member companies comply with the MHRA regulations on labelling and marketing?

[1] *Note by witness:* this is a matter for the fitness to practice panel and may result in a striking off the register if the case was proven.

Mr Wilson: All of our members have what are called GMP licences, which are good manufacturing licences. They are inspected by the MHRA on a two-year basis; so every two years.

Q77 Mr Boswell: This is primarily about safety?
Mr Wilson: Safety and making sure that all the labelling is in line. All our members are licensed and the products they sell are all licensed, and there is a very rigorous set of disciplines that you have to go through to make sure of that and there is also a checking mechanism with the MHRA regularly. All our labels are approved by them; all our leaflets are approved by them. So everything that goes out from many of our members would have been—

Q78 Mr Boswell: Is there much evidence of complaint or failure to comply with that, or not?
Mr Wilson: None whatsoever.

Q79 Mr Boswell: Final question: it is slightly more numinous but I think it might be appropriate to clear it now. In making the case for homeopathic remedies, which you made, and we have had a discussion about evidence, which is our primary concern today, are you at all attracted by the argument (I have to admit I have used it myself in relation to organic farming, where you get the same kinds of arguments about what is or is not evidence) or do you ever use the argument that it is quite important for the scientific community to have that body of practice in place, irrespective of the evidence, in order, perhaps, that some evidence might emerge at a later stage? In other words, when you are looking at the case for homeopathy is this not just a matter of the particular products at the particular time but, also, as it were, having a body of custom and practice which is at least in existence separately from conventional medicine and can be assessed against it from time to time?
Mr Wilson: I think it is very important that homeopathic community makes the case that we are very much pro-research, but, as I said earlier, it has to be good research. Also, this discussion about placebo, I think, is a very interesting one because there are a great deal of things within orthodox medicine that people do not understand—for instance, anaesthetics; they do not know why anaesthetics work but it does not mean that they do not work. The same with electro-shock therapy, or ECT; the schizophrenia treatments, benzodiazepines—there are lots and lots of areas of conventional medicine where they do not understand the mechanism but that does not mean you do not use them.

Q80 Dr Harris: Would you agree that where you do not understand the mechanism, or the proposed mechanism does not make scientific sense, there is a higher onus to show effectiveness than in medicines where there is good evidence and there is a very clear knowledge? So, if anything, the evidence base on homeopathy should be stronger because of the implausible scientific basis for it.
Mr Wilson: I would agree entirely on that, but I come back to the question of who will pay for this? One important point to make is that we do not have patents at the end of our process; we have generic medicines. Anyone can make an Arnica pill, and we are very small—my business in homeopathies is £5 million in this country; we are not talking about huge multinationals here. Who is going to pay for this research? Some of the good research—and there is a lot of good research—in Germany has been funded, interestingly, by some of the healthcare insurance companies, and this Witt Trial that I made reference to has shown, and it was funded by the healthcare companies because they wanted to see was it worth their while funding homeopathies through private health insurance, and the answers came back that, actually, it was cost-effective—not just on cost, it was effective for the patient.

Q81 Chairman: I just wanted to pin you down. Ainsworth is one of your members, is it not?
Mr Wilson: It is, yes.

Q82 Chairman: It sells a Swine Flu Formula—"Swine Pneumonia 36C" online. Is it still doing it?
Mr Wilson: I understand that we had words with them about removing that. However, I am not sure.
Dr Harris: Kind words?

Q83 Chairman: Even though that was clearly quite a dangerous product to be selling, given the pandemic which is sweeping the world, you are still happy to sell that through one of your members?
Mr Wilson: No, absolutely not.

Q84 Ian Stewart: Can I start at this end and work through and just ask: can any of you say categorically that homeopathy does not work in any circumstances to reduce illness, ailments or adverse conditions?
Mr Bennett: Again, it is back to the evidence point. So I could not categorically say it does not work, and I know that there is a strong belief in a number of people that it is efficacious.

Q85 Ian Stewart: So, for you, there is no evidence to show that it works but there is no evidence to show that it does not work. Is that right?
Mr Bennett: Correct.
Ms Brown: I think that misunderstands what the placebo effect is. The placebo effect is very powerful and people do heal, and this accounts for the effects of a lot of medicines—or a certain part of their effects. I think that you would expect to see people benefit from taking a placebo.

Q86 Ian Stewart: Let me help you. I did understand the placebo effect. Other than the placebo effect, can you answer my question?
Ms Brown: I have not seen any evidence to suggest there is any systematic benefit beyond the placebo benefit.

Q87 Ian Stewart: That is not what I asked; I asked if you could categorically say that it does not work?
Ms Brown: Yes. Insofar as I can categorically say anything in this life, I would say yes.
Dr Goldacre: There have now been around 200 trials of homeopathy against placebo sugar pills and, taken collectively, they show that there is no evidence that homeopathy pills are any better than a placebo. So I would say, on the basis of that, that they do not and, also, that it is not worth doing any more placebo controlled trials because you would be throwing good money after bad and you would have to have a huge number of very strongly positive trials to outweigh all of the negative ones.
Professor Lawrence: I agree there is no evidence on controlled trials. However, patients do feel benefit, and I think that may come from the fact that when they go to a homeopathy practitioner, often, they have a consultation and there are others things associated with treatment other than pills, in some cases.

Q88 Ian Stewart: Does that mean, Jayne, that you cannot categorically say it does not work?
Professor Lawrence: In randomised controlled trials I categorically say it does not work.

Q89 Dr Iddon: How do you interpret the arnica trials that Robert Wilson was mentioning? Have you looked at those?
Professor Lawrence: The arnica trial?

Q90 Dr Iddon: Yes.
Professor Lawrence: I have not seen that.

Q91 Dr Iddon: Bruising is a physically observable effect and he is claiming that arnica reduces bruising quicker in a random controlled trial with people in who do not have any application of medicine.
Professor Lawrence: I have not seen the data so I really cannot comment on the trial. However, as Ben said before, you will always get some positive and negative trials, and you have to take overall the results.

Q92 Ian Stewart: Paul, can I start with you again—
Mr Wilson: Can I just come in? Actually, there was a trial by Mollinger et al in April this year which showed that "patients given homeopathic remedies showed responses characteristic of those expected from the remedy, while those given natural placebos did not. This points to a genuine homeopathic effect rather than a mere placebo response." I am very happy to submit any of the things I have mentioned to the Committee afterwards. Just one other thing on a more personal level: teething granules—a teething product we give for babies, which is one of our bestsellers and is recommended highly by pharmacists because it is effective. Babies do not manifest the placebo effect and mothers continue to buy this product enormously because they see it working and working incredibly quickly.

Q93 Ian Stewart: Can I start again at your end, please, Paul? Is there any evidence that patients are being put at risk from unregulated homeopaths?
Mr Bennett: Absolutely no evidence that I am aware of, and if there was we would probably act on that.
Ms Brown: From unregulated homeopaths?

Q94 Ian Stewart: Yes.
Ms Brown: Meaning they are not professionally registered homeopaths?
Ian Stewart: I will say it again—in an effort to get balance into these questions—is there any evidence that patients are being put at risk from unregulated homeopaths? I will bring in some other questions.
Dr Harris: The question is in the context of a proposal to regulate them—

Q95 Chairman: I am sorry, Dr Harris; a colleague is asking his questions, and I want him to ask them.
Ms Brown: If you are referring to the professional registration as regulation then I have not seen any evidence to suggest a significant difference between regulated and unregulated. They are currently unregulated. The difference I have seen, referring back to the anti-malarial prophylaxis issue, was that at the time we tested, having found that various pharmacies were willing to provide anti-malarial prophylaxis and homeopathies with consultations, we tested also whether a similar thing would happen if you consulted GPs who also practised homeopathy, or people who were medically trained, and the answer was no; we did not find (I cannot categorically say) anybody with a medical training who was willing to prescribe homeopathic anti-malarial prophylaxis.

Q96 Ian Stewart: Maybe for Ben's benefit and the others, I have spent the last four years working with the British Acupuncture Council and the Traditional Chinese Medicine Association, on the basis of developing the regulation that has just been implemented by the Government. So I am very much in favour of appropriate regulation and safeguards. The question that then follows—and perhaps the others will take this into consideration—is: how do you determine between a good homeopath and a bad homeopath, in the current circumstances?
Ms Brown: Anybody offering medical advice, I believe, needs to have medical training. I think that the best way of ensuring that patient care is at its optimal is to ensure that they have medical training.
Dr Goldacre: It is not entirely clear to me what is being asked.

Q97 Ian Stewart: The question is that whenever a patient goes to a pharmacy or any other outlet and is offered homeopathic remedies, whether that is being done on the basis as explained by Paul earlier—this is a worse situation for the patient than if it was a regulated and licensed situation?
Dr Goldacre: It depends how well they are regulated, but Professor Ernst has shown that the Society of Homeopaths are not adequately regulating their

own members at present and that they make claims which breach their own regulations. The evidence of the Sense About Science and *Newsnight* stint, if you like, where they went to ten homeopaths and found that nine out of ten were happy to give advice on malaria—I do not imagine that a problem like that will go away just because of regulation; I think there is a deeply ingrained systemic problem with people who believe that sugar pills are medically effective. I think you can tweak at the edges but, fundamentally, when you are talking about people who believe that sugar pills have medical effects without evidence then you are starting from a position that is actually quite difficult to reason with.

Q98 Ian Stewart: In our briefing, Ben, we had it explained that homeopathy claims that water has a memory. In the statement that we received against homeopathy it said that if that was true it would turn the science upside down. Do you agree with that?
Dr Goldacre: Physics is not really anything that interests me; I do not know if it would turn the world upside down, but the bottom line is it does not matter about the mechanism by which homeopathy is claimed to work or does not work; it does not work.

Q99 Ian Stewart: Are you sure it is not just the level of knowledge and understanding we have at this point in time? I remember the story about Niels Bohr going to Max Planck and saying: "Nobody accepts my theories and work" and Max Planck saying to him: "You'll need to wait till they die before you are accepted". Is this not the same case here; that the evidence just is not there yet?
Dr Goldacre: No. I think 200 trials which, taken collectively, showed that homeopathy pills worked no better than a placebo is very good evidence against homeopathy.

Q100 Ian Stewart: Do you accept Robert Wilson's critique of those trials?
Dr Goldacre: No. What Robert Wilson has done is exaggerate what homeopaths—

Q101 Ian Stewart: I am sorry, do you accept his answer that those trials were done in an insignificant sample?
Dr Goldacre: No, and the criticisms that he made did not hold up. For example, it is the smaller, poorer quality trials which he criticises which are more likely to give a result that favours homeopathy, and it is when you remove those smaller and less effective trials that homeopathy is shown to be no more effective than placebo. What Mr Wilson has done on several occasions today is pull out individual trials. It is a basic, central tenet of evidence-based medicine that you cannot pull out individual trials which go against the grain of what the totality of the evidence shows. You would not accept that for any medical treatment.

Q102 Ian Stewart: Jayne, would you like to comment?
Professor Lawrence: There were several questions there. Which one do you want me to answer?
Ian Stewart: You choose.

Q103 Chairman: The most interesting!
Professor Lawrence: First of all, I think the Pharmaceutical Society would recommend some regulation of homeopaths, because while we are sure a lot of homeopaths are responsible there are a number of them that do make irresponsible claims, and I think it is very important that that is actually stopped.

Q104 Ian Stewart: Is it fair to say that that is the same in any discipline?
Professor Lawrence: Yes. With respect to the science issue, I think it probably would be revolutionary if homeopathy was proved to be right, because it does go against a lot of fundamental understanding of science as it stands at the moment.

Q105 Ian Stewart: Is that what subatomic particle physics did for Newtonian physics?
Professor Lawrence: I do not know. There is the question of dark matter at the moment—that may turn science on its head as well.

Q106 Ian Stewart: Robert, do you want to conclude?
Mr Wilson: Just on your science question, I think you have hit the nail on the head; that we just have not yet understood these highly dilute substances. Two points: it is interesting that since the mapping of the human genome we are now talking about bespoke remedy, or medicines, for cancer treatment; not a blanket cancer treatment. Hahnemann talked about treating the person not the disease 200 years ago. Secondly, with highly diluted substances, again, we are now pushing at the boundaries of this. Some of the drugs used in psychosis and in mental conditions are using extremely high dilutions. So I believe that we will find the answers to why homeopathy works because, clearly, in our view, it does work and there is a lot of evidence. I am not just cherry-picking because the other side, equally, cherry-picks. I would say, again, that as far as the homeopathic industry is concerned we would welcome research.

Q107 Dr Harris: What are your scientific qualifications?
Mr Wilson: Can I answer your second question?

Q108 Chairman: I will let you have the last word, Dr Harris.
Mr Wilson: On regulation, obviously I work for the manufacturers—I represent the manufacturers here today—but we would strongly support regulation. If you look at, for instance, the osteopaths, who have set up a very strong regulatory body of their own, I think it is a shining example that has benefited the osteopaths, because all of their members are regulated by the same authority, and the patients know that they have got the protection of that body

behind them. So I think the osteopaths are an example of a very successful complementary system that is working well with regulation at its centre.
Chairman: At least we have found one point of agreement, that better regulation would help. You have, literally, 30 seconds.

Q109 Dr Harris: You opined, Mr Wilson, on the dilution of anti-psychotics and other treatments for mental health. I was just wondering what your scientific qualifications were. I know you are an expert in marketing and manufacturing of homeopathic medicines, but I was wondering what your scientific qualifications were that made you confident to opine on the science and the pharmacology of anti-psychotics.
Mr Wilson: What interests me are arguments within conventional medicine that resonate with some of the principles of homeopathy. One of the great stumbling blocks that homeopathy has today is its dilution. That is the central question—

Q110 Dr Harris: I was just asking whether you have any qualifications.

Mr Wilson: I have none other than an interest and having spent 25 years in this field.

Q111 Dr Harris: Finally, you said that you regretted that in recent years the volume of sales had reduced because of what you described as "attacks" on homeopathy from the science community. Would you say that, if the scientific community think they have the data, that is probably a good thing? Is it not? You could say that that is an effect of memory of data versus memory of water; that people are making data-based decisions.
Mr Wilson: Yes, I think my view is that we need to have more research into homeopathy; research that can stand up to some of the criticisms that have been placed at it.
Dr Harris: We should continue to do research until it shows it works?
Chairman: On that note we will call this session to a halt because I think that is something else we can agree on, that more research would help. Saved by the bell. Can I thank our panel very, very much indeed. It is a difficult area but you have done brilliantly this morning, and we thank you very much indeed.

Memorandum submitted by Dr Peter Fisher (HO 21)

HOMEOPATHY: THE EVIDENCE FROM BASIC RESEARCH

Background

1. Its "implausibility" from a scientific standpoint is often cited as a reason for scepticism about homeopathy, even in the face of positive clinical evidence. For instance a systematic review of clinical trials, published in the BMJ stated "we would accept that homeopathy can be efficacious, if its mechanism of action were more plausible" [1]. Contrary views have also been expressed: "Indeed it is often stated…that the burden of proof it requires should be much greater than for other scientific hypotheses. Such an attitude may itself be considered unscientific: the same level of supporting evidence should be accepted for all scientific developments. If a lower level of proof is set for hypotheses that fit prior beliefs then we bias our view of science in favour of such beliefs and may be easily misled".[2]

2. This submission examines the basic science evidence concerning homeopathy and related areas of science to cast light on the alleged implausibility of homeopathy.

3. Homeopathy is based on the idea of "like cures like", also known as the similarity principle. Medicines are selected on the basis that they may, in healthy people, provoke syndromes similar to those from which the patient is suffering. Homeopathy emphasises the "secondary" effects of medicines, these are the reactions of living systems to drugs, as opposed to the primary actions of drugs per se.

4. The most controversial aspect of homeopathy is its use of very high dilution. These are prepared by a process of sequential dilution with vigorous shaking at each stage of dilution, known as succussion. Dilution is usually in steps of 1:10 or 1:100, referred to as x or d (decimal) or c (centesimal) respectively.

5. Avogadro's Constant (also known as Loschmidt's Constant) is the number of particles (atoms or molecules) in a gram mole of a pure substance. Its value is 6.02×10^{23} mol^{-1}. The implication is that material quantities of the original substance are extremely unlikely to remain in homeopathic medicines diluted to concentrations greater 12c or 24x (10^{-24} M). Such dilutions are referred to as are referred to as "ultramolecular" or BRAN (Beyond the Reciprocal of Avogadro's Number).

6. It is important to note that the use of ultramolecular dilutions is not a defining characteristic of homeopathy. Many homeopathic medicines are not in ultramolecular dilutions.

7. It is sometimes claimed that it is impossible for such highly diluted substances to have "real" physiological effects. Randomised placebo-controlled trials are, in principle, capable of demonstrating such effects for homeopathic medicines. But they are expensive, cumbersome and difficult to repeat. The question of whether extreme dilutions are capable of exerting "real" (as opposed to psychologically mediated) effects, and if so, how such effects might be mediated is best answered by laboratory experiments.

8. This submission focuses on:

— Scientific research on "like cures like".

— Evidence from biological experiments that very high dilutions can have effects. This includes work based on intact animals, plants and isolated cells and cell cultures.

— Research concerning possible ways in which such effects might be mediated, this is mostly in the form of physical and physical chemistry research.

Similarity

9. The primary principle of homeopathy is that of similarity. In this area there is substantial overlap with other areas of science including toxicology and pharmacology.

10. In Toxicology hormesis, the stimulatory or beneficial effects of small doses of toxins[3,4,5,6]has been extensively studied. The recent concept of "postconditioning hormesis" refers to a small stimulus exerting a beneficial effect after a biological system has experienced a harmful stress of similar nature.[7]

11. The main competing toxicological hypothesis to hormesis is the threshold dose response model. This model predicts that the effects of a toxin decline in a linear fashion with reducing dose; hormesis predicts a J-shaped or "hockey stick" curve, with a reverse effect at low dose levels. Analysis of a very large dataset of a standard cancer drug screening method based on yeast show the hormesis model to be more accurate in predicting response at low doses.[8]

12. Wiegant's group at the University of Utrecht, Netherlands studied the specificity of low dose responses in cultured rat hepatoma cells. The cells were subjected to heat shock followed by low doses of chemical toxins. The greater the similarity between the two stresses, the greater the cell survival.[9]

13. Relevant pharmacological concepts include drug rebound effects, dose-dependent reverse effects and paradoxical pharmacology[10,11,12]. Such effects are very widely observed. For instance that β-agonist drugs which stimulate the heart and have positive effects in acute heart failure, increase mortality in the chronic heart failure while the reverse is true for β-antagonist drugs.

14. The toxicological and pharmacological phenomena mentioned above have in common the occurrence secondary, reverse or paradoxical effects of drugs and toxins in living organisms as a function of dose or time

15. In some cases the biological basis of these secondary reversed effects is understood: known mechanisms include "chaperone" protein induction, cell surface receptor up—or down-regulation and enzyme induction. In other cases the mechanism is unknown.

Biological Models of High Dilution Effects

16. A meta-analysis led by Prof Claudia Witt of the Charité University Medical Centre, Berlin evaluated the quality and results of in-vitro biological experiments with ultramolecular stepwise agitated dilutions. Quality was assessed by a modified SAPEH score. 75 publications were found of which 33% were replications. 73% showed an effect with ultramolecular dilutions including 68% of high quality experiments. 73% of replication experiments were also positive.[13]

17. The most frequently used in-vitro model was basophils, used in 42% of experiments. Basophils are white blood cells involved in the immune response. One series of experiments comprises 17 experiments on the inhibition of basophil activation by high dilutions of histamine. It spans over 25 years and includes multi-centre and independent replications.[14,15,16] There has been steady refinement of the method, including automation. All but two repetitions have reported positive results. There is growing insight into possible mechanisms of action, for instance the response is highly specific to histamine. It is not induced by the structural analogue histidine, and it is blocked by histamine antagonist drugs. Experiments with series of dilutions show alternating peaks and troughs of effect at different dilutions. The reason for this is not understood, but there is a consistent peak of activity at 16c (Histamine 10^{-32}M), well into the ultramolecular range

18. Another cellular system which has been the subject of repeated experiments over a long period is the effect of ultramolecular dilutions of aspirin on blood clotting. The effect is the reverse of that found with substantial doses: ultramolecular dilutions promote clotting.[17,18] Recent work with "knock-out" mice demonstrates that the effect depends on the enzyme COX-2.[19]

19. Several white blood cell models indicate that homeopathic medicines modulate cytokine expression. These suggest testable hypotheses on the locus of in-vivo effects of homeopathic medicines.[20,21,22,23]

20. Among plant models the most reproduced is that examining the effects of ultramolecular, homeopathically diluted arsenic on arsenic-intoxicated wheat seedlings.[24,25,26]

21. The most robust animal model is the effect of thyroxine on the rate of metamorphosis of frogs. In substantial dose thyroxine increases the rate of metamorphosis, it has the reverse effect in ultramolecular dilution.[27], This effect has been reproduced in multi-centre experiments[28] and by independent workers with different species of frog.[29]

22. Many other biological model experiments in homeopathy have been conducted. The HomBRex Database on Fundamental Homeopathy Research is maintained by the Carstens Foundation.[30] It contains details of approximately 1,300 such experiments using intact organisms or parts of organisms (including organs, cells, subcellular structures). The most commonly studied animal is the rat, used in 67 experiments. The most frequent type of model was intoxication, most frequently with arsenic. Other rat studies examined behaviour, oedema and inflammation and hormonal disturbances among others. There are also a number of biological models including cell, plant and animal models which consistently show effects with ultramolecular dilutions of various biologically active substances including drugs, toxins, hormones and immune mediators.

23. There is thus substantial scientific evidence that biologically active substances including drugs and toxins may have reversed or paradoxical secondary effects as a function of time or dose, and that these effects are highly specific.

Possible Mechanisms of Action of Ultramolecular Dilutions

24. These findings pose a challenge in terms of understanding the mechanism of action. Homeopathic medicines are prepared in water alcohol mixtures and most attention has focussed on structural or coherence effects induced in water by the preparation process. It has been suggested that hydrogen bond mediated structural or coherence effects, dissolved gases and perhaps dissolved silicates from the glassware play a role.

25. Experiments using a range of standard physical and physico-chemical methods have reported structural anomalies in water prepared according to the homeopathic method. Methods include low temperature thermoluminesence, flux calorimetry, conductometry, pHmetry Raman and Ultra-Violet-Visible (UV-VIS) spectroscopy and Nuclear Magnetic resonance (NMR).

26. Low temperature thermoluminesence involves freezing water to the temperature of liquid nitrogen, bombarding it with x- or y-rays, then warming it, whereupon it emits a characteristic glow. The "signature" of lithium is detectable in ultramolecular lithium chloride by this method[31]. This result has been independently verified.[32] The effect appears to be dependent on the atmosphere in which the dilution is conducted, the effect is more marked with dilutions prepared in an oxygen atmosphere and less so in dilutions prepared under reduced pressure, compared to normal atmosphere.[33]

27. The group led by Elia at the University of Naples has, over a decade published series of papers investigating physico-chemical properties of ultramolecular dilutions. They have detected, using standard methods, anomalies of specific conductivity, heat of mixing and other parameters.[34,35,36] These findings suggest the extended, ordered dynamics involving liquid water molecules, in the form of dissipative structures, within such dilutions. Dissipative structures, described by the Nobel Laureate Ilya Prigogine, are complex, self-organising systems, far from thermodynamic equilibrium.[37] Within a dissipative structure there is long-range interaction between particles, and they exchange energy and matter with their environment. Examples include cyclones, lasers and living organisms

28. NMR results have varied, depending on the parameters measured.[38,39] But when 20MHz T1 and T2 water proton NMR relaxation rates are measured, homeopathic dilutions of histamine are distinguishable from solvents up to ultramolecular levels. The effect is attributed to stable supramolecular structures, involving nanobubbles of atmospheric gases and highly ordered water around them. It is deleted by heating.[40,41,42]

29. Work from the Materials Research Institute of Pennsylvania State University shows that ultradilute homeopathic medicines can be distinguished from controls and each other by Raman and Ultra-Violet-Visible (UV-VIS) spectroscopy[43,44] . These effects may be due to epitaxy, the transfer of information, not material, from the surface of one material, usually solid, to another, usually liquid. Semiconductor manufacturing often uses epitaxial growth to generate specific types of microtransistors and integrated circuitry.

30. Diverse but standard physical and physico-chemical methods have detected structural anomalies of water in homeopathic preparations. There is convergence among the results which suggest mesoscale (of the order of microns) organisation of water molecules in ultramolecular dilutions prepared by the homeopathic method. Dissolved gases may play an important role. It appears likely that this organisation is hydrogen-bond mediated.

Criticisms

31. The claim that water can "remember" substances with which it has been in contact, and that such "memory" is mediated by hydrogen bonds has been criticised, mostly on theoretical grounds.[45] Such arguments mostly involve the short duration of individual hydrogen bonds in liquid water (about a picosecond).

32. But this does not imply that the mesoscale structure of water must change on the same time scale. For instance in ice hydrogen bonds are also very shortlived but an ice sculpture can "remember" its shape over extended periods. On a smaller scale, cation hydrates are commonly described with particular structure (eg the octahedral $Na + (H2O)_6$ ion) even though the individual water molecules making up such structures have very brief residence times (microseconds).[2]

33. Such arguments ignore the fact that the behaviour of a large population of water molecules may be retained even if that of individual molecules is constantly changing: a wave can cross an ocean, remaining a wave although its molecular content is continuously changing.

34. Evidence denying the long life of water clusters is mostly based on computer simulations but these cover only nanoseconds of simulated time. Such short periods are insufficient to show longer temporal relationships, for example those produced by oscillating reactions. They also involve relatively few water molecules (100–1000), small (nanometre) dimensions, insufficient to show mesoscale (micron) effects. They use models of the water molecule whose predictions correspond poorly to the real properties of water.

35. Certain "memory" effects in water are well established and uncontroversial: for instance the formation of clathrate hydrates from aqueous solutions whereby previously frozen clathrates within the solution, when subsequently melted, predispose later to more rapid clathrate formation.[46] This is explained by the presence of nanobubbles, extended chain silicates or induced clathrate initiators.[47]

Conclusions

36. I have examined basic science research of relevance to homeopathy with a view to establishing how "implausible" it is. I have briefly reviewed the evidence in three main domains: similarity, using toxicological and pharmacological sources; biological models of ultramolecular response, including isolated call, plant and whole animal models; possible mechanisms by which effects of ultramolecular dilutions might be mediated, drawing on physical, physico-chemical and materials science.

37. Toxicological and pharmacological phenomena such as hormesis, drug rebound effects and paradoxical pharmacology are very widely observed. They have in common the occurrence secondary, reverse or paradoxical effects of drugs and toxins in living organisms as a function of dose or time and are closely analogous to the homeopathic concept of secondary drug action.

38. There is a substantial body of work on the effects of ultramolecular dilutions in various biological models, including isolated cells, plants and animals. Several lines of research now yield repeatable results. These include inhibition of basophil activation by ultramolecular dilutions of histamine, the effect of ultramolecular dilutions of aspirin on blood clotting; and the effect of ultramolecular thyroxine on the rate of metamorphosis of frogs. Several models suggest loci for these effects.

39. Experiments using a range of standard physical and physico-chemical methods have detected structural anomalies of water in ultramolecular homeopathic preparations. Methods include low temperature thermoluminesence, flux calorimetry, conductometry, Raman and Ultra-Violet–Visible spectroscopy and Nuclear Magnetic resonance.

40. The contention that homeopathy is implausible, impossible or isolated from other areas of science is untenable. Although the total volume of research in the area is relatively small, high-quality and repeated experiments have yielded positive results. These raise important and unanticipated scientific questions.

Declaration of Interest

I am Director of Research and Clinical Director of the Royal London Homoeopathic Hospital, part of University College London Hospitals NHS Foundation Trust. I occasionally accept speaking fees from homeopathic manufacturers, and have undertaken research projects funded by such companies. I do not have a private practice.

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(note: I have not attempted to give comprehensive references. Where there are multiple references to a body of work, I have attempted to span it by giving references which reflect the duration and scope).

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November 2009

Memorandum submitted by Professor Edzard Ernst (HO 16)

Many years ago, I have worked as a homeopath and therefore understand the concepts of homeopathy (eg like cures like and dilution increases effectiveness). These concepts are not supported by science and most homeopaths would probably admit that. However, they claim that several in vitro experiments suggest that the homeopathic dilution process does demonstrably alter the structure of water. The counter-arguments are that this only happens for nano-seconds; it also does not explain how such dilutions generate health effects in vivo; nor does it explain why (water-free) globuli used widely in homeopathy should be effective.

Homeopaths claim that, while we do not understand *how* their remedies work, clinical evidence shows *that* they work. The truth, however, is that systematic reviews or meta-analyses of the totality of the clinical data fail to show that homeopathic remedies generate clinical effects beyond those of placebo. Homeopaths counter by criticising the methodology of the latest Lancet meta-analyses by Shang *et al*. This, however, ignores the fact that over a dozen similar systematic evaluations have all come to the same conclusion.

Homeopaths furthermore claim that animal studies also show the effectiveness of homeopathic remedies. This implies that they must be more than placebos. Yet, if one reviews the totality of these data, a picture emerges which closely resembles the human trial data alluded to above.

Homeopaths also often refer to large observational studies, for instance, one from the Bristol Homeopathic Hospital, which imply that ~70% of patients improve after homeopathic treatment. Such "real life" studies and their years of experience, they claim, is more meaningful than clinical trials. Yet the discrepancy between the two sets of results is easy to explain: the patients in observational studies improved because of placebo-effects, regression towards the mean, concomitant treatments and many other confounders. In clinical trials, all of these factors are eliminated and therefore no differences are observed between homeopathic remedies and placebos.

Finally homeopaths claim that their approach is risk-free. This is, clearly not true. Highly dilute homeopathic remedies may well be free of side-effects. But forfeiting or delaying effective treatments, as homeopathy often does, can cause real harm. This issue is not well-researched, except for one particular area: many studies have confirmed that (lay) homeopaths tend to discourage parents from immunizing their children, often recommending using homeopathic vaccinations (which are ineffective) instead.

In conclusion, there is no good evidence to suggest that homeopathic remedies have any specific therapeutic effects and there is some evidence to show that homeopathy can cause harm. Thus its risk-benefit profile is negative.

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Supplementary memorandum submitted by Professor Edzard Ernst (HO 16a)

In the document submitted on 5 November 2009, I stated that "systematic reviews or meta-analyses of the totality of the clinical trial data fail to show that homeopathic remedies generate clinical effects beyond those of placebo". This is an appendix substantiating this claim which I ask to be attached to my previously submitted evidence.

1. Systematic Reviews of Homeopathy

In 2002, I published a summary[1] of all systematic reviews that emerged after Linde's positive Lancet meta-analysis (first row in Table 1). Six re-analyses of Linde's data—including two by Linde himself [never cited by homeopaths!]—arrived at a less than positive conclusion (Table 1). Furthermore, 11 new and independent systematic reviews published after Linde's article also fail to conclude that homeopathy is effective (Table 2). Since the publication of my article[1], further negative systematic reviews have appeared, eg the well-known one by Shang *et al* in the *Lancet*[2] and our review of homeopathy for childhood conditions.[3]

2. Shang et al

Probably, the review by Shang *et al*[2] has been criticised by homeopaths. While no review can ever be without limitations, these criticisms have been refuted. If needed, I can provide further written evidence on this issue.

3. The Evidence is Getting Weaker

We published a further analysis testing whether the evidence for or against homeopathy is getting stronger.[4] It compares the old[5] with the new edition[6] of one of our books. Both are based on systematic reviews employing virtually the same methodology.[5,6] The indications included in our books are those which are common in primary care, frequently treated with CAM and for which clinical trials are available. The literature was searched up to March 2000 for the first[5] and up to May 2005 for the second edition.[6] To evaluate the data, we created a parameter which we called the "weight of the evidence". This was a compound variable consisting of the level of evidence (eg whether there was a single trial or a meta-analysis), the quality of the primary studies and the volume (ie total number of trials and their total sample size).[7] The weight was graded in three categories: low, moderate and high. We graded the direction of the evidence in five categories: clearly positive, tentatively positive, uncertain, tentatively negative and clearly negative. In Table 3, we compared the weight and direction of the evidence of homeopathy for treating those conditions which were included in our book: AIDS, anxiety, asthma, cancer, chronic fatigue syndrome, fibromyalgia, hay fever, headache, hypertension, labour induction, migraine, osteoarthritis, overweight, premenstrual syndrome, rheumatoid arthritis, stroke, tinnitus and upper respiratory tract infection. Our comparison suggests that, as more clinical trials of homeopathy become available, the overall evidence gets not stronger but weaker. For four conditions for which no trial evidence had been available in 2000, new evidence had emerged in 2005. In three cases, this was clearly negative, and in one it was rated as uncertain. Changes in

either the weight or the direction of the evidence were observed in four of the 18 homeopathy-related indications (Table 3). By definition, the weight could only grow between 2000 and 2005. For one condition, namely chronic fatigue syndrome, the direction of evidence changed in a "positive" sense. For three indications, the evidence had altered in the opposite sense: anxiety, asthma, rheumatoid arthritis. (Table 3)

4. Other Evidence

Homeopaths often argue that there are further systematic reviews which allegedly do show that homeopathy works. Examples are a recent Swiss Health Technology Assessment or the review by Mathie.[8] The problem is that these articles do not fulfil the formal criteria for a systematic review, originate from homeopaths, are open to bias and can be criticised on important methodological grounds.[9]

5. Conclusion

Systematic reviews of rigorous trials of homeopathy fail to demonstrate that homeopathic remedies have effects beyond those of placebo. Monitoring the development of the evidence over time we find that the overall evidence-base of homeopathy is becoming more and more negative. Confronted with such data, homeopaths tend to counter that the method of testing homeopathy in clinical trials is flawed and the hierarchy of evidence is of disputed value. Nowadays they frequently cite Sir Michael Rawlins (NICE) in support of this view who recently gave a lecture discussing that the evidence from randomised clinical trials should not be seen in isolation. Homeopaths fail to mention, however, that Sir Michael also made the following statement about homeopathy: "As far as homeopathy is concerned it breaks every rule in the evidential base! It is biologically implausible; it is almost always used to treat conditions where the natural history is unpredictable; and the signal to noise ratio is close to one!".[10]

Table 1

THE SYSTEMATIC REVIEW BY LINDE ET AL[11] AND ITS SUBSEQUENT RE-ANALYSES

Reference	*Included trials (number)*	*Total patient number*	*Assessment of methodological quality*	*Meta-analysis*	*Overall conclusion**	*Comment*
Linde (1997) [11]	all double-blind and/or randomized placebo-controlled trials of any clinical condition (n = 186)	2,588	yes	of 89 trials which could be submitted to meta-analysis: OR = 2.45; of 26 "good quality trials": OR = 1.66 (both in favour of homeopathy)	clinical effects of homeopathy are not completely due to placebo	review was criticised for 1) including different remedies 2) including different conditions 3) including non-randomized trials
Ernst (1998) [12]	all studies from Linde *et al*[11] which received 90 (of 100) points in at least 1 of the 2 quality ratings, using highly dilute remedies, following the principles of "classical"* homeopathy (n = 5)	587	yes	OR = 1.0 (no evidence in favour of homeopathy)	homeopathic remedies are associated with the same clinical effects as placebo	this analysis specifically tested the efficacy of highly diluted remedies (other remedies could still work via conventional pharmaceutical effects)
Linde (1998) [13]	all trials from Linde *et al*[11] which tested "classical"* homeopathic remedies against placebo, no treatment or another treatment (n = 32)	1,778	yes	19 placebo-controlled trials were submitted to meta-analysis; OR = 1.62; however, when this analysis was restricted to the methodologically best trials the effect was no longer significant	individualised homeopathy has an effect over placebo; the evidence, however, is not convincing	not all of the included trials were randomized and many had other serious methodological weaknesses

Reference	*Included trials (number)*	*Total patient number*	*Assessment of methodological quality*	*Meta-analysis*	*Overall conclusion**	*Comment*
Linde (1999) [14]	all trials from Linde *et al*[11] which could be submitted to meta-analysis (n = 89)	n.d.p.	yes	the mean OR of the best studies was not in favour of homeopathy	there was clear evidence that studies with better methodological quality tended to yield less positive results	the authors felt that these results "weaken the findings of [their] original meta-analysis"
Morrison (2000) [15]	26 trials classified by Linde *et al*[11] as high quality (n = 26)	n.d.p.	yes	none	no significant trend was seen when correlating security of randomisation and trial result	large multicenter trials were recommended
Ernst (2000) [16]	all trials from Linde *et al*[11] that received quality ratings between 1–4 on the Jadad score (n = 77)	n.d.p.	yes	none	there is a . . . strong linear correlation between OR and Jadad score (n = 0.97, $p < 0.05$); homeopathic remedies are, in fact, placebos	extrapolation from this correlation implies that the most rigorous studies yield an effect size of zero
Sterne (2000) [17]	89 trials of Linde *et al*[11] review compared to 89 trials of allopathic medicines	n.d.p.	yes	strong evidence for publication bias causing a false positive result in favour of homeopathy	when adjusting high quality trials [of homeopathy] for publication bias, the OR changed from 0.52 to 1.19 but remained unchanged for allopathy	paper probably not peer-reviewed, adjusting for bias nullified the effect of homeopathy but not for allopathy

RCT = randomized clinical trial, OR = odds ratio, * = verbatim quotes, n.d.p. = no details provided.
* classical homeopathy = approach where remedies are individualised according to patient characteristics deemed important by homeopaths.

Table 2

INDEPENDENT SYSTEMATIC REVIEWS OF HOMEOPATHY

Reference	*Included trials (number)*	*Total patient number*	*Assessment of methodological quality*	*Meta-analysis*	*Overall conclusion*	*Comment*
Barnes (1997) [18]	all placebo-controlled trials of homeopathy for post-operative ileus (n = 6)	776	yes	weighted mean difference to time until first sign of peristalsis was in favour of homeopathy (−7.4 hours)	homeopathic treatment can reduce the duration of post-operative ileus, however, several caveats preclude a definitive judgement	the methodologically best trial was convincingly negative
Ernst (1998) [19]	all placebo-controlled trials of homeopathy for delayed onset muscle soreness (DOMS) (n = 8)	311	yes	no meta analysis possible, all randomized trials were negative	the evidence does not support he hypothesis that homeopathic remedies are more efficacious than placebo for DOMS	DOMS was chosen because it was submitted to clinical trials more often than any other condition
Ernst (1998) [20]	all placebo-controlled trials of homeopathic arnica (n = 8)	338	yes	no meta-analysis possible, no clear trend in favour of homeopathy	the claim that homeopathic arnica is efficacious beyond a placebo effect is not supported by rigorous clinical trials	this analysis set out to test the remedy that had been most frequently submitted to clinical trials, ie arnica (see also Lüdtke below)
Ernst (1999) [21]	all RCTs of homeopathy for migraine prophylaxis (n = 4)	284	yes	no meta-analysis possible; 3 of 4 trials were negative (including the methodologically best)	the trial data . . . do not suggest that homeopathy is effective in the prophylaxis of migraine or headache beyond a placebo effect	this analysis tested the efficacy for a condition that homeopaths often treat in clinical practice
Ernst (1999) [22]	all controlled clinical trials of "classical"* homeopathy versus conventional treatments (n = 6)	605	no	no meta-analysis possible	no clear trend in favour of homeopathy	non-randomized studies were also included

Reference	*Included trials (number)*	*Total patient number*	*Assessment of methodological quality*	*Meta-analysis*	*Overall conclusion*	*Comment*
Lüdtke (1999) [23]	all controlled clinical trials of homeopathic arnica (n = 37)	n.d.p.	yes	no meta-analysis possible	no clear evidence in favour of homeopathic arnica was found	paper probably not peer-reviewed, trials that used arnica in combination with other remedies and those which were not placebo controlled were also included
Cucherat (2000) [24]	all RCTs of homeopathy vs placebo with clinical or surrogate endpoints (n = 16)	2,617	yes	combined 2-tailed p value was highly significant (p = 0.000056) in favour of homeopathy	there is some evidence that homeopathic treatments are more effective than placebo	strength of evidence was estimated to be low by the authors
Vickers (2000) [25]	all RCTs of homeopathic oscillococcinum vs placebo for influenza (n = 7)	3,459	yes	RR = 0.64 for influenza prevention; RR = 0, 28 for influenza treatment	treatment reduced length of illness significantly by 0.28 days	the authors stated that "the data are not strong enough to make a general recommendation"
Linde (2000) [26]	all RCTs of homeopathy vs placebo for chronic asthma (n = 3)	154	yes	no meta-analysis possible	no clear tread in favour of homeopathy	not enough evidence for reliable assessment
Jonas (2000) [27]	all controlled clinical trials of homeopathy for rheumatic conditions (n = 6)	392	yes	combined OR = 2.19	homeopathic remedies work better than placebo	not enough trials for any specific condition to allow reliable assessment
Long (2001) [28]	all RCTs of homeopathy for osteoarthritis (n = 4)	406	yes	no meta-analysis possible	no clear trend in favour of homeopathy	not enough evidence for reliable assessment

RCT = randomized clinical trial, OR = odds ratio, RR = relative risk
* classical homeopathy = approach where remedies are individualised according to patient characteristics deemed important by homeopaths.

Table 3

SUMMARY OF CLINICAL EVIDENCE FOR HOMEOPATHIC MEDICINES (COMPARISON OF OLD AND NEW EDITIONS OF "THE DESKTOP GUIDE TO COMPLEMENTARY AND ALTERNATIVE MEDICINE")

Condition	*Weight of Evidence*		*Direction of evidence*	
	2000	*2005*	*2000*	*2005*
AIDS/HIV infection	O	O	↗	↗
anxiety	O	OO	↗	↘
asthma	OO	OO	→	↘
cancer palliation	no entry	O	no entry	↓
chronic fatigue syndrome*	O	OO	↗	↑
fibromyalgia	O	O	↗	↗
hay fever*	OO	OO	↑	↑
headache	O	O	↓	↓
hypertension	no entry	O	no entry	↓
labour induction	no entry	OO	no entry	↓
migraine	OO	OO	↘	↘
osteoarthritis	O	O	↗	↗
overweight/obesity	no entry	O	no entry	→
premenstrual syndrome	O	O	↑	↑
rheumatoid arthritis	OO	OO	↗	→
stroke	O	O	↓	↓
tinnitus	O	O	↓	↓
upper respiratory tract infection	OO	OO	→	→

* For two conditions, the direction of the evidence is positive but the weight of the evidence is not sufficient to justify positive recommendations

Legend

OOO high weight of evidence
OO moderate weight of evidence
O low weight of evidence
↑ clearly positive evidence
↗ tentatively positive evidence
→ uncertain evidence
↘ tentatively negative evidence
↓ clearly negative evidence

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Memorandum submitted by the NHS West Kent (HO 39)

EVIDENCE CHECK 2 HOMEOPATHY

1. *Background to Homeopathy Commissioning Review*

1.1 The West Kent PCT Board made a decision to withdraw routine NHS funding of homeopathy at its meeting on 27 September 2007. This decision was challenged via judicial review and subsequently rescinded while the PCT conducted a full Equality Impact Assessment (EIA), which took place between December and June 2008.

1.2 The full EIA found that whilst homeopathy has no proven clinical effectiveness there may be an impact on a small cohort of patients with complex long-term conditions and/or life-limiting illness who no longer find relief in conventional medicines and who perceive benefit from their experience of homeopathy.

1.3 The review included public consultation and was conducted between April and July 2007.

1.4 The original public consultation process was challenged in the courts and found to be sufficient. The consultation was not about whether homeopathy works but rather whether the NHS, in light of competing priorities, should fund it. A Homeopathy Consultation Advisory Group (HCAG) consisting of representatives of the PCT, GPs/Practice Based Commissioners, West Kent Patient & Public Involvement Forum, Kent County Council's NHS Overview & Scrutiny Committee, Maidstone & Tunbridge Wells NHS Trust (Homeopathic Practitioners and Management), and the TWHH League of Friends was established to oversee the process. The PCT's Director of Civic Engagement chaired the group.

1.5 The HCAG agreed a series of options, which formed the basis of public consultation between 23 April and 2 July 2007.

1.6 The consultation process included:

— A systematic review of the high quality evidence base

— Production of a consultation document and related questionnaire—sent to a random sample of 1,000 of the PCT's registered patient population in addition to those who requested it directly or received a copy through their personal connection with homeopathy and/or the TWHH

— A series of public meetings

— An audit of all GPs in West Kent

2. Evidence Base

2.1 *Clinical effectiveness*

2.1.1 The PCT commissioned an independent review of studies meeting the criteria for evidence based medicine. The review found no clear evidence to support or oppose the commissioning of homeopathy.

2.1.2 The PEC concluded that there is limited evidence in favour of homeopathy; the PCTs resources should be directed towards treatments that have a greater evidence-base.

2.2 *Population needs*

2.2.1 PCT commissioning data indicates that in total 52% of all GP practices across West Kent refer patients to secondary homeopathic services.

2.2.2 The PCT conducted an audit of all GPs, which showed that in those practices that use homeopathy, less than 1% of the registered population are referred.

2.2.3 Almost all referrals for homeopathy are at the request of the patient rather than as a result of a clinical decision to refer.

2.2.4 There is no information available about the proportion of people with the conditions most commonly referred to homeopathy that use the service, or what the outcomes of their treatment is, to enable a clinical needs analysis.

2.2.5 The PEC's view was that in light of the many competing demands on PCT budgets and the range of treatments that cannot currently be routinely funded, homeopathy is not a priority for the general population of West Kent.

2.3 *Value for money*

2.3.1 The financial value of homeopathy is small—c. £200,000 per annum, however, since clinical effectiveness is not proven it is not possible to conduct a cost effectiveness analysis.

2.3.2 In terms of cost-benefit, results of the GP audit, TWHH's own audit and personal anecdote from service users suggest that homeopathy may provide help for some individuals and/or conditions where conventional medicine is perceived to have failed or created unacceptable side effects. In some cases this is additionally reported to have resulted in a reduction in the use of conventional healthcare resources.

2.3.3 Levels of satisfaction amongst those who use the TWHH are high according to the hospital's own audit.

2.3.4 Data is not available to quantify relative health gain to individuals for each pound spent on homeopathy, nor is it possible to conclude whether greater health gain could be achieved for those individuals by spending the same money on other services.

2.3.5 The PEC's view was that homeopathy is often an "option of last resort", which may mask the need to deal with difficult problems in a different way, and that patients can be treated effectively through other mechanisms, for example pain management programmes. They are concerned about the high rate of ongoing/follow up visits, which may indicate some dependence on homeopathy.

2.3.6 The PEC also recognised, however, that homeopathy offered as part of a multi-faceted and primary care based approach for treating people with complex problems may add benefit, if fully integrated within a multi-professional approach; this would not require a secondary care service.

2.4 *Impact on other services*

2.4.1 Results of the GP audit suggest that on average about half of people referred for homeopathy simultaneously access conventional treatment for the same condition.

2.4.2 About 40% of the GPs who had referred someone for homeopathy said that they would probably refer to other forms of treatment if homeopathy were withdrawn.

2.4.3 Some service users report a significant reduction in their use of conventional services as a result of their experience of homeopathy, and this is backed up anecdotally by some GPs.

2.4.4 The PEC's conclusion was that whilst additional services may be required they might also be more effective overall than homeopathy and support a wider group of patients than those who would use homeopathy.

2.4.5 The services that GPs suggest might be impacted if homeopathy were withdrawn are, for example, allergy specialists and dermatologists, GPs and psychological services, but this is not quantified.

2.5 *Public demand*

2.5.1 Less than 1% of the PCT population use homeopathy services, with the majority focused in Tunbridge Wells. Service use is not spread equally throughout West Kent.

2.5.2 Despite extensive national and local publicity about West Kent PCT's review of the commissioning of homeopathy services, only 22 letters and e-mails and 197 feedback forms were received during the consultation period, and only 63 people in total attended one of five public meetings.

2.5.3 Across the UK and in other parts of Europe, funding for homeopathy is being withdrawn in light of other priorities.

2.5.4 The PEC's view was that funding of homeopathy should be considered in context of all the priorities of the PCT and as such is not a priority. They believed that the fact of having a NHS funded Homeopathic Service within PCT boundaries means homeopathy receives undue weight in the public's mind compared to other services and treatments that are under funded or cannot currently be provided on the NHS.

3. Options for Change

3.1 The consultation document identified three possible options for change, which were discussed and agreed with the HCAG, as follows:

— Referrals to the Individual Exceptional Treatment Panel for decision

— Fixed number of visits for homeopathy

— Withdraw routine funding of homeopathy

3.2 As a result of the consultation a number of additional options were suggested. The HCAG considered all of them and finally added three further options:

— Renegotiate the tariff

— Introduce a homeopathy exclusions policy

— "Multi-faceted" option (incorporating a number of other options)

4. Mitigating Actions

4.1 Actions to mitigate the potential impact on existing service users were approved at the time of the Board decision. These included:

— Establish an Individual Case Review Service for those people who wished to continue homeopathy treatment

— Agree exceptionality criteria for use by the Individual Treatment Panel when deciding on requests for homeopathy treatment

— Conduct a review of services available for people with complex multiple long-term conditions for whom conventional medicines may no longer be effective, including the provision of self-care support

4.2 In January 2009 the NHS West Kent Board received an update on the process of implementation of the agreed EIA mitigating factors and approved a set of decision making criteria in relation to exceptionality for use by the Individual Treatment Panel (ITP) from April 2009.

5. Individual Treatment Panel

5.1 From April 2009 new referrals for homeopathic treatment are required to go via the ITP.

5.2 Guidelines for exceptionality in the case of referral for homeopathy treatment were developed in conjunction with the Clinical Leadership Board and approved by the PCT Board in July 2008.

6. Conclusion

6.1 The weight of evidence collected as part of the initial review indicates that homeopathy services are not a clinical priority when compared with the many competing priorities of the PCT.

7. Declaration of Interest

7.1 NHS West Kent operates a policy not to fund routine homeopathy treatment.

Dr James Thallon
Medical Director, NHS West Kent

November 2009

Memorandum submitted by The British Homeopathic Association (HO 12)

1. Background

1.1 Homeopathic medicines are normally prescribed to patients by homeopathic practitioners and on an individualised basis, with importance placed on the unique character and lifestyle of the person concerned. Some randomised controlled trials (RCTs) of homeopathy have reflected this approach. Others have investigated a given, standardised, homeopathic medicine taken by the entire sample of eligible patients, and where the input of a homeopathic practitioner may or may not have been involved.

1.2 This document is a summary and update of the overview submitted jointly by the British Homeopathic Association and the Faculty of Homeopathy in 2008 to the Government Office for Science.[3] It is a factual account of best clinical research evidence in homeopathy published in peer-reviewed scientific journals up to and including October 2009. It focuses primarily on systematic reviews of published RCTs and reconciles those data with results obtained in the original RCT literature. Findings from non-randomised clinical studies are presented in brief. We conclude with a number of recommendations for future research development in homeopathy.

2. Systematic Reviews of Randomised Controlled Trials

2.1 *Comprehensive systematic reviews (all medical conditions with homeopathy research)*

Four out of five comprehensive systematic reviews of RCTs in homeopathy have reached the qualified conclusion that homeopathy differs from placebo.[1,2,3,4] One of those four reviews also stated there was "insufficient evidence […] to draw conclusions about the efficacy of homeopathy for any specific medical condition".[4] The fifth systematic review concluded there was "weak evidence for a specific effect of homeopathic remedies";[5] the methodology of that review and its conclusions have been challenged.[6] The value of any comprehensive systematic review, moreover, is limited by the small number of RCTs in homeopathy, the differing criteria used by reviewers for data extraction, the disparate modes of homeopathy investigated, the narrow focus typically on placebo controlled trials, and by the heterogeneous range of medical conditions being examined collectively.

2.2 *Systematic reviews focusing on particular medical conditions*

The issue of heterogeneity of medical condition has been avoided in each of 17 systematic reviews that have focused, to date, on homeopathy RCTs (individualised or standardised treatment) in one of 16 particular clinical conditions. Five reviews concluded there was positive evidence for homeopathy (childhood diarrhoea;[7] post-operative ileus;[8] seasonal allergic rhinitis;[9,10] vertigo[11]); three concluded there was little or no evidence (attention-deficit hyperactivity disorder;[12] delayed-onset muscle soreness;[13] headache and migraine prevention[14]); nine did not offer a clear conclusion either way (anxiety;[15] chronic asthma;[16] dementia;[17] depression;[18] headache and migraine treatment;[19] HIV/AIDS;[20] induction of labour;[21] influenza;[22][4] osteoarthritis[23]).

2.3 *Systematic reviews focusing on particular groups of diagnoses*

There are seven systematic reviews in this category. Four of these reviews were positive (allergies;[24] upper respiratory tract infections;[25,26] rheumatic diseases[27]); two were negative (ailments of childhood and adolescence;[28] cancer[29]); one was non-conclusive (cancer side-effects[30]). Homeopathic *Arnica montana* (often used in RCTs of post-operative pain or swelling) has itself been the subject of two systematic reviews: one was negative;[31] a more recent one was non-conclusive.[32]

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[3] a Fisher P, Mathie RT. The research evidence base in homeopathy. Government Office for Science, January 2008.

[4] The review reported that *Oscillococcinum* reduced the length of influenza illness by 0.28 days (95% confidence interval, 0.50 to 0.06). The authors concluded "though promising, the data are not strong enough to make a general recommendation to use *Oscillococcinum* for first-line treatment of influenza".

3. Randomised Controlled Trials of Homeopathy: The Original Peer-Reviewed Research Literature

3.1 *Criteria and methods for data extraction*

3.1.1 We set clear criteria for including research papers in this overview. Non peer-reviewed research such as book chapters, conference proceedings and theses were excluded from consideration, as were papers in which the medicine tested had concentration greater than the homeopathic dilution 1X. This overview therefore contains references to all full papers of RCTs of homeopathy (any medical condition, treatment or prevention) that have been published in explicitly peer-reviewed journals in any country and in any language from 1950 to October 2009 inclusive. RCTs were categorised by whether: (a) they were controlled by placebo or by other than placebo (usual treatment or no treatment); and (b) the mode of homeopathic treatment was individualised or standardised.

3.1.2 A peer-reviewed trial was eligible for inclusion only if a minimum standard of intrinsic quality was met. A study was defined as an RCT if the paper unequivocally stated there had been prospective random assignment to treatment. In the case of placebo-controlled trials, explicit mention of double blinding was also required; for other-than-placebo controlled (including equivalence) trials, observer blinding was sufficient for inclusion. These and a number of additional criteria of quality were met by a total of 142 RCTs in 129 peer-reviewed journal papers.

3.1.3 Fewer than half the eligible RCTs included a power calculation and the associated pre-defined minimum effect that would be regarded as clinically important. In view of this low proportion of properly powered trials, positive or negative RCT findings are described here in terms only of their statistical significance, not their clinical importance.[5]

3.1.4 A statistically conclusive trial result required that the 95% confidence interval (CI) of the mean difference in the outcome variable did not include 0 (or $P \leq 0.05$); a statistically non-significant trial result meant that the 95% CI included 0 (or $P > 0.05$). A study reporting statistically significant findings was either "positive" or "negative", depending on whether the homeopathy group was superior or inferior to control in at least one principal outcome. Relevant corresponding criteria were applied to other-than-placebo controlled trials.

3.1.5 To be regarded as statistically conclusive, we required at least one significant finding out of no more than three statistical analyses of a given study's principal outcomes. Secondary outcomes were disregarded. This approach avoided the possibility of interpreting a trial as statistically conclusive based on merely one statistically significant positive or negative result out of many.

3.2 *Randomised controlled trial findings*

3.2.1 Summary based on nature of control group: One hundred and twenty out of the total of 142 RCTs (85%) were placebo controlled. The other 22 RCTs (15%) were controlled by other than placebo. Of the 142 trials overall, the summary finding was positive in 44%, negative in 8% and statistically non-conclusive in 48%. Findings in the other-than-placebo controlled RCTs were conclusively positive or negative more frequently than those in placebo controlled RCTs:

	Summary trial finding: no. of RCTs (%)			
Control group	*Positive*	*Negative*	*Statistically non-conclusive*	*Total*
Placebo	52 (43%)	3 (3%)	65 (54%)	120
Other than placebo	11 (50%)	8 (36%)	3 (14%)	22
TOTAL	63 (44%)	11 (8%)	68 (48%)	142

3.2.2 Summary based on mode of homeopathy: Forty out of the total of 142 RCTs (28%) have reflected the normal individualised mode of homeopathic treatment. Each of the other 102 RCTs (72%) has investigated a standardised homeopathic medicine. The percentage distribution of the summary findings does not differ between the two modes of treatment:

	Summary trial finding: no. of RCTs (%)			
Mode of homeopathy	*Positive*	*Negative*	*Statistically non-conclusive*	*Total*
Individualised	18 (45%)	3 (8%)	19 (47%)	40
Standardised	45 (44%)	8 (8%)	49 (48%)	102
TOTAL	63 (44%)	11 (8%)	68 (48%)	142

[5] This and further aspects of intrinsic trial quality in homeopathy are included in a new evaluation of the research literature that the British Homeopathic Association is currently pursuing.

3.2.3 The above RCTs represent research in a total of 80 different medical conditions. There is replicated research (≥2 peer-reviewed RCTs per medical condition) in each of 28 conditions (90 RCTs in total). There is a singleton RCT for each of the other 52 conditions.

3.2.4 Of the 28 conditions for which there is replicated research in RCTs, there are 13 that have not been the subject of formal systematic review to date. Viewed per condition, the balance of evidence from these RCTs is positive for fibromyalgia[33,34,35] and sinusitis,[36,37,38,39] and non-conclusive for insect bites,[40,41] menopause in breast cancer survivors,[42,43] post-operative pain or swelling (*Arnica montana* used in the majority of trials),[44,45,46,47,48,49,50] stroke,[51,52] and warts.[53,54] There was no identifiable balance of evidence in dermatitis,[55] irritable bowel syndrome,[56,57] leg ulcers,[58] otitis media[59,60] or post-operative analgesic intake.[61]

4. Non-Randomised Research

4.1 *Controlled trials*

Non-randomised, controlled, parallel-group design has been applied to homeopathy. It has focused on homeopathy for either a particular medical condition (eczema;[62] insomnia;[63] otitis media;[64] vertigo[65]) or a specified range of complaints.[66,67,68] Results have been positive; in the absence of group randomisation, however, one cannot infer a clear causal relationship between the intervention and the clinical outcome in this type of trial.[69]

4.2 *Non-controlled studies*

Non-randomised, non-controlled, studies can make a useful contribution to developmental research in complementary medicine including homeopathy.[70,71] Findings from studies in this category may be considered as an adjunct to research evidence obtained from RCTs and from non-randomised controlled trials; they do not in themselves constitute research evidence. Findings have been strongly positive, including those for dysmenorrhoea,[72] headache,[73] menopausal flushes[74] and sinusitis.[75] A cross-sectional survey undertaken collectively by the five NHS homeopathic hospitals reported improved patient-reported outcome whose extent and timing varied between the different principal medical complaints (eczema, chronic fatigue syndrome, menopausal symptoms and osteoarthritis).[76] This paper emphasised homeopathy's contribution to the healthcare of patients with multiple, complex, morbidities.

5. summary of Clinical Research in Homeopathy to Date

5.1 Most comprehensive systematic reviews of RCTs in homeopathy (individualised or standardised treatment) have concluded there is evidence that the homeopathic intervention differs from placebo treatment.

5.2 Condition-specific systematic reviews have indicated effectiveness of homeopathy (individualised or standardised treatment) in childhood diarrhoea, post-operative ileus, seasonal allergic rhinitis, and vertigo. They indicate non-effectiveness in attention-deficit hyperactivity disorder, delayed-onset muscle soreness, and in prevention of headache and migraine. Findings are non-conclusive for all other conditions that have been the subject of review.

5.3 Homeopathy research has focused on a total of 80 different medical conditions, in which there is a total of 142 peer-reviewed RCTs that met a number of key quality criteria for this overview. Findings in 44% of those RCTs were positive, 8% were negative and 48% were non-conclusive. The majority of trials have examined standardised homeopathy and used placebo-controlled design. There has been replicated RCT research in each of only 28 medical conditions; of those without formal systematic review to date, there is a balance of positive RCT evidence for fibromyalgia and sinusitis.

6. Recommendations

6.1 New and independently conducted RCTs are essential to confirm or refute the currently available research evidence in homeopathy for specific conditions. There is a need to enhance the quantity and the quality of research on the effectiveness of individualised homeopathy, particularly in chronic conditions, as well as on efficacy of specific homeopathic medicines compared with placebo. Future trials must be statistically powered to ensure conclusions may be made about clinically relevant effects.

6.2 Greater collaboration between homeopathic practitioners, conventional physicians and basic scientists would enhance the scope and quality of homeopathy research. Integration of homeopathic research in existing academic and clinical settings (by practitioners of homeopathy working within the NHS, where regulated and safe clinical practice is assured) raises standards of research in homeopathy, encouraging mutual understanding and promoting agreement on the interpretation of findings. An example of this approach recently has been the effective collaboration between the Universities of Leeds and Sheffield with Barnsley Hospital NHS Foundation Trust in an RCT of individualised homeopathy for fibromyalgia.[35]

6.3 In focusing research on areas in homeopathy where positive findings from RCTs might be corroborated, the most promising targets include those with already replicated findings, such as fibromyalgia, seasonal allergic rhinitis, sinusitis, and vertigo. Attention must also be paid to areas where there is mainly non-conclusive or negative trial evidence to date.

6.4 Moreover, emphasis should be placed on those clinical areas where RCT evidence is currently scanty but where homeopathy is frequently used in NHS practice,[76,77] particularly in diagnoses that are difficult to treat using conventional medicine and that have promising data from non-randomised studies. In this respect, especially worthwhile research targets include atopic eczema, chronic fatigue, depression, irritable bowel syndrome, menopausal symptoms, otitis media and premenstrual syndrome. Patients with complex medical predicaments are not normally eligible for RCT research but should be included in suitable clinical outcome studies, most notably in the clinical context of the homeopathic hospitals.

6.5 The above recommendations for research development are consistent with comments made about homeopathy in the GO-Science Review of the Department of Health:

> *"A programme for a stronger evidence base would necessitate agreement between practitioners, patients and researchers on what should be evaluated, and on relevant endpoints. Flagship trials should be run in the most promising areas, chosen on plausibility, and patient demand. These should be well planned, including pre-defined agreement on what constitutes a minimally important clinical effect, and adequate resource, so that the results were clear-cut. […] The Health Technology Assessment Programme provided a framework that should be as applicable to research on homeopathy as to any other therapy."*

GO-Science Review of the Department of Health, Annex 1 (2008). Government Office for Science: Department for Innovation, Universities and Skills; Paragraph 3.16.

7. Declaration of interest

The author of this overview is Robert T Mathie PhD, Research Development Adviser, British Homeopathic Association; he is not a homeopathic practitioner. The sole aim of this document is to provide a transparent, balanced and constructive summary of the clinical research evidence in homeopathy.

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November 2009

Witnesses: **Professor Edzard Ernst,** Director, Complementary Medicine Group, Peninsula Medical School, **Dr Peter Fisher,** Director of Research, Royal London Homeopathic Hospital, **Dr Robert Mathie,** Research Development Adviser, British Homeopathic Association, and **Dr James Thallon,** Medical Director, NHS West Kent, gave evidence.

Chairman: We now welcome our second panel this morning: Professor Edzard Ernst, the Director of Complementary Medicine Group at Peninsula Medical School—welcome; Dr Peter Fisher, the Director of Research at the Royal London Homeopathic Hospital—welcome to you; Dr Robert Mathie, the Research Development Adviser at the British Homeopathic Association and Dr James Thallon, the Medical Director at the NHS West Kent. Thank you all very, very much indeed for coming. I am going to ask Graham Stringer to begin this set of questions.

Q112 Mr Stringer: Can I start with the central question of the last panel: is there any evidence that homeopathy shows any efficacy beyond the placebo effects?

Professor Ernst: I would echo what has been said and warn people to pick cherries out of a bigger cake; if you look at the bigger cake the bottom line is there is no good evidence that homeopathic remedies are better than placebos.

Dr Fisher: I diametrically disagree and am shocked, actually, by the statements that have repeatedly been made this morning that there is no evidence. You have, in fact, a submission before you that actually enumerates the meta-analyses and systematic reviews. It is actually due to my colleague, Robert Mathie, but to summarise: there have been five, comprehensive, global systematic reviews or meta-analyses of homeopathy which look at the whole thing, of which four were positive. If you look at the condition based systematic reviews and meta-analyses there are 24, of which nine are positive, five negative and ten inconclusive for various reasons, including the trials were not large enough or they were heterogeneous—the trials were somewhat different and they could not really be compared. I say it is quite clear if you actually look at the evidence, and they are enumerated in a document you have before you.

Dr Mathie: I think it is important to ensure that when one looks at systematic reviews one also looks at individual medical conditions, for which homeopathy may or may not be effective. In terms of the placebo effect, there is evidence from three systematic reviews and meta-analyses of homeopathy showing a specific homeopathic medicine is efficacious compared with a placebo. Seasonal allergic rhinitis and vertigo would be two particular examples that I could mention in more detail, if you wish.

Dr Thallon: I will give my view from an NHS commissioning perspective, as that is the organisation I represent, and we found quite clearly that, in terms of competing priorities, evidence in favour of homeopathy is so weak as to not make it a priority within the context of the other priorities facing the NHS.

Q113 Mr Stringer: That is an interesting point. Should the NHS spending on any treatments be based on evidence of efficacy or effectiveness?

Dr Thallon: Absolutely; I think it should be an organising principle of our provision of health care.

Q114 Mr Stringer: I am sorry, I perhaps was not as clear about that. What is your understanding of the difference between efficacy and effectiveness?

Dr Thallon: I do not know if I have one, really. What I would stick to is that we would expect that treatments which we commission to have been tested insofar as it is possible—insofar as there is evidence of effectiveness (I certainly understand what that is)—I would expect them to have passed that by a wide margin and, also, for there to have been a demonstrable need for that treatment in order for it to be commissioned.

Dr Mathie: Can I answer the question about efficacy compared with effectiveness?

Q115 Mr Stringer: Yes.

Dr Mathie: It is indeed a fundamental point. Efficacy is judged in placebo controlled trials of a very specific medicine or intervention. So it is very specific, usually in terms of pharmacological investigation; it is a very specific drug and a very specific dose; it is a very specific schedule treating a very specific type of patient, who may be limited by gender, age and so on. So efficacy is almost a laboratory experiment, if you like; it is testing the way in which a drug, in principle, could have an effect. Effectiveness is something that usually non-placebo controlled trials are designed to do, usually against usual care, or sometimes no treatment—for example, waiting list controls—in which the real world effect of a system of care is judged against what is usual up to that point—a new intervention that is compared in the real world against usual care.

Q116 Mr Stringer: Just on the first part of the question, do you believe that NHS spending should be based on efficacy or effectiveness?

Dr Mathie: Both.

Dr Fisher: In simple terms the distinction is between ideal conditions and real world conditions—efficacy being ideal conditions and effectiveness being real world conditions. Yes, they should be based on decisions particularly about real world effectiveness, because in the real world issues like long-term use, the co-morbidity of people who have got multiple illnesses, side-effects, and so on, are much more prominent than they are in the short term, very rigorous efficacy studies. You may think the distinction is academic but actually I can quote you numerous examples where looking at the two different types of evidence leads to different conclusions; treatments which appear to be efficacious in small-scale but rigorous trials may not actually be effective in the real world because of adverse effects or whatever.

Professor Ernst: I would agree that good decisions are based on both. Efficacy tests whether treatment works under ideal conditions; for instance, a hypertensive agent may well be effective under ideal conditions and then will not work in the real world because people experience side-effects, etc, etc. Good decisions need to be both based on efficacy and effectiveness. I would add, however, that without efficacy effectiveness can be quite meaningless, and there are trials that are designed in such a way that, for instance, could test standard care plus homeopathy versus standard care alone. If you understand what homeopathy entails, the empathetic encounter of one hour of empathy and understanding towards the patient, it is predictable that such a trial will generate a positive result simply because of its non-specific effect—its placebo effects—and therefore because it is predictable (and we have shown that this is predictable) such a trial should not be done because you know the result before the trial, and arguably such a trial is even unethical.

Q117 Mr Boswell: Can I come in on this, and I think it is primarily for Dr Fisher. I wonder if you would like to comment on the tolerance of homeopathic remedies over a relatively long period of administration. I think it is sort of implicit in the distinction you were drawing between the necessary metrics for efficiency and effectiveness. Clearly, if there are problems with long-term medication of, say, hypertension, as Professor Ernst has mentioned, it might be helpful to the Committee to know whether that is a factor which, at least, would colour the advice which pharmacists would be giving to people.
Dr Fisher: Sure. It is normally assumed that homeopathy is completely safe—at least direct, in terms of the distinction between direct safeness and indirect safeness.

Q118 Mr Boswell: There is no direct harm derived from taking—
Dr Fisher: Actually, that is not quite true. We did survey the literature, we asked the MHRA, we asked the USFDA, we asked the companies and, actually, if you look at placebo-controlled trials of homeopathy you do find a slightly increased incidence of adverse effects in the active arm compared to the placebo arm, but there is no evidence of serious or life-threatening adverse effects. There is evidence that active homeopathy can cause certain problems, and that comes from a systematic review of the world literature.

Q119 Mr Stringer: Can you be more specific about that?
Dr Fisher: There are a number of reports. For instance, there was a trial done in Italy on homeopathic medicine for prevention of flu where quite a lot of people who actually got the homeopathic medicine got flu-like symptoms but did not actually get flu. That was more frequent in the group that got the active homeopathy than the ones who got the placebo. It was quite a large study—800 patients studied—and that is the largest, single report of adverse effects with homeopathy. Again, the MHRA has a number of yellow cards; the FDA has reports of adverse effects—generally mild and transient—but there do appear to be some.
Professor Ernst: I think what Peter just referred to, at least partly he referred to, is called "homeopathic aggravation"; homeopaths believe that if they find the ideal optimal remedy then there will be or can be an aggravation in about 20 per cent of patients that is expected. Peter also knows, because he has in his journal published our systematic review of testing with these aggravations, we looked at all the clinical trials and counted such events and we found no statistically significant difference between the aggravations reported in the placebo arms as compared to the homeopathic treated arms. So the story of homeopathic aggravations may well be a myth.

Q120 Mr Stringer: Thank you. Dr Thallon, is it ethical for the NHS to prescribe placebos? Should the NHS prescribe placebos?
Dr Thallon: I struggle with the notion that it is ethical to prescribe placebos. I am not saying that it does not happen; I think that a number of the ways in which people behave or prescribe could be described as prescribing placebos but, in principle, if you prescribe a drug which you know to have no clinical efficacy on a basis which is essentially dishonest with a patient, I personally feel that that is unethical behaviour.

Q121 Mr Stringer: Is the natural conclusion from that that the NHS should not spend money on a placebo?
Dr Thallon: I would very much think that is a logical conclusion. To me, this is all about following the evidence to its logical conclusion.

Q122 Mr Stringer: Does anybody else want to comment?
Dr Mathie: Can I clarify, I think, the key point that has not yet been raised this morning, and that is that there are significant numbers of homeopathic medicines that are not diluted to the point where the molecular content is uncertain.

Q123 Mr Stringer: I am sorry, can you say that again?
Dr Mathie: There are a substantial number of homeopathic medicines where there is molecular content. There seems to be an assumption that they are, to quote from an earlier commentator, "just sugar pills"; in fact, many are not just sugar pills and many of those have been investigated in randomised controlled trials, and some of those have shown clinical effectiveness beyond placebo, and some of those, in turn, have shown clinically relevant and meaningful effects of homeopathic medicines compared with placebo. So there are trials out there which are of good quality and of good design, with good sample sizes where positive evidence is available, and it is not cherry picking.

Q124 Chairman: Would you give us one example and get Dr Thallon to say whether it is NHS prescribed?
Dr Mathie: Vertigo. There is a product made in Germany—regrettably it is not available for use in the UK—called Vertigoheel and there is systematic review of the original randomised controlled trials showing that that product is efficacious beyond a placebo effect.

Q125 Mr Stringer: Professor Ernst?
Professor Ernst: I had my hand up to answer your question on whether the NHS should prescribe placebo or allow placebos. First, about Vertigoheel, this is not even a homeopathic product; this is homotoxicological, which strictly speaking is not homeopathic. This may be too technical. I would argue—
Mr Stringer: It sounds very interesting, actually.
Chairman: We can cope with technical data; we are okay with that. We are called the Science Committee.

Q126 Dr Harris: Do not raise expectations!
Professor Ernst: If one defines homeopathy as curing like with like, the homotoxicological treatments are not homeopathic—that is the point I was trying to make. Back to the placebo question. I would argue it is unnecessary, unreliable and unethical to prescribe placebos through the NHS; unnecessary because if you do it well then an active treatment will also generate a placebo effect. If I give my patient an aspirin for his or her headache and I do it with empathy, time and understanding this patient will benefit from the pharmacological effect of the aspirin and she will also benefit from the placebo effect through the encounter with her clinician. It is unreliable and there is lots of data to show that placebo effects are notoriously unreliable; somebody who responds today may not respond tomorrow; responses are not large in effect size and they are not usually long-lasting. Foremost, it is unethical. That is my third point.

Q127 Mr Stringer: You get to the same conclusion as Dr Thallon that, therefore, the NHS should not spend money on placebos?
Professor Ernst: Correct, yes.
Dr Fisher: If I could just comment, firstly, on Vertigoheel; it is actually registered as a homeopathic product in Germany and prepared according to the HAB, the Homeopathische Arzneibuch, which is the German Homeopathic Pharmacopoeia. To come back to the other question of placebo effects, I believe I am the only person called today who actually practises homeopathy. I am a rather atypical homeopath in the sense that I am a doctor; I am also an accredited rheumatologist—I could prescribe all those nasty toxic drugs that my friends and colleagues prescribe and freely acknowledge are less safe than they might wish. I practise homeopathy because I think it works, and I believe the evidence supports me in that. I would not practise it for two minutes if I thought I was conning the patients. We just need to be clear about placebo effects, because sometimes a lot of concepts get muddled up. There are non-specific effects, sometimes also called context effects, and that means that every good doctor should talk to their patient, explain to their patient, give their patient good advice on diet and lifestyle and do all of that before even thinking of reaching for the prescription pad. However, having done that—and I have absolutely no shame about maximising my non-specific effects (I think every good doctor should do it)—I would not use homeopathy for two minutes if I thought it was only a placebo. I think the strongest evidence that it is not a placebo comes from an area that has not even been mentioned this morning, which is basic science. There is now a burgeoning area of basic science—there are models which you can do in a test tube—which show effects with high dilutions which have been replicated by multiple laboratories, multi-centre groups. I believe there are seven such models now, by the last count; the best known one is inhibition of basophil degranulation by high dilutions of histamine (basophils is a model of the immune response); there is another one concerning aspirin and blood-clotting and another one concerning metamorphoses of tadpoles to frogs. These have been replicated by independent groups or multi-centre groups. The frog one was done originally in Austria and recently repeated in Brazil.

Q128 Mr Stringer: Just a final question to the whole panel. Should money that is spent on homeopathic consultations be redirected to elsewhere in the NHS?
Dr Thallon: We very much take that view. We would not swap it from one treatment directly to another, but clearly if the business of PCTs is about prioritisation then the treatment which the balance of scientific opinion says is of either virtually no efficacy or effectiveness or none we would prioritise at a far lower level than other treatments we wish to commission.
Dr Mathie: For me it begs the question that there is a need for cost-effectiveness evaluation of homeopathy. There is almost none, at this stage, and the whole question about the cost and the impact of homeopathic consultation could be tested in appropriate studies. The other problem, I think, is that where does the patient go if he or she does not go to the homeopathic practitioner? I am talking about in, typically, a medical practitioner of homeopathy. They will go elsewhere in the NHS and they may not get the rounded approach to treatment of the person which is what homeopathy is characterised by. So this is not a straightforward point.

Q129 Mr Stringer: Dr Fisher?
Dr Fisher: What was the question—I am sorry?

Q130 Mr Stringer: The question was should the money that is spent on homeopathic consultations be redirected within the NHS?
Dr Fisher: I think the evidence, such as it is (for instance there is good evidence from France and Germany) is that you get more bang for your bucks with homeopathy. If you integrate homeopathy you get better outcomes and it does not cost any more. So I do not think it should be redirected; you get more bang for your bucks.

Q131 Mr Stringer: Professor Ernst?
Professor Ernst: If the NHS's commitment to evidence-based medicine is more than lip service then, surely, money has to be spent for treatments that are evidence-based, and homeopathy is not.

Q132 Dr Harris: Dr Fisher, you mentioned that there were some adverse effects found in homeopathic treatments. How many homeopathic treatments over the 200 years that it has been in existence have been withdrawn from the market due to safety fears because of these adverse effects, as one sees in conventional medicine?
Dr Fisher: Not many but some have been. The most recent one was something called Malaria-officinalis which was most regrettably (and I opposed it) used by some non-medical homeopaths allegedly to prevent malaria.

Q133 Dr Harris: It had side-effects, did it?
Dr Fisher: No, it was withdrawn because of safety concerns.

Q134 Dr Harris: On the basis of adverse effects?
Dr Fisher: No, nothing has been withdrawn.

Q135 Dr Harris: That is interesting. When Graham Stringer was asking the questions he started with you, Professor Ernst, so you did not get a chance to respond to the assertion made by the witnesses on your left that systematic reviews overwhelmingly showed effectiveness of homeopathy.—five out of six, I think, was the expression used.
Dr Fisher: Four out of five.
Dr Mathie: I do not think we used the word "overwhelming".

Q136 Dr Harris: Four out of five seems to be a majority. Would you comment on that? Have there only been five systematic reviews and do they show that positive result, in your opinion?
Professor Ernst: I have supplied you with a list of systematic reviews as published a few years ago, and in that list there are already, I think, almost two dozen.

Q137 Dr Harris: Two dozen?
Professor Ernst: None in that list, which was after a very prominent systematic review and meta-analysis by Klaus Linde was published in *The Lancet*, including the ones we analyse in *The Lancet* data including Linde re-analysing his own data, none of these systematic reviews were positive.

Q138 Dr Harris: Why do you think that homeopaths say that systematic reviews are positive if it seems to you that they are not positive? Both sides cannot be right.
Professor Ernst: I know of some reviews which are not systematic. I know of a Swiss health technology assessment which is not what I understand by a systematic review because it includes everything such as case series observational studies, non-controlled studies, non-randomised studies, and so forth. When you do that indeed the majority of publications is positive, but in a systematic review, typically, you define your entry criteria and we usually define them as randomised clinical trials—if possible, randomised placebo controlled clinical trials and in homeopathy that is possible—and the vast majority of these systematic reviews do not confirm that homeopathic remedies are more than placebos.

Q139 Dr Harris: Dr Mathie, do you accept that the overwhelming view of independent researchers, who do not make money from conventional medicines competing with you or make money from practice or selling or manufacturing of homeopathic medicine—do you accept, even though you may disagree with them, that the overwhelming majority of people who have looked at this from an independent perspective say that the evidence base is poor for efficacy of homeopathy when looking at good quality systematic reviews?
Dr Mathie: Given that most people in that category probably have not investigated the research literature in sufficient depth to really form a well-judged opinion, my answer would be yes.

Q140 Dr Harris: Because they are ignorant, essentially? I do not mean that in a pejorative way; they just have not done the job well enough—all these people like Professor Ernst, who is a Professor in this field. They are just inadequate in their research?
Dr Mathie: Not at all. What I would say is that there are those with whom I have endeavoured to collaborate and do have collaborations with who are mainstream academic researchers—for example, in atopic eczema at the University of Nottingham—who are seriously engaged by the idea of conducting randomised controlled trials in homeopathy because atopic eczema is not well treated conventionally and they see an effectiveness gap there, and it is worth trying and worth testing in an objective, open-minded fashion. There are many people in the country who are prepared to engage in homeopathic research and it is those types of people that I am very eager to collaborate with.

Q141 Dr Harris: However, systematic reviews take a lot of time; you have to look through thousands of papers—
Dr Mathie: Of course they do.

Q142 Dr Harris: You have to check them and the entry criteria. You have to be quite dedicated to do these systematic reviews and to review systematic reviews. The majority of those people, without an axe to grind, say that they do not show an effect. Does that worry you?
Dr Mathie: It does. However, reviews are designed to distil the literature out into a single paper or two, compared with maybe a dozen randomised controlled trials. Can I just address the question about the discrepancy of opinion regarding the results of systematic reviews. May I just quote a recent paper by Dr Klaus Linde himself in a paper published just a few months ago. He says: "With small and heterogeneous datasets, the most likely situation in complementary and alternative medicine—these decisions [about the validity of trials and which trials are contained within systematic reviews] can lead to quite different findings. A powerful example of how different approaches, summarising the available evidence, can lead to very different conclusions are the two large meta-analyses on homeopathy published in *The Lancet* 1997 and 2005"—and we know which ones he is talking about there—"although the basic datasets [themselves] yielded similar findings"; it is the interpretation that differs depending on one's perspective.

Q143 Dr Harris: Feel free to send that into us. That is probably the easiest thing.

Dr Mathie: I can hand it to you if you would like.

Q144 Dr Harris: I just want to deal with this ideal world/real world thing. If you cannot find an effect, if you cannot demonstrate efficacy in an ideal world where everything is set up to identify that effect, it is hard to see that an effect you see in the real world—dirty clinical practice if you like—is based on the cited efficacy. It might be due to confounding factors.
Dr Mathie: I understand your question.

Q145 Dr Harris: It is not the other way round, is it?
Dr Mathie: However, it is based on a false premise, if I may say so, because in fact there is efficacy research there. There are published efficacy studies. There are something like 37 of them, if I remember offhand, where there is positive evidence. There are another 50 in which there is inconclusive or perhaps negative evidence. What I would make a plea for is that the efficacy studies that do exist—and I could name them all and I can send the details to you because they exist out there—should transform gradually over time with active research into effectiveness research where those homeopathic medicines that are shown to be effective are used within the armamentarium of the homeopathic process because, after all, what has not become fully clear this morning is that homeopathy is a system of care. There are 3,000 homeopathic medicines in the pharmacopoeia. We need to understand the efficacy of each, ideally, but let us do it gradually with those specific medicines where they are frequently used and have been researched in efficacy research and can become gradually evidence-based contributions to homeopathy as a system of care.

Q146 Dr Harris: Dr Thallon, you have sent in evidence setting out how you did your review, and I do not think it is worth you repeating that because it is in the written evidence which will be published if we do a report on this, as I suspect we will. Why do you think it is right that what you did should have to be replicated many times in every commissioning organisation or is there something in the water, or not in the water in West Kent, that makes your findings different from something that might be done in Manchester?
Dr Thallon: We are in a particular circumstance because there is a homeopathic hospital within our geographical locality and that is why we had to go to the lengths we did in order to prove the case, because other commissioning organisations who spend a bit of money on homeopathy did not have the facility within their borders that meant that the resistance to the commissioning decision was likely to be as intense as it was for us. I think our process in terms of its quality and the way that it is done with scrutiny is a good roadmap for other organisations to adopt, and we would be very happy to act as a guide to other commissioning organisations that wish to follow this path. Personally, I feel that if effectiveness in clinical treatment and evidence-based medicine is going to be an organising principle of the NHS, then to do this in every locality would be a diversion of otherwise scarce resources, and if it were possible to learn from our experience then we would be very happy to give that learning out.

Q147 Dr Harris: Have you considered either circulating it yourself, would you have objections to other people circulating it, or do you think it would save time and money if the Department of Health circulated your work?
Dr Thallon: I certainly do not think the issue of the decommissioning of non-evidence based practice should be beneath the Department of Health to help commissioning organisations with. Yes, I would have thought there could well be a role for the Department of Health in helping other organisations get to the point we have got to should they choose to do so.

Q148 Dr Harris: The Department of Health has not issued any guidance and has not asked NICE to look at this. That may be a reluctance by the Department of Health to give any advice or instructions or guidelines or policies to commissioners, but my experience locally is that commissioners are overwhelmed with guidance and advice and executive letters and circulars from the Department of Health.
Dr Thallon: Not overwhelmed but there is plenty of it.

Q149 Dr Harris: As an individual doctor who has the views you have, having looking at it, why do you think the Department of Health and ministers are not dealing with this?
Dr Thallon: I think this would have to be a personal rather than an organisational view.

Q150 Dr Harris: Of course.
Dr Thallon: I think the politics of homeopathy and what homeopathy is are difficult because homeopathy, to an extent, appears to my mind to go beyond the debate purely about the science, because I feel that we have taken a view about where the balance of the scientific community's opinion is on homeopathy and to me and my colleagues it is pretty clear. Clearly there is something that perpetuates the notion that homeopathy is important which goes beyond purely the scientific debate because to my mind—and it can never be settled because you never know what might happen—the balance of the current research at the moment suggests to us, essentially scientifically trained but lay people, that the issue of the effectiveness of homeopathy is not in question.

Q151 Dr Harris: My last question is to Dr Fisher. In your written submission to us, which I read, and in your answer, you talked about the basic science that shows a basis for the function of how homeopathy might work. I think it is fair to say that some of it is radical stuff. Why do you think that there has been

no Nobel Prize given to the people who have made these astonishing discoveries of the potential for the memory of water and a physiological impact of some homeopathy remedies where the dilution is such that it is accepted that there is unlikely to be a single molecule left?
Dr Fisher: It may yet happen. I think we are at a very early stage. The research has burgeoned in the last few years and it needs more work. We are talking about a sociological phenomenon within the scientific community and of course new ideas often encounter strong resistance. I think that is what is going on. People say loosely that it challenges the basic laws of physics; it does not. It may yet happen.

Q152 Dr Harris: On that basis then why is it that when you have a solution of water that used to have some homeopathic substance in it but it has been diluted that the water is said to retain that memory but does not remember all the poo, you could call it, that has been in it, because all water has bits of our effluent.
Dr Fisher: I am surprised you did not mention Oliver Cromwell's bladder. In this context it is traditional to mention Oliver Cromwell's bladder because apparently somebody once calculated that in each glass of water you drink it is statistically probable that one of those molecules once passed through Oliver Cromwell's bladder.

Q153 Dr Harris: The point I am making is that you have a higher chance of having that molecule but you do not believe the molecule is necessary, so why is it that the specific effect is from the homeopathic element that has been in it and not someone's ammonia that has been in it?
Dr Fisher: It is quite straightforward. The point is that we use highly purified water and highly purified ethanol there. There is no such thing as absolutely pure water but this is highly purified, it is double-distilled and deionised.

Q154 Dr Harris: It has not even got sugar in it?
Dr Fisher: At that stage no, so the impurities are a concentration of parts per million or parts per billion. You then add something at a concentration of parts one in ten or one in 100 and shake it. .

Q155 Dr Harris: The shaking is important?
Dr Fisher: The shaking is important.

Q156 Dr Harris: I would have thought it would have less memory if you shook it. I can understand if you left it alone it might form a memory.
Dr Fisher: This has been looked at and the answer is that it does not induce the same structural effects. You are inducing structural effects which may involve silica and which may involve dissolved oxygen molecules—it is not quite certain—but you can show that this water is different from water that is just shaken without the stuff being in it.

Q157 Dr Harris: How much do you have to shake it?
Dr Fisher: That has not been fully investigated.

Q158 Dr Harris: A random amount of shaking?
Dr Fisher: You have to shake it vigorously but exactly how much you have to shake it, no. If you just gently stir it, it does not work.

Q159 Dr Harris: Does the MHRA check how much it has been shaken before it approves it for treatment?
Dr Fisher: You would have to ask the MHRA, I do not know.

Q160 Chairman: Dr Harris, I am going to leave the shaking at that point. Professor Ernst, you just wanted to have a last word on that.
Professor Ernst: Just a quick comment. Even if the water is different it leaves totally unanswered the question of how it exerts any health effects in human bodies. The water in my kitchen sink is also different from distilled water yet it is unhealthy and not healthy.
Chairman: Okay, we will ponder on that. Dr Iddon?

Q161 Dr Iddon: This year the Department of Health announced that it was going to run some pilot studies on personal health budgets allowing people to spend public money, to a degree, on whatever they desire to spend it on, including homeopathy. Bearing in mind that the National Health Service is always short of money—this has already been referred to—is it right, do you think, gentlemen, that people should be able to take money away from perhaps more deserving areas in the NHS and spend it on homeopathy if that is what the patient desires?
Professor Ernst: This is presumably from the ill-conceived notion that patient choice has to dominate in health care. I am an ex-clinician and I know about the importance of patient choice, but patient choice that is not guided by evidence is not choice but arbitrariness, and therefore I am not in favour of it.
Dr Fisher: I strongly support patient choice and clearly where patients do get the opportunity to choose they very often do choose homeopathy and other forms of complementary medicine.

Q162 Dr Iddon: And it is right that that should be with public money rather than their own money?
Dr Fisher: Yes, I think so. There needs to be a balance but, yes, successive Governments have been committed to patient choice and rightly so, in my view.
Dr Mathie: The British Homeopathic Association strongly supports patient choice for treatments that are evidence-based and would propose the development of much greater research in order to secure that evidence base.
Dr Thallon: Personally I support the issue that clinical effectiveness should be an organising principle of the NHS. It is conceivable that personal

health budgets may cause some inefficient use of NHS resources, however, there are limits and the NHS is not purely governed by clinical effectiveness. There are issues of patient consent and it is public money at the end of the day. It may well be right for people to have an element of choice in what they spend their money upon. However, I think there are issues around whether or not they should be able to choose a treatment which is clearly lacking in evidence. What would happen once that treatment had been used, found to be ineffective and they were forced to return to the NHS; what would the attitude of the NHS be at that point?

Q163 Dr Iddon: I think I can only put this question to these three gentlemen and it is this: if a patient came to you for homeopathic treatment and you felt that you might put that patient at risk by treating them in such a way, would homeopaths have the courage to refer them to a traditional clinician because with a homeopath the patient might be at risk with the homeopathic treatment as against the traditional treatment?
Professor Ernst: I find it impossible to generalise across homeopaths. There are good homeopaths, in the sense that they are responsible and try their best to look after patients, and there are homeopaths who are less well equipped to do that and indeed less well-trained, and I would argue that doctor homeopaths, by and large, are better equipped to do that. There are too many different types of homeopaths for me to be able to answer that question.

Q164 Dr Iddon: I know it is difficult to generalise, I accept that point but do you think homeopaths are adequately qualified to recognise by a clinical diagnosis a serious medical condition?
Professor Ernst: Doctor homeopaths should be because they have studied medicine. Anybody who has not studied medicine is unlikely to be well-equipped for all difficult situations.
Dr Fisher: I can only speak on behalf of the Faculty of Homeopathy which is a statutory body which only admits members of registered health professions, so that includes doctors but also veterinarians, dentists, pharmacists and so on, and for them the answer to your questions is absolutely yes; they are equipped to make a diagnosis and indeed to recognise the domain of professional competence. It is normal for a pharmacist, for instance, to give advice over the counter in the shop and also to say, "You need to go to see a doctor about that." Of course the answer is yes, they are equipped and they would refer on when required.
Dr Mathie: Unequivocally yes.

Q165 Dr Harris: One quick question to Dr Mathie. You are an adviser to the British Homeopathic Association. You do not register homeopaths?
Dr Mathie: No, the Faculty of Homeopathy does that. We are a charity and I work as a research development adviser for the charity. And I am not a homeopathic practitioner, by the way.

Q166 Dr Harris: I want to ask you if you are able to answer this and if you are not, I am sorry, but, presumably, if there is a register—and I know it is an unofficial register and it is not government-regulated—that means homeopaths who stray outside what they should do ethically and beyond their competence are subject to being struck off essentially or disciplined?
Dr Mathie: Yes.

Q167 Dr Harris: I am just wondering why it is that we have not heard, and maybe I have just not heard correctly, that the 10 or 11 homeopaths that are willing to prescribe prophylactic homeopathic anti-malarials, in the absence of advice about conventional anti-malarials and bed nets for avoiding being bitten, which is essential, fundamental, first year medical student advice you give to a traveller going to a malaria area, whether any action was taken against them by their regulatory bodies? Have you or Dr Fisher heard through your experience that either this practice is rife or that the penalty is that you cannot advertise as being a Member of the Faculty?
Dr Fisher: It did not involve any member of the Faculty. The Faculty of Homeopathy was incorporated by Act of Parliament and it only admits registered health professionals and none of its members were involved in that particular case.

Q168 Dr Harris: So it is the Society of Homeopaths I am maybe thinking of?
Dr Mathie: To answer your question more completely, the Faculty of Homeopathy is very clear in its statement to its member practitioners that prophylactic homeopathy is not recommended, and that includes of course malaria. We would not support the use of prophylactic homeopathy for malaria.

Q169 Dr Harris: But should the Society of Homeopaths deregister someone who prescribes them? These things are on the market, are they not? I do not understand why they are on the market if even you think they should not be used. It does not make sense to me.
Dr Mathie: It is not for me to suggest the behaviour of the Society of Homeopaths.

Q170 Chairman: But you are suggesting, Dr Mathie, that everybody practising homeopathy should be appropriately registered?
Dr Mathie: Of course they should be and there is an aim to do just that.

Q171 Dr Harris: I really cannot understand this. You say you should not give homeopathic anti-malarials and yet they are on the market. Have you urged or has the Faculty urged or has the BHA, whom you advise scientifically, urged manufacturers to stop manufacturing these things that people might buy?

Dr Mathie: Not quite so explicitly but we are unequivocally against the practice.
Dr Fisher: I am not aware that homeopathic anti-malarials are on the market, but certain people are using existing homeopathic medicines and claiming they will prevent malaria. To my knowledge, they are certainly not legally on the market labelled "this will prevent malaria".

Q172 Dr Harris: What was your reaction to the Society of Homeopaths symposium which argued that AIDS could be treated homoeopathically? Were you embarrassed by that?
Dr Fisher: I was not at it and I do not know what happened. Certainly in our hospital, for instance, we have a complementary cancer treatment service which uses homeopathy, among other things, and we have recently, indeed, completed a Cochrane review on homeopathy for the management of the adverse effects of cancer.

Q173 Dr Harris: But can you say that you think there is a role for homeopathy in the treatment of AIDS?
Dr Fisher: I have certainly treated people who have AIDS, not for the primary condition but for the complications and problems they have with the disease or with the treatment of it, but I would never claim to be able to cure AIDS.
Dr Mathie: And nor would we.
Chairman: I am sorry, Dr Harris, I am going to finish on that note. Can I thank you all very much indeed for joining us this morning for what has been an incredibly useful session.

Supplementary memorandum submitted by Professor Edzard Ernst

1. Background

Following my oral evidence to the committee on Wednesday 25th November 2009 and having read the written evidence published that day, I am submitting this supplementary memo on the references made to systematic reviews.

The memorandum submitted by The British Homeopathic Association (BHA) contains a section on "systematic reviews of randomised controlled trials" which requires clarification, particularly as numerous other submissions (e.g. those by Dr Lionel R Milgrom, Prof H Walach, Prof G Lewith, Dr Sara Eames, Society of Homeopaths, Complementary Medicine Research Group, Homeopathy Research Institute, Alliance of Registered Homeopaths, Homeopathy: Medicine for the 21st Century, European Central Council of Homeopaths) also allude to the subject of allegedly positive systematic reviews.

2. Comprehensive Systematic Reviews

The BHA state that 4 of a total of 5 comprehensive reviews reached positive conclusions. These reviews are (full references see submission of BHA):

1. Kleijnen et al, BMJ 1991[1]
2. Boissel et al, 1996[2]
3. Cucherat et al, Eur J Clin Pharm 2000[3]
4. Linde et al, Lancet 1997[4]
5. Shang et al, Lancet 2005[5]

This statement is misleading for the following reasons:

1. The Kleijnen review[1] is now 18 years old and thus outdated
2. Boissel et al[2] merely combined p-values of the included studies. This article is now also outdated. Furthermore it is not unambiguously positive.
3. Cucherat et al[3] is the publication of the Boissel document which was a EU-sponsored report.
4. Linde et al[4] has been re-analysed by various authors, including Linde himself, and all of the 6 re-analyses (none of which were cited in the BHA's submission) have come out negative (see my previous submission to this committee).
5. Shang et al[5] very clearly arrived at a devastatingly negative overall conclusion.

3. Systematic Reviews Focussing on Particular Medical Conditions

The BHA cites 17 systematic review of which 5 allegedly "concluded there was positive evidence for homeopathy". These relate to the following conditions.

1. Childhood diarrhoea[6]
2. Post-operative ileus[7]
3. Seasonal allergic rhinitis (2 reviews)[8, 9]
4. Vertigo[10]

This statement is equally misleading for the following reasons:

1. Childhood diarrhoea; this is a meta-analysis by the US homeopath Jenifer Jacobs which consists solely of her own 3 trials in this area.[6]
2. Post-operative ileus; this is our own meta-analysis which included the important caveat that the only reliable trial of good quality in our meta-analysis was clearly negative.[7]
3. Seasonal allergic rhinitis; two reviews/meta-analyses by Wiesnauer[8] as well as Taylor[9] are analyses of the respective authors' own studies.
4. Vertigo; this is a meta-analysis of Vertigohel, a homeopathically diluted preparation which is administered not according to the philosophy of homeopathy but that of homotoxicology (humans are assumed to be poisoned by toxins, particularly those from pork meat consumption!)[10]

It seems crucial to stress that one main purpose of science in general and systematic reviews in particular is to insist on independent replication of results. Therefore systematic reviews of author x reviewing nothing but his or her own studies are complete nonsense.

4. Systematic Reviews Focussing on Particular Group of Diagnoses

Here the BHA claim that 4 positive reviews exist. These relate to

1. Allergies[11]
2. Upper respiratory tract infections (2 reviews)[12, 13]
3. Rheumatic diseases[14]

This statement is misleading for the following reasons:

1. Allergies. The Bellavite article (eCAM 2006)[11] is (according to its authors) "a lecture series" not aimed to provided a meta-analysis. It clearly is not a systematic review of controlled clinical trials and includes uncontrolled studies.
2. Upper respiratory tract infections. The Bornhft article (Forsch Komp Med 2006)[12] is not a systematic review of controlled clinical trials but a "Health Technology Assessment" that includes mostly uncontrolled data. The second Bellaviste article (eCAM 2006)[13] has the same limitations as the first (see above).
3. Rheumatic disease. This review[14] is based on a selection of the 5 "rheumatic" trials from Linde's Lancet meta-analysis (see above). Not enough trials in any specific rheumatic condition were available to allow firm conclusions. Furthermore, the data can be criticised on the same ground as Linde's original Lancet article (see above).

5. Systematic Reviews Omitted by the BHA

It should also be noted that the BHA's evidence omits several systematic reviews and meta-analysis which were published. My list is not necessarily complete and includes:

1. Ernst E. Are highly dilute homoeopathic remedies placebos? Perfusion 1998; 11: 291–292.
2. Morrison B, Lilford R J, Ernst E. Methodological rigour and results of clinical trials of homoeopathic remedies. Perfusion 2000;13:132–138.
3. Ernst E, Pittler M H. Reanalysis of previous meta-analysis of clinical trials of homeopathy. J Clin Epidemiol 2000; 53: 1188.
4. Sterne J, Egger M, Smith, G D. Investigating and dealing with publication and other biases. In *Systematic Reviews in Healthcare: Meta-analysis in Context*, eds Egger M, Smith GD, Altman DG. Pp 189–208. London: BMJ Publishing Group, 2001.
5. Ernst E. Classical homoeopathy versus conventional treatments: a systematic review. Perfusion 1999; 12: 13–15.

It is noteworthy that all of these five "forgotten" systematic reviews must have been known to the BHA as there were cited in my "systematic review of systematic reviews" (Br J Pharmacol 2002),[15] and that all of them arrived at negative conclusions.

6. Specific Criticism of the Shang Review[5]

Several submissions (eg those by the BHA, Dr Sara Eames and the European Central Council of Homeopaths) criticise specifically the review by Shang et al.[5]

— Dr Eames states that "all meta-analyses . . . have been broadly positive until the last one published by Shang et al in the Lancet". The details provided above clearly demonstrate that this is erroneous.

— The European Central Council of Homeopaths state that "7 out of 8 . . . reviews/analyses found results in favour of homeopathy . . . The 8th study . . . Shang et al, has since been severely criticised . . ." Again, the details provided above here show this to be incorrect.

It is, of course, unsurprising that numerous homeopaths tried to find faults with the Shang meta-analysis. It is also clear to me that no such paper can ever be entirely free of limitations. Yet it is equally obvious that Shang et al[5] does not stand alone: the vast majority of evaluations by independent experts failed to show that homeopathic remedies are different from placebo.[15]

Reference List

(1) Kleijnen J, Knipschild P, Ter Riet G. Clinical trials of homoeopathy. BMJ 1991; 302:316–332.

(2) Boissel J P, Cucherat M, Haugh M, Gauthier E. Critical literature review on the effectiveness of homoeopathy: overview of the homoeopathic medicine trials. In: *Homoeopathic Medicine Research Group, Report of the Commission of the European Communities, Directorate-General XII - Science, Research and Development E - RTD Actions: Life Sciences and Technologies* - Medical Research, Brussels, Belgium. 1996.

(3) Cucherat M, Haugh M C, Gooch M, Boissel J P. Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials. Eur J Clin Pharmacol 2000; 56:27–33.

(4) Linde K, Clausius N, Ramirez G, Melchart D, Eitel F, Hedges L V *et al*. Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials. Lancet 1997; 350:834–843.

(5) Shang A, Huwiler-Muntener K, Nartey L, Juni P, Dorig S, Sterne J A *et al*. Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. Lancet 2005; 366:726–732.

(6) Jacobs J, Jonas W B, Jimenez-Perez M, Crothers D. Homeopathy for childhood diarrhoea: combined results and metaanalysis from three randomized, controlled clinical trials. Pediatr Infect Dis J 2003; 22:229–234.

(7) Barnes J, Resch K L, Ernst E. Homeopathy for Postoperative Ileus. J Clin Gastroenterol 1997; 25:628–633.

(8) Wiesenauer M, Lüdtke R. A meta-analysis of the homeopathic treatment of pollinosis with Galphimia glauca. Forsch Komplementarmed Klass Naturheilkd 1996; 3:230–236.

(9) Taylor M A, Reilly D, Llewellyn-Jones R H, McSharry C, Aitchison T C. Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. BMJ 2000; 321:471–476.

(10) Schneider B, Klein P, Weiser M. Treatment of vertigo with a homeopathic complex remedy comapred with usual treatments: a meta-analysis of clinical trials. Arzneimittelforschung 2005; 55:23–29.

(11) Bellavite P, Ortolani R, Pontarolo F, et al. Immunology and homeopathy. 4. Clinical studies - Part 2. eCAM 2006; 3:397–409.

(12) Bornhft G, Wolf U, von Ammon K, Righetti M, Maxion-Bergemann S, Baumgartner S *et al*. Effectiveness, safety and cost-effectiveness of homeopathy in general practice - summarized health technology assessment. Forsch Komplementmed 2006; 13(Suppl2):19–29.

(13) Bellavite P, Ortolani R, Pontarolo F, *et al*. Immunology and homeopathy. 4. Clinical studies - Part 1. eCAM 2006; 3:293–301.

(14) Jonas W B, Linde K, Ramirez G. Homeopathy and rheumatic disease. Rheum Dis Clin North Am 2000; 26:117–123,x.

(15) Ernst E. A systematic review of systematic reviews of homeopathy. Br J Clin Pharmacol 2002; 54:577–582.

November 2009

Supplementary memorandum submitted by the British Homeopathic Association

NOTES ON DRAFT TRANSCRIPT OF ORAL EVIDENCE SESSION OF 25 NOVEMBER 2009

Q112

As regards systematic reviews of homeopathy showing a specific homeopathic medicine has efficacy beyond that of placebo, more precise examples are seasonal allergic rhinitis and *post-operative ileus*. The previously cited example of vertigo relates actually to comparison with usual care, not with placebo.

Q123

Out of the 142 randomised controlled trials (RCTs) in total, there are 55 in which the homeopathic medicine was not diluted beyond the point (ie potency 12C and above) where its molecular content is uncertain. Of those 55, there are 38 RCTs with sample size ≥50 subjects; 18 of those RCTs were non-conclusive or negative; the remaining 20 RCTs were positive—see Table 1 below.

Table 1

PUBLISHED RCTs WITH POSITIVE FINDINGS, POTENCY < 12C, SAMPLE SIZE N > 50, INDICATING STATISTICAL POWER STATUS AND NATURE OF CONTROL GROUP (PLACEBO, P/OTHER THAN PLACEBO, OTP)

Medical condition	*Journal reference*	*N*	*Powered*	*P/OTP*
1 Ankle sprain	Zell J, Connert W D, Mau J, Feuerstake G (1988). [Treatment of acute sprains of the ankle. Controlled double-blind trial to test the effectiveness of a homeopathic ointment]. *Fortschritte der Medizin,* **106**: 96–100.	69	Yes	P
2 Bronchitis	Diefenbach M, Schilken J, Steiner G, Becker H J (1997). [Homeopathic therapy in respiratory tract diseases. Evaluation of a clinical study in 258 patients]. *Zeitschrift fr Allgemeinmedizin,* **73**: 308–314.	209	No	P
3 Common cold	Maiwald V L, Weinfurtner T, Mau J, Connert W D (1988). [Treatment of common cold with a combination homeopathic preparation compared with acetylsalicylic acid. A controlled, randomized single-blind study]. *Arzneimittelforschung,* **38**: 578–582.	115	Yes	OTP
4 Cough	Bordes L R, Dorfman P (1986). [Evaluation of the antitussive effect of Drosetux syrup: double-blind study versus placebo]. *Cahiers d'ORL,* **21**: 731–734.	60	No	P
5 Influenza (prevention)	Brydak L B, Denys A (1999). The evaluation of humoral response and the clinical evaluation of a risk-group patients' state of health after administration of the homeopathic preparation Gripp-Heel during the influenza epidemic season 1993/94. *International Review of Allergology and Clinical Immunology,* **5**:223–227.	124	No	P
6 Irritable bowel syndrome	Rahlfs V W, Mssinger P (1978). [Asa foetida in the treatment of the irritable colon—a double-blind trial]. *Deutsche medizinische Wochenschrift,* **104**: 140–143.	89	No	P
7 Low back pain	Stam C, Bonnet M S, van Haselen R A (2001). The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomized, double-blind comparative clinical trial. *British Homeopathic Journal,* **90**: 21–28.	155	No	OTP
8 Obesity	Werk W, Lehmann M, Galland F (1994). [Comparative controlled trial on the effect of the homeopathic botanical medicinal product Helianthus tuberosus D1 as an adjuvant in the treatment of obesity]. *Therapiewoche,* **44**: 34–39.	102	No	P
9 Osteoarthritis	Shealy C N, Thomlinson R P, Cox R H, Borgmeyer R N (1998). Osteoarthritic pain: a comparison of homeopathy and acetaminophen. *American Journal of Pain Management,* **8**: 89–91.	65	No	OTP
10 Osteoarthritis	van Haselen R A, Fisher P A G (2000). A randomized controlled trial comparing topical piroxicam gel with a homeopathic gel in osteoarthritis of the knee. *Rheumatology,* **39**: 714–719.	172	No	OTP
11 Post-operative wound healing	Karow J-H, Abt H-P, Frhling M, Ackermann H (2008). Efficacy of Arnica montana D4 for healing of wounds after Hallux valgus surgery compared to diclofenac. *Journal of Alternative and Complementary Medicine,* **14**: 17–25.	88	No	OTP
12 Postpartum lactation	Berrebi A, Parant O, Ferval F, *et al* (2001). [Treatment of pain due to unwanted lactation with a homeopathic preparation given in the immediate post-partum period]. *Journal de gynécologie, obstétrique et biologie de la reproduction,* **30**: 353–357.	71	No	P
13 Seasonal allergic rhinitis	Wiesenauer M, Häussler S, Gaus W (1983). [Treatment of pollinosis with Galphimia glauca]. *Fortschritte der Medizin,* **101**: 811–814.	86	No	P
14 Seasonal allergic rhinitis	Wiesenauer M, Gaus W, Häussler S (1990). [Treatment of pollinosis with the homeopathic preparation Galphimia glauca. A double-blind trial in clinical practice]. *Allergologie,* **13**: 359–363.	201	No	P

Medical condition	*Journal reference*	*N*	*Powered*	*P/OTP*
15 Sinusitis	Friese K-H, Zabalotnyi D I (2007). [Homeopathy in acute rhinosinusitis. A double-blind, placebo controlled study shows the efficiency and tolerability of a homeopathic combination remedy]. *HNO,* **55**: 271–277.	144	No	P
16 Sinusitis	Weiser M, Clasen B (1994). [Randomized, placebo-controlled, double-blind study of the clinical efficacy of the homeopathic Euphorbium compositum-S nasal spray in cases of chronic sinusitis]. *Forschende Komplementärmedizin,* **1**: 251–259.	104	Yes	P
17 Sinusitis	Zabolotnyi D I, Kneis K C, Richardson A, *et al* (2007). Efficacy of a complex homeopathic medication (Sinfrontal) in patients with acute maxillary sinusitis: a prospective, randomized, double-blind, placebo-controlled, multicenter clinical trial. *Explore (NY),* **3**: 98–109.	113	Yes	P
18 Varicose veins	Ernst E, Saradeth T, Resch K L (1990). Complementary therapy of varicose veins—a randomized, placebo-controlled, double-blind trial. *Phlebology,* **5**: 157–163.	61	No	P
19 Vertigo	Issing W, Klein P, Weiser M (2005). The homeopathic preparation Vertigoheel versus Ginkgo biloba in the treatment of vertigo in an elderly population: a double-blinded, randomized, controlled clinical trial. *Journal of Alternative and Complementary Medicine,* **11**: 155–160.	170	No	OTP
20 Vertigo	Weiser M, Strösser W, Klein P (1998). Homeopathic vs. conventional treatment of vertigo: a randomized double-blind controlled clinical study. Archives of *Otolaryngology—Head and Neck Surgery,* **124**: 879–885.	105	Yes	OTP

Q124

As per the answer to Q112 above, the cited evidence regarding vertigo (Vertigoheel) relates to comparison with usual care, not with placebo. The systematic review concluded that effectiveness of the medicine was at least as good as that of usual treatments. A pdf of the paper is attached (Annex 1).

Q125

Regarding Professor Ernst's rebuttal that Vertigoheel is "not even a homeopathic product; this is homotoxicological", the following statement is submitted, further to Dr Fisher's (Q127), in response:

> "The reference to it being a 'homotoxicological product' is incorrect. Homotoxicology is a 'school' of homeopathy that may use Vertigoheel and other homeopathic combination medicines produced in accordance with a nationally recognised homeopathic pharmacopoea as part of this therapeutic approach."
>
> Dr Robbert van Haselen, Head of Research, Biologische Heilmittel Heel GmbH, Baden-Baden, Germany.

Q135

"Four out of five" refers to the comprehensive, global, systematic reviews cited at Q112. As stated then by Dr Fisher, there are also 24 condition-based systematic reviews of homeopathy, 9 of which are positive.

Q142

A pdf of the cited paper is attached (Annex 2), as requested by Dr Harris (Q143).

Q145

There are 87 RCTs that studied the efficacy of a given homeopathic medicine. From those 87, there are 37 RCTs that reported positive findings—see Table 2 below.

Table 2

PLACEBO-CONTROLLED RCTS OF NAMED HOMEOPATHIC MEDICINES: PAPERS REPORTING POSITIVE FINDINGS, INDICATING SAMPLE SIZE (N), STATISTICAL POWER STATUS AND POTENCY (>12C/<12C)

Medical condition	*Name of medicine*	*Journal reference*	*N*	*Powered*	*Potency*
1 Allergic asthma	Isopathy	Reilly D, Taylor M A, Beattie N G M, *et al* (1994). Is evidence for homeopathy reproducible? *Lancet,* **344**: 1601–1606.	24	Yes	>12C

Medical condition	*Name of medicine*	*Journal reference*	*N*	*Powered*	*Potency*
2 Anal fissure	Nitricum acidum	Bignamini M, Saruggia M, Sansonetti G (1991). Homoeopathic treatment of anal fissures using Nitricum acidum. *Berlin Journal on Research in Homeopathy,* **1**: 286–287.	31	No	< 12C
3 Ankle sprain	Traumeel S ®	Zell J, Connert W D, Mau J, Feuerstake G (1988). [Treatment of acute sprains of the ankle. Controlled double-blind trial to test the effectiveness of a homeopathic ointment]. *Fortschritte der Medizin,* **106**: 96–100.	69	Yes	< 12C
4 Blood coagulation	Antimony	Heusser P, Berger S, Stutz M, *et al* (2009). Efficacy of homeopathically potentized antimony on blood coagulation. A randomized placebo controlled crossover trial. *Forschende Komplementärmedizin,* **16**: 14–18.	30	No	< 12C
5 Bronchitis	Bronchiselect ®	Diefenbach M, Schilken J, Steiner G, Becker HJ (1997). [Homeopathic therapy in respiratory tract diseases. Evaluation of a clinical study in 258 patients]. *Zeitschrift für Allgemeinmedizin,* **73**: 308–314.	209	No	< 12C
6 Cough	Drosetux syrup ®	Bordes L R, Dorfman P (1986). [Evaluation of the antitussive effect of Drosetux syrup: double-blind study versus placebo]. *Cahiers d'ORL,* **21**: 731–734.	60	No	< 12C
7 Infertility (oligomenorrhoea)	Phyto-Hypophyson ®	Bergmann J, Luft B, Boehmann S, *et al* (2000). [The efficacy of the complex medication Phyto-Hypophyson L in female, hormone-related sterility. A randomized, placebo-controlled clinical double-blind study]. *Forschende Komplementärmedizin und Klassische Naturheilkunde,* **7**: 190–199.	37	Yes	< 12C
8 Influenza	Oscillococcinum ®	Ferley J P, Zmirou D, D'Adhemar D, Balducci F (1989). A controlled evaluation of a homoeopathic preparation in the treatment of influenza like syndromes. *British Journal of Clinical Pharmacology,* **27**: 329–335.	462	No	> 12C
9 Influenza	Oscillococcinum ®	Papp R, Schuback G, Beck E, *et al* (1998). Oscillococcinum in patients with influenza-like syndromes: a placebo-controlled double-blind evaluation. *British Homeopathic Journal,* **87**: 69–76.	372	Yes	> 12C
10 Influenza (prevention)	Combination preparation	Rottey E E D, Verleye G B, Liagre R L P (1995). [The effect of a homeopathic preparation in the prevention of flu symptoms: a randomized double-blind trial in primary care practice]. *Tijdschrift Integrale Geneeskunde,* **11**: 54–58.	501	No	> 12C
11 Influenza (prevention)	Gripp-Heel ®	Brydak L B, Denys A (1999). The evaluation of humoral response and the clinical evaluation of a risk-group patients' state of health after administration of the homeopathic preparation Gripp-Heel during the influenza epidemic season 1993/94. *International Review of Allergology and Clinical Immunology,* **5**: 223–227.	124	No	< 12C

Medical condition	*Name of medicine*	*Journal reference*	*N*	*Powered*	*Potency*
12 Irritable bowel syndrome	Asa foetida	Rahlfs V W, Mssinger P (1978). [Asa foetida in the treatment of the irritable colon—a double-blind trial]. *Deutsche medizinische Wochenschrift,* **104**: 140–143.	89	No	<12C
13 Muscle soreness	Arnica	Tveiten D, Bruseth S, Borchgrevink C F, Norseth J (1998). Effects of the homoeopathic remedy Arnica D30 on marathon runners: a randomized, double-blind study during the 1995 Oslo Marathon. *Complementary Therapies in Medicine,* **6**: 71–74.	46	No	>12C
14 Obesity	Helianthus tuberosus	Werk W, Lehmann M, Galland F (1994). [Comparative controlled trial on the effect of the homeopathic botanical medicinal product Helianthus tuberosus D1 as an adjuvant in the treatment of obesity]. *Therapiewoche,* **44**: 34–39.	102	No	<12C
15 Plantar fasciitis	Ruta graveolens	Clark J, Percivall A (2000). A preliminary investigation into the effectiveness of the homeopathic remedy, Ruta graveolens, in the treatment of pain in plantar fasciitis. *British Journal of Podiatry,* **3**: 81–85.	14	No	>12C
16 Post-operative agitation	Aconite	Alibeu J P, Jobert J (1990). [Homeopathic therapy with Aconite for post-operative pain-agitation syndrome]. *Pédiatrie,* **45**: 465–466.	46	No	<12C
17 Post-operative bruising	Arnica	Seeley B M, Denton A B, Ahn M S, Maas C S (2006). Effect of homeopathic Arnica montana on bruising in face-lifts: results of a randomized, double-blind, placebo-controlled clinical trial. *Archives of Facial Plastic Surgery,* **8**: 54–59.	29	No	Mixed
18 Post-operative pain	Arnica	Robertson A, Suryanarayanan R, Banerjee A (2007). Homeopathic Arnica montana for post-tonsillectomy analgesia: a randomised placebo control trial. *Homeopathy,* **96**: 17–21.	111	Yes	>12C
19 Post-operative swelling	Arnica	Brinkhaus B, Wilkens J M, Lüdtke R, *et al* (2006). Homeopathic arnica therapy in patients receiving knee surgery: results of three randomised double-blind trials. *Complementary Therapies in Medicine,* **14**: 237–246.	57	Yes	>12C
20 Postpartum bleeding	Arnica + Bellis perennis	Oberbaum M, Galoyan N, Lerner-Geva L, *et al* (2005). The effect of the homeopathic remedies Arnica and Bellis perennis on mild postpartum bleeding—a randomized, double-blind, placebo-controlled study –preliminary results. *Complementary Therapies in Medicine,* **13**: 87–90.	40	Yes	Mixed
21 Postpartum lactation	Apis mellifica + Bryonia	Berrebi A, Parant O, Ferval F, *et al* (2001). [Treatment of pain due to unwanted lactation with a homeopathic preparation given in the immediate post-partum period]. *Journal de gynécologie, obstétrique et biologie de la reproduction,* **30**: 353–357.	71	No	<12C

Medical condition	*Name of medicine*	*Journal reference*	*N*	*Powered*	*Potency*
22 Radiodermatitis	Belladonna + X-ray	Balzarini A, Felisi E, Martini A, De Conno F (2000). Efficacy of homeopathic treatment of skin reactions during radiotherapy for breast cancer: a randomized, double-blind clinical trial. *British Homeopathic Journal,* **89**: 8–12.	61	No	Mixed
23 Renal failure	China rubra	Saruggia M, Corghi E (1992). Effects of homoeopathic dilutions of china rubra on intradialytic symptomatology in patients treated with chronic haemodialysis. *British Homeopathic Journal,* **81**: 86-88.	35	No	< 12C
24 Seasonal allergic rhinitis	Betula	Aabel S, Laerum E, Dlvik S, Djupesland P (2000). Is homeopathic "immunotherapy" effective? A double-blind, placebo-controlled trial with the isopathic remedy Betula 30c for patients with birch pollen allergy. *British Homeopathic Journal,* **89**: 161–168.	66	Yes	> 12C
25 Seasonal allergic rhinitis	Galphimia glauca	Wiesenauer M, Gaus W, Häussler S (1990). [Treatment of pollinosis with the homeopathic preparation Galphimia glauca. A double-blind trial in clinical practice]. *Allergologie,* **13**: 359–363.	201	No	< 12C
26 Seasonal allergic rhinitis	Galphimia glauca	Wiesenauer M, Häussler S, Gaus W (1983). [Treatment of pollinosis with Galphimia glauca]. *Fortschritte der Medizin,* **101**: 811–814.	86	No	< 12C
27 Seasonal allergic rhinitis	Isopathy	Kim L S, Riedlinger J E, Baldwin C M, *et al* (2005). Treatment of seasonal allergic rhinitis using homeopathic preparation of common allergens in the southwest region of the US: a randomized, controlled clinical trial. *Annals of Pharmacotherapy,* **39**: 617–624.	34	Yes	< 12C
28 Seasonal allergic rhinitis	Isopathy (grass pollen)	Reilly D T, Taylor M A (1985). Potent placebo or potency? A proposed study model with initial findings using homoeopathically prepared pollens in hayfever. *British Homeopathic Journal,* **74**: 65–75.	36	No	> 12C
29 Seasonal allergic rhinitis	Isopathy (grass pollen)	Reilly D T, Taylor M A, McSharry C, Aitchison T (1986). Is homeopathy a placebo response? Controlled trial of homeopathic potency, with pollen in hayfever as model. Lancet, **ii**: 881–885.	144	Yes	> 12C
30 Seasonal allergic rhinitis	Isopathy (grass pollen)	Taylor M A, Reilly D, Llewellyn-Jones R H, *et al* (2000). Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *British Medical Journal,* **321**: 471–476.	50	Yes	> 12C
31 Seborrhoeic dermatitis	Combination preparation	Smith S A, Baker A E, Williams J H (2002). Effective treatment of seborrhoeic dermatitis using a low dose, oral homeopathic medication consisting of potassium bromide, sodium bromide, nickel sulfate, and sodium chloride in a double-blind, placebo-controlled study. *Alternative Medicine Review,* **7**: 59–67.	32	No	< 12C

Medical condition	*Name of medicine*	*Journal reference*	*N*	*Powered*	*Potency*
32 Sinusitis	Combination preparation	Friese K-H, Zabalotnyi D I (2007). [Homeopathy in acute rhinosinusitis. A double-blind, placebo controlled study shows the efficiency and tolerability of a homeopathic combination remedy]. *HNO,* **55**: 271–277.	144	No	< 12C
33 Sinusitis	Euphorbium compositum	Weiser M, Clasen B (1994). [Randomized, placebo-controlled, double-blind study of the clinical efficacy of the homeopathic Euphorbium compositum-S nasal spray in cases of chronic sinusitis]. *Forschende Komplementärmedizin,* **1**: 251–259.	104	Yes	< 12C
34 Sinusitis	Sinfrontal ®	Zabolotnyi D I, Kneis K C, Richardson A, *et al* (2007). Efficacy of a complex homeopathic medication (Sinfrontal) in patients with acute maxillary sinusitis: a prospective, randomized, double-blind, placebo-controlled, multicenter clinical trial. *Explore (NY),* **3**: 98–109.	113	Yes	< 12C
35 Stomatitis	Traumeel S ®	Oberbaum M, Yaniv I, Ben-Gal Y, *et al* (2001). A randomized, controlled clinical trial of the homeopathic medication Traumeel S in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation. *Cancer,* **92**: 684–690.	30	No	< 12C
36 Tracheal secretions	Potassium dichromate	Frass M, Dielacher C, Linkesch M, *et al* (2005). Influence of potassium dichromate on tracheal secretions in critically ill patients. *Chest,* **127**: 936–941.	50	No	> 12C
37 Varicose veins	Poikiven ®	Ernst E, Saradeth T, Resch K L (1990). Complementary therapy of varicose veins—a randomized, placebo-controlled, double-blind trial. *Phlebology,* **5**: 157–163.	61	No	< 12C

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December 2009

Annex 1

Schneider B, Klein P, Weiser M (2005). Treatment of vertigo with a homeopathic complex remedy compared with usual treatments: a meta-analysis of clinical trials. Arzneimittelforschung, **55**: 23–29.

Annex 2

Linde K (2009). Can you trust systematic reviews of complementary and alternative therapies? *European Journal of Integrative Medicine,* **1**: 117–123.

Monday 30 November 2009

Members present

Mr Phil Willis, in the Chair

Dr Evan Harris	Ian Stewart
Dr Brian Iddon	Graham Stringer

Memorandum submitted by the Department of Health (HO 00)

This response was provided by the Department of Health in answer to a Committee question submitted on 30 July 2009 as part of the Innovation, Universities, Science and Skills Committee's "Evidence Check".

HOMEOPATHY

Q1. *How does the Government license homeopathic products?*

Homeopathy has a long tradition in Europe and is a recognised system of medicine across the EU. Homeopathic medicinal products are included in the scope of European Directives and the Medicines Act 1968 and therefore require regulation.

Under current licensing arrangements, homeopathic products either have Product Licences of Right (PLRs) or certificates granted under a Simplified Scheme, or have been granted homeopathic marketing authorisations under the National Rules Scheme. PLRs are licences that were issued to all products on the market at the time that the Medicines Act 1968 was implemented in 1971.

The Simplified Scheme for homeopathic medicinal products was introduced in 1992 under European Directive 92/73/EC. The procedure is regarded as simplified because there is no requirement in the Directive for data to demonstrate clinical efficacy and the eligibility criteria confer a certain reassurance on safety so that the data requirements on safety are usually minimal. The Simplified Scheme does not permit therapeutic indications to be stated on the product label.

In 2006, the UK introduced the National Rules Scheme, which allows the marketing of homeopathic products, with a strictly limited range of therapeutic indications under European Directive 2001/83, in accordance with the principles and characteristics of homeopathy as practised. Only products which are indicated for the relief of minor symptoms and minor conditions in humans are eligible for a homeopathic marketing authorisation under this scheme. For these purposes, minor symptoms are those which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

The Simplified Scheme, which has been operating successfully in the UK for 17 years, and the new National Rules Scheme ensure that consumers who choose to use homeopathic products are better informed about their purpose, and that they are assured that standards of quality and safety are maintained.

Q2. *What scientific evidence was considered during the formulation of the licensing regime?*

Because homeopathic products have a long and established traditional use in the UK, the licensing regime functions primarily to ensure that they are both safe and of suitable quality. It also functions to provide improved and consistent product information for consumers.

The three elements of the licensing regime probably lie outside the scope of the IUSS Select Committee Inquiry, because government consideration of scientific evidence was not the basis for their establishment.

Firstly, the Product Licences of Right were granted to all existing marketed medicines in 1971, under the provisions of the Medicines Act 1968.

Secondly, the Simplified Scheme derives from European Directive 92/73/EC, so probably lies outside the scope of the Inquiry; and

Thirdly, no scientific evidence was examined in drawing up the National Rules Scheme, which also derives from a European Directive. Definitions of "product safety" and "product quality" are commonly understood and did not need to be embedded in the scheme itself. Therefore, the onus to provide supportive scientific evidence is on each individual product that manufacturers put through the scheme—to demonstrate that the product is used as a homeopathic medicine, that it is safe, and that it is of suitable quality.

November 2009

Memorandum submitted by the Department of Health (HO 34)

Executive Summary of Main Points

1. Decisions on commissioning and funding of any treatment are the responsibility of the National Health Service and the Government expects local providers and practitioners to take into account issues to do with safety, clinical and cost-effectiveness, and the availability of suitably regulated/qualified practitioners.

2. The Department of Health has tried to ensure there is good quality, accessible information available about complementary and alternative treatments so that consumers can make informed decisions if they are considering using any such treatment. NHS Choices is creating a directory of available CAM services and a package of information about the various therapies.

3. Homeopathic products are licensed by the MHRA and either have Product Licences of Right (PLRs), have been granted certificates under a Simplified Scheme, or have been granted homeopathic marketing authorizations under the National Rules Scheme.

4. There is capacity for research into Complementary and Alternative Medicine therapies through the National Institute for Health Research (NIHR) which rarely turns down high quality proposals. NICE considers particular CAM therapies (where suitable evidence exists) alongside conventional treatments when developing clinical guidelines for specific conditions but it cannot provide a blanket assessment of a particular type of treatment.

5. The only complementary and alternative medicine (CAM) practitioners regulated by statute are chiropractic and osteopathy and a consultation is currently underway to consider whether, and if so how, to regulate acupuncture, herbal medicine and traditional Chinese Medicine practitioners. There are no plans to regulate homeopathic practitioners by statute.

Brief Introduction

6. Commissioning in the National Health Service is a collaborative process involving all partners including patients, public, local authorities, clinicians and is focused on outcomes. This paper will seek to provide the background to the commissioning of homeopathy on the National Health Service.

7. Homeopathy is a controversial subject and one on which the Department of Health receives correspondence both for and against in equal volume. The Department does not maintain a position on any complementary or alternative treatments, leaving decisions on their use *by* the National Health Service, *to* the National Health Service.

8. Clinicians need to take into account any policies on commissioning such services that their Primary Care Trust may have in place. They also need to be mindful of their obligations in relation to patient choice and Joint Strategic Needs Assessment.

9. There are three NHS Homeopathic Hospitals in England—these are located in London, Bristol and Liverpool. There was another Homeopathic Hospital based in Tunbridge Wells which ceased providing services in March 2009 following a significant drop in referrals in recent years and, following a public consultation, a decision to stop commissioning and funding treatments at the hospital. Scotland has one NHS homeopathic hospital located in Glasgow.

10. The homeopathic hospitals fall under the jurisdiction of the NHS trust in which they are based.

National Health Service Commissioning

Background

11. Commissioning is the process by which healthcare services are secured to meet the needs of the populations. Primary Care Trusts (PCTs) are responsible for commissioning high quality care services, within allocated resources, to meet local patient needs and with a clear focus on improving health outcomes for the population.

12. Commissioning is one of the most important vehicles for delivering the NHS vision of a health and care system that is fair, personalised, effective and safe, and focused on reducing health inequalities, adding life to years and years to life.

13. In 2005, the Department published *Commissioning a Patient led NHS*. It focused on the process needed for effective commissioning, and precipitated a large-scale restructure of PCTs into larger organisations. Since this time, the focus of our programmes has been on developing PCT commissioning capability by developing an inspiring vision and a means for achieving it.

14. Weaknesses in NHS commissioning were identified through the Fitness for Purpose exercise (May 2006–March 2007). A joint review in May 2007 by the Department and the Prime Ministers Delivery Unit highlighted similar challenges and identified a number of recommendations to ensure all PCTs become more effective commissioners. The world class commissioning programme was established in response to these recommendations.

World class commissioning

15. World class commissioning (WCC) seeks to bring a different approach to PCT commissioning: one that is focused on outcomes and one that involves all partners including patients, public, local authorities, clinicians and providers in making tough choices about priorities and how to deliver them.

16. WCC has been developed in partnership with the service involving representatives from SHAs, PCTs, Local Government and external stakeholder organisations. The service has welcomed this way of working through co-production.

17. There are three main components of the WCC programme: the vision for WCC, an assurance system that holds commissioners to account and to reward performance and development and an ongoing framework of support and development to ensure that commissioners have the resources to enable them to achieve WCC.

NHS spend on homeopathic products and services (including NHS homeopathic hospitals)

18. Data on spending in the area of homeopathy on the National Health Service has never been routinely collected. However, we have requested that Primary Care Trusts provide estimates on this to the Department, through their Strategic Health Authority, at the earliest opportunity. We have also asked for details about what they base their decisions on when commissioning and funding homeopathy.

Why the NHS funds homeopathy

19. The Department does not maintain a position on any complementary or alternative treatments, leaving decisions on their use *by* the National Health Service, *to* the National Health Service. The Government expects local providers and practitioners to take into account issues to do with safety, clinical and cost-effectiveness, and the availability of suitably regulated/qualified practitioners. Each of these are considered in detail below.

What evidence the NHS has considered in its decision to fund homeopathy

20. The Department of Health has tried to ensure there is good quality, accessible information available about complementary and alternative treatments so that consumers can make informed decisions if they are considering using any such treatment. NHS Choices is creating a directory of available CAM services and a package of information about the various therapies. In the meantime however there is a considerable amount of information about homeopathy on the NHS Evidence website (www.evidence.nhs.uk).

RESEARCH

21. There are over 20 systematic reviews, and in excess of 150 trials, of homeopathy. The Department considers for this reason that commissioning a further systematic review would not be appropriate. However, the Department is one of the largest mainstream UK funders of research into complementary and alternative medicine (CAM).

22. The Department of Health commissions research to underpin policy and practice in health and healthcare through the National Institute for Health Research (NIHR) and the DH Policy Research Programme.

23. The Department does not exclude, *a priori*, any areas from investigation and has funded and continues to fund research on various branches of CAM. Over the last 10 years, central funding and local NHS R&D budgets have both contributed to the total investment.

24. Implementation of the Department's research strategy *Best Research for Best Health* has resulted in an expansion of our research programmes and in significant new funding opportunities for health research. The strategy is delivered by the NIHR.

25. DH-funded research aims to support the best science and so achieve the best outcomes for patients and for the NHS. For that reason our NIHR programmes do not ring fence funds for expenditure on particular topics. Research proposals in all areas compete for the funding available. Applications are then are subject to peer review and judged in open competition, with awards being made on the basis of the scientific quality of the proposals made.

26. A number of NIHR awards have been made in the last year or so in support of studies directly concerned with demonstrating whether specific CAM therapies work and whether they represent good value. If researchers continue to come up with high quality proposals, there is no reason why they should not continue to attract NIHR support

27. A £3.4 million complementary and alternative medicine personal award scheme was included in our research capacity development programme. The scheme, which began in 2003, has supported 18 CAM researchers at the doctoral and postdoctoral level. These award holders have undertaken a total of nine studies

and have nurtured the methodological skills of the more junior researchers in their teams. Their presence in the Research Development Capacity Programme has allowed factors specific to CAM practice to be incorporated into approved generic research methodologies.

28. The Department has also funded research on the role of CAM in the care of cancer patients (three projects were commissioned, are complete and have been published); and on the use of complementary medicine in primary care.

29. The research capacity development programme also funds CAMEOL (Complementary and Alternative Medicine Evidence Online). This is a collaboration between the Research Council for Complementary Medicine and the University of Westminster School of Integrated Health. It involves a detailed review and critical appraisal of the published research in specific complementary therapies, focusing on their use in NHS priority areas.

30. The R&D funding regime that operated from 1998 to 2006—under which we allocated some £500 million a year to individual NHS organisations—gave those organisations the means of supporting a large number of projects concerned with the use of CAM. The former National Research Register lists well over 100. It also allowed the Department to provide research and development support to the Royal London Homeopathic Hospital.

Safety: Licensing of Homeopathic Products

31. Homeopathy has a long tradition in Europe and is a recognised and widely used system of medicine across the EU. The Government takes the view that consumers who choose to use homeopathic medicines should be fully informed about their purpose and assured that standards of quality and safety are maintained.

32. If homeopathic medicines were not subject to any kind of regulatory control consumers would not have access to such information or assurances. Conversely, if regulation was applied to homeopathics as understood in the context of conventional pharmaceutical medicines, these products would have to be withdrawn from the market as medicines. This would constrain consumer choice and, more importantly, risk the introduction of unregulated, poor quality and potentially unsafe products on the market to satisfy consumer demand.

33. Under current licensing arrangements, homeopathic products either have Product Licences of Right (PLRs), have been granted certificates under a Simplified Scheme, or have been granted homeopathic marketing authorizations under the National Rules Scheme. PLRs are licences that were issued to all products on the market at the time that the Medicines Act 1968 was implemented in 1971.

34. The Simplified Scheme for homeopathic medicinal products was introduced in 1992 under European Directive 92/73/EC. In 2006, the UK introduced the National Rules Scheme, which allows the marketing of homeopathic products, with a strictly limited range of therapeutic indications in accordance with the principles and characteristics of homeopathy as practised in the UK. Only products which are indicated for the relief of minor symptoms and minor conditions in humans are eligible for a homeopathic marketing authorization under this scheme. For these purposes, minor symptoms are those which can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

35. Applicants for both the Simplified Scheme and the National Rules scheme must submit a dossier demonstrating the safety and quality of the product. Safety and quality are monitored during the life cycle of the product in similar terms to pharmaceutical medicines with full marketing authorisations. The schemes recognise that these products contain a very low level of active principles and recognises the difficulty of applying to them the conventional statistical methods relating to clinical trials. However, the regulatory framework requires that in accordance with the principles and characteristics of homeopathy as practised in the Member State, the applicant must provide one or more of the following:

— Study reports in relation to the product which is the subject of the application;

— Published scientific literature;

— The method by which the profile of a homeopathic remedy is determined

36. Whatever data are provided must be sufficient to demonstrate that UK homeopathic practitioners would accept the efficacy of the product for the indications sought.

Clinical and Cost-Effectiveness: NICE and CAM Therapies

37. This Government established NICE to provide authoritative, independent advice on different health-related interventions and pathways of care, increase fairness in access to treatments, to be a national source of robust clinical guidance and to speed up the uptake of cost-effective treatments in the NHS.

38. NICE helps to tackle variations in prescribing practice by issuing robust, evidence-based guidance which we expect clinicians to take fully into account. NICE also spreads good practice, and helps protect patients from out-dated or unproven treatments. Broadly, NICE develops four forms of clinical guidance: clinical guidelines (management of particular clinical conditions), technology appraisal guidance (guidance on specific health interventions, including pharmaceuticals), public health guidance and guidance on the safety and efficacy of interventional procedures.

39. NICE considers particular CAM therapies (where suitable evidence exists) alongside conventional treatments when developing clinical guidelines for specific conditions. Some guidelines produced by NICE have already included references to CAM therapies—most recently in May 2009 guidance on non-specific lower back pain including recommendations for the use of osteopathy, spinal manipulation and massage.

40. What NICE cannot produce, however, is blanket guidance on complementary medicine, which has been called for in the past.

41. Where possible, we have also aimed to develop the evidence base on which NICE makes its judgements on clinical and cost-effectiveness.

Regulation of Homeopathic Practitioners

42. At present there is no statutory regulation system in the UK governing the practice of complementary and alternative medicine (CAM), with the exception of chiropractic and osteopathy which are regulated by statute. A report (May 2008) from a UK working group made recommendations which are the subject of a consultation which ends on 2 November 2009. It seeks respondents' views on whether, and if so how, to regulate acupuncture, herbal medicine and traditional Chinese Medicine practitioners.

43. Once the consultation responses have been analysed, a decision will be made as to whether or not to move towards statutory regulation of these professions. Previous experience of regulating new professions suggests that, if a decision were made to regulate these professions by statute, we would be unlikely to reach statutory regulation until 2011–12 at the earliest.

44. DH commissioned the Prince's Foundation for Integrated Health (FIH) to develop voluntary self-regulation amongst a range of currently unregulated therapies. FIH were awarded a Government grant of £900,000 over three years to carry out this work. As a result of the work carried out by the working group, the Complementary and Natural Healthcare Council (CNHC) was set up in 2008 and its register opened in January 2009.

45. The CNHC is a new voluntary professional regulator. Individuals who belong to one of the therapies it covers may choose to register with it (but do not have to do so). Registration with the CNHC will enhance public safety as it gives assurances that the practitioner has met certain entry standards (eg has an accredited qualification), that they subscribe to a set of professional standards, and hold appropriate and sufficient insurance. Breach of these standards could result in removal from the register. The Department of Health supports the work of the CNHC and has funded its start up costs.

November 2009

Witnesses: **Mr Mike O'Brien QC, MP**, Minister for Health Services, Department of Health, **Professor Kent Woods**, Chief Executive, Medicines and Healthcare Products Regulatory Agency, and **Professor David Harper CBE,** Director General, Health Improvement and Protection, and Chief Scientist, Department of Health, gave evidence

Q174 Chairman: Could I first of all welcome our three witnesses this afternoon to our evidence check on homeopathy. We welcome Mike O'Brien QC MP, the Minister for Health Services at the Department of Health; Professor Kent Woods, the Chief Executive of the Medicines and Healthcare Products Regulatory Agency—that is a mouthful; and Professor David Harper, the Director General, Health Improvement and Protection, and Chief Scientist at the Department of Health. Could I first of all apologise that we are slightly late starting today and also put on record, because there seems to be a little confusion about the nature of the work that we are doing, this is not an inquiry into whether homeopathy works or not. This is an inquiry which follows a series of evidence checks across a number of government departments to see whether in fact there was any evidence to support the Government's policy towards homeopathy. I want to make that absolutely clear. I wonder if we can therefore start with you, Minister. Does the Government have any credible evidence that homeopathy works beyond the placebo effect?
Mr O'Brien: Certainly there is the placebo effect. There was also some research done in Northern Ireland in an examination of the effect of a number of complementary and alternative medicines not including homeopathy.

Q175 Chairman: Keep with homeopathy.
Mr O'Brien: In that case the straight answer is no.

Q176 Chairman: The answer is no. Professor Harper?

Professor Harper: This is clearly a very challenging area. There are mixed views from the scientific community, as you are well aware from the evidence that already has been given, but I think it is undoubtedly the case that the majority of independent scientists feel that the evidence is weak or absent.

Q177 Chairman: Can you point us to any specific piece of scientific evidence which would stand up to normal scientific scrutiny that the Department has used to support the Government's policy on homeopathy?
Professor Harper: There are a number of meta-analyses and randomised controlled trials and I think you have heard and seen from previous evidence that it is possible to be quite selective about how that information is used. One of the real difficulties that we face is that it is not so much a lack of research or a lack of randomised controlled trials; it is a lack of agreement between experts working in this field.

Q178 Chairman: But you have a key responsibility within the Department of Health, you are the Chief Scientist within the Department of Health; can you point me to a single piece of clear evidence that supports the use of public money on homeopathy?
Professor Harper: I really cannot add very much to what I said that the evidence base is—

Q179 Chairman: Can you point me to any specific piece of evidence?
Professor Harper: There are papers. There is a paper that was quoted—

Q180 Chairman: You tell me one. You are the Chief Scientist. Can you tell me one?
Professor Harper: There is a paper but it seems a strange one to pick out because there are a whole lot of randomised trials and what I am saying to you is for every one that is picked out to support one point of view there is another that is picked out to—

Q181 Chairman: No, that is not what I am asking you. You are the Department's Chief Scientist. Can you give me one specific reference which supports the use of homeopathy in terms of Government policy on health?
Professor Harper: Yes, if we could come back to how we use evidence in policy-making, a randomised controlled trial was on the effects of arnica as a homeopathic remedy. That was published some time ago and shortly afterwards there was another randomised controlled trial. This was using arnica as a means of reducing inflammation in knee surgery but there was another paper that was published shortly afterwards that said that that paper did not demonstrate that, so you can pull out different randomised controlled trials that will demonstrate one thing or another.

Q182 Chairman: Okay. Professor Kent Woods, can I push you on the same question. Are you aware of any evidence to show that homeopathy works beyond the placebo effect?
Professor Woods: One has to look at the totality of the evidence and in my view there is no single piece of evidence that gives that reassurance. It is difficult from the point of view of research in that the underlying theory does not really give rise to many testable hypotheses and therefore I think the research effort has been bedevilled by that. One could then ask what about the empirical evidence that homeopathy has a beneficial effect and, as you have heard, the studies are ambiguous; they present a variety of results. In aggregate I do not think there is anything there that one would take as robust evidence of an effect over and above the placebo effect, which can of course be quite powerful in its own right in some individuals. From the point of view of evidence, certainly from a regulatory perspective, it is very important evidence that something like ten per cent of the population have used a homeopathic remedy or have gone to a homeopath in the previous 12 months, and that I think is a starting point for deciding what is the public health significance of this phenomenon. It is the way in which they are used rather than, as you said in your very first words, the argument about whether homeopathy works or not. I think in terms of developing evidence we have to acknowledge that there are some people who firmly believe that homeopathy works. There is a degree of use which suggests we might have to consider the public health implications of a significant group of people using homeopathic remedies and if there are potential public health implications, how should we regulate it?

Q183 Chairman: So if a significant number of people believed in witchcraft we would seriously consider that?
Mr O'Brien: That really is not what people here are saying. With the greatest respect, Chairman, you have asked two different questions here, both of which elicited slightly different answers, and I want to be exactly clear what you are saying. You tried to exclude the placebo effect. What you asked was whether there was any evidence, by which I assumed you meant, and I think so did both my colleagues, any empirical peer group-assessed—

Q184 Chairman: The word I used was "credible" evidence.
Mr O'Brien: In which case we assumed that you meant empirical evidence which has been peer group-assessed and validated. The answer to that is beyond the placebo effect, which is powerful, and the fact that some doctors and those who are well-qualified take the view that it does have an effect, but it is not been validated in the sense of a peer group-assessed empirical study (of which I am aware at least) to show the full validity. There is nonetheless some evidence that the placebo effect works. There

is also a body of people who are reputable who take the view that it works and it is therefore the case that we have a body of people who believe in it—and I think that is probably the best word. However, if you are asking me as a minister do I have evidence that it works which is empirical and peer group-assessed, the answer is no, but that does not mean there is no justification for the Government policy, so I think we just need to be clear about that.

Q185 Chairman: That is fair and the reason for having you here, Minister, is to make exactly that defence of Government policy. If in fact efficacy has not been proven, and it would in any other area where you are spending money on behalf of the taxpayers within this very, very vital area of health, do you feel that more research should be done and therefore you should be spending more money on research or would that simply be throwing good money away?
Mr O'Brien: Of course, we have spent some money, in fact £910,000 over three years, in trying to get some regulation set up in this area. We also took the view at the start of this year that it would be useful to undertake some testing of some of the homeopathic "medicines". At this point we have not started such a study. We were looking to see the outcome of the Northern Ireland study which did not deal with homeopathic medicine but did deal with complementary and alternative medicines of different kinds. We took the view that we would wait a while to look at the overall budgetary situation before deciding whether to proceed with this.

Q186 Chairman: In terms of Government policy in terms of homeopathy you are not really saying that it is evidence-based other than that there is a community who believe that they work?
Mr O'Brien: Yes.

Q187 Chairman: And you feel that that is acceptable?
Mr O'Brien: And also that there is a placebo effect, so there are the two arguments there. Certainly in terms of the placebo effect there is a view that that makes a significant number of people better, if indeed it be a placebo, and there is also a community of GPs and others who take the view that this is an area which does work, and therefore we take the view as ministers that it is not our job in relation to this, which is a somewhat controversial area—again I say in inverted commas—of "medicine", to stop clinicians who take the view they want to prescribe it from doing so.

Q188 Dr Harris: Could I just pursue that because I understand where you are coming from and I empathise with your position. I do not think it is controversial in any of the evidence we have had that there is a placebo effect and that might well be powerful enough to justify a number of policies based on it, as Professor Woods said.
Mr O'Brien: Can I just pause you there. We do not need to justify it. What we need to do is the opposite. We would need to justify stopping the funding now. It is a subtle but possibly important difference.

Q189 Dr Harris: I think this comes up in a question I was going to ask anyway myself—but I will be interrupted if I am wrong—the placebo effect is stronger, it is understood, when people do not realise it is a placebo effect. When people are told it is a placebo effect, strangely, studies have shown it is still there but it is significantly weaker and therefore less effective and therefore less cost-effective. Minister, do you think it is appropriate to fund a placebo effect and maximise its effectiveness by essentially deceiving patients into thinking that they are taking a substance that has memory of it in the water and which they are told would work because there are indications for it but in fact it is only placebo effect, or should we say, "This is a placebo. Here you are; hope it works", ethically?
Mr O'Brien: If I were to take that view, then I would be assuming that doctors who are prescribing this are doing so only in the belief that it has a placebo effect and that they do not actually have a view, however formed, that this actually has some degree of efficacy. As I understand it, most of the doctors who take the view that they are going to practise in this area take the view that it has validity. The question is whether it does or not, and there is that debate, but if you are suggesting would doctors merely prescribe something which they knew to be a placebo, they might decide to do that for proper professional and ethical reasons, but should they then go to the extent of prescribing more generally homeopathy, not believing that any of it works, then I think that would place them in a very difficult ethical position.

Q190 Dr Harris: That is very curious because what you are saying is, let us assume that it does not work beyond placebo, let us have that as an assumption for this question only, that would mean that for one doctor, who had it right, it what would be unethical for a doctor who was correct in knowing that it did not work but still said, "This will help," and that would be unethical because they were not of the view that it worked, whereas it would be entirely ethical for a doctor to prescribe something where they were wrong because they thought it worked. That is my first question. Secondly, where would that end? You could send someone to an astrologer—and there are doctors, believe me, I have met them, who believe in astrology—and they would say, "I think this works; try that", and that would have a placebo effect as well in many patients who also thought that the constellations when they were born impacted on their health or well-being now.
Mr O'Brien: Certainly I think doctors can, if they feel that there is an ethical and efficacious reason for doing so, prescribe a placebo. It may well be their view that that would assist a particular patient. I think they would have to think carefully about doing

it, but I suspect they could probably justify that. If, however, they prescribed homeopathy believing in it, as I think is your argument, and believing that it had an efficacious outcome, would they be somehow wrong to do that? Of course if they believed it would have a benefit why would they be wrong to prescribe it?

Q191 Dr Harris: So you are saying it is ethical. Is it the Government's view that it is ethical to prescribe a placebo on the basis that—
Mr O'Brien: I think you have to separate two things.

Q192 Dr Harris: What is your advice to doctors on the NHS here, please?
Mr O'Brien: You have to separate two things here. The Government's position is very clear. The Government's position is that this is a controversial area of "medicine"—and let us assume we put the quotes wherever I make such reference in future—and it should be a matter for clinicians to make decisions in relation to this area, in conjunction with discussions with the primary care trust who have a responsibility for funding any medicine that is prescribed. That is our view, so in terms of the ethics, as you put it, of the situation, I think we would be reliant upon the professional organisations in order to regulate the judgments that clinicians make about what kind of medicine should be prescribed. You were asking me to speculate and I did that a little bit but then you turned to what is the Government's position and I just want you to be clear that there is a Government position. What you were inviting me to do was speculate and I followed your invitation.

Q193 Dr Harris: I am not clear. Maybe to be clear, let me ask you, would you as a patient be happy to be given something that did not work but be told it worked in the hope that it would make you better, so paternalistic deception? No-one is profiteering out of this in terms of the relationship between you and the GP. Would you be happy as a patient to be misled in that way if it made you better?
Mr O'Brien: I would not be happy to be misled and I suspect most patients would not. However, that was not the question you asked me. What you were asking me was a different question, with respect, which was whether it would be unethical for a doctor ever to prescribe a placebo. That seemed to me to be what you were asking. I thought about it and I took the view that there might be circumstances, but would you generally do it? Of course you would not.

Q194 Dr Harris: I do not want to drag you back to what you think you have answered. Let us go on to this one: so you are saying that you do not think most patients would want to be prescribed something that did not work and be paternalistically misled in that?
Mr O'Brien: I would not want to be told that—

Q195 Dr Harris: Should we ask each patient?
Mr O'Brien: —a sugar tablet—let us move away from homeopathy for a moment—would do something that it would not. However, it is the case of course that for all sorts of reasons, particularly for research, it may well be that a sugar tablet is prescribed to some patients for comparison with an operating drug as part of a trial. There are all sorts of reasons why that may be done.

Q196 Dr Harris: It is said to be randomised and there is very clear informed consent that they consent to be randomised to active treatment or placebo, so that, with respect, is an entirely different matter. Let us move on to this question of research to something that was touched on in the Chairman's question but not fully dealt with. We heard evidence that there is a settled view out there, the one that Professor Harper gave, looking across the systematic reviews of the evidence base, that there is weak or absent evidence for the effectiveness or the efficacy of homeopathy, so the question was put to us, indeed it was put in the previous evidence session we had by a number of our witnesses; is it wise for NHS or MRC or any other publicly funded money, or indeed patient time, to be put into more research in this area, because you will be aware that if something is settled then it is unethical (I think Professor Woods would agree) or at least it is hard to get ethical approval for a trial that is not going to achieve anything. There is a threshold that has to be passed of usefulness. The question is: do you think on the basis of what your chief scientific adviser says about the settled nature of the view that there is room for research using public money on the efficacy of homeopathy?
Mr O'Brien: There is a level of public interest and controversy, and there is a strong medical lobby in favour of homeopathy, and there is also government funding. Okay, in terms of drugs it is £152,000 out of a massive £11 billion drugs budget, so therefore it is quite a small amount in that drugs budget but it is £152,000 nonetheless. Should we look into how that money is spent? I think there is an argument for doing that, yes. What your argument seems to be is because at the moment the generally settled view is that there is not an empirically peer group tested piece of research which justifies it, that therefore we should not do that research.

Q197 Dr Harris: That was not my point. Do not go on any more. I will just say it one more time because this is key and it is a question that we really have to have answered. There is a view out there, and I think it is the orthodox scientific opinion, and I think the view of Professor Harper, that if you look across all the systematic reviews of all the trials there is no good evidence that homeopathy works, and the view is further that there is no point doing any more randomised controlled trials or indeed any more systematic reviews. They have been done to death and the answer is negative. On that basis, can you justify spending any more taxpayers' money on researching a question for which the settled view is that it is not going to change the research? We do not fund research into exploring whether the earth is flat. It is a settled view that it is not. I would like to ask you, Minister, and then maybe the other two could answer. I hope that question is clear now.

Mr O'Brien: It was not clear earlier and I am grateful to you for clarifying it. As far as the research is concerned, my view is that because there is a significant area of controversy around this. You can raise your eyebrows. I can do those sorts of things too, Evan—

Q198 Dr Harris: The record will show I said nothing!
Mr O'Brien: It does not in any way change the fact that there is a group of people who are qualified, they are clinicians, who take a view that this thing works. You may well take the view, I may well take the view, Professor Harper and Professor Woods may take the view that there is not the scientific body of evidence to justify it, but there is still a group of people who believe that this stuff works. Not only that—

Q199 Dr Harris: But your scientific adviser says look at the evidence—
Mr O'Brien: Not only that—let me finish—but it does have a placebo effect which I think not even you would dispute. Therefore, is it worth researching into? I think there is an argument for doing that, yes, given that there is NHS money being spent on it and has been over a considerable period of time, so the straight answer to your question is yes. Despite the fact that I can see exactly what Professor Harper has said and to a significant extent what you have said, there still is justification.

Q200 Dr Harris: Professor Harper?
Professor Harper: I think it might be helpful to distinguish between what I started talking about—randomised controlled trials and meta-analyses of that sort of information—and other types of research because I think, as the Minister is saying, there is, looking at orthodoxy, to use your word, or conventional scientific thinking, a lack of scientific plausibility in how homeopathic remedies might work. That is not to say there should not be research into like cures like or molecular memory. I think that is a different thing.

Q201 Dr Harris: But RCTs using patients?
Professor Harper: If you are talking about randomised controlled trials, I personally do not think it is an issue of conducting more randomised controlled trials because there are a whole lot that have been done and meta-analyses.

Q202 Dr Harris: So you would advise the Government against doing it? Even though you heard the Minister say that it is controversial and money is being spent, your advice would be not to?
Professor Harper: I think there are two different things here. If we are talking about research or randomised controlled trials—

Q203 Dr Harris: RCTs, yes.
Professor Harper: I do not think the Minister was necessarily aware that you were talking only about randomised controlled trials. I think he was thinking of research in a broader sense and what I am saying is that there might be room for looking at the scientific plausibility of homeopathic remedies.

Q204 Dr Harris: But not RCTs.
Mr O'Brien: We were looking at the outcome of the Northern Ireland test. I think I said earlier that there was no homeopathy involved. I think there was some small bit involved, but that is what we were looking at earlier this year, and I think the real issue is what priority you would put on to that research and the answer is at the moment not a high one. That sort of takes further your question, but we were looking at whether we would have a similar pilot looking at homeopathy in the UK or not. At the moment we have not decided to do that; we are looking at the financing of it.
Chairman: I know Graham Stringer wants to come in here briefly.

Q205 Graham Stringer: Mike, can I take you back to the ethics question. If you put randomised trials to one side, and if you put to one side doctors who prescribe sugar pills because they believe they have a malingerer and they do not want to waste the NHS's money, is not the real ethical question that if somebody is genuinely poorly and you prescribe a placebo that actually you are denying them access to a drug that might have some effect and would almost certainly have as much of a placebo effect as a placebo, so you are actually reducing the care or the potential treatment for that patient? Does that not make it unethical to prescribe sugar pills and water?
Mr O'Brien: In terms of how a clinician makes an individual decision about how they treat their patient, I understand your question and it is a perfectly reasonable one to ask generally to a Member of Parliament, but I think what you are really asking me as a government minister, which is a slightly different category, is whether it would be unethical in every single situation and therefore if as a matter of policy I would take a view on it, and then the answer is I would say that that is a decision which would appropriately be made between the clinician and a patient. I may well have a view on that as an individual. There may well be ethical issues around it but, as a Minister, is it my job to tell clinicians, in what may be some very particular circumstances, in detail what their ethical approach to a patient should be, I think that goes an a little bit beyond the brief.

Q206 Graham Stringer: I think any Minister who starts interfering with clinical decisions is heading for the scrap heap, we can agree on that, but what we have here is regulations that apply to homeopathic products which amount, not in every single case because there are other things governed by it, to handing out water and sugar pills, knowing that to be so, and the Government has regulated this. I do not think you can quite get off the hook by saying you will not interfere with an individual clinical decision, and I would agree with that, but what the question gets to is the ethics of having regulations regularly for handing out sugar pills.
Mr O'Brien: The question for me is who does that? The appropriate bodies would be the professional bodies rather than the government. I think the area

where government needs to be involved is how are these decisions to be made, not the detail of individual decisions in particular cases. Are we in a position where we should say—and it was the point I made earlier to Evan—that you should be able to do this or are we making a decision, as I would be as a Minister in relation to this, that we should not, that we should stop funding homeopathy, and I do not believe at this stage that I would be in a position, despite all we have discussed, to say that homeopathy should not be funded because a view might be taken that it was similar to giving water and a sugar pill. That is not the situation I am in at the moment, so ethically it should be the professional bodies who make that discussion and the GP, not at this point a Minister.

Q207 Chairman: So when the medical director of the NHS West Kent, who was a witness before us last week, said it was unethical to deliberately prescribe a placebo, you would support him in that because that is his decision down the food chain?
Mr O'Brien: He is entitled to take a view on that. If a clinician takes a view that is different from that, am I going to have to support that clinician and support the person you have just described? As a Minister, what I am doing is saying that people are entitled to all sorts of views that they may have on ethics --

Q208 Chairman: But the clinical director of an NHS Trust is more than just an individual. He is stating a policy for the whole of that NHS Trust.
Mr O'Brien: He is stating a view for that area as he is entitled to do because he has discussed it with his colleagues and taken a view. Other people in the NHS may take a different view. They may even be at the GP level; they may take a view that, in a particular circumstance, they want to take this step. As a Minister should I say: "There is no way you can ever do that because it is unethical for you to do that, Mr GP"? No.

Q209 Ian Stewart: Good afternoon. I am one of the two non scientists on this Committee and I have a completely open mind. I have never used homeopathic remedies and I want to keep an open mind, but it is important in pursuing the question that the Chairman outlined right at the beginning, that we ask pointed questions. My constituents and other MPs' constituents will have written to them saying: "We are totally against or we are totally for the provision of homeopathic remedies on the NHS". One of the things that any reasoned person would say is: "How do you research these issues? How do you make the decisions?" It is quite difficult and I thought you gave an interesting answer, Mr O'Brien, on the Government's view, but one of the things we are told in the approach to homeopathic remedies is the subject of provings, and as I have read my papers I have come to realise there is more than one definition of a proving. To start with you, Kent, the MHRA is supposed to ensure that medicines and medical devices work and are acceptable and safe. Is there any justification, therefore, for the MHRA to continue to license homeopathic products under any scheme?
Professor Woods: That is a very important question, and I should set the background. The Agency's role is specifically about trying to protect and promote public health through regulating products which are used in medical care and, as you heard, there is a significant use of these products in medical care. Therefore our concern is to put limits around how that is done in ways which will protect patients, for instance, from the use of a homeopathic remedy in a situation where they have a serious condition which needs an orthodox remedy. The background to the regulation of homeopathy going back 40 or 50 years has struggled with this issue that you have the matter of patient choice; you have, if you like, a belief system which is very strong, an evidence base which does not lend itself easily to being tested, and you can never prove a negative.

Q210 Ian Stewart: Let me then put a sceptical point of view to you, so we can hear your answer. Some people would ask, is it the purpose of the National Rule Scheme to facilitate the growth of the homeopathic industry?
Professor Woods: No, and, if it were, it has failed because since the National Rule Scheme was introduced we have exactly one product registered under it since 2006. There was a somewhat disorderly situation following on from the 1968 Medicines Act, and the number of homeopathic products which had so-called product licences of right, they had been there before 1968, they had the right to stay on the market with whatever indications were attached to them at that time. Then there was the EU Directive, which came into force in 1992—
Mr O'Brien: It was passed in 1992 and came into effect in May 1993.
Professor Woods: That is right, and that was the simplified scheme which essentially said, firstly, you cannot make any claims for the indications of this product because we do not think you can provide evidence of efficacy, but at the same time you do not have to submit any evidence of safety provided the product is so dilute it could not conceivably contain anything noxious because most of it is water, in fact, all of it is water. Now that led to a situation where on the market some products had indications, they had product licences of right, and some products were not allowed to have indications simply because they had come along later. The National Rule Scheme which was permitted under the European Directive was an attempt to put a boundary around the types of indication that could be claimed, to simple, self-limiting, minor conditions. It seems that resolves one of the concerns in public health terms that we have, we do not want homeopathic remedies being offered for the treatment of serious disease.

Q211 Ian Stewart: What was the public health justification for that decision?

Professor Woods: The public health justification is absolutely empirical and it is that 10 per cent of the population use these products so what are the risks that that pattern of, if you like, self-determination might create? One is that a homeopathic product might be used where a conventional treatment is necessary, and therefore if you have, as under the National Rule Scheme, a system which only allows for claims in relation to minor, self-limiting illnesses, you are protecting the patient against that eventuality. It means, when, for instance, as has happened in the last year or two, we find on the market homeopathic remedies with alleged indications for the prevention of malaria, or the treatment of malignancies, because we have a regulatory control over homeopathic remedies we can very rapidly see those removed from the market, and that is good for public health. You heard in your last evidence session how slow and difficult it is to take action when you are doing it through professional regulation, but as we regulate the products we can say: "That is not an acceptable labelling on your product, it must go now", and that is one strong defence for having a regulatory regime.

Q212 Ian Stewart: I will come back to regulation later, but we have certainly been told that a homeopathic proving is not the same as evidence of efficacy, so why are homeopathic provings accepted as evidence by the MHRA?

Professor Woods: They are not accepted as evidence of efficacy: they are accepted as evidence that this is a product used by homeopaths within the homeopathic tradition for that indication. It does not mean to say we endorse that indication; it is simply a marker that that product is used within the homeopathic community for the purpose for which the homeopath wishes to use it.

Q213 Ian Stewart: Are you making that statement in light of the Minister's statement earlier about why the Government comes to the decision it does?

Professor Woods: This issue about NHS provision and regulation are conceptually different. The question for me is what in public health terms should we be doing to control the availability on the market with products. It is a separate question about whether the NHS should be spending money to make these products available for individual NHS patients. My concern is about the issue of the public health dimensions of allowing them out there.

Ian Stewart: I am interested in appropriate but minimum regulation and effective research into the efficacy, and my colleague, Dr Iddon, will press you further on one of those issues.

Q214 Dr Iddon: My concern about homeopathic products is that the people who sell them are not required to produce any evidence of their efficacy in terms of clinical use, yet in another area I am very interested in, namely the sale of vitamins, minerals and herbal products, you are not allowed to advertise those according to EU regulations now for medical use unless the evidence is available, and I am slightly worried—well, I am more than worried—about that contradiction. Could you, Minister, or one of your colleagues explain the difference?

Mr O'Brien: There has historically been an encouragement of people to take various vitamins and, therefore, quite an industry has built up around the taking of various tablets which provide vitamins. If it is the case that something goes on the market which, in theory, has been generally encouraged, and there is a claim made for it that it has an impact but it simply does not, then in those circumstances we do need to say you should not be doing that because we have encouraged people to take vitamins. There is not a government policy of encouraging people to take homeopathic drugs of any kind or medicine of any kind, and certainly we do not want people to be deceived. Earlier on we were being asked about whether an individual could ever be prescribed a placebo and should a Minister intervene in that and I took a view on it, but it certainly is the case that a Minister should take a view on whether, as a whole, there is a wish for the public to be deceived, and the Minister's view is that we do not want that to happen, certainly in terms of vitamins. In terms of homeopathic medicines my view is this: that most people who buy those medicines are aware of the debate around homeopathy; they may take a view that they want to buy it and should they be entitled to it? Yes. Some clinicians take a view that homeopathy works and they want to prescribe it for their patients, should they be able to do that. I do not take a view particularly that they should do that; I take a view that a minister should not at this point, given the controversy around it, stop them from doing that.

Q215 Dr Iddon: But in the public health pilots that are coming, a patient will be able to spend some public money on an area of treatment of their choice which may well include homeopathic medicine, so in a way indirectly the Government is encouraging people to respond to homeopathic medicine, is it not?

Mr O'Brien: Are you talking about personal health budgets?

Q216 Dr Iddon: Yes.

Mr O'Brien: First of all, there are about 70 pilots, none of them around homeopathy. At some stage in the future, if these pilots worked and we went ahead with it, could this happen? It would depend to some extent on two factors. First, there has to be an agreement on the health package with a GP. Let us say, for the sake of your argument, there was a GP who believed in homeopathy and, therefore, thought this was the right thing to do. Secondly, there would have to be a PCT who was prepared to fund that. There would have to be the agreement of three parties, in effect: the patient, the doctor (the GP) and the PCT. All would have to agree that that funding would be forthcoming for homeopathy. In theory it is possible. Is it going to happen in the next few

years? No. Is it possible it could happen in the long term? Theoretically yes, but you would have to get the three to agree.
Dr Iddon: We will press that point a little further later.

Q217 Chairman: You said earlier, Minister, that you did not want to deceive the public.
Mr O'Brien: Yes.

Q218 Chairman: Presumably you would say exactly the same, Professor Woods?
Professor Woods: Absolutely.

Q219 Chairman: Do you remember your consultation LX312 in 2005?
Professor Woods: Yes.

Q220 Chairman: This was the summary of your recommendation following that consultation to Government: 32 responses were received from a range of organisations including manufacturers of homeopathic products, homeopathic trade associations, professional bodies including the Royal Colleges, patient consumer representatives, organisation of the general public; there was widespread support for the introduction of national rules for the authorisation of homeopathic medicinal products. That was your comment. Out of the 32 responses you got two were not publicly available because of commercial sensitivity; one was regarding a totally different consultation on herbal medicines; five were acknowledgements which simply said "No comment"; three were concerned with the inclusion of anthroposophic medicines; one was from the Royal College of Radiologists in support but they mistook what the consultation was about herbal medicine; and of the remaining 20 that were concerned with the licensing of homeopathic products the members of the public referred to are two vets and the editor of a US website who all strongly objected to the proposals. The British Veterinary Association, the Royal College of General Practitioners, the Royal College of Physicians, and the Royal College of Obstetricians and Gynaecologists all opposed homeopathy, yet your recommendation to the Minister was there was widespread support for the introduction of National Rules, and this goes back to my colleague's question whether this is not simply a support for the industry rather than a genuine response to a consultation.
Professor Woods: No. As you have heard, views on this are very divided. The advantages of a National Rule Scheme I would be very happy to talk about, and the consultation reflected, and I have not been back to it recently, that diversity of views which we have already talked about.

Q221 Chairman: But the vast majority, and these are on public record apart from the two that are of commercial sensitivity, virtually to a man and a women, or an organisation, does not support the view that you gave to the Minister.
Professor Woods: But you mentioned to me in the list a number of active homeopathic organisations whom I am quite sure were supportive of the National Rule Scheme.

Q222 Chairman: Of course they would be.
Professor Woods: Of course, but the consultation covered the whole spectrum.

Q223 Chairman: It is like saying "Do jockeys like horse racing?"
Professor Woods: But we had a consultation across all stakeholders and they are included in the stakeholder groups.

Q224 Chairman: Do you not find it a little strange that you seem to have rejected anyone who was opposed?
Professor Woods: I would have to go back to remind myself of the details of the consultation responses but I have to say that there has been very little objection to the scheme itself. There is discussion about the concept of regulating homeopathic remedies by any means but, on the other hand, this is an attempt to bring a little more order to an existing environment where there was already a market in regulated homeopathic products.

Q225 Chairman: Could I ask you, Professor Kent Woods, if you would first make the consultation public, because it has not been made publicly available, and also let this Committee have a note as to why you made that assessment? I think it is unfair of me to pull something out from 2005 and expect you to keep that in your head.
Professor Woods: We will certainly do that.

Q226 Dr Harris: Professor Woods, let's take this arnica example since 2006. I think you accepted that you do not require any evidence of efficacy before allowing a health claim to be made for the indication for that product, is that right? Because provings, you said, were not an indication of efficacy.
Professor Woods: They are not in any sense analogous to evidence of efficacy.

Q227 Dr Harris: So you do not require any evidence of efficacy before allowing an indication on that label under this National Rule Scheme?
Professor Woods: The descriptor on the packet says, which is agreed with the Regulator: "A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches, bruising and swelling". That is what we wish to confirm and this is used within the homeopathic tradition for that purpose. It is not the same as us accepting it as evidence.

Q228 Dr Harris: It is helpful to have that on the record. Now, if you could answer my question, you do not require any evidence of efficacy for that to have been agreed to be the wording on the label?

Professor Woods: No.

Q229 Dr Harris: Do you think that people reading that will think that it works for symptomatic relief of those minor conditions, or do you think that label that you have read out—and please feel free to read it out again—would make the average person think, which is the truth, as far as you are concerned, that there is no evidence of efficacy backing it up. Which of those two do you think is most likely, for the average person?
Professor Woods: Well, fortunately, by law all packaging and patient information leaflets are subjected to user testing to ensure that they are comprehensible to the man in the street, and indeed that seems to be a very straightforward statement of the reality. This is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising or swelling after contusions. That is what it says and the user testing is part of the approval of that leaflet, has the labelling been tested on the average man in the street.

Q230 Dr Harris: Sadly my question was not "What does it say? Has it been tested?" My question is, and maybe it is the result of this testing and you need to tell me, does the average person think that that label suggests that it is going to be useful for the symptomatic relief of those indications?
Professor Woods: I cannot really speak for everybody who reads that --

Q231 Dr Harris: What about the testing you did? What is the result of the testing? Did most people read that as saying "This is not going to work but I might try it anyway", or that it might be useful? What?
Professor Woods: The testing was that the messages attached to this were clearly understood.

Q232 Dr Harris: But what was the understanding, because you cannot tell if they are clearly understood unless you find out what the understanding is, unless we are in a parallel universe?
Professor Woods: To begin with the fact that this is a homeopathic remedy, we are making provision for a group of people who believe in homeopathic remedies and, therefore, the first thing to establish is that this particular remedy is recognised by homeopathic practitioners as a homeopathic remedy. That is the essence of what we are trying to prove. We are not trying to make any statement whatever as to whether it works or not. I would add, however, that there are several other things relating to the package of information. One is, as you see, the explicit statement this is homeopathic. Secondly, there is the requirement on the packaging that if the condition persists for longer than seven days they seek a clinician's advice.

Q233 Dr Harris: I will come back to that because what it does not say is there is probably no active molecule if this is beyond 14C dilution active, which many of them are, so it does not explain what homeopathy is. So let's work on the assumption that a label that says: "This is used for the symptomatic relief" makes the average person think that it is useful for the symptomatic relief, and I would put it to you that that is not a huge leap. So do you think the public is helped, and that is your mission, by patients being led to believe that something is useful for a symptom when there is no evidence that it is useful for a symptom? Is that something that makes you as a clinician happy, your organisation having that effect?
Professor Woods: You are asking me two questions, one about regulation and one about what I personally believe. I have practised medicine for 30 years and I have never deliberately prescribed a patient a placebo, but the point is that there is a significant group of people who accept and choose to believe the homeopathic tradition. If you take a simple example, somebody with a sprain who is going to get better from a minor inconvenience can walk down to their chemist and either buy themselves this product or a bottle of aspirin, and within a week the sprain will have got better anyway. Which of those two courses of action is the greater risk to their health?
Dr Harris: I don't know, but I am not supposed to be answering questions!
Chairman: But it was a reasonable response.

Q234 Dr Harris: If it was a reasonable response let's come to something more significant. Let's say, and I do not think this is unreasonable either, that the MHRA imprimatur on homeopathy helps the credibility of homeopathy. Do you think there is a risk that people then might go to seek anti-malarial treatments from homeopaths? Because they do, and you know that some homeopaths dole out homeopathic malarial treatment.
Professor Woods: There have been instances and, as I said in reply to a previous question, we used the powers of regulation to take that product off the market immediately. The whole point about regulation is it enables us to put in a degree of protection for the public which still allows the public the personal choice as to whether or not they buy into homeopathy, but we need to protect them, firstly, from taking a homeopathic remedy when they need something for a serious condition; secondly, from being misinformed as to whether this is homeopathic or not, and, thirdly, in terms of the quality of manufacture of other products.

Q235 Dr Harris: But for them to be protected from being led to believe that it works when there is no evidence that it works is a valuable public health message to get across, all other things being equal. Would that be good?
Professor Woods: It is certainly not our intention to do that.

Q236 Ian Stewart: I spent probably the last four years or so working with the British Council for Acupuncture and the Traditional Chinese Medicine

Association on working on appropriate regulation covering acupuncture. Should homeopathic practitioners be regulated through a similar statutory regulatory system?
Mr O'Brien: We do not propose at this stage to have statutory regulation. We did fund some work by the Princes Foundation for Integrated Health through £900,000 pounds over three years to set up some voluntary self-regulation. Basically the Complementary and National Healthcare Council was set up in 2008; it is still having some discussions, shall we say, with the Society of Homeopaths—or maybe sometimes not having discussions, because I still think there is some disagreement there—and the question is whether voluntary self-regulation in an area like this is the better approach. There is to some extent some statutory recognition, of course, of homeopathy, which is very limited, but the question as far as we are concerned is should we undertake a larger scale statutory regulation, and at this point we are not convinced that is the right approach.

Q237 Ian Stewart: I was interested by the comments you made about the problem of recognition. Can I press you on that? The core of this is whether there is any perceived harm to patients from homeopathic remedies? Do you know?
Mr O'Brien: I think I would defer to Professor Woods on this.
Professor Woods: I can identify three potential harms, and I am covering ground I have touched on already—

Q238 Ian Stewart: Can I stop you there, please? Before we move on to potential harms, and I am happy to hear those, are there any harms we know of, rather than potential harms?
Professor Woods: As an Agency we are constantly looking for potential harm rather than waiting until it has happened. You have already drawn attention to the issue of homeopathics being quite inappropriately recommended for anti-malarial prophylaxis. That is a real harm. I cannot tell you whether anybody has died of malaria as a consequence but I would rather not wait.

Q239 Ian Stewart: We did get previous evidence from a practitioner that there were potential harms, so perhaps you could move on to the potential harms.
Professor Woods: I can be very brief. The examples are a homeopathic remedy being used where something is seriously amiss which needs orthodox treatment; the risk of a defective product which, by contamination in manufacture, either chemical or bacterial, harms the patient; and the third comes down to this question of the patient being adequately informed that he or she is taking a homeopathic remedy. Those are the only harms I can perceive. They are not large harms when I consider that we are interested as an Agency in risk benefit relationships, and the fact that the level of risk is perceived to be very low makes us a little less stringent than we would be in the conventional sphere in the evidence for efficacy.

Q240 Dr Iddon: If a patient who had a serious condition believed in their own mind that a homeopath might be able to help with that condition and they went to the homeopath, would the homeopath be adequately trained in all cases to be able to diagnose that more serious condition and refer the patient to where they should have gone in the first place? That is the question we are concerned about.
Professor Woods: I am afraid from the Agency's perspective I cannot answer that because we regulate products, not practitioners.

Q241 Chairman: But the Minister says we do not need to regulate homeopaths—
Mr O'Brien: That is not quite what the Minister said, with respect, Mr Chairman. What the Minister said --

Q242 Chairman: You have no plans to do so?
Mr O'Brien: No, that was not what I said. What I said was we had no plans to have statutory regulation. However, we have put in place voluntary self-regulation because we did think that that form of regulation was necessary.

Q243 Dr Harris: I am puzzled by the fact that none of the homeopaths in the *Newsnight* programme who sold the anti-malarials have, as far as we know, been struck off by their voluntary regulators.
Mr O'Brien: Maybe because they are not at the moment signed up to the Complementary and National Healthcare Council. As I indicated in answer to an earlier question, the Society of Homeopaths is currently talking or not quite talking to the CNHC at this point, so striking off may not arise. Whether it arises in relation to the Society of Homeopaths itself is a matter I cannot answer.

Q244 Graham Stringer: How much does the NHS spend on homeopathy?
Mr O'Brien: In terms of drugs it is £152,000 a year which comes from a budget of £11 billion. It is approximately 0.001 per cent, we calculated, of the drugs budget. In terms of overall funding it is very difficult to know. We have done some work to see if we can find out what it is. We have four hospitals—one in Glasgow, three in England—which provide homeopathic assistance to people and we do provide some NHS funding for those, so it would run into several million on that basis, so probably less than 12—I think I saw that in *the Guardian* as a quote for the total cost between 2005 and 2008—so probably less than that but not too much less.

Q245 Graham Stringer: Should NHS spending not be dependent on proved effectiveness or efficacy, whether it is £10,000 or £12 million?
Mr O'Brien: You are asking two slightly different questions: one concerns effectiveness and the other efficacy. It is arguable that if two people, ie the

clinician and the patient, genuinely believe that homeopathy works, and it happens to but maybe not in the efficacious way they believe, then is that something that the NHS should stop spending money on? That is essentially your question. My answer is that at this point I have not got the evidence to do that, and I would not seek to do that. At the same time if you are asking me a slightly separate question, and it is a distinction I made earlier to Evan Harris, which is would I advocate that we should, if we were not now doing it, spend that money, then I would probably be looking for some more evidence, but we are at the moment in a position where we are spending this money; there is a considerable lobby which does believe it works; they are not stupid people; many of them are very able, very capable people who have done quite a lot of work in this area; and they do believe that it works. Now, there may not be the empirical evidence at the moment for that, but should we stop that spending? Not at this point.

Q246 Graham Stringer: That is a curious answer, if you do not mind me saying so. We are covering some of the ground we went through before about placebo and efficacy and you are saying essentially that we do not have the evidence but we do have a tough lobby on this issue, therefore—

Mr O'Brien: No, I am not quite saying that, because I was distinguishing between efficacy and effectiveness. If it is the case that some people believe they are better as a result of being involved in homeopathy and should we then stop that funding, that is not evidence of efficacy. Is it evidence of effectiveness? Well, people are feeling better.

Q247 Graham Stringer: But it is indistinguishable from the placebo effect. The long discussion we had before established that fact, that the placebo effect exists and that --

Mr O'Brien: It depends what you mean. We can get into exactly what the placebo effect is --

Q248 Graham Stringer: I understood the discussion both at the last evidence session and today to be that there was no evidence over and above the placebo effect, and I understood your answer to be agreeing with that but saying that there is a large lobby of intelligent people and therefore we will continue spending, and I do find that a curious answer.

Mr O'Brien: That is not the argument I am putting; it is only part of the argument I am putting. What I certainly do say is this: that there is a significant lobby of people who are clinicians who are quite capable of looking at data and who take a view that this works, and to say, therefore, that we should stop funding because other clinicians, the majority, take a view that it does not work at all, and to say we are going with the vast majority of the scientific community who take a different view is a stance I have real problems with. I think there is an illiberality in saying that personal choice in an area of significant medical controversy should be completely denied, and I think the Government should be cautious about constraining that illiberality, or interfering with it. We should not take the view that patients should not be able to have homeopathic medicine when they want it. There are some clinicians who take the view that it works.

Q249 Graham Stringer: Can I make one point and ask a question, because we could go round and round this for quite a long time. If that argument was applied to climate change and you used the arguments of what appeared to be the minority of scientific opinion that climate change was not happening, you would come to a very different Government response than you appear to be coming to on this. The real point is that you do have more evidence than you are owning up to at the moment, because West Kent PCT looked thoroughly at the effectiveness and efficacy of the homeopathic hospital in West Kent and we had the person here who carried out that survey who said, in words of one syllable: "This is a waste of public money". So if West Kent believes that spending that money is a waste of public money, why is it different in Liverpool or Gloucester or wherever else these hospitals are?

Mr O'Brien: As far as that study is concerned that was an examination of a particular clinical experience and the person who did it was entitled to reach the conclusion they did. There are others who take a different view. They may not have done any substantial empirical peer reference study that will enable us to say: "This works", but the question for me as a Minister is not so much the one you are putting to me, in a sense, which is fairly reasonable, but is there a justification for stopping spending in relation to homeopathy now, and my judgment is there is not that amount of evidence to justify me stopping spending on homeopathy. If you are asking me a different question which is whether I can justify all the spending on homeopathy today the answer would probably be "No" too, but that spending is there and a significant group of people believe it works, and therefore my view is that it would be illiberal and a denial of personal choice, because there is a significant "scientific" community behind it who take a view that it should be allowed to continue. At this point as a Minister I am taking the view that we are prepared to allow this spending to occur, we are not going to interfere in it, and it is a local judgment. We wrote around to the PCTs, and I think you may have seen the responses. 88 PCTs took the view that they would not routinely prescribe homeopathy, 26 did so in exceptional cases, 31 do provide it, and seven in London did not respond, so there are different views in the NHS among people who are quite reputable as to whether they should fund this.

Q250 Graham Stringer: I will move on but I do find it an extraordinary liberal view that we have a study within the NHS which shows it is not effective --

Mr O'Brien: I think, with the greatest respect, Graham, that it is extraordinary indeed. I am expressing the liberal view and Evan Harris is expressing the illiberal view.

Dr Harris: Evan Harris is not expressing anything!

Q251 Graham Stringer: Do you think we could get out of this difficulty with different parts of the NHS spending public money on quite different criteria by getting homeopathic treatments evaluated by NICE?
Mr O'Brien: I have no objection to NICE evaluating this but they do have a couple of problems with it. Firstly, they have a large queue of drugs that they need to evaluate and there are greater priorities. Secondly, there is a somewhat limited evidential base and before evaluating things NICE want to see an evidential base, and for the reasons we have already discussed it simply is not there at the moment. They could decide to spend a lot of public money—probably with great objection from some people on this Committee—establishing that evidential base, but that is not a priority for them or us at the moment.

Q252 Graham Stringer: Have you asked them to look at it, or asked them not to look at it?
Mr O'Brien: I understand there have been some discussions with them as to whether they would do it, but for the reasons I have described they have taken the view that, although they have no objection to doing it if we ask them to and the evidence base is there, at this point they do not feel it is a priority for them, and I would endorse that view. It is not a priority.

Q253 Graham Stringer: Politics is a practical business; we are in the same party and we want to get elected. How important is the size of the homeopathic lobby in affecting your decisions on not asking NICE to evaluate it and having different policies in different parts of the NHS?
Mr O'Brien: I am not sure there are any votes in it one way or the other.

Q254 Dr Harris: If the Chairman of NICE asked you if he could do an evaluation, would you have any objection?
Mr O'Brien: I cannot imagine this would happen and I think I probably would object, actually. I would probably say, "Is that the best you can think of to do at the moment given the queue of drugs we are asking you to deal with very quickly?" I think the answer is I would have an objection but it would be a practical and not an ethical one.

Q255 Dr Harris: Professor Harper, you said earlier that you thought there was an evidence base on RCTs, meta-analyses and systematic reviews to underpin a decision about whether NICE is efficacious, therefore effective beyond placebo, and therefore cost effective because you can cost it. How, therefore, do you respond to the assertion that there is not a testable evidence base, which is what the Minister said just now or before, to judge whether the spending of this money, in itself, on the basis of effectiveness and cost effectiveness, is a valid question to test, because that would suggest we need more research of the RCT type, which you thought we did not earlier?
Professor Harper: What I tried to flag up earlier is that there is an evidence base but it is subject to different interpretation, and that is at the crux of the challenge we face on this. It is a very difficult evidence base to test, so there have been quite a number of randomised controlled. Whilst I am not a homeopathic practitioner, homeopathic practitioners would argue that the way randomised controlled trials are set up they do not lend themselves necessarily to the evaluation and demonstration of efficacy of homeopathic remedies, so to go down the track of having more randomised controlled trials, for the time being at least, does not seem to be a sensible way forward.

Q256 Ian Stewart: We have evidence that there was nothing more than a placebo effect involved here, but other evidence to say there was more than a placebo effect. In those circumstances and in light of the answer you just gave Evan, why would you not put more money into research?
Mr O'Brien: Because there are other priorities.
Chairman: I am going to close the session at this point, so can I thank you all very much indeed for coming this afternoon, and for the frankness of your responses.

Supplementary memorandum submitted by the Department of Health (HO 34a)

Letter from Rt Hon Mike O'Brien QC MP, Minister of State for Health Services, to the Chairman of the Committee, 16 December 2009

I refer to your letter dated 2 December 2009 in which you asked for a note on a supplementary question—"To what extent does the support of the Royal Family for homeopathy influence the Department's policy to continue to support homeopathic services? More specifically, have members of the Royal Family made representations to the Department in respect of homeopathy?"

The Department does not maintain a position on any complementary or alternative treatments, including homeopathic services, leaving decisions on their use by the National Health Service, to the National Health Service.
The Department engages with a wide range of stakeholders when formulating policy. We consider all such views on their merits.

Ministers have sometimes had contact with members of the Royal Family. For example, the Secretary of State occasionally has meetings with members of the Royal Family the most recent of which was with HRH Prince Charles on 29 October 2009. These are private meetings, have no fixed agenda and cover a wide range of topics of interest to both parties, which may sometimes include homeopathy.
I hope that this is helpful.

Yours sincerely,

Mike O'Brien QC MP
Minister of State for Health Services

December 2009

Memorandum submitted by the Medicines and Healthcare Products Regulatory Agency (HO 53)

MLX312: LICENSING OF HOMEOPATHIC: PROPOSALS FOR A NEW NATIONAL RULES SCHEME

RESPONSES TO CONSULTATION

Symbol	*Meaning*
S	Support
O	Oppose
N/c	No comment
C	Reply Confidential

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
1	Pharmaceutical Society of NI	S	Support proposals for National Rules Scheme, proposals to review PLRs and expanded remit of ABRH. Also support in the type of information listed to support efficacy of homeopathic products given that the products cannot be evaluated in the same way as other medicines; support in restricting indications to minor self-limiting conditions.	09/08/2005	MHRA noted the supportive comments.
2	Royal College of Obstetricians and Gynaecologists	S	Recognises current inconsistencies in the way homeopathic products are marketed and believe that option 4 in RIA is sensible way forward. Also some concerns with permitting indications for symptomatic relief of infections including fungal diseases concerns with regard to vulval fungal conditions as allergic reactions to excipients are common.	13/08/2005	MHRA noted the supportive comments. Only self limiting indications would be allowed under the National Rules; indications for infections would be reviewed by the expert Committee ABRH and appropriate warning on excipients-known to causes unwanted effects would be included in product information.
3	UK Clinical Pharmacy Association	S	Pharmacists keen to see reduction of risks to patients from all medicines. Proposals will add scrutiny to safety and effectiveness of this type of product and enhance patient safety. Particularly supports review of PLRS and expansion of remit of ABRH.	17/08/2005	MHRA noted the supportive comments.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
4	Quackwatch Inc (Stephen Barrett MD)	O	States that homeopathic products do not work as it is not possible to separate safety and effectiveness. In addition to limiting their use to self-limiting conditions, require that all products be labelled "There is no scientific evidence for the treatment of any health problem. The MHRA permits them to be marketed because enough people want to use them to make it impractical to try to ban them".	22/08/2005	Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive for any other information to be included. In order to make the user aware that of the homeopathic nature of the product, they are clearly labelled "Homeopathic medicinal product" and the indication is state as "A homeopathic medicinal product used within the homeopathic tradition to relieve . . ." Product information for homeopathic products authorised under the National Rules Scheme clearly state that if symptoms worsen or persist after 7 days, then a doctor must be consulted.
5	Nursing & Midwifery Council	N/C	Acknowledgement only.		
6	Royal College of Physicians & Surgeons of Glasgow	S	Happy to support the initiative.	24/08/2005	MHRA noted the supported comments.
7	British Association of Dermatologists	N/C	Acknowledgement only. No comments.	25/08/2005	
8	British International Doctor's Association	S	BIDA supports the basic proposals for the NR Scheme, types of information to be listed to support efficiency, Option 4 of the RIA with some concerns that additional costs may be passed on to the consumers, proposals to permit only indications for minor self-limiting conditions, and the expanded remit of the ABRH.	21/07/2005	MHRA noted the supportive comments. Cost would be minimised, see Regulatory Impact Assessment.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
9	R K Ward—VETWARD	O	Does not believe homeopathic remedies are effective, recognise that these products may not cause physical harm but may possibly cause harm due to delay in seeking effective treatment or instil confidence in these as yet unproven effectiveness.	01/09/2005	The National Rules scheme does not endorse clinical efficacy of homeopathic products, as clinical efficacy is understood in the context of conventional pharmaceutical medicines. It provides consumer safety assurances in terms of product quality and improves patient information for users of homeopathic medicinal products. The indications for products authorised under the National Rules scheme are limited to the relief or treatment of minor symptoms or minor conditions ie symptoms or conditions which can ordinarily and with reasonable safety be relieved or treated without the supervision of a doctor.
10	Orchard Veterinary Group	O	Strongly opposes the licensing of homeopathic remedies as prescription only medicines without proof of efficacy. Concerns about lobbying from industry. No scientific evidence demonstrating effectiveness and its use runs contrary to scientific tenet; concerns that lay persons may regard homeopathic remedies have the same efficacy status as real medicines. Sad day if legislation is endorsed.	01/09/2005	The National Rules scheme does not endorse clinical efficacy of homeopathic products, as clinical efficacy is understood in the context of conventional pharmaceutical medicines. It provides consumer safety assurances in terms of product quality and improves patient information for users of homeopathic medicinal products. The indications for products authorised under the National Rules scheme are limited to the relief or treatment of minor symptoms or minor conditions ie symptoms or conditions which can ordinarily and with reasonable safety be relieved or treated without the supervision of a doctor. Products authorised under the National Rules scheme are intended for over the counter sale.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
11	Royal College of Physicians Edinburgh	S	Proposals for National Rules Scheme are reasonable. Judgements will be needed on what constitutes minor conditions and length of time product can be used without review. MHRA may wish to build this into their thinking. Broadly agree with Option 4 of the RIA.	01/09/2005	MHRA noted the supportive comments. Product information must include a statement that users should consult a doctor if symptoms persist or worsen after 7 days. Depending on the indications for use, this time limit maybe reduced. Indications are considered on a case by case basis. However, in general, minor conditions are considered to be those that can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor. Indications for serious conditions are prohibited. Furthermore the range of appropriate indications would be reviewed by the expert Committee ABRH.
12	Patients Association for the Furtherance of Anthroposophic Medicine	S	Supports labelling of anthropasophic medicine that is clear and helpful to the patient. Would support expert input from prescribers, pharmacists and consumers during the assessment phase.		MHRA noted the supportive comments.
13	Anthroposophical Medical Association	S	Welcome the proposed approach which they feel is in general terms is pragmatic and realistic. Concerns about the cost of maintaining PLRs, as addressed in the MLX 324 response. Would support UK recognition of the Anthroposphic Pharmaceutical Codex and British Homeopathic Pharmacopoeia. Consider that PLRs are likely to remain the only status for anthroposopic medicines currently on the market.	29/08/2005	MHRA noted the supportive comments. The scheme is designed for Homeopathic products and anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme.

	Organisation			*Organisation Comments*	*Date*	*MHRA Comments*
14	Nelsonbach	S	C	Have asked for responses to be kept confidential.	05/09/2005	
15	The Royal College of Radiologists	S		Proposals are important step forward. Strongly support the NR scheme. Supports option 4 in the RIA. Agrees with proposal to only permit indications for minor self limiting conditions. Strongly support expanded remit of ABRH. Recognises cultural dimension in attitudes to medication generally and to alternative therapies in particular. Scheme gives ABRH sufficient flexibility to take account of history and attitudes of the UK I respect of homeopathic products and practices whilst also ensuring patient safety.	07/09/2005	MHRA noted the supportive comments.
16	The Paediatric Chief Pharmacists Group	S		Agree with proposals for National Rules Scheme particularly to limit indications. Agree the type of information listed to support efficacy of homeopathic products. Supports Option 4 for PLRs.	12/09/2005	MHRA noted the supportive comments.
17	The Alliance of Registered Homeopaths	S		In favour. List of limited indications should be expanded. Not happy with the term "symptomatic relief of" as it implies suppression, not cure, which is contrary to the principles of homeopathic philosophy. Agree with the list of information to support efficacy. Agree with the expanded remit of ABRN, provided there is sufficient professional homeopathic input.	September 2005	MHRA noted the supportive comments. Since rigorous clinical trial data is not required, indications for use are limited to the relief or treatment of minor symptoms or minor conditions. The ABRH consists of members of multi disciplinary backgrounds, including homeopathic practitioners.
18	Laboratoires Boiron	S		Welcomes the NR scheme. Supports expanded remit of ABRH, including the provision of advice on indications. Important for members of the ABRH to be familiar with products intended for self-medication for minor conditions. Quality, Safety and Efficacy.	07/09/2005	MHRA noted the supportive comments.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
19	Royal College of Nursing	S	Support the removal of current anomalies and permitting some previously prohibited products onto the market. Welcomes proposal to print indications for use on products. Supports expanded remit of ABRH, but also supports the inclusion of representation from the nursing profession as the training in homeopathy for registered nurses now involves prescribing homeopathic remedies. Supports the quality assurance and safety elements of the scheme, the publication of the list of toxic stocks. ABRH should continually review the POM parenteral products. In relation to the compulsory variation of PLRs for more serious illnesses—this should be referred to the ABRH rather than CSM.	08/09/2005	MHRA noted the supportive comments.
20	British Pharmacological Society	N/C	Acknowledgement only. No comments.	07/09/2005	
21	British Association of Anthroposophic Pharmacists	S	Generally supportive—supports introduction of NR scheme, but considers it essential that the scheme ensures the continued availability of anthroposopic medicines. Those that are not eligible under the NR scheme must be safeguarded by their legitimate licensing as PLRs. Supports the IAAP definition of anthroposophic medicines. Quality—standards for anthroposophic medicines are defined in a number of national pharmacopoeias. Due to the nature of these products, it is not always possible to verify the content of the individual components of the product (therefore there is a reliance on QA measures).	September 2005	MHRA noted the supportive comments. The scheme is designed for Homeopathic products and anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme. Manufacturers holding PLRs will be encouraged to authorise the product under National Rules Scheme. For products reviewed and renewed, the indications for use will be brought in line with the requirements of the National Rules Scheme and indications for serious conditions will be removed. Applications will be referred to the ABRH for advice.

Organisation	*Organisation Comments*	*Date*	*MHRA Comments*
	Safety—support lists of toxic stocks and proposal to consider stocks derived from food substances or GSL medicines only requiring a reduced safety statement. Efficacy—anthroposophic bibliographic data should be accepted. Demonstrating efficacy should include reference to anthroposophic doctors. Consideration should be given to length of time products have been on the market as PFRs. There are a number of pharmacy only anthroposophic medicines with indications that require the intervention of a counter prescribing pharmacist 9choleodoron drops, fragaria/vitis tablets etc—list in MLX response). Legal status—essential that pharmacy only option is retained for certain products. Labelling—essential that products contain the statement "an anthroposophic medicinal product". Review of PLRs—supports option 4. Keen to retain a level playing field between anthroposophic and homeopathic products. ABRH needs appropriate anthrosophic expertise. Concerned that the review of PLRs will impose a heavy burden on license holders.		

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
22	WELEDA	S	Initial reaction to the proposals in MLX 312 was positive. Support proposals for Option 4 and will actively co-operate during the review of PLRs for serious indications. However, have concerns about the status of anthroposophic medicines—they should be afforded the same opportunity to participate in the NR scheme as homeopathic products. NR scheme should reflect the special circumstances applicable in different Member States. Specifically, the NR scheme should allow an anthroposophic PLR the possibility of obtaining a UK NR license. Specific comments re anthroposophic products— Medical definition need to recognise anthroposophic pharamaceutical codex. Anthroposophic products should be clearly labelled as such. Anthroposophic literature should be accepted. Relevant experts should include anthroposophic professionals. Review of PLRs—involves more products than simply the number of existing PLRs as in many cases one PLR will relate to several products. In terms of resources, the task of reviewing 1600 PLRs as well as new applications, with current resources, would probably take longer than 5 years. Weleda would also suffer resource concerns. Quality assessment—little in the MLX relating to the approach to quality for PLRs. For those manufactured under GMP certified conditions, there should be little concern.		MHRA noted the supportive comments. The scheme is designed for Homeopathic products and anthroposophic products that fulfil the European Directive definition of a homeopathic product will be eligible for authorisation under the National Rules Scheme. Manufacturers holding PLRs will be encouraged to authorise the product under the National Rules Scheme. For products reviewed and renewed, the indications for use will be brought in line with the requirements of the National Rules Scheme and indications for serious conditions will be removed. Applications will be referred to the ABRH for advice.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
			Labelling—how would reviewed PLR products be labelled? Review of indications—strongly support enlisting the support of the Anthroposophic Medical Association. Front line assessors in the MHRA would have little experience of anthroposophic products, and the ABRH will not be involved in all assessments. Fairness—anthroposophic medicines need to be included. Proposals would resolute in an unfair regulatory burden for established companies.		
23	Royal College of General Practitioners	S	Whilst the approach (with no rigorous scientific data on safety or efficacy but with assurances on quality of production) is attractive for those with faith in homeopathy, a more scientific alternative would have been to withdraw all PLRs with indications unless there was proven evidence of effectiveness. But think that MHRA proposals are acceptable provided the MHRA and the ABRH are content that the public is fully protected. Supports introduction of fees—this will ensure quality control in their production. Ask how homeopathic remedies be assessed for safety and quality, as they are merely water containing vibrations from many products at infinite dilution. Ask if herbal teas and other infused drinks be included.	13/09/2005	The MHRA believes that the NR scheme provide a sound basis to regulate quality and safety of homeopathic products used within the homeopathic tradition. The homeopathic nature and its use within the tradition are clearly labelled and are only suitable for self-limited conditions. Homeopathic products are expected to meet the same quality standards as required for conventional products. The applicant is required to submit a dossier describing how the homeopathic stocks are obtained and controlled and rigorous assessment of this data is critical to sufficiently guarantee reproducible product quality. The safety of a product is often closely linked to its quality and the two issues need to be considered together. As with applications for conventional medicines, information must be provided in order to demonstrate the pharmaceutical quality and safety of the products concerned. Only products which fulfil the European Directive's definition of a homeopathic medicinal product are eligible for the National Rules Scheme.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
24	Royal College of Paediatrics and Child Health	S	Agree with basic proposals for the National Rules Scheme. Agree that types of information listed could form the basis of support for the proposal. Agree that indication should be limited. Pleased to note that packaging will indicate whether product is suitable to use in babies and children. Supports Option 4. Supports expanded remit of ABRH.	13/09/2005	MHRA noted the supportive comments.
25	British Association of Homeopathic Manufacturers	S	Broadly supportive of proposed scheme, with the following comments: Efficacy—anthroposophic products and bio chemic tissue salts should be covered—provided sufficient data for anthroposophic and bio chemic practitioners could demonstate efficacy. Labelling—the words anthroposophic and bio chemic should be used on labelling where appropriate. PILS/Braille—reducing the regulatory burden brought about by the user testing and Braille requirements (transitional facilities) would be welcomed. Pharmacovigilance should not be too onerous for the products in question. Review of PLRs—Option 4 is the best way forward. 5 years is less than adequate, both in terms of workload and cost. Indications—further consideration is needed on the preamble to Annex 2—ie homeopathic medicine is not concerned with the symptomatic relief of illness. It seeks to deal with the cause of the problem. Psychiatric conditions should also be covered.	12/09/2005	MHRA noted the supportive comments. Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. The MHRA will consider to extend the review period to 7 years and keeping the cost to a minimum, see Regulatory impact assessment. Noted.

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
			ABRH—special arrangements for expert groups should apply to section 4 committees. RIA—concerned about the overall cost burden of the capital fees (see response to MLX 324). NR application fees for products that already hold a HR registration should be substantially lower. In addition, the 5 year transition period should be extended to spread the overall compliance costs.		
26	Royal College of Physicians	S	Use of homeopathic medicines is not supported by many physicians who strive for robust evidence of efficacy, safety and quality, via randomised CT. Welcome proper regulation as homeopathic products are widely used. Provided it is not misconstrued by the public as official endorsement of unfounded claims of efficacy. Use of homeopathic produce for minor self limiting condition sis often preferable to real medicines, which carry the risk of adverse reactions. Placebo effect is potentially helpful and should not be discouraged in the case of harmless but comforting measures unless it is at the expense of actually misleading patients. RCP think that factually correct statements in the product information or labelling regarding traditional use should be compulsory qualified by statement to be agreed with regulator along the lines of "but there is not evidence that it is more effective than dummy treatment".		MHRA noted the supportive comments. The MHRA believes that the NR scheme provides a sound basis to regulate quality and safety of homeopathic products used within the homeopathic tradition. The homeopathic nature and its use within the tradition is clearly labelled and is only suitable for self-limiting conditions. Indications are considered on a case by case basis. However, in general, minor conditions are considered to be those that can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor. Indications for serious conditions are prohibited. To avoid misdiagnosis or delay in treatment, users are advised to consult a doctor if symptoms worsen or persist after 7 days. The time frame within which a doctor should be consulted maybe reduced depending on the condition. The suggestion comments regarding making users aware that there is no evidence for the use of homeopathic products has been noted. Homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
			Draw attention to risks to misdiagnosis and inappropriate use. RCP could not support an option that did not make it mandatory for the indication to be stated on the product literature. ABRH should set the stand for "serious conditions". Recognise that RCT provides the best evidence of efficacy but in most circumstances, this will not be available for homeopathic products. Practitioners unlikely to accept bibliographic data unless efficacy evidence was robust, thus "efficacy" would be acceptable for minor, self-limiting conditions where a placebo response is acceptable. Support self-limiting conditions, rigorously defined. Support option 4.		requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive for any other information to be included. Consequently the suggested statement would not be permitted. In order to make the user aware that of the homeopathic nature of the product, they are clearly labelled "Homeopathic medicinal product" and the indication is stated as "A homeopathic medicinal product used within the homeopathic tradition to relieve . . ." Noted The range of appropriate indications would be reviewed by the export Committee ABRH.
27	National Eczema Society	S	Agrees in general with proposals and the type of information listed to support efficacy of homeopathic products. However, concerned that patients should be given some information about lack of rigorous clinical trials, even for minor self-limiting conditions. Support indications for self-limiting conditions and expanded remit of ABRH.	13/09/2005	MHRA noted the supportive comments. MHRA noted the suggestion that patients should be given some information about lack of clinical trials. However, homeopathic products must be labelled in accordance with Article 54 (labelling requirements), Article 59 (package insert requirements) and Article 68 (which requires that the homeopathic nature of the product is clearly stated) of the European Directive. There is no provision in the Directive provide for any other information to be included.
28	Royal Pharmaceutical Society of GB	N/C			

	Organisation		*Organisation Comments*	*Date*	*MHRA Comments*
29	British Veterinary Association	O	BVA considers the licensing and thus endorsement of homeopathic remedies by the MHRA to be a serious cause for concern for the following reasons: Products will be licensed with no requirement for any proof of efficacy. The permitting of remedies to be marketed with "indications" which are scarcely distinguishable from therapeutic claims. No genuine "provings" of homeopathic remedies have ever successfully been performed in animals. Wild extrapolation of disproven human therapeutic modality to animals is therefore an offence to animal welfare. Providing homeopathic remedies with yet more official licences and endorsement, even permitting "indications" (essentially therapeutic claims), is a retrograde and damaging step, and we urge the MRHA to reject this course.	15/09/2005	The National Rules scheme to be set up is intended for Human use.
30	Scottish Consumer Council	N/C	Acknowledging letter only	28/06/2005	
31	Health Professionals Wales	N/C	Acknowledging letter only	28/06/2005	
32	Stewart France Ltd	S	Reject Options 1, 2 and 4. Supports Option 3. Would like Candida Albicans and cholesterol to be allowed under the NR scheme as self-limiting conditions as they occur naturally in the body.	27/07/2005	MHRA noted the supportive comments. Comments are from a homeopathic manufacturer that does not currently hold a PLR and their objections are related to financial matters.

December 2009

Supplementary memorandum submitted by the Medicines and Healthcare Products Regulatory Agency (HO 53a)

As part of your evidence check into homeopathy you have asked for details of the label testing on the homeopathic product Arnica and, in particular, what questions were asked during the test and what perceptions of the label were being tested.

As you are aware, homeopathic products authorised under the National Rules Scheme must be labelled in accordance with Articles 54 and 68 of Directive 2001/83 EC as amended. The package leaflet must comply with Article 59 of the Directive and be user tested to ensure that the information is legible, clear and easy to use. However if all of the information required under Article 59 is stated clearly on the label, then a package leaflet may not be included.

I would also draw your attention to the European Commission guideline on the readability of the labelling and package leaflet of medicinal products for human use (12 Jan 2009). This can be found at http://www.emea.europa.eu/htms/human/qrd/qrdguide.htm

In the case of Arnica 30C pillules, all of the information required under Article 59 of the Directive could be clearly stated on the label and therefore a separate package leaflet was not required.

Three rounds of user testings were carried out with 10 participants in each testing. Twelve questions relating to the key safety messages were asked and were designed to assess whether the respondent was able to find the information, understand it and use the information. The questions asked were as follows:

1. Can you tell me the name of this medicine?
2. What does the label say that this medicine is for?
3. If you take too much of this product (overdose) what does the label tell you to do?
4. Is there any advice on the label for women who are pregnant or breast feeding?
5. What does the label say is the active ingredient in this medicine?
6. If you have missed a dose of this medicine, what does the label tell you to do?
7. Once you have opened your medicine, how does the leaflet tell you that you should store it?
8. This medicine contains Arnica Montana 30C. What are the other ingredients in this medicine?
9. How many pillules are there in the Clikpak container?
10. This medicine contains lactose and sucrose which are types of sugar. If you have an intolerance to some sugars, what does the pack tell you to do before taking this product?
11. How many pillules does the pack say that you should take in a dose and how many times a day should you take them?
12. The pillules in this medicine are contained in a plastic Clikpak to help protect them. What instructions does the label give you as to how to dispense the pillules from the Clikpak?

Participants' answers were provided and the ease with which the information was located was graded as very easily; easily; little difficulty or lots of difficulty. Assessment of understanding the information was graded as yes or no. Some issues raised with the early user tests have been satisfactorily addressed in the subsequent user test. Participants were also asked to comment on the layout and design of the label and the response was positive, indicating that the label was well structured and easy to read. Overall and on each occasion, a satisfactory test outcome was achieved meeting the success criteria ie 90% of participants were able to find the information requested, of whom 90% could show that they understood the information by providing the correct answer and it was concluded that no further user testing was required.

Professor Kent Woods
CEO

December 2009

Written evidence

Memorandum submitted by the Dental Practitioners Association (HO 01)

On the following issues:

— Government policy on licensing of homoeopathic products

— Government policy on the funding of homoeopathy through the NHS

— the evidence base on homoeopathic products and services

GOVERNMENT POLICY ON LICENSING OF HOMOEOPATHIC PRODUCTS

1. No homoeopathic products should be licensed.

GOVERNMENT POLICY ON THE FUNDING OF HOMOEOPATHY THROUGH THE NHS

2. There should be no funding for homoeopathy through the NHS.

THE EVIDENCE BASE ON HOMOEOPATHIC PRODUCTS AND SERVICES

3. As far as we are aware there is no evidence base to support the use of homoeopathic products in dentistry or in the NHS as a whole. Any apparent effects are entirely explainable as the placebo effect.

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Chief Executive Officer

November 2009

Memorandum submitted by Professor David Colquhoun (HO 02)

1. *Government policy on licensing of homeopathic products*

1.1 By their own admission, the government has simply ignored the evidence. The Government's responses to the Committee's questions
(http://www.parliament.uk/documents/upload/091021_Final_Evidence_Check_response.pdf) said:

> "Thirdly, no scientific evidence was examined in drawing up the National Rules Scheme,"

This is a quite astonishing admission for a government that claims to base policies on the best scientific advice. The same document asserts:

> "Homeopathy has a long tradition in Europe and is a recognised system of medicine across the EU".

It is most certainly not a "recognised system of medicine" for anyone with the most rudimentary scientific education. Quite on the contrary. Throughout my life time homeopathy has been a sort of bad joke. Indeed it has been a joke ever since Oliver Wendell Holmes famous essay "Homeopathy and Its Kindred Delusions", written in 1842.

1.2 It is however, a joke in poor taste. Homeopaths endanger the lives of patients when they try to treat serious conditions like malaria and AIDS, which they routinely do. The government must be aware that two homeopaths in Australia were charged with manslaughter and sentenced to six and four years in prison, when their own daughter died for lack of proper treatment. It is only a matter of time before the same thing happens here. If and when it does, the Department of Health will bear some of the blame because of its shameful disregard for evidence.

1.3 For some reason that I have never been able to discover, the MHRA was pushed in 2006 into allowing highly misleading labelling of homeopathic products. It should be investigated whether the new labelling is legal under the Consumer Protection Unfair Trading Regulations of May 2008. These regulations state, inter alia, that

> "One of the 31 commercial practices which are in all circumstances considered unfair is "falsely claiming that a product is able to cure illnesses, dysfunction or malformations"

Such claims are, of course, rife in the homeopathic industry and in my opinion the labelling that has been allowed by the MHRA is illegal because the regulations refer to the way labels will be interpreted by the "average consumer". I do not believe that the average consumer will interpret the words "traditionally used for the treatment of" as a synonym for "ineffective in the treatment of", though that is the actual meaning.

1.4 It is nothing short of surreal that the MHRA should have a committee to earnestly consider whether pills, which mostly contain nothing whatsoever, are safe and manufactured properly (http://careers.bmj.com/careers/view-job.html?id = 20018826). This sort of absurdity makes a mockery of any claim that the government is interested in evidence. It is surely the ultimate example of the precedence of mindless process and procedure over common sense. Pure comedy.

2. *Government policy on the funding of homeopathy through the NHS*

2.1 At present the government (disgracefully) has no policy on this. Every time the government is asked about it, no answer has been forthcoming. The question is merely referred to PCTs. The Department of Health (DH) has consistently evaded its responsibility to assess the evidence and it should now live up to that responsibility. Many PCTs have stopped, or greatly reduced their funding for homeopathy. One homeopathic hospital has shut altogether, and funding for homeopathy at the Royal London Homeopathic Hospital has been greatly reduced. But there is no consistency in policy whatsoever, because the DH has offered no direction and has ignored scientific advice.

2.2 To allow sugar pills to be paid for by the NHS is an absurdity. If it is not sufficiently absurd for the DH to take action itself then they should refer homeopathy as a whole to NICE, just as any other proposed treatment would be (and it must be made sure that NICE does the evaluation properly, and not appoint a lot of homeopaths to do the evaluation). This was recommended in the House of Lords report (2000). It was recommended again in the Smallwood report (sponsored by the Prince of Wales). It is beyond comprehension that DH has still not done it.

2.3 If it is thought that a placebo is something worth having available (a highly contentious idea) then it should be done honestly. The present practice combines the worst of both worlds. Doctors are not allowed to prescribe an honest placebo, even if they think that is the best they can do for the patient. But they are allowed to prescribe a dishonest placebo by referring the patient to a homeopath.

3. The evidence base on homeopathic products and services.

3.1 I see no point in my going through the evidence yet again. It has all been done very well in, for example, Singh & Ernst's book, *Trick or Treatment*. There is clearly no convincing evidence that it works. In addition, the prior odds of a pill that contains no active ingredient having an effect is so small that enormously strong evidence would be needed to persuade one that it worked. After 150 years the homeopaths have still failed to produce any remotely convincing evidence.

3.2 The homeopaths who submit responses to this committee will, as always, pick out the few small and badly designed trials that appear to support their cause. Their approach to evidence is, in my view, nothing short of dishonest. I can only presume that one of the reasons for this is that they have the ultimate vested interest insofar as they would lose their livelihoods if they were to admit that there was no worthwhile evidence for the efficacy of their pills.

3.3 If homeopathy worked the whole of chemistry and physics would have to be overturned. The idea is quite simply preposterous. It is a waste of time and money to look for evidence if you aren't, at the same time, willing to abandon chemistry and physics. To pretend otherwise is simple duplicitous double-think. It is time that the government decided whether or not it believes in Avogadro's number or not. Government policy at the moment is based on the absurd proposition that Avogadro's number is right if you are talking about chemistry but wrong if you are talking about homeopathy.

4. *Declaration of interests*

I am a pharmacologist. My research has been funded entirely by the MRC and the Wellcome Trust, never by the pharmaceutical industry. I have financial interests in neither the pharmaceutical industry nor the alternative medicine industry. I do have a strong interest in the quality of evidence and in how to distinguish what works from what doesn't. I have written a textbook of statistics (*Lectures on Biostatistics*, Clarendon Press Oxford, 1970) and so have knowledge of that field and particular its application to clinical trials of treatments.

(You will, no doubt, be aware that many of those who write to you to advocate homeopathy make their living from it.)

David Colquhoun FRS
Professor of Pharmacology
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November 2009

Memorandum submitted by John Boulderstone (HO 03)

This submission refers to Government policy on Licensing Homeopathic Products and the Evidence base on homeopathic products and services.

1. As you are aware there is a lot of controversy on the internet and in the press about homeopathy. A vast amount of the problems come from people who think they understand what homeopathy is but have not checked with the original source. It is important that the Science and Technology Committee have an understanding of what homeopathy is and not get their understanding from ill-informed journalists, websites or "quack-busters" who distort the definition of homeopathy for their own purposes. In short a scientific (meaning accurate) definition is needed.

2. Initially, I would like to point out what homeopathy is not. Homeopathy is not the prescription of diluted substances. The proof of this, if any is needed, lies in the fact that initially Samuel Hahnemann administered homeopathic substances that were not diluted and still called what he did homeopathy. In fact he gave the same medicines as the orthodox medical practitioners of the time. What made, and makes, medicines homeopathic is ONLY the philosophy by which they are prescribed and NOT that they are diluted.

3. Some journalists, comedians and the "quack-busters" choose to not understand this fact about homeopathy because it is then easy to make jokes about it.

4. The misunderstanding of what homeopathy is runs very deep and some people who call themselves homeopaths have also forgotten what homeopathy is.

5. Homeopathy is badly defined on websites and in newspapers. It is definitively defined by its founder Samuel Hahnemann in his "Organon of Medicine". However, this book is difficult to read which is why there is so much misinformation. It is not defined well by Wikipedia.

6. Also, most, if not all, scientific trials test for the efficacy of potentised substances and these tests do not test homeopathy. Even so, very often the scientists conducting these trials believe they are testing homeopathy.

7. What is currently used as an explanation is the phrase "like cures like". While this is a succinct explanation and useful for homeopaths, it allows non-homeopaths to believe the prescribed remedy does the work and not the reaction from the patient. This then leads to the inevitable focus on the remedy and its "strength" instead of the way the remedy is selected. The phrase "like cures like" misleads.

8. A better explanation comes in two parts. Two parts are needed to emphasise an important point that is missed in other explanations. The first is: *Homeopathy is a prescription that causes a reaction in the patient*; A remedy becomes homeopathic only when it matches the symptoms of the patient so it is the act of prescribing that makes it homeopathy. Notice that there is no mention of dilutions because this is not a requirement for homeopathy. The second part is: *this reaction cures the patient*.

9. Reiterating the explanation: Homeopathy is a prescription that causes a reaction in the patient; this reaction cures the patient.

10. Allopathy may be explained in a similar way as: A prescription that removes the problem. Usually using an anti-drug (antibiotics, anti-depressants, anti-inflammatories, anti-virals), taking little account of the differences in different patients. This explanation could be accepted by both homeopaths and allopaths. And now the difference between the two therapies can be clearly seen.

11. Therefore, the term "homeopathic products", used to describe potentised material is misnamed. Products used by homeopaths vary in strength from highly dilute to NOT DILUTE AT ALL, they can also be orthodox medicines if they are prescribed in the correct way. Remember, it is not the substance or its method of manufacture that makes it homeopathic but the reason for prescribing.

12. So, to be accurate, scientific and not misleading the term "homeopathic products" cannot be used before the products are prescribed. To do so misunderstands what homeopathy actually is. Instead, the appropriate term may be "potentised substances". If this distinction between "homeopathic products" and "potentised substances" is not made a nonsense will result when looking at the evidence base and licensing of products.

John Boulderstone

Declaration of interests: I am a homeopath that does not prescribe potentised substances.

November 2009

Memorandum submitted by Dr Lionel R Milgrom (HO 04)

1. Introduction

1.1. The main purpose of this response is not so much to provide an exhaustive account of the evidence for homeopathy—this will be provided by others—but to question what in calling for a "second evidence check", the S&TC means by "evidence", and evidence for homeopathy compared to what?

1.2. As Prof Harald Walach (University of Northampton) has pointed out,[1] the problem here revolves around the widely-held assertion, currently circulated by "sceptics" (more properly, "detractors": the term "sceptic" should be reserved for those who have yet to make up their minds) that homeopathy/CAMs (CAM = complementary and alternative medicine) are not evidence-based, while conventional medicine by and large is. Prof Walach,[1] myself,[2,3] and others,[4] have effectively deconstructed this assertion.

1.3. Further, it is my intention to question the term "evidence-based" and that applying it to conventional medicine is also difficult. In so doing, I hope to level the "evidence-based" playing field that has been tilted against homeopathy.

1.4. My chief concerns, however, relate to the motivation and objectivity of the Science and Technology Committee given the current campaign that is being waged against homeopathy and other CAM therapies in the UK by various high profile detractors in the media,[2,3] and certain organisations.[5]

1.5. Their explicit intention is to pressurise the NHS and PCTs into terminating their commitment to fund and provide homeopathy/CAM services.

1.6. This is being perpetrated regardless of the wishes of a large segment of the UK population who by choice avail themselves of these services, and that a minuscule amount of the NHS budget is currently spent on homeopathy.

1.7. Thus, though perhaps not considered part of its remit, the meaning of the term "evidence-based" is something the Science and Technology Committee might usefully wish to consider.

2. Evidence-Based Medicine (EBM)?

2.1. As first formulated, EBM was:

> "*an approach to health care that promotes the collection, interpretation, and integration of… patient-reported, clinician-observed, and research-derived evidence. The best available evidence, moderated by patient circumstances and preferences, is applied to improve the quality of clinical judgments.*"[6]

2.2. Thus, the double-blind randomised placebo-controlled trial (DBRCT) was meant originally as part of an evidence "package" derived from multiple sources. David Sackett, one of EBM's founders, emphasized this in 1992:

> "*Evidence-based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions. … If no randomised trial has been carried out for our patient's predicament, we follow the trail to the next best external evidence and work from there.*"[7]

2.3. EBM as currently practiced, now concentrates solely on the "gold-standard" double-blind randomized-controlled trial (DBRCT) and meta-analyses as the only acceptable scientific evidence for a therapy or procedure.[8]

2.4. Supposedly, this enables purely objective clinical decisions to be taken: other forms of evidence Sackett referred to as essential parts of the decision-making process, have been effectively downgraded or ignored. EBM's original intentions therefore, have been subsumed by over-emphasis on medicine's science to the exclusion of its art.[9,10]

2.5. Complex procedures (where it is virtually impossible to separate the therapy from the context in which it is delivered eg, CBT, homeopathy, etc) do not readily lend themselves to the DBRCT—itself, implicitly flawed[11–14]—and are seemingly left out in the cold.

2.6. This much narrower interpretation of EBM has elicited trenchant responses, even from within conventional medicine,[15–17] but in particular for its intolerance of therapeutic pluralism.[4]

2.7. The change in EBM's emphasis equates with rapid increases in our biochemical understanding of life, health, and disease, combined with globalization of the pharmaceutical industry's commercial and political reach. From this has arisen a desire to place medicine on a similar intellectual footing as other sciences.

2.8. Its concomitant is a resurgence of logical positivism[1] as an accessible (media-friendly) interpretation of science, and ultimately to justification of the globalised pharmaceutical industry's attempts to monopolize the health care market.

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[1] Logical positivism is a school of philosophy that combines empiricism (the idea that observational evidence is indispensable for knowledge of the world), with a version of rationalism incorporating mathematical and logico-linguistic constructs and deductions in epistemology. It was the dominant philosophy of science between the First World War and the Cold War, and has been criticised by among others, Popper, Ayer, Quine, Kuhn, and Putnam.

2.9. Though out-dated[18–28] within the physical sciences (especially quantum physics), logical positivism goes unchallenged, especially in public arenas (eg, the media and in political debates about science), and still holds sway in biomedicine.

2.10. Logical positivism effectively dominates the discourse of EBM, resulting not only in a downgrading and/or ignoring of other valid forms of evidence; it now means the medical research community potentially has saddled funding agencies and taxpayers with a huge and expensive problem: that of subjecting *all* medical procedures and therapies to the DBRCT, so they can be judged fit for clinical use.

2.11. This will not be easy because:

> "*Of around 2,500 treatments covered, 13% are rated as beneficial, 23% likely to be beneficial, 8% as trade off between benefits and harms, 6% unlikely to be beneficial, 4% likely to be ineffective or harmful, and 46%, the largest proportion, as of unknown effectiveness. … The figures above suggest that the research community has a large task ahead and that most decisions about treatments still rest on the individual judgements of clinicians and patients.*"[29]

2.12. Therefore, the charge often levelled at homeopathy that it is "unscientific" rings hollow when compared to this clear lack of evidence for many conventional medical treatments and procedures.

2.13. Thus, if the challenge against homeopathy raised by EBM is to be at all taken seriously then, by default, it has to be applied with equal rigour to conventional therapies, which will mean that roughly half of all procedures, including nearly all surgical ones, will have to be banned.

3. EBM and Conventional Medicine

3.1. Such a procedure is set to become a double-edged sword for biomedicine, as the following example shows. Thus trials of one of the world's biggest selling drugs Prozac, recently found it to be no better than placebo.[30]

3.2. Interestingly, homeopathy/CAM detractors are not campaigning for the removal of Prozac, as they do so vociferously against homeopathy/CAM (even when Prozac and Prozac-like drugs have been known to induce suicidal tendencies). Fortunately, such scientistic[2] "fundamentalism"[2] is not shared by all in medicine.

3.3. Thus, cancer clinician Karol Sikora (60% of whose patients use some form of CAM as adjuvant therapies) has uncompromisingly castigated the more vociferous homeopathy/CAM detractors as "inexperienced armchair physicians", while berating their "Stalinist" attempts to rid the NHS of its CAM services.[31]

3.4. Sir Michael Rawlins (Chair of NICE and no supporter of homeopathy/CAM) in his Harveian Oration last year,[15] warned:

> "*RCTs, long regarded as the 'gold standard' of evidence, have been put on an undeserved pedestal. Their appearance at the top of hierarchies of evidence is inappropriate; and hierarchies are illusory tools for assessing evidence. They should be replaced by a diversity of approaches that involve analysing the totality of the evidence base.*"

3.5. In this respect, Sir Michael Rawlins simply echoes David Sackett's much earlier concern that EBM would turn into an evidence "mono-culture", where the primacy of an assumed "ideal" scientifically-determined efficacy would subsume other no less important forms of patient and clinician derived evidence.[7]

3.6. That over a decade later, voices in the nursing profession have been raised concerning EBM's intolerance of therapeutic pluralism in healthcare systems,[4] suggests Sackett's early warning went completely unheeded. This scientistic version of EBM throws up for itself several alarming contradictions.

3.8. Thus, in a recent German randomised controlled back-pain study, acupuncture "placebo" was shown to be nearly twice as effective as the best conventional medicine has to offer. So, according to the principles of EBM as currently practiced, conventional medicine is less effective than an acupuncture placebo.[19]

3.9. The H1N1 swine flu vaccine is being rushed into production and distribution with little evidence from trials of its effectiveness or safety in humans.

3.10. One of the most frequently quoted studies (by the sceptical literature and the media), supposedly demonstrating homeopathy is no better than placebo, is a 2005 *Lancet* meta-analysis,[32] which has been shown by leading researchers to be thoroughly biased,[33–36]

3.11. In addition, two recent studies have concluded this meta-analysis was also a scientifically seriously flawed piece of work,[37,38] which broke the *Lancet*'s own strict guidelines on methodological and publication transparency.[39]

3.12. The question arises therefore as to why it was ever allowed to appear in such an eminent journal as the *Lancet* in the first place. This leads onto the whole thorny issue of abuse of science in medical and pharmacological research,[40] reported recently in the magazine Prospect.[41]

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[2] Scientism describes the view that natural science is superior to all other interpretations of life, such as philosophical, religious, mythical, spiritual, or humanistic explanations, and over other fields of inquiry, such as the social sciences.

3.13. In 2008, the journal *Nature*, stated that

> "*in the US around 1,000 incidents of suspected fabrication, falsification, and plagiarism go unreported every year*".[42]

In the UK, the Committee on Publication Ethics estimates that there are about 50 cases per year of serious fraud in biomedical research, and that academia has been trying to cover up this abuse of science.

3.14. The Prospect article concludes,

> "*We may have to wait for fresh scandals before anyone acts. Until then, patients will remain in real danger of taking expensive drugs whose risk of harm or inability to cure, have been fraudulently suppressed.*"

And there is clear evidence of harm perpetrated by conventional medical practice.

3.15. The House of Commons Public Accounts Committee concluded that in 2006 alone, *at least* 2.68 million people in Britain were harmed by conventional medical interventions: a staggering 4.5% of the UK population.[43] In the US, the situation is even worse.[44]

3.16. When no such evidence of fraud or large-scale danger of homeopathy in clinical practice have been reported, one wonders why so much energy is expended trying to demonise homeopathy/CAMs and those who practice them, as "unproven, unscientific, deadly and dangerous".

4. Evidence for Homeopathy

4.1. There are many scientific trials and meta-analyses providing evidence that the effects of homeopathy are more than a placebo response. These are summarised on the Faculty of Homeopathy website.[45]

4.2. If the more inclusive Rawlins and Sackett definitions of evidence are utilised however, then it is clear that there is growing evidence from clinical observation studies[46,47] for the positive health benefits of homeopathy, and its cost effectiveness.[48–50]

4.3. There is also mounting basic science evidence that homeopathically prepared solutions may very well differ from those that are simply diluted, suggesting the operation of a "water-memory" effect that surely deserves further exploration.[51–54]

4.4. In addition, laboratory studies suggest that even very high homeopathic dilutions (beyond Avogadro's number) may exert biological effects, though even high quality studies have yet to achieve consistency in experimental methodology.[55–58]

4.5. Some intriguing results which have just been published demonstrate that extremely low doses of cytokines achieve relief from the symptoms of allergic asthma induced in experimental mice, but only when the cytokines have been serially diluted and violently agitated in the homeopathic manner.[59]

5. An Aside: Is the "Memory of Water" (MoW) Possible?

5.1. As someone who originally came into homeopathy with over 30 years experience in chemistry (BSc, MSc, PhD, CChem, FRSC), MoW as a possible mechanism for how homeopathic remedies might produce effects (even when the original substance has been diluted out of existence), has produced in me feelings ranging from outrage to intrigue.

5.2. Consequently, I can sympathise with those for whom MoW[60] seems to contravene "common sense" and fundamental scientific principles, such as the Laws of Thermodynamics.

5.3. The problem with understanding MoW is the prevalence of so-called "common sense", which ultimately is only an indication of a particular paradigm's power over peoples' imaginations. New experiences, repeated often enough make prevailing paradigms redundant.[61]

5.4. Not so long ago, the idea that the world was flat was "common sense." So, one's experience and common sense are just as likely to be shaped by one's beliefs, as the other way around, and are not fundamental.

5.5. MoW describes the apparent ability of bulk water to be "imprinted" with the "signature" of a substance once dissolved, but now diluted *and violently agitated out of existence*. The agitation is absolutely necessary, as mere dilution on its own does not reproduce this phenomenon. The term was first coined by Prof Jacques Benveniste, and in his controversial *Nature* paper, he clearly distinguishes between mere dilution and dilution plus agitation.[62,63]

5.6. In chemical terms, MoW might be considered a *supra-molecular* phenomenon involving trillions of water molecules. Thus, it is an *emergent* dynamic property of bulk liquid water (ie, the whole is more than the sum of its individual molecular parts) and, as such, defies simple explanation in terms of conventional chemical ideas of static bonding and additive behaviour of individual water molecules.

5.7. Certainly, water molecules' ability to dynamically switch hydrogen bonding to each other is of crucial importance here, as are other weak intermolecular interactions (eg, van de Waals forces). Prof Martin Chaplin gives a fulsome account of this behaviour on his website.[64]

5.8. The point is, the principles of *equilibrium* thermodynamics that one learns at school and university *cannot* explain this behaviour, because it involves so-called critical or instability points very far from chemical equilibrium. It is a type of behaviour first described by Prof Ilya Prigogine's Nobel Prize-winning work on the thermodynamics of non-equilibrium chemical reactions very close to chaos, *such as those that necessarily occur in all living organisms*.[65]

5.9. One plausible hypothesis is that such instability points act as local *dynamic attractors* of the system. These necessarily exist in such microscopic form, it requires a novel quantum description that predicts effects at the macroscopic level, with consequences not dissimilar to those of superconductors and super-fluids in low-temperature physics. The model is applicable to several systems of complementary medicine, including homeopathy.[66]

5.10. This means that it is quite possible for the physical and chemical properties of a solution to depend on its dilution history: in other words, for it to have a "memory" of what has been diluted in it. A series of interesting experiments indicating this possibility, was reported recently using solutions of different substances at various (non-homeopathic) dilutions.[67]

5.11. Sixteen years after Benveniste's controversial work, a successful version of his experiments was performed involving a multi-centre European trial over five years, in five separate laboratories.[56]

5.12. In a completely different area, Rey obtained thermoluminescence data from homeopathically prepared ultrahigh dilutions of lithium and sodium chloride, which were reproducibly different from pure water diluted with itself.[51] This suggests that the dynamically-altering pattern of hydrogen bonds described in 5.7., might survive removal of the original material.

5.13. The field of materials science has demonstrated that it is changes to the *structure* of water rather than its *composition* that fundamentally affects its properties.[68] In this regard, water can adopt a range of dynamic structures which have been used to account for its many well-known anomalies as a liquid.[64]

5.14. There is also compelling thermodynamic evidence that extremely diluted solutions prepared in the homeopathic manner, by sequential dilution and violent agitation, are measurably and reproducibly different from similar solutions that have simply been diluted.[53]

5.15. Dr Cyril Smith in the UK has for over 30 years researched how living things make use of electro-magnetic fields and frequencies, and their connection with MoW.[69]

5.15. All the above experimental work supports a theoretical mechanism for MoW first put forward by Italian physicists Profs Del Guidice and Preparata over 20 years ago,[70] that the homeopathic process of serial dilution and violent agitation triggers formation of dynamic "structures" in water that can survive removal of all traces of the original dissolved substance.

5.16. Contrary to what some homeopathy/CAM detractors think therefore, MoW is not only possible, it does NOT contravene known scientific laws and principles.

6. Conclusions

6.1. The charge often levelled at homeopathy by is detractors, that it is "unscientific" even "deadly" does not withstand close scrutiny when compared to the clear lack of evidence for many conventional medical treatments and procedures, including some of the latest vaccines, and the clear evidence of harm through side-effects of some conventional interventions.

6.2. With its increasing reliance solely on the results of randomised-controlled trials, Evidence-based Medicine as currently understood and practiced is no longer a reliable or cost-effective "tool" for investigating the efficacy or safety of many conventional medical procedures, let alone homeopathy/CAMs.

6.3. There is clear evidence of bias and dependence on flawed science by some assessing and reporting the supposed lack of efficacy of homeopathy, while at the same time, abuse of science and its cover-up are unfortunately not rare occurrences in medical and pharmaceutical research.

6.4. From RCTs, meta-analyses, clinical observational studies, and basic science experiments, there exists a steadily growing evidence base for homeopathy, the efficacy of some of its remedies, and their possible mode of action. Work is also beginning to elaborate homeopathy's cost-effectiveness

6.5. Finally, I would bring to the S&TC's attention this quote from Professor Martin Ryder of Colorado University on the dangers of scientism encroaching into public policy

> "*… Policy can be informed by science, and the best policies take into account the best available scientific reasoning. Law makers are prudent to keep an ear open to science while resisting the rhetoric of the science industry in formulating policy. It is the role of science to serve the primary interests of the polity. But government in a free society is not obliged to serve the interests of science … positivism and scientism move in where the discourse of science lacks self-reflection and where the spokesmen of science exempt themselves from public scrutiny."* [71]

6.6. In conclusion, I would hope therefore that the S&TC considers the substantive points I have made, in regard to the growing evidence for this more than 200-year-old therapy, regardless of the accompanying bias and abuse I have itemised above. For without that, it will be doubtful in my view, whether the STC will be able to achieve an objective assessment of the evidence for homeopathy.

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November 2009

Memorandum submitted by Katherine Boulderstone (HO 05)

1. The phrase "homeopathic products" is meaningless in this context. There are no products that are produced by the application of homeopathy.

2. The word "homeopathic" cannot be used to describe a product. A remedy is only "homeopathic" when matched to an individual according to the law of similars. It cannot be homeopathic in isolation but only in relationship to the state it is homeopathic to.

3. Pharmacists and some homeopaths do sometimes use the term "homeopathic" to describe a potentised remedy, but it is scientifically incorrect and leads to confusion over the definition of homeopathy.

4. Potentised remedies are sometimes, but not always, used as part of the application of the homeopathic method of healing.

5. Homeopathy is not synonymous with very dilute substances.

6. Instead of the phrase "homeopathic products", I suggest the more accurate term "potentised substances" or "potentised remedies".

November 2009

Memorandum submitted by Professor John C McLachlan (HO 06)

Response to the Consultation on Government policy on licensing of homoeopathic products, Government policy on the funding of homoeopathy through the NHS, and the evidence base on homoeopathic products and services.

I will consider the topics listed for consultation in reverse order, since the evidence base is paramount.

THE EVIDENCE BASE ON HOMOEOPATHIC PRODUCTS AND SERVICES

1. Currently, regulated health professions are bound by the requirement for evidence based treatment. The GMC states[3] *"In providing care you must provide effective treatments based on the best available evidence"*. The Code of the Nursing and Midwifery Council[4] states "*You must deliver care based on the best available evidence or best practice"*. Even in government, one of the Essential Professional Skills for Government competencies is: "*Analysis and use of evidence: Links evidence with specific outputs to challenge decision-making and identify ways to improve its quality and use*". Evidence-based medicine and public health have radically improved health, and continue to do so. It is hard to understand why this requirement should be arbitrarily abandoned for alternative medicine practices. Yet despite the MHRA claiming that they "*ensure medicines work"*, they license homoeopathic products for which there is no evidence of efficacy, and indeed, evidence that they do not work.

2. It is sometimes erroneously claimed that the rules of evidence do not apply to homoeopathic medicine. Indeed the MHRA state so explicitly: *"Because of the philosophy of homoeopathy and the nature of the products, it is difficult to establish efficacy for homoeopathic products by way of clinical trials"*.[5] This is quite untrue. The nature of homoeopathic products (frequently, pillules indistinguishable other than by the label) render them particularly well suited to randomised controlled trials: the argument that treatments are individualised is irrelevant, since a patient can be prescribed an individualised homoeopathic treatment, then entered into an allocation process by which they are randomised to either the homoeopathic or placebo arm. It is not philosophy or the nature of products which renders efficacy difficult to establish: it is lack of efficacy.

3. This line of argument by homoeopaths can be summarised as "Evidence does not support homoeopathy—so let us attack the concept of evidence". However, since homoeopathic advocates cite the outcomes of randomised trials when they believe they are favourable, and only denigrate them when they are not, this argument is used inconsistently. If the normal standard for statistical significance is set at $p < 0.05$, then some false positives are inevitable, even with inert substances. It is consistent performance which is important, and I do not know of any examples of consistent efficacy for homoeopathic remedies in double blind randomised controlled trials. NHS Evidence[6] on Complementary and Alternative Medicine, despite being led by a homoeopath practitioner, produces a paltry handful of debatable findings each year. Although meta-analyses showing no effects of homoeopathy have been criticised by homoeopaths,[7] they then rather miss the observation that any effects which are present are too small to be meaningful.

4. Accepting homoeopathic beliefs about the consequences of dilution also requires acceptance that the basic rules of physics and chemistry are held in abeyance. If this were true, it would be a revolution in physics thinking comparable with that of relativity. Yet no serious physicist is interested in everlasting fame by exploring it—because none assess it as other than fatuous.

5. The MHRA may have been misled by the view that homoeopathic remedies must be harmless, since they contain no active ingredients. And indeed, homoeopathy is only dangerous if you believe in it. The dangers that arise if you truly believe are two fold.

6. Danger 1. Misdiagnosis by homoeopaths. It might be thought that homoeopathy merely operates as a placebo effect and for conditions which are chronic, difficult to diagnose or difficult to treat, and therefore does not pose potential harms. However, to tell which conditions are treatable by rational means requires training in evidence based methods, and misdiagnosis can be lethal.

7. Danger 2. Withdrawal from rational treatment. As private practitioners, homoeopaths have a vested interest in patients using their services. Alternative practitioners frequently attack rational evidence based medicine in a variety of ways, often tacitly, but sometimes explicitly. The natural outcome is for clients under their care to *abandon* evidence based methods for methods which do not require evidence. The consequences for this can be lethal, as in promoting homoeopathy for the treatment of HIV/AIDS.[8] Some case histories are adduced to support this.

8. Nine year old Nahkira Harris died of diabetes after she did not receive insulin treatment which would have preserved her life.[9] The prosecutor said that the parents ignored advice to return her to hospital and sought homoeopathic remedies. The judge also criticised a GP, author of a book called "How to use homoeopathy effectively", who was later severely admonished by the General Medical Council. Nahkira's

[3] GMC Good Medical Practice—Delivering Good Clinical Care. Para 3. In GMC documents "must" means that it is obligatory, as opposed to "should". http://www.gmc-uk.org/guidance/good_medical_practice/index.asp
[4] http://www.nmc-uk.org/aArticle.aspx?ArticleID=3056
[5] Explanatory memorandum to the medicines for human use (national rules for homoeopathic products) regulations 2006.
[6] http://www.library.nhs.uk/CAM/ViewResource.aspx?resID=317091
[7] http://hawk-handsaw.blogspot.com/2007/11/whats-wrong-with-shang-et-al.html
[8] http://www.dynamis.edu/new/HomeoforAIDS4UKrevlores.pdf
[9] *Daily Telegraph* 6 November 1993.

parents were convicted of manslaughter. Six months old Cameron Ayres "died from a rare disorder after being denied conventional care by his parents who held strong beliefs in alternative medicine".[10] *The Telegraph* headed the story "Homeopathy couple refused help for their dying baby". Nine month old Gloria Thomas died from an eminently treatable condition (eczema) because her parents, adherents of homoeopathy, withdrew her from rational treatment.[11] "Ms A" died after a doctor with homoeopathic beliefs asked Ms A, to follow only "homoeopathic remedies". The GMC found the doctor guilty of professional misconduct.[12]

9. The MHRA have lent credibility to homoeopathic remedies, increasing the risks of such outcomes. As a leading homoeopathic manufacturer commented "*The fact that therapeutic indications may now be included on the packaging of licensed homoeopathic medicines not only opens the practice of homoeopathy up to new users but also gives it added credibility*"[13]

10. Further examples of risks posed by validation of homoeopathic remedies by government are that homoeopaths may advise travellers that their remedies act prophylactically against malaria[14] or advising patients not to get vaccinated.[15]

11. The MHRA has indicated that they are prepared to accept "homoeopathic provings" as evidence. What does this mean? An article called "Trituration Proving of the Light of Saturn" by Patricia Maher was recently published in the e-journal "*Interhomeopathy*".[16] It says "*The remedy was made by exposing powdered milk sugar to a powerful telescope in Boston, Massachusetts while it was focused on the planet Saturn during April 2009*". After exposure to the remedy, seven "provers" (two of whom knew what the "remedy" was) recorded their conversations. There was a long conversation in which provers named their five favourite Beatle songs. From the start, conversation was filled with erotic double-entendres ("*How's my technique?"*). One prover demonstrated a seductive way of eating a sandwich: "*if I could get food that way I would never be hungry… I want to draw you naked…*" Now, given that there were four females and three males present, mild flirtation does not seem so surprising. Nonetheless, some physical symptoms were recorded. "*The female provers especially experienced a great deal of itchiness: Head, nose, eyes itchy. Head itchy. Back itchy, breasts itchy, thighs. Desire to yawn and stretch*". Yet clear therapeutic conclusions could be drawn. "*From a homoeopathic point of view, both the physical symptoms that appeared and the content of the discussion during the proving suggest that this remedy might be effective for accident-related trauma, bone and nerve damage. This remedy may also be effective for allergies, in light of all the itching that occurred*". These quotations are of course selected: read the entire article lest you think I am parodying it. Of course, Venus does not emit light but merely reflects sunlight, and so this proving is as rational as astrology. Other provings (presumably acceptable to the MHRA) have been conducted for cobwebs,[17] barn owl feathers,[18] AIDS infected blood,[19] and mobile phone radiation.[20]

Government Policy on the Funding of Homoeopathy through the NHS

12. It follows from the foregoing that Government should not fund treatments which have zero efficacy, and pose hazards of misdiagnosis and withdrawal from treatment. Particularly regrettable is the attempt to hijack the term "integrative" to conceal the nature of alternative treatments. The positive aspects of integrative medicine are already a key part of the curricula of modern medical schools, and are a routine part of the armoury of good doctors and health care practitioners.

13. It might be argued that the placebo effect of homoeopathy is sufficiently valuable to be worth paying for. However there is a profound dilemma relating to this use of NHS funds. If the practitioner believes that homoeopathy is a placebo, then prescribing it requires her/him to lie to the patient, and this runs contrary to ethical practice in health care. If the practitioner believes that homoeopathy works as advertised, then they are a danger to the patient as the case histories above (frequently involving qualified medical personnel) demonstrate. Further, whether or not the practitioner believes in homoeopathy, the patient who is being misled might reasonably choose to believe in it, since it was endorsed by the NHS, and subsequently choose to take advice on vaccination from a homoeopath, for instance.

Government Policy on the Regulation of Homoeopathic Products

14. Policy should be based on evidence of efficacy as required for other products making medicinal claims. It is particularly regrettable that the MHRA should think it has a role in promoting this particular industry.[21] The MHRA stated "*Although the development of national rules by Member States under the 2001 Directive is optional, failing to introduce the scheme would inhibit the expansion of the homoeopathic industry*". This solicitude is not extended to any other industry.

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[10] *Daily Telegraph* 5 April 2000.
[11] http://www.smh.com.au/national/parents-guilty-of-manslaughter-over-daughters-eczema-death-20090605-bxvx.html
[12] http://news.bbc.co.uk/1/hi/england/london/6255356.stm
[13] Robert Wilson, chairman of Nelsons, quoted BMJ 2009;338:b2055
[14] http://news.bbc.co.uk/1/hi/programmes/newsnight/5178122.stm
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[16] http://www.interhomeopathy.org/index.php/journal/entry/trituration_proving_of_the_light_of_saturn/
[17] http://www.homoeopathy.co.uk/resources.htm
[18] http://www.welshschoolofhomoeopathy.org.uk/proovings.htm
[19] http://www.hominf.org/aids/aidsfr.htm
[20] http://www.littlemiracle.freeuk.com/#Proving%20of%20Mobile%20Phone%20Radiation
[21] MHRA Memorandum, 2006.

15. Arguments might be made to the effect that more research needs to be done. However, the US National Centre for Complementary and Alternative Medicine has spent $2.5 billion dollars on alternative medicine research, and achieved no significant benefits.[22]

Conflicts of Interest

16. The author is John McLachlan, Professor of Medical Education and Associate Dean of Medicine at the University of Durham, although he writes here in a private capacity. He does not earn money from pharmaceutical industries, provision of health care, homoeopathic practice, or sale of homoeopathic products.

November 2009

Memorandum submitted by the UK Advisory Committee on Malaria Prevention in UK Travellers (ACMP) (HO 07)

1. The UK Advisory Committee on Malaria Prevention in UK Travellers (ACMP), an independent expert committee of the Health Protection Agency has been asked to respond by the HPA to the call of your committee for evidence on:

— Government policy on licensing of homeopathic products

— Government policy on the funding of homeopathy through the NHS

— the evidence base on homeopathic products and services.

2. The ACMP has on several occasions considered the third question in relation to travellers who have been advised to take homeopathic prevention against malaria (not by NHS homeopathic practitioners) and subsequently contracted the disease.

3. Malaria is a potentially fatal disease, almost completely preventable by a combination of mosquito bite prevention and antimalarial prophylaxis, which kills several people every year and causes over 1,000–2,000 cases of malaria in the UK. There is no convincing evidence that homeopathic prevention or treatment works, although no scientifically robust trials have been conducted.

4. There is clear scientific evidence based on trials that several antimalarial drugs do substantially reduce the risk of malaria, as do insecticide-treated bednets. There is clear evidence that current antimalarial drugs are highly effective at treating malaria.

5. Given the seriousness of the disease and the clear evidence of other measures being effective no responsible homeopathic practitioner would consider recommending homeopathy in the view of the ACMP. We would strongly advise against homeopathic products for preventing or treating malaria being licensed in the UK on the basis of current evidence. The ACMP has no views on homeopathy more widely.

Professor Christopher Whitty FRCP FFPH
Acting chair, ACMP

November 2009

Memorandum submitted by Cyril W Smith (HO 08)

Executive Summary

1. Homeopathy involves frequencies and their effects on living systems.

2. Clinical evidence comes from hypersensitive patients whose reactions can be treated with specially prepared homeopathic potencies.

3. Homeopathic potencies involve the memory of water for frequencies.

4. A theory based in quantum physics is supported by experimental evidence.

1. Introduction

Homeopathy is one of the branches of Complementary and Alternative Medicine which involves the therapeutic use of frequency. For at least the past 60 years, the promulgated and accepted wisdom is that the only biological effects of non-ionising electromagnetic fields are thermal and as such can be reliably predicted from "Classical Physics". One must conjecture that the motives for this have been military,

[22] http://abcnews.go.com/Business/wireStory?id=7804031

commercial and legal. The majority of healthy persons have regulatory systems well able to cope with the natural and man-made electromagnetic environment as with other environmental stresses so, any frequency effects are not apparent.

Since the 1970's the writer (Smith, 2008) has been involved with research into the ways that living systems make use of electric and magnetic fields and frequencies and has over 100 publications in this area. In 1982, he commenced an involvement with the problems of chemically sensitive patients who had become hypersensitive to their electrical environment. This work quickly showed that once a threshold of intensity had been exceeded, the relevant factor was frequency. Initially, patients were challenged with frequencies from an oscillator at environmental field strengths. Their reactions to specific frequencies were the same as their reactions to the chemicals, volatiles or particulates to which they happened to be sensitive.

The "Miller Technique" used in the treatment of such patients involves successive serial dilutions of the allergen until one is found which turns-off the patient's reaction. This needs to be more precise than the standard homeopathic potencies. Here, succussion takes place by vortexing in the syringe. For the treatment of electrical sensitivities a therapeutic frequency could be found, imprinted into water and used in the same way as an allergen dilution even though there was no chemical component present. This fitted conveniently into the existing facilities and practice of the hospital involved (Breakspear Hospital, Hemel Hempstead) and did not require an electrical oscillator for each patient. Rea *et al.* carried out a double-blind trial at the Environmental Health Centre, Dallas, Texas. Selected patients with electrically sensitivity could respond to a frequency to which they happened to be sensitive with 100% success and 0% response to placebos.

Examination of frequencies which had a clinical effect showed a correlation with the endogenous frequencies on the acupuncture meridians. When an acupuncture point is stressed either by pressure or with a needle, its endogenous frequency spreads throughout the body. Appropriate choice of meridians and points enables the acupuncturist to create a therapeutic frequency pattern from the patients own body fields. Dr. Reinhardt Voll showed that certain acupuncture meridians were linked to the autonomic nervous system (ANS). Homeopathic potencies can be selected to stimulate specific acupuncture meridians and thence specific parts of the ANS.

2. The Physics of Homeopathy

2.1 *Frequency, Coherence and Fractality*

Figure 1

DIAGRAM OF THE QUANTITIES ASSOCIATED WITH FREQUENCY

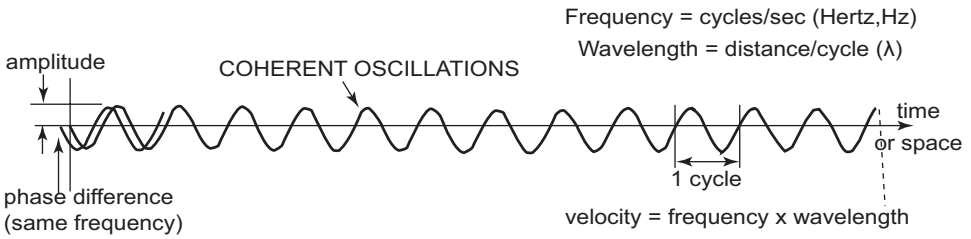


Figure 1 shows the quantities associated with frequency irrespective of what is oscillating. If a frequency is propagating through space, there is a velocity and an associated wavelength.

The importance of frequency in biological systems was recognised by Herbert Fröhlich FRS (Smith, 2008) who in the 1930's when told that the cell membrane potential was a fraction of a volt and existed across an extremely thin cell wall realised it represented an enormous electric field, strong enough to align molecules for assembly and resonating at about 100 GHz. By 1967, he had applied the theory of coherent modes of oscillation in non-linear systems and long-range phase correlations to biological order. The subsequent development of his ideas and the work of his world-wide circle of collaborators were edited by him into two *"Green Books"*: "Coherent Excitations in Biological Systems" and "Biological Coherence and Response to External Stimuli".

In 1995, Preparata with Del Giudice and co-workers showed through quantum electrodynamics (QED) theory that water had phase coherence as a fundamental property arising from the exchange of radiation at the natural resonant frequencies of the water molecule. In a coherent system, the distance over which frequency coherence persists (*coherence length)* replaces velocity as the constant quantity making frequency proportional to velocity (see Figure 1) and a fractal quantity. Fractality enables the chemical, technological and biological frequency bands to interact. Table 1 shows the frequency fractals for light from a mercury discharge lamp imprinted into water. If the chemical bond was not associated with frequency, spectroscopic analysis would be impossible. Chemistry cannot be described by "Classical Physics".

Table 1

MULTIPLE FREQUENCIES FRACTAL EFFECT FOR THE MERCURY (Hg) OPTICAL SPECTRUM IMPRINTED INTO WATER.

Hg lines nm	*Optical Hz*		*Microwave Hz*		*ELF Hz*
	$\times 10^{15}$	$\times 10^{6}$	$\times 10^{6}$	$\times 10^{6}$	$\times 1$
185	1.62		935		19.31
254	1.18		680		14.38
365/6	0.820		472		9.843
405	0.740		425		8.925
436	0.688		396		8.358
492/6	0.607		347		7.235
546	0.549		315		6.633
577/9	0.519		298		6.262
615	0.488		280		5.832
623	0.482		276		5.832
Ratio		1.7340		47.70	
Std. Dev.		$\pm 0.34\%$		$\pm 0.75\%$	

2.2 *Fields*

In mathematics, a *field* is a region of space containing mathematical objects, rather like the "field of view" seen with binoculars. In physics, a *field* is a region in which a mechanical force acts, for example the gravitational field.

The "Classical Electromagnetic Field" is the basis of electronics and radio. "Classical Physics" describes a system for which the phase is well defined and the number of particles (quanta) is too large to matter. In contrast, a "Quantum Field" involves less particles and has a fundamental uncertainty described by the Heisenberg Relation (Smith, 2008).

These fields can be electric or magnetic. The magnetic field only exists in closed loops and a mathematical consequence is the magnetic vector potential explained theoretically by Aharanov and Bohm and later found experimentally. This generates an electric field proportional to its frequency and in a coherent region this gives an oscillating potential which can be measured.

3. The Physics of Water Memory

One important result from our clinical work was finding that the reactions of patients to environmental electromagnetic fields, chemicals, or potencies could be reproduced with frequency imprinted water. Water in flame-sealed glass ampoules could be imprinted with frequencies through the glass and no possibility of any chemical contact. This confirmed the basis of homeopathy as frequencies in water.

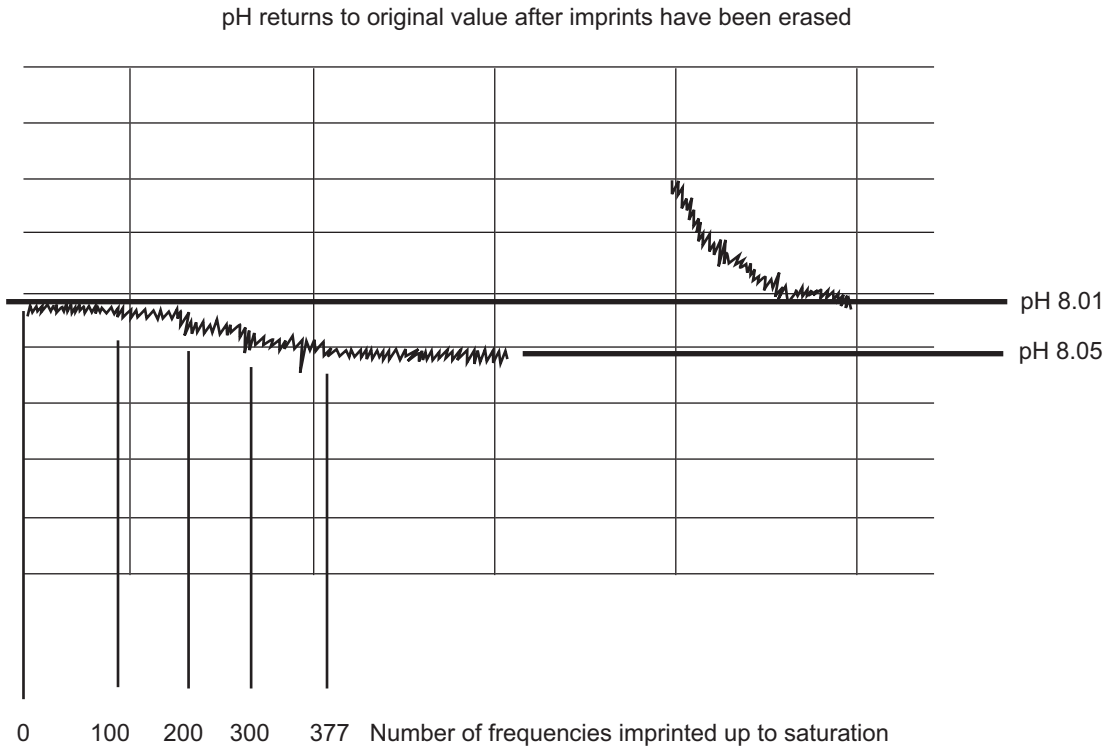
In 1983, my laboratory (Smith, 2008) showed that living systems could respond to magnetic resonance conditions at geomagnetic field strengths. This is a quantum effect but following its publication a cyclotron theory attempted to the keep the effects within "Classical Physics".

Later this suggested that a frequency might be retained in water if the precession of proton spin could be synchronised to an applied frequency to generate an internal magnetic field which exactly satisfied the proton magnetic resonance conditions locally within a coherence domain. This condition turned out to be independent of the frequency to be remembered and would be stable unless the domain is thermally broken up by removing the stabilising geomagnetic field. The critical field for this is about 340 nT making the coherence domain 53 μm in diameter. The statistical fluctuation in the number of protons involved determines the bandwidth of the frequency imprint which can be parts per million in agreement with experiment.

Imprinting a frequency into water immobilises free protons increasing the pH value. Figure 2 shows the pH of a solution of sodium hydroxide at pH 8.01 had increased to pH 8.05 at memory saturation after 377 separate frequencies had been imprinted. On erasure the pH returned to its initial value.

Figure 2

CHANGES OF Ph ON IMPRINTING AND ERASING FREQUENCIES.



3.1 *Writing Frequencies into Water*

Frequency information can be imprinted into a glass vial of water by succussion. This is what creates a homeopathic potency. Frequency information from a patient's body also can be imprinted if the vial is held in a clenched fist while succussing the protruding end.

Imprinting can take place through the glass of a vial containing water by immersing it in frequency imprinted water. Water placed near to a source of frequencies such as an oscillator and coil, a chemical or homeopathic potency can be imprinted by succussion or, with a strong permanent magnet or, by succussing a toroid (ring) of ferrite material. A sequence of 7-voltage pulses will effect an imprint; imprinting can also be done chemically.

3.2 *Erasing Water Memory*

A homeopathic potency or a water imprint will be erased if the geomagnetic field is shielded by placing it briefly in a steel box. Erasure occurs when thermal energy becomes greater than the internal magnetic energy. This threshold, at about 1% of the Earth's magnetic field, is independent of the imprinted frequency over at least the 13-decades from 10^{-4} Hz to 10^{+9} Hz. Heating imprinted water alters the imprint so that it becomes "hidden" and living systems do not recognise it. It can be recovered by the application of certain frequencies including that of the heart acupuncture meridian. Certain combinations of frequencies will self-erase, that is they are "nilpotent".

3.3 *Reading Water Memory*

Frequencies in water and living systems present a great measurement problem. Clinically, they may be anywhere in the electromagnetic spectrum from milliHertz to GigaHertz and the bio-information is carried on the magnetic vector potential component of the field.

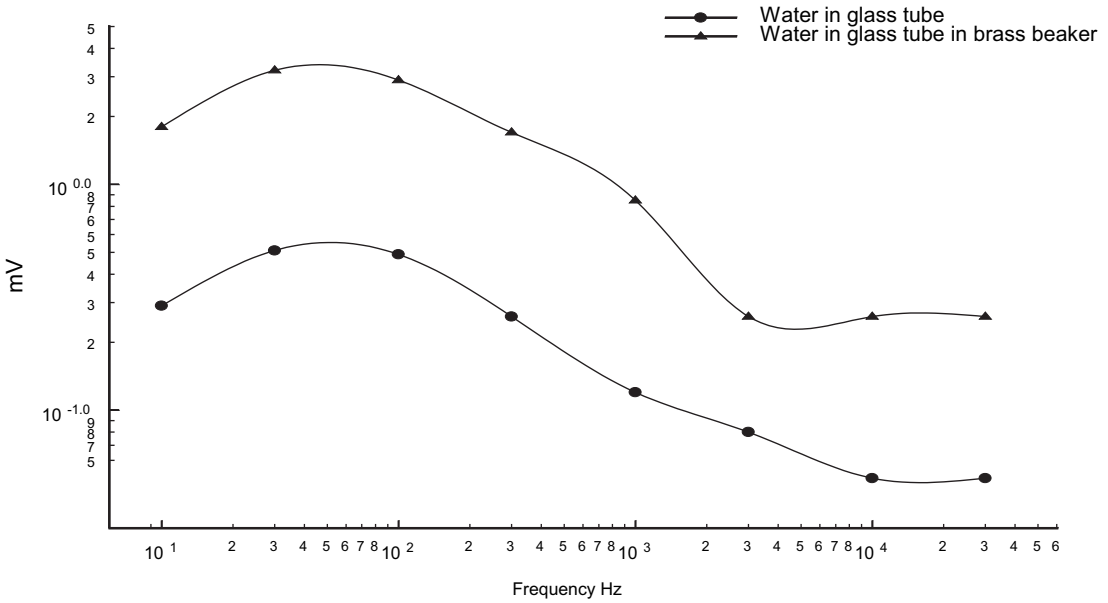
Several techniques have been applied to the objective measurement of frequencies in water and homeopathic potencies. They can be made to work over a limited range of frequencies (Smith, 2008).

1. Electrodes immersed in water or a potency and connected to a low-noise high-gain amplifier have been used by the writer and Dr. Wolfgang Ludwig.
2. Dr. Peter Gariaev has used a special 2-beam laser interacting with a potency; this results in the emission of a radiofrequency modulated with the signature of the potency.
3. Professor Vittorio Elia has used microcalorimetry to show a difference in heats of mixing between control water and a potency and in cooperation with Professor Claudio Cardella has shown the same effect with water imprinted by placing in a microwave resonator.

4. Dr. Karen Langer has used both delayed luminescence and also the coupling between Tesla coils to demonstrate effects from potencies.
5. Dr. Louis Rey has irradiated samples with high energy ionising radiation after freezing and on warming found differences in the thermoluminescence between potencies and controls.
6. Professor Luc Montagnier has shown that some DNA sequences in pathogenic bacteria and viruses have a characteristic frequency signature even at high dilutions of agitated aqueous solutions.

Figure 3

MEASUREMENT OF FREQUENCIES IMPRINTED INTO WATER—USING A LOW-NOISE AMPLIFIER AND PHASE-SENSITIVE DETECTOR (BROOKDEAL ELECTRONICS LTD. LA350). LOWER CURVE: SINGLE ELECTRODE IN WATER; UPPER CURVE: WATER IN ELECTROACUPUNCTURE BEAKER.



The magnetic vector potential (**A**-field) component is in the direction of a current ie the proton precession and since $\mathbf{dA/dt} = -\mathbf{E}$ an alternating **A**-field will generate an alternating **E**-field proportional to the frequency and an alternating potential in a coherent system. This is not a potential difference. It is in effect what electroacupuncture apparatus does without explaining the physics involved.

Table 2

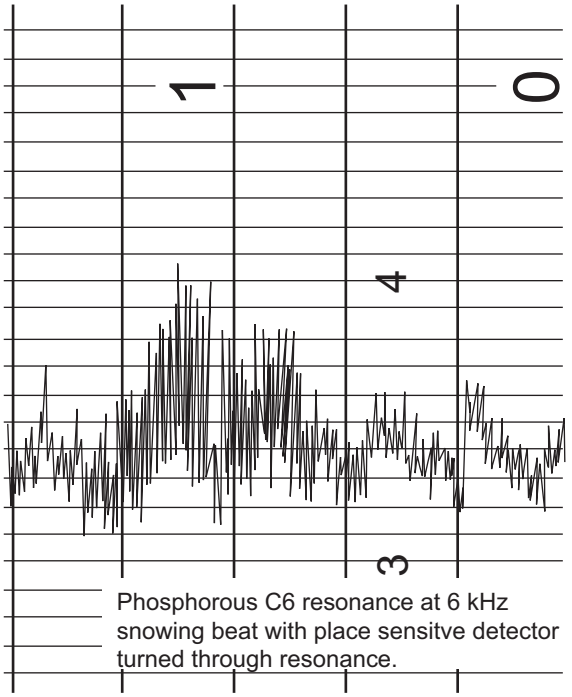
FREQUENCY PATTERN OF HOMEOPATHIC PHOSPHOROUS C6 TABLETS

Phosphorous C6 *Hz*
2.113×10^{-1}
5.003×10^{0}
$5.000 \times 10^{+1}$
$3.003 \times 10^{+2}$
$6.005 \times 10^{+3}$
(± 1 Hz)

The frequency pattern of homeopathic phosphorous C6 tablets is shown in Table 2. Figure 4 shows this resonance measured with a low noise amplifier and phase sensitive detector (Brookdeal Electronics Ltd. LA350). The tablets were placed in an electroacupuncture brass beaker. The frequency was stepped manually in 1 Hz intervals to show the beats between the potency resonance and the reference frequency. The chart speed was 20mm/min.

Figure 4

MEASUREMENT OF A FREQUENCY RESONANCE IN PHOSPHOROUS C6.



3.4 *Chemical Frequency Signatures*

Homeopathic potencies start from a "Mother Tincture" which is usually of chemical or biological origin. *Its chemical frequency signature is all that is needed for potentising.* A homeopathic repertory shows the wide range of frequency templates available for potentisation.

Experiments with n-hexane showed that only 14 ppm of water is needed for a frequency signature to develop. Since the n-hexane spectrum is in the far-infra-red (FIR), water can only interact here. Of the many FIR water lines a few (357 cm^{-1}, 213 cm^{-1} and 128 cm^{-1}) are coherent enough for a water vapour laser and for "water memory". The chemical frequency signatures calculated for n-hexane were as measured. The same calculation applied to pairs of FIR water lines gave the measured frequency signatures of water. When a frequency is imprinted into water, the FIR frequencies develop two sidebands proportional to the imprinted frequency with corresponding fractal sidebands in other parts of the electromagnetic spectrum.

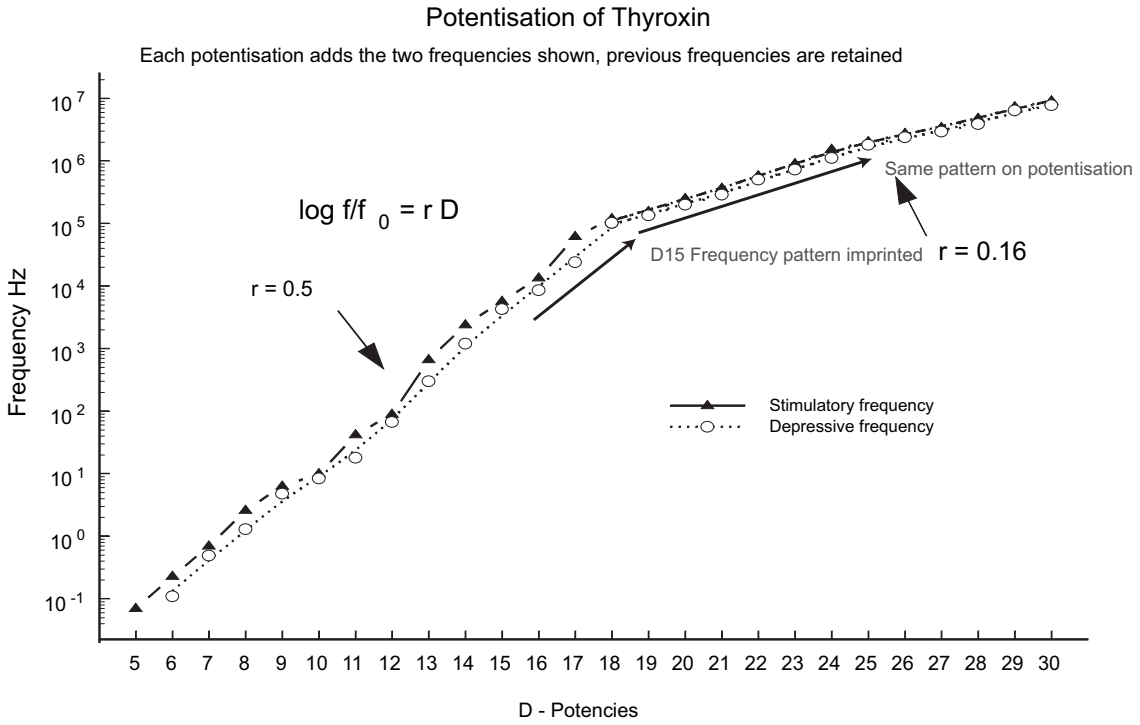
4. Homeopathic Potencies

When a single frequency is imprinted into water which is then serially diluted, the original frequency disappears to be replaced by the original frequency multiplied by the dilution ratio. Not all dilution ratios do this, some have no effect, others erase everything. Patterns developed from frequency signatures may be more complicated.

Figure 5 shows the frequency pattern for a set of potencies of thyroxin. It demonstrates the frequency basis for potentisation of homeopathic remedies. Frequency erased water was imprinted with the complete pattern of frequencies previously determined for thyroxin of potency D15. This was then potentised by conventional dilution and succussion. The frequencies measured for each synthesized potency were exactly the same as those for the potencies prepared from the "Mother Tincture" chemical thyroxin. Yet, the synthesized potencies had started from nothing but water. There is no discontinuity at potency D24 the dilution at which no molecule of an original substance should remain (Avogadro's Number).

Figure 5

FREQUENCY PATTERN FOR POTENCIES OF THYROXIN. THE POTENCY D15 WAS SYNTHESISED FROM ALL CONSTITUENT FREQUENCIES. ON DILUTION AND SUCCUSSION THIS GAVE THE FREQUENCIES AS MEASURED IN POTENCIES COMING FROM THE "MOTHER TINCTURE".



The frequency signature of chemicals must apply to pharmaceuticals which must also have a homeopathic activity. Table 4 compares aspirin and aconite; combined they would stimulate the Du Mai meridian.

Table 4

FREQUENCY SIGNATURES FOR SOLUBLE ASPIRIN AND ACONITE C6.

↑ = stimulatory (hyperactive); ↓ = depressive and stressful (hypoactive).

Soluble Aspirin	*Aconite 6C*	*Aspirin + Aconite C6*
	$\uparrow 4.911 \times 10^{-4}$	
$\uparrow 3.032 \times 10^{-1}$	$\downarrow 3.013 \times 10^{-1}$	
	$\uparrow 7.712 \times 10^{0}$	$\uparrow 4.133 \times 10^{0}$
	$\downarrow 5.513 \times 10^{+2}$	
$\downarrow 1.23 \times 10^{+6}$	$\uparrow 1.22 \times 10^{+6}$	
$\uparrow 7.10 \times 10^{+6}$	$\downarrow 7.10 \times 10^{+6}$	
	$\uparrow 3.35 \times 10^{+7}$	

5. Chaos

Between the states of health and disease there may be a state of mathematical chaos (Smith, 2009). Chaos has been demonstrated in respect of the cardiac signal of a healthy human as well as in electroencephalograms, epidemics, fluid flow and oscillatory chemical reactions. A chaotic system eventually settles down to its "attractor"—a stable condition that may be a point focus or a limit-cycle oscillation. From the clinical and homeopathic point of view, any experiment involving a patient in a chaotic domain is non-repeatable from the same initial condition. Homeopathy can operate in the chaos region to switch a patient back from chaos to health.

6. Similiters and Provings

Hahnemann wrote, "…that for the totality of symptoms to be cured, one must seek that medicine which has demonstrated the greatest propensity to produce either *similar* or *opposite* symptoms".

Frequencies patterns are generally biphasic showing alternately stimulation and depression of biological activity. Endogenous frequencies in biological systems fluctuate around their nominal value in a quasi-periodic manner which may be chaotic. Frequencies of acupuncture meridians can be entrained by

homeopathic potencies which may stimulate or depress biological activity and hence can be "therapeutic" or "proving". Chronic exposure to frequencies can result in "proving" symptoms which may become indistinguishable from a disease state.

In Table 5, the frequency pattern from a patient is compared to the frequency pattern of the homeopathic potency Lachesis C200 which may be the patient's similiter.

Table 5

FREQUENCY MATCHING INDICATES A POSSIBLE SIMILITER
(paired-values correlation coefficient 0.94)

↑ = stimulatory (hyperactive); ↓ = depressive or stressful (hypoactive).

Patient's Frequencies Hz	*Nearby Meridians*	*Lachesis 200C Hz*
$\uparrow 1.514 \times 10^{-2}$	Small intestine	$\uparrow 3.112 \times 10^{-2}$
$\downarrow 7.611 \times 10^{0}$	Heart	$\downarrow 6.142 \times 10^{0}$
$\uparrow 5.000 \times 10^{+1}$	50 Hz	$\uparrow 5.013 \times 10^{+1}$
$\downarrow 6.006 \times 10^{+1}$	Triple-Warmer (Sanjiao)	$\downarrow 6.114 \times 10^{+1}$
$\uparrow 2.95 \times 10^{+5}$	Skin Degeneration	$\uparrow 2.25 \times 10^{+5}$
$\downarrow 1.23 \times 10^{+6}$	Small intestine	$\downarrow 1.32 \times 10^{+6}$
$\uparrow 3.45 \times 10^{+6}$	Organ Degeneration	$\uparrow 3.15 \times 10^{+6}$
$\downarrow 7.70 \times 10^{+6}$		$\downarrow 7.30 \times 10^{+6}$
$\uparrow 3.18 \times 10^{+7}$	Fatty Degeneration	$\uparrow 2.80 \times 10^{+7}$
$\downarrow 8.40 \times 10^{+7}$	Allergy	
$\uparrow 1.80 \times 10^{+8}$		

7. Conclusion

The theory of homeopathy has implications for both alternative and orthodox medicine and the chemical and electrical environments. It challenges convenient and comfortable paradigms.

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Declaration of Interests

The writer is a scientific consultant for the Breakspear Medical Group Ltd. and does measurements for them and other medical practitioners.

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November 2009

Memorandum submitted by the Northern Ireland Association of Homeopaths (NIAH) (HO 09)

1. Our submission is based on findings from the Northern Ireland Integrated Medicine Pilot Programme 2007–08.[23] The Pilot Programme was unique in that it was the first of its kind in the United Kingdom to be commissioned by a Minister for Health. It was not a clinical trial per se, but an evaluation of a service in which GPs were able to refer patients for a range of Complementary and Alternative Medical (CAM) treatments, including homeopathic medical treatment.

The Nature of Evidence

2. Evidence from observational studies is highly appropriate for homeopathic medicine as the treatments are individualised and therefore not fully amenable to analysis by, for example, randomised controlled trials. We welcome the acknowledgment by the Chair of the National Institute for Clinical Excellence, Sir Michael Rawlins that greater weight should be accorded to evidence from observational studies of this kind.

[23] Evaluation of a CAM Pilot Project in Northern Ireland (2008) D McDade2008

3. The findings and the recommendations in the evaluation report (executive summary appended) bear out the proposals made by the NIAH in the years prior to the announcement of the Pilot Programme. Since 1999 we briefed successive Ministers of Health and Department of Health officials that the provision of Complementary and Alternative Medical (CAM) therapies such as Homeopathy would produce benefits in:

- Reduction in drugs expenditure
- Alleviation of GP and hospital workload
- Savings accruing from reduced sick leave
- Increased creativity and productivity
- General well-being of society[24]

4. We also proposed that CAM therapies such as Homeopathy would make a significant contribution toward solving the intractable problems in Government healthcare priority areas such as:

- health inequalities
- deprived areas
- effectiveness gaps in conventional medical treatments[25]

5. The Report confirms that CAM treatments including homeopathic treatment delivered significant health gains and cost-efficiencies in all of the above circumstances. The evaluation includes analyses across a range of indicators, all of which bear out the case we presented in our briefings, as follows:

6. Comparison of NIAH Briefing Points and Reported Findings

NIAH Briefing	*Reported findings*
Reduction in drugs expenditure	— Half of GPs reported prescribing less medication and all reported that patients had indicated to them that they needed less — 62% of patients reported suffering from less pain — 55% reported using less painkillers following treatment — Patients using medication reduced from 75% before treatment to 61% after treatment — 44% of those taking medication before treatment had reduced their use afterwards
Alleviation of GP and hospital doctor workload	— 24% of patients who used health services prior to treatment (ie primary and secondary care, accident and emergency) reported using the services less after treatment — 65% of GPs reported seeing the patient less following the CAM referral — Half of GPs said the scheme had reduced their workload and 17% reported a financial saving for their practice — Half of GPs said their patients were using secondary care services less
Reduced sick leave …increased productivity …general wellbeing of society	— "Not only has this project documented significant health gains for patients, but it has also highlighted the potential economic savings likely to accrue from a reduction in patient use of primary and other health care services, a reduction in prescribing levels and reduced absenteeism from work due to ill health."

7. Health Improvements by Therapy

Using the MYMOP protocol—a validated audit tool for measuring patient health gain in general practice:

- Patients receiving acupuncture treatment reported an average 33% improvement in their health and wellbeing.[26]
- Patients receiving chiropractic and osteopathy treatment reported an average 38% improvement in their health and wellbeing.[27]
- Patients receiving homeopathic treatment reported an average 54% improvement in their health and wellbeing.[28]

The clinical assessments of the referring doctors concurred with these figures.

[24] Homeopathy—A Briefing for Healthcare Policymakers in Northern Ireland, NIAH 2000, 2004
[25] Kenneth Mayne, NIAH. Presentation to DHSSPSNI Primary Care Conference, 2006
[26] Measure Yourself Medical Outcome Profile (MYMOP) aggregate score decreased from before treatment 4.76 to 3.18 after treatment
[27] Measure Yourself Medical Outcome Profile (MYMOP) aggregate score decreased from before treatment 4.28 to 2.66 after treatment
[28] Measure Yourself Medical Outcome Profile (MYMOP) aggregate score decreased from before treatment 4.42 to 2.05 after treatment

8. Value for Money and Efficiency

We wish to draw the attention of the Committee to the amount of detail in the evaluation report in respect of wider social and economic context, which is more often than not omitted from such studies. We submit that this provides not only evidence of cost-effectiveness of healthcare investment, but extremely useful information relating to the problems and management of healthcare inequalities and the acknowledged effectiveness gaps in conventional medical treatment, especially of chronic conditions endemic in deprived areas.

9. We are confident that if the homeopathic treatments provided in the Pilot Programme were subjected to full Social Return on Investment analysis, they would produce a high index of return compared to many conventional treatments in the same circumstances. Government wishes to see more proof of value for money and return on future healthcare investment, as reported by the NHS Cross-Regional Social Value Commissioning Project:

10. *Value for money is concerned not just with unit costs, but with what has been called the full value or public benefit that a provider brings to delivering a service. This recognises that every time the public sector spends money, it should do so in a way that achieves as many of its objectives as possible.*

That is, it is concerned with the value a provider creates across a range of outcomes over the longer term with the resources it is given. The draft NHS Constitution states that PCTs "will use (their) resources for the benefit of the whole community". This is where social value concepts have a vital role to play.[29]

11. Conclusions and Recommendations

We respectfully suggest that:

12. In respect of the evidence for homeopathy the Committee considers and accords appropriate weight to evaluations of observational studies such as the Northern Ireland Integrated Medicine Pilot Programme.

13.In evaluation of the effectiveness of medical treatments the Committee takes into consideration the wider social and economic contexts for the treatments and outcomes, particularly in respect of social value and Social Return on Investment analysis.

14. Declaration of Interests

The Northern Ireland Association of Homeopaths is a non-profit group which represents professional homeopaths and homeopathic medicine, and has had representation in the Northern Ireland Department of Health CAM Advisory Group.

Appendix One

15. EXECUTIVE SUMMARY of the Independent Evaluation Report on the Northern Ireland Integrated Medicine Pilot Programme.

16. This report presents the findings from an evaluation of a pilot project which provided patients with access to a range of Complementary and Alternative Medicine (CAM) through their GP practice.

17. Overall 713 patients were referred to the project by their GP. Patients presenting to their health centre with musculo-skeletal and mental health conditions, were referred for a range of CAM therapies including acupuncture, chiropractic, osteopathy, homeopathy, reflexology, aromatherapy and massage.

18. The project was commissioned by the Department of Health, Social Services and Public Safety with a view to exploring the potential for CAM within existing primary care services in Northern Ireland. The project was implemented by Get Well UK in two primary care centres in Northern Ireland: Shantallow Health Centre in Londonderry and The Arches Centre in Belfast.

19. The evaluation, conducted independently by Social & Market Research (SMR), is based on an analysis of project monitoring data provided by Get Well UK; and focus groups and surveys of patients, CAM practitioners and GPs from the two participating health centres.

20. Key Findings: The Patient Experience

Using the various data sources, the evaluation has found a significant level of health gain for the vast majority of patients who have received complementary and alternative medicine as part of the pilot project. This is evidenced by the following:

— Analysis of MYMOP (Measure Yourself Medical Outcome Profile) data, which was generated using a validated health instrument used for measuring patient health gain in general practice, found statistically significant improvements on each of the health outcome indicators measured ie the severity of patient symptoms; the level of patient activity associated with their symptoms; and, overall patient wellbeing (source, MYMOP);

— The proportion of patients reporting that the severity of their symptoms were "as bad as it could be", fell from 31% prior to treatment to 5% following treatment (source, MYMOP);

[29] NHS Cross-Regional SHA Social Value Commissioning Project Bulletin No1 July 2009 p4

— 80% of patients recorded an improvement in the severity of their main symptom, with 73% recording an improvement in their level of activity associated with their main symptom (source, MYMOP);

— 67% of patients recorded an improvement in their wellbeing (source, MYMOP);

— 81% of patients said that their general health had improved, with a similarly high proportion of patients (82%) reporting to be less worried about their symptoms following treatment (source, MYMOP);

— 81% of patients reported an improvement in their physical health, with 79% reporting an improvement in their mental health (source, patient survey);

— 84% of patients directly linked the CAM treatments to an improvement in their overall wellbeing (source, patient survey);

— 62% of patients were suffering less pain, with 60% having more control over pain (source, patient survey);

— There was a 14 percentage point reduction in the proportion of patients using medication between the pre and post-treatment stages (ie down from 75% to 61%) (source, project monitoring data);

— 44% of patients who were taking medication prior to their treatment, had reduced their use of medication (source, patient survey);

— Among patients using pain killers prior to treatment, 55% said that they use fewer pain killers following treatment (source, patient survey);

— In the majority of patient cases, CAM practitioners reported an improvement in: patient quality of life; relief of presenting symptoms; relief of chronic conditions; increased mobility; increased emotional stability; and, a reduction in patient worry (source, project monitoring data);

— 24% of patients who used other health services prior to treatment (eg other primary care services, secondary care services and Accident and Emergency), said they now use these services less often (source, patient survey);

— 64% of patients in employment said that following treatment they now take less time off work. Among patients not in employment, 16% said that having the CAM treatments had encouraged them to think about going back into employment (source, patient survey);

— 94% of patients would recommend CAM to other patients with similar health conditions (source, patient survey);

— 89% of patients expressed an interest in continuing with CAM, with just 30% saying they would be able to afford to continue with CAM treatments (source, patient survey);

— Patients were supportive of CAM being integrated into primary health care, with a call for increased public awareness of the potential of CAM for health gain (source, patient focus groups);

— Patients identified a need for CAM to be promoted among GPs in Northern Ireland, and for initiatives to be taken to help reduce the level of scepticism held by some GPs towards CAM (source, patient focus groups);

21. Key Findings: The GP Experience

— In 65% of patient cases, GPs documented a health improvement, with a high degree of correlation between GP and patient assessment of health improvement (source, project monitoring data);

— In 65% of patient cases, GPs said they had seen the patient less often following the patient's referral to CAM (source, project monitoring data);

— Improving patient health was found to be the main motivation for GPs getting involved in the pilot project (source, GP survey and focus groups);

— Most GPs said that their understanding and knowledge of CAM had improved by participating in the pilot project, with most conceding that their knowledge was limited at the initial stages. Some GPs had experienced difficulty initially in matching their patients with appropriate therapies, with most of the GPs supporting the need for further educational interventions such as seminars, talks with practitioners and having more written information on CAM (source, GP survey and focus groups);

— Half of GPs reported prescribing less medication for chronic or acute patients (source, GP survey);

— Half of GPs reported that the option to refer their patients to CAM had reduced their workload, with two GPs pointing to a financial saving for their practice. All but one of the GPs had seen the project as a positive development for their practice, with all agreeing that it provided them with more referral options (source, GP survey);

— Most GPs reported that their patients were using Allied Health Professionals less often, with half saying that their patients were using secondary care services less often (source, GP survey);

— Ten out of the 12 GPs surveyed had a more positive view of the potential for CAM within primary care, with all wishing to continue with the option of referring their patients to CAM (source, GP survey);

— In 99% of patient cases, the GP said that they would be willing to refer the same patient, or another patient, to the Get Well UK service. Also in 98% of patient cases, the GP said they would be willing to recommend the service to another GP (source, project monitoring data);

22. Key Findings: The CAM Practitioner Experience

— CAM practitioners reported a health improvement in 77% of their patients on average, with health gains including: pain relief; improved quality of life;

— improved mobility, stress relief and improved emotional wellbeing (source, practitioner survey);

— CAM practitioners identified a need for a series of educational interventions targeted at GPs to improve their understanding of CAM and to better support them with matching health conditions with appropriate therapies (source, practitioner survey and focus groups);

— CAM practitioners called for GPs to supply more information on patient medical condition as part of the referral process (source, practitioner survey and focus groups);

— CAM practitioners identified a tendency for GPs to refer patients with chronic medical conditions to the project, with practitioners concerned that the therapies may not be as responsive to this type of patient compared to, for example, patients with acute medical conditions (source, practitioner survey and focus groups);

— Affordability was identified as the main barrier for patients wishing to continue with CAM (source, practitioner survey and focus groups);

— All CAM practitioners supported the integration of CAM within primary health care, with patient health gain cited as the key benefit (source, practitioner survey and focus groups);

— CAM practitioners reported a more positive attitude to CAM among GPs who had participated in the project, with ongoing contact and communication between GPs and CAM practitioners identified as a key requisite if CAM is to be rolled out more extensively across Northern Ireland (source, practitioner survey and focus groups);

23. Recommendations

(i) Given the evidence of health gain documented by patients, GPs and CAM practitioners, it is recommended that DHSSPS and the project partners explore the potential for making CAM more widely available to patients across Northern Ireland. Not only has this project documented significant health gains for patients, but it has also highlighted the potential economic savings likely to accrue from a reduction in patient use of primary and other health care services, a reduction in prescribing levels and reduced absenteeism from work due to ill health.

(ii) This pilot project has clearly demonstrated that CAM fits well within a primary health care context, with patients valuing the support and judgment of their GPs in accessing treatments. It is recommended that DHSSPS and the project partners examine ways of integrating CAM within primary care, taking on board the need for a strategy to promote GP knowledge and understanding of CAM to ensure that health conditions are matched appropriately with CAM therapies. A strategy to promote awareness and understanding of CAM among GPs, as well as the positive health gains for patients, should also go some way to addressing issues around scepticism held by some GPs.

(iii) To further assist the process of integrating CAM with primary health care, it is recommended that consideration be given to exploring the potential for sharing medical records with CAM practitioners. Furthermore, consideration should be given to exploring the potential for CAM practitioners to be involved in clinical meetings and case conferences, which may provide patients, particularly those with chronic health problems, with more treatment options. This may also lead to significant cost savings for the health service.

(iv) The project has highlighted a number of areas where the operation of a CAM service can be further improved. In particular, it is recommended that DHSSPS and the project partners explore ways of ensuring that patients are provided with accurate and up to date information at all points of the referral process, as well as at the point of receiving treatments. In addition, the evaluation has found that patients may benefit from a "triage" system to ensure appropriate matching of health conditions and CAM treatments;

(v) Given that the pilot project has raised expectations among patients, DHSSPS and its partners should consider a mechanism for ensuring that patients who presented with long-term illnesses, and in particular those who experience pain, be offered booster or maintenance sessions beyond the life of the project.

(vi) Given the limited number of CAM practitioners in Northern Ireland, and the difficulties in identifying practitioners to participate in the pilot project, it is recommended that DHSSPS and the project partners consider ways of retaining this resource within a model for wider service delivery.

(vii) Given that the health outcomes for patients have been significant, it is recommended that DHSSPS and the project partners consider the development of a public health information campaign aimed at promoting the potential benefits of CAM. Allied to this point, it is recommended that DHSSPS and its partners examine the role of CAM in supporting health prevention and health promotion strategies, given the evidence that patients are likely to adhere strongly to the advice provided by CAM practitioners.

(viii) The evaluation has documented the positive impact of CAM on patients who are economically active, particularly in the context of helping people back into work following illness. It is recommended that the outcomes from this project be shared with colleagues in other departments (eg Department for Employment and Learning), to allow them to examine the potential for CAM within their own operational areas.,

(ix) Given that the evaluation outcomes are based on the perception of the various stakeholder groups (ie patients, CAM practitioners and GPs), it is recommended that DHSSPS and the project partners give consideration to integrating other approaches to measuring health impact (eg a formal case control study) on an ongoing basis.

November 2009

Supplementary memorandum submitted by Northern Ireland Association of Homeopaths (HO 9a)

We wish to draw your attention to an error in the oral evidence given to the Science and Technology Committee by Mr Mike O'Brien MP, Minister for Health Services, on 30 November 2009.

In response to Q174, Mr O'Brien said *"…There was also some research done in Northern Ireland in an examination of the effect of a number of complementary and alternative medicines not including homeopathy."*

Presumably the research to which Mr O'Brian was referring was the Complementary and Alternative Medicines Pilot Project, run by the Northern Ireland Department of Health during 2007–08, which was a direct result of a campaign by our organisation.

As you will see from the written evidence we have submitted to the Committee, Homeopathy was absolutely central to this successful project, and was found by the auditors to be rather more effective than other therapies across a range of chronic health problems.

Kenneth Mayne RSHom
Chair

December 2009

Memorandum submitted by Les Rose (HO 10)

1. Licensing

1.1 *The National Rules Scheme*

This allows homeopathic products to bear therapeutic indications, and is not based on any evidence at all. The MHRA consultation which preceded the new legislation, MLX312, openly admitted that "homeopathic products have difficulty in demonstrating efficacy in clinical trials". As the MHRA rightly insists on clinical trial evidence for orthodox drugs, this was the clearest admission that the MHRA knew homeopathic products to be ineffective. One reason that the MHRA gave for forcing though the rules was that to do nothing would have inhibited the expansion of the homeopathic industry. It is not at all clear as to why this was important to the MHRA, or why it was in the public interest to be offered an increasing number of ineffective products—and to be lied to about their lack of effect. However the MHRA is not funded by taxation but by fees, and it is certain that not issuing new licences would have cut off an income stream.

1.2 *Double Standards*

The MHRA's report on the MLX312 consultation minimised opposition and emphasised support from industry. Yet the new legislation does not comply with classical homeopathic teaching, which is that treatment must be individualised. The labelling regulations cater for pre-packaged products available in retailers such as (and especially) Boots, which are of course not individualised. There can be absolutely no possibility of the careful recording of history and symptoms which are the homeopath's stock in trade. Yet the homeopathy companies supported the regulations enthusiastically. This shows the level of duplicity endemic in the practice of homeopathy.

Curiously, the first product to receive a licence under the new rules was homeopathic arnica, which has most recently been tested in clinical trials and found to be ineffective. Also, it violates the "like cures like" principle of homeopathy, so makes no sense even under the bizarre requirements of the new rules.

2. Funding

2.1 *Cash Costs*

I have submitted a separate report on primary care trust funding trends. There are however other costs of homeopathy. For example, central government paid some £20 million for the refurbishment of the Royal London Homeopathic Hospital. The business case for this project said nothing at all about the clinical outcomes that would result from this expenditure.

2.2 *Potential Cost Savings*

The actual amount of money spent on homeopathy is a small part of the NHS budget. But it has the effect of undermining the effort to make evidence based practice (EBP) the norm. Critics of orthodox medicine state that a large proportion of it is not evidence based. This is not true to the extent claimed, but apart from falling victim to the *tu quoque* fallacy, it misses the point. The NHS could make very large savings by progressing more rapidly towards full EBP. There would be no better demonstration of such a commitment than to close its homeopathic hospitals as soon as possible.

Yet it is astonishing to see that the NHS seems determined to repudiate EBP. It has just been announced that the pilot patient budgets scheme will allow the money to be spent on complementary medicine, including homeopathy. If the idea of this scheme was to put patients in control of their health, what message does this transmit? Here was an opportunity to educate patients about cost-effectiveness, but instead they are put in charge of wasting public money. Patients will therefore demand the right to spend their budgets on whatever they like. There is a virtually endless choice of medical fads and fashions to feed that demand.

3. Evidence

3.1 *The Quality of Evidence*

It is important to focus on the best quality evidence. Randomised controlled trials (RCTs) provide the most rigorous test of a therapeutic claim. Homeopaths either denigrate RCTs as inappropriate for their speciality, or select poor quality RCTs that spuriously show positive results. They also cite uncontrolled observational studies which are no more than customer satisfaction surveys. It is true that a broad and inclusive approach needs to be taken to clinical evidence. Thus pragmatic trials and observational studies are part of the mix. But it is a serious mistake to rely on these and to dismiss RCTs. Evidence based medicine is one of the greatest achievements of science. It has the RCT at its core. RCT evidence has overturned many accepted practices, often by showing them to be harmful, and commonly by showing them to be ineffective.

3.2 *Spurious Evidence*

Homeopaths claim that substances diluted beyond Avogadro's number have specific therapeutic effects. RCTs, especially when assembled into meta-analyses and systematic reviews, clearly show that this is not true. Some homeopaths argue that specific and non-specific effects cannot be separated (as do some sociologists). These arguments try to recruit support from unrelated fields such as quantum mechanics. For example, long papers have been written on "patient-practitioner entanglement". No experimental or observational evidence has been offered to support these ideas. They are no more than a smokescreen to hide the fact that specific effects of homeopathic dilutions do not exist.

3.3 *The Ethical Dilemma*

There is a serious ethical problem if treatments that are effectively placebos are to be offered to patients. Doctors are required by the terms of their registration to give treatments that they reasonably expect to be effective. By any scientific test, homeopathic products are ineffective, placing them outside EBP. Also, doctors have to obtain informed consent for treatment. Therefore to prescribe homeopathy doctors must inform patients that they are giving them a placebo. They must convey to patients what the scientific evidence is. This is a principle that is extremely poorly enforced by the GMC and the medical Royal Colleges. The various professional bodies for homeopaths ignore EBP altogether, as does the voluntary regulation scheme launched by the Complementary and Natural Healthcare Council. This is dishonest, and demeaning for patients. If patient choice is to mean anything, it must be informed choice.

Declaration of Interests

I am a freelance clinical science consultant with over 30 years of experience in clinical research. I do voluntary work for two charities, Sense About Science and HealthWatch, in support of evidence based medicine. I do not receive any payments, in cash or in kind, for these activities. Most of my professional clients are pharmaceutical companies, but they have no connections with this voluntary work.

Les Rose BSc CBiol FSB FICR MAPM

November 2009

Memorandum submitted by Dr Andy Lewis (HO 11)

Government Policy on Licensing of Homeopathic Products

1. Currently, the licensing of homeopathic products is not made on the basis of evidence. This is in stark contrast to how other medicinal products are licensed in this country. Indeed, it would only be possible to give MHRA licences to homeopathic products if the requirement of evidence of efficacy were dropped as these products are not medicinal products but pseudomedical products based on magical thinking and pre-scientific ideas.

2. The MHRA allow sellers to submit evidence from homeopathic "provings" as evidence. A proving is where a homeopath takes a new type of homeopathic pill to see what symptoms it generates. Homeopaths believe "like cures like", so an onion, which makes your eyes stream, can cure hayfever—allegedly. However, homeopathic pills have been so diluted that no ingredients actually remain. What homeopaths "prove" is plain sugar pills—any symptoms they note are either coincidental or imaginary. There is no good evidence to suggest that homeopathic proving are a reliable means of generating a homeopathic "symptom picture". The largest ever controlled homeopathic proving showed that there were no observable effects.[30] This is consistent with proving being nonsense and MHRA rules relying on nonsense methods to show efficacy.

3. Despite the regulations, many homeopathic pharmacists continue to sell homeopathic pills with specific indications without a license. To test this, last year, visited London's Nelson's Homeopathic Pharmacy just off Oxford Street. I went in and said I needed something for an upset stomach and that I had diarrhoea. "Do you have anything like Imodium?" I was told that the stuff they had would not just "suppress my symptoms"

4. I was given a tub of pills with the following label:

TRAVELLER'S DIARRHOEA
RELIEVES SYMPTOMS OF DIARRHOEA & VOMITING DUE TO CONSUMPTION OF UNWASHED FRUITS, VEGETABLES, BAD MEAT OR FISH. DOSAGE. TAKE 2 TABLETS EVERY HOUR UNTIL BETTER
ARSENICUM 30/PODOPHYLUM 30/PYROGEN 6/CARBO VEG 30/NUX VOMICA 30
EXP 12/12 KEEP OUT OF CHILDRENS REACH
NELSON'S HOMEOPATHIC PHARMACY
73 DUKE STREET, LONDON W1K 5BY 020 7629 3118 P

5. On 28 March 2008, I submitted an enquiry to the MHRA suggesting that this might be an illegal product as it had no marketing authorisation. On 14 April 2008 I was told that the case had been passed onto the MHRA's Enforcement and Intelligence Group. I finally got a reply some 17 months later to tell me that "The outcome of the investigation is that following advice from the Enforcement Unit, Nelson's have removed the product you mentioned from their display shelves."

6. To date, the product is still available for sale[31] on the Nelson's web site along with many other similar products with specific indications. You can also see other similar products that are intended to cure constipation, accident & injury, allergic reactions, bites & stings, hangover & indigestion, heat exhaustion, jet lag, and sun exposure. All are similarly ineffective.

7. Whilst these conditions may be relatively minor, other homeopathic pharmacies sell remedies for much more serious conditions. Neal's Yard Remedies were selling sugar pills to customers and telling them that these could prevent malaria. The BBC undertook an investigation and interviewed their "Medicines" Director, who stormed out of the meeting after being asked if this was ethical and legal.[32] After the BBC forwarded on their evidence, the MHRA investigated and merely slapped their wrists. This is despite the fact that this product has the potential to kill if taken in the place of a real malaria prophylactic.

8. It would appear that the MHRA take a very light touch and piecemeal approach to investigating this widespread abuse of the regulatory system.

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[30] Ultramolecular homeopathy has no observable clinical effects. A randomized, double-blind, placebo-controlled proving trial of Belladonna 30C. Brien S, Lewith G, Bryant T. Br J Clin Pharmacol. 2003 November;56(5):562–8.
[31] http://www.nelsonshomeopathy.com/shop-online/The-Nelsons-Travellers-Companion_prod1731.aspx
[32] http://news.bbc.co.uk/1/hi/england/devon/7385718.stm

Examples of other products are: Migraine Headaches (Helps with migraine symptoms.) http://www.nelsonshomeopathy.com/shop-online/Migraine-Headaches_prod1628.aspx

- Morning Sickness Relief (To help relieve symptoms of morning sickness….) http://www.nelsonshomeopathy.com/shop-online/Morning-Sickness-Relief_prod1629.aspx
- PMT (To help relieve symptoms of premenstrual tension.) http://www.nelsonshomeopathy.com/shop-online/P.M.T._prod1634.aspx
- Sore Throat (To help relieve symptoms of sore throat) http://www.nelsonshomeopathy.com/shop-online/Sore-Throat_prod1639.aspx
- The Nelsons Quit Smoking Kit http://www.nelsonshomeopathy.com/shop-online/The-Nelsons-Quit-Smoking-Kit_prod1664.aspx

9. Homeopathic pharmacies are full of products with direct and implied claims. In order to understand the extent of the problem it is necessary to understand mainstream homeopathic beliefs. The pharmacies are stocked with products that are often derived directly from diseased tissues, vaccines and infectious samples. These are designed to treat or prevent the diseases they are derived from. Visiting a homeopathic pharmacy web site will show many products with implied indications.[33] These are often in the form of what homeopaths call *nosodes* where some diseases tissue or some other "infectious" agent is taken and serially diluted and shaken and probably banged against a leather bible many times to create the homeopathic pill. The remedy lists of Ainsworths show products for each Influenza strain going back 20 years. You will find homeopathic replacements for Measles vaccine, Parotitis vaccine (mumps) and Rubella. You find homeopathic sugar pills for all forms of Hepatitis, strains of TB, and Typhoid, as well as the usual comedy remedies such as shipwreck, trout and Ayres rock.

10. These products are making implicit claims to be alternatives to real vaccines. They would appear to be all unlicensed remedies.

11. In my opinion, it is a mistake to regulate homeopath products as if they were medicines, with or without different levels of evidence for efficacy. Homeopathy is not a medicine. It is a pseudo-medicine with believers who belong to more of a cult than a profession. It is a disgrace that these products can appear on the same shelf-space as real medicinal products with misleading claims ratified by the MHRA. Claims made or implied by homeopaths should be subject to Trading Standards laws rather than given the false legitimacy of MHRA approval.

12. It is wrong to allow this to continue on the basis of consumer "choice". Choice can only be meaningfully be exercised when it is informed. In buying medicines, we so often have to defer to experts—we cannot always check all claims all the time—we are all "vulnerable" consumers in this context. The MHRA has an overriding duty to ensure it is not helping to mislead consumers when they are making their choices about medicines.

The Evidence Base on Homeopathic Products and Services.

13. It is absurd to continue to question the evidence base of homeopathy. The question was settled in the 1830's. It is only homeopaths who continue to believe that there is something special going on in their pills. If homeopathy had not been invented around 1800 but turned up today, would be seriously be considering funding this with millions of pounds in the NHS? The concept would appear absurd and the work of fevered imaginations. It is mere familiarity of this delusion that stops us taking this approach now.

14. Homeopaths continue to press that there is an evidence base. This is usually based on the following fallacies:

(a) A "wealth" of positive evidence. Of course, it is possible to make a case for any absurd proposition if you only present positive evidence. Clinical research can very often create false positive results by chance, poor study design or fraud. In order, to evaluate a proposition, all evidence must be taken into account—positive, negative and neutral. Homeopathy does not stand up to such scrutiny.

(b) Selective quoting of review conclusions. Many systematic reviews have show the weakness of the evidence base. However, within such reviews there have been some hints of positive results. It is now thought that such hints are the result of poor input studies—garbage in, garbage out. As the years have gone by, the reviews have become more sophisticated and clearly shown that studies with better methodologies and larger numbers of participants fail to show positive effects for homeopathy. Shang (2005) is the most definitive here.[34]
Homeopaths have attempted to discredit Shang. They have failed. They assert that Shang would have come to different conclusions if different studies or different criteria were included. This is self evident and irrelevant. Shang could be discredited if homeopaths could show a quality reanalysis that came to a conclusion opposite to that given—they have not been able to do so.

[33] http://www.ainsworths.com/site/combination.aspx
[34] Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. Lancet. 2005 August 27–September 2;366(9487):726–32.

(c) Claims of success in distant lands and distant times. Very often claims exist that homeopathy cured the 1918 flu epidemic or is used successfully in Cuba. These are anecdotal stories with no hard evidence to back them up.

(d) Claims of physical experiments that show genuine effects of the "memory of water". None of these experiments have been taken seriously and have not been authoritatively replicated.

(e) Claims that quantum mechanics hold the answer. A few academics have fiddled with the language of quantum theory and tortured it into the world of magic medicine. It is muddled and unconvincing and the authors involved appear to have a very poor grasp of the quantum theory.

Declaration of Interests

I am a writer about quackery on the web site quackometer.net. It is a hobby. I have no financial interest matters relating to medicine or pseudomedicine.

November 2009

Memorandum submitted by Jean Kinchen (HO 13)

YES, YES, YES to HOMEOPATHY

29 years ago two of our daughters were cured by homeopathic treatment when after four years orthodox treatment just wasn't working. The eldest, with a physical problem—tenosynovitis with eight pills—one a week for eight weeks, the younger, a mental upset—severe depression after flu—three pills one of the flu remedies, and she was back to school by the end of the week.

We were convinced. And our members have found homeopathy an effective and valuable method of healing without any side effects.

Jean Kinchen, Hon Sec Norwich Homeopathic Group

November 2009

Memorandum submitted by Professor Harald Walach and Professor George Lewith (HO 14)

HOMEOPATHIC PATHOGENETIC TRIALS—A SUMMARY OF 20 YEARS OF REFLECTION, DATA COLLECTION AND ANALYSIS

1. Introduction

1.1 Homeopathic Pathogenetic Trials (HPTs), or, as they used to be called, homeopathic remedy provings, are the pillar of homeopathy.[1] Given their scientific importance, we submit this document to the Commons Science & Technology Committee in its Evidence Check of Homeopathy.

1.2 Hahnemann founded homeopathy on the basis of his own experience by ingesting China bark;[2,3] these were the first HPTs proper. The Hahnemannian version of an HPT is the following idea: Take a purportedly medicinal substance whose therapeutic or pharmacological effect you do not know. Have some healthy volunteers ingest it in a dose that is likely not harmful. Note down the symptoms these volunteers experience. Use the symptoms to guide your application in ill people: whenever ill people present with a collection of symptoms that could be seen in healthy volunteers, use the same substance to treat the ill person. Thus, the HPT is in fact an operationalisation of the similia rule. In order to know what the similar symptoms are that should be looked out for, you need to know them in the first place. An HPT provides you with this knowledge.

1.3 A large part of the Materia Medica Pura is actually a result of these early provings. Later on he discovered a good way of diminishing the strong symptoms by diluting his medications, serendipidously hitting at succussion and potentisation, the other important principle of homeopathy. In his final edition of the Organon, he made 30CH[35] the standard potency for HPTs. This seems to be a practice adhered to for quite some time.[4,5] In fact, a lot of the standard polychrest medicines in use by homeopaths today date back to Hahnemann's own HPTs. They have not gone unchallenged,[6–11] but pragmatically seem to be still useful.

1.4 Although the first blinded and placebo controlled trials in the history of medicine were such early HPTs,[12–14] the circular epistemology of homeopathy placed less emphasis on the methodological rigour of HPTs than on the usefulness of the symptoms derived from them. It was only in more recent years, during the revival of homeopathy research in the seventies and eighties in Germany and elsewhere that the question was asked, whether symptoms derived by such HPTs or provings are actually different from the placebo. A recent systematic review of all HPTs available from 1945 until 1995—156 studies altogether—is not very flattering regarding the methodological sophistication of HPTs.[15,16]

[35] ie a potency that has been diluted 30 times in the ratio 1:100 (hence "C" for centum—hundred) in separate glass vials (hence "H" for "Hahnemann").

2. The Naïve Approach

2.1 *Testing the Individualised Difference Hypothesis: Randomised Single Case Studies*

2.1.1 Walach *et al* had participants take Belladonna 12/30CH or placebo in a randomised order, double blind. Randomising the sequence of Belladonna and placebo periods, four weeks each, where only the first day of each week was a day when a remedy was to be taken. Participants noted their symptoms in diaries that collected a predefined set of symptoms, half of which were Belladonna symptoms, the other half symptoms not typical for Belladonna. This enabled straightforward randomisation tests that allow the definition of statistical significance on an individual level to determine whether the number of Belladonna symptoms was different with Belladonna from placebo. Quite paradoxical results were reported.[17,18] Of the 25 experiments, one individual had significantly ($p = 0.01$) more Belladonna symptoms with Belladonna, one had significantly more Belladonna symptoms with placebo, and in several cases there were interesting changes with Belladonna that were graphically obvious but that were not significant.

2.2 *Replicating the Naïve Approach*

2.2.1 In the meantime Walach *et al* ran a larger replication study using a similar design as in the first Belladonna study, improved by several design features:[19] they had more participants ($n = 87$), we introduced a wash-out period of one week between the experimental phases of the crossover-design and reduced the intake of medication or placebo to two weeks each, gave medication only during the first three days of the first week and then had people observe for the rest of the two weeks. They used the same structured diary and, based on our previous study, formulated some hypotheses that guided us towards combining symptom categories to clusters to be tested experimentally. Although there was a clear and significant difference between baseline and each of the experimental interventions in some of the variables, there was no significant difference between homeopathy and placebo in those predefined categories. Thus, the initial tentative results were not replicable, and there was no indication from this study that symptoms produced by placebo and those produced by Belladonna 30CH were in any way different from each other.[20]

3. Scrutinising the Data More Carefully using Grade-of-Membership Analysis

3.1 Intrigued by the phenomenology of the results Walach thought that something different was actually going on in the background variability in both groups. The problem was that there were not only *any* symptoms that were indistinguishable under both conditions, but that *Belladonna-specific* symptoms were seen to a large extent also with placebo. That was the scientific puzzle. Having ruled out methodological artifacts, such as carryover effects or response bias, we were quite convinced that this was a genuine effect. To probe this further Walach employed a very sensitive multivariate method: Grade-of-Membership (GoM) Analysis on the dataset of the 2001 study.[21]

3.2 In essence GoM analysis is a multivariate model.[22,23] While most multivariate analysis models, such as the General Linear Model, use additive models, GoM uses a multiplicative algorithm solved by an iterative maximum-likelihood approximation. This allows for the multivariate usage of many variables even with few cases and it is very sensitive. Normally, we think of group membership as a categorical event: we either cast a vote for a candidate, or we don't; we either belong to a group, or we don't. GoM allows us to group people according to a grading, a kind of probability judgment of belonging to a group, expressed in percent. So a particular person might belong to an experimental group to some degree of probability, and also, to a lesser degree of probability, to another group. More importantly, the analysis also defines the relevance of the variables that are used to reach the decision.

Using GoM, Walach identified to which extent each individual belonged to the Belladonna and to the placebo condition and which variables predicted this group membership, analysing the first and second half of the crossover design separately. The results are revealing (Table 1):

3.3 Table 1—Results of a Grade of Membership Analysis of the Data from the Replication Belladonna HPT:[19,21] Variables used to Predict Membership of Participants to Groups in Phase 1 or Phase 2 of the Crossover Study, and Likelihood of Group Membership Predicted by a Variable

Category	*Homeop. Phase 1*	*Homeop. Phase 2*	*Placebo Phase 1*	*Placebo Phase 2*
forehead right	12.6	2.4	9.2	11.8
nose	60.6	5.1	6.6	29.8
mouth	43.7	11.7	6.2	8.7
skull back right	3.47	0	0	8.15
whole throat	56.2	16.6	4.9	8.0
shoulder right	–	8.28	–	0.0
genitals	57	28.8	14	7.5
small of back	22.8	12.2	0.0	0.0
whole body	57.8	28.9	13.2	13.3
feelings, mind	100	72.8	29.4	57.2
always	100	56.6	40	40.9

Category	*Homeop. Phase 1*	*Homeop. Phase 2*	*Placebo Phase 1*	*Placebo Phase 2*
afternoon	100	41.2	6.3	31.7
pain	100	55.8	27.8	54.4

3.4 This is the output of the analysis using only the most important variables to predict group membership. The first column indicates the variable used, the following two columns show the prediction of membership (expressed as percentage) in the first and the second phase of the trial, when homeopathy (Belladonna C30) is taken, the last two columns when placebo is taken. It is interesting to compare the percentages of membership prediction for columns Homeopathy phase 1 and Placebo phase 1, and then the same for phase 2. Ideally, if separation of the groups were perfect, the two homeopathy columns should be relatively similar to each other and very different from two placebo columns. They are not. So we see symptoms that define membership in the Belladonna condition (symptoms of the nose, for instance, 60% membership association with Belladonna in phase 1) that are virtually reduced to unimportance in phase 2 (only 5%), and the other way round. More importantly some of the symptoms are quite typical for Belladonna (symptoms of the throat, for instance, or symptoms starting in the afternoon). It seems that some symptoms typical for Belladonna have emerged during the HPT. So the problem really is that the typical symptom pattern is shifting to placebo, at least partially, during the second half of the trial. Although only exploratory it highlights the phenomenology of HPTs with a very sensitive quantitative pattern-recognition technique. Most recently, a careful German re-proving of Galphimia glauca has produced exactly this result.[24]

3.5 The tentative conclusion from this re-analysis was that obviously homeopathic remedies do produce some specific symptoms but they also produce these specific symptoms under placebo. Is it due to the shortcomings of our method, or is the phenomenon real? Walach had started working on the assumption that the effects of homeopathy are due to what we have called generalised entanglement[25] and which I have used to render a rational reconstruction of a non-classical model of homeopathy.[26] By that we mean that the effects of homeopathy may be specific, but they are due to non-local correlations as a consequence of the systemic set-up of homeopathy and the treatment situation. This is a consequence of how the whole system is formally constructed. A corollary of this model is that it would predict some specific symptoms also in the control group and that, with repeated experimentation, the specificity is bound to vanish.[27]

3.6 This sets up a conundrum: How are we to prove experimentally that homeopathic remedies are producing specific symptoms if, by the very experimental set-up, we are likely to destroy this effect?

4. Exploring New Roads

4.1 *A New HPT Model*

4.1.1 Walach *et al* developed a completely new approach out of the experiences of the previous trials[28] and decided to use a different HPT methodology. The methodological reasoning is the following:

(a) A full phenomenological account of all experiences should enter the database. All participants are encouraged to report every occurrence that is unusual for them in a diary. To enhance the recall of such events, a supervision interview is conducted every day either by phone or personal interview by a supervisor.

(b) As controls we introduce blinding and randomisation. Hence none of the participants knows what remedy is being used, nor whether they are randomised to receiving placebo or real substance.

(c) In order to exclude any effects of suggestion and social desirability, the substance is chosen out of a predefined list by a third party at random, blinding also the director of the study and all staff associated with handling data. This ensures an unbiased experience and processing of symptoms as much as possible.

(d) Medication is taken individually, until symptoms appear. If no symptoms appear after three days, the intake is stopped and the individual taken out of the study.

(e) If the symptom database has been created and is closed, all symptoms are scrambled up, dissociated from their temporal and individual ordering by putting them into the head-to-foot-scheme familiar from homeopathic repertories, in symptom units that correspond to these rubrics.

(f) The database is then given to a materia medica expert not otherwise associated with the study. This expert does not have access to the randomisation code but is given the name of the remedy tested. At this stage, this person and the pharmacist who chose the remedy are the only ones privy to this information.

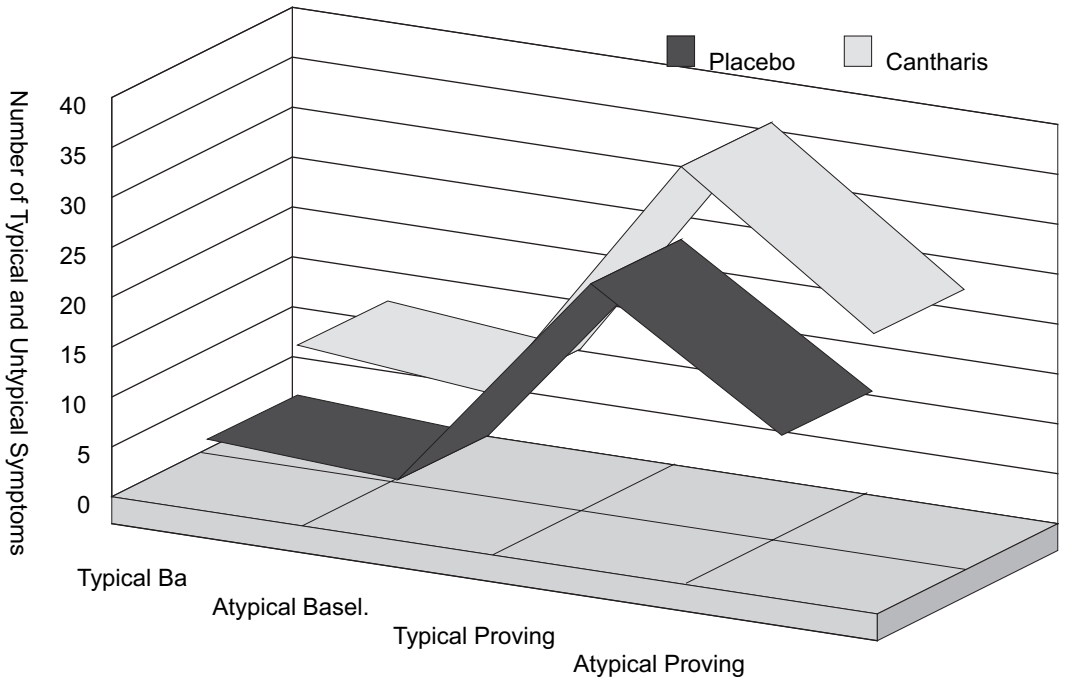
(g) The expert then uses a computerised repertory to decide, for every symptom, whether it is a symptom typical for the remedy according to the sources, or not. Thus, the remedy typical symptoms are counted as "1", the atypical symptoms as "0".

(h) The database is transformed back into the group system. For every participant we count the number of symptoms typical for the remedy and the number of atypical symptoms, averaging across the experimental and control group. This gives a clear testable quantitative outcome score that can be easily tested.

4.2 *Pilot Studies Using the New Methodology*

4.2.1 Walach *et al* then completed four studies following this model. The first two studies were pilot studies.[29,30] In one study Cantharis (chosen randomly from a list of 12 lesser remedies) was evaluated against placebo, in the other Calendula, Ferrum muriaticum (also chosen randomly from a list) and placebo in a three-armed design. In the first study there were more symptoms typical for Cantharis in the Cantharis group than in the placebo group during and less atypical symptoms, but there were also more symptoms typical for Cantharis in the placebo group, which was unexpected (Figure 1).

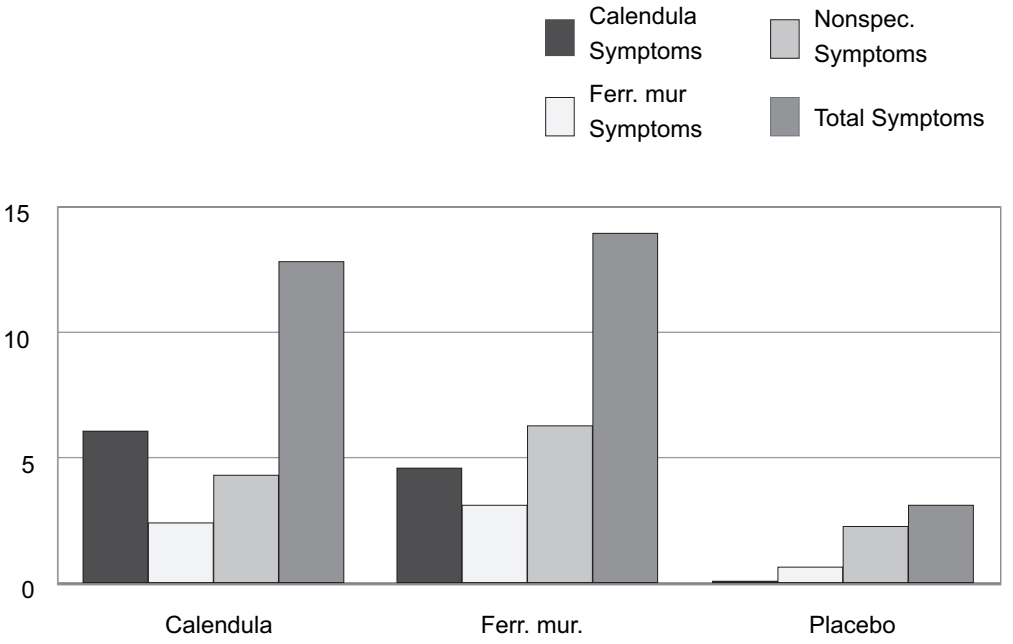
4.2.2 Figure 1—Results of the Cantharis Proving:[30] Symptoms Typical for Cantharis and Atypical Symptoms During Baseline and During the Proving Period, for the Cantharis and the Placebo Group



4.2.3 Although the effect was not significant in this pilot it was quite sizeable (d = 0.4). When the group were randomised to receive homeopathic Cantharis but were dosed with it later there were also more symptoms typical for Cantharis. This effect size was very large—d = 1.0. Ideally, one would have double or triple-evaluation of the same database and only use symptoms that all agree on for calculating inter-rater reliability. This process mirrors faithfully normal practice where one homeopath translates symptoms into remedy pictures.

4.2.4 In the three-armed study[29] we found a similar and quite puzzling result. Here the total number of symptoms experienced during the proving phase in the experimental groups was significantly different between the experimental and the placebo control group, as were the number of Calendula symptoms in the Calendula group (Figure 2) with a large effect size of d = 2.8.

4.2.5 Figure 2—Three-Armed HPT of Calendula vs. Ferrum muriaticum vs. Placebo (n = 7 participants in each group): Mean Number of Symptoms Typical for Calendula, Ferrum muriaticum or Atypical Symptoms in each Group.[29]

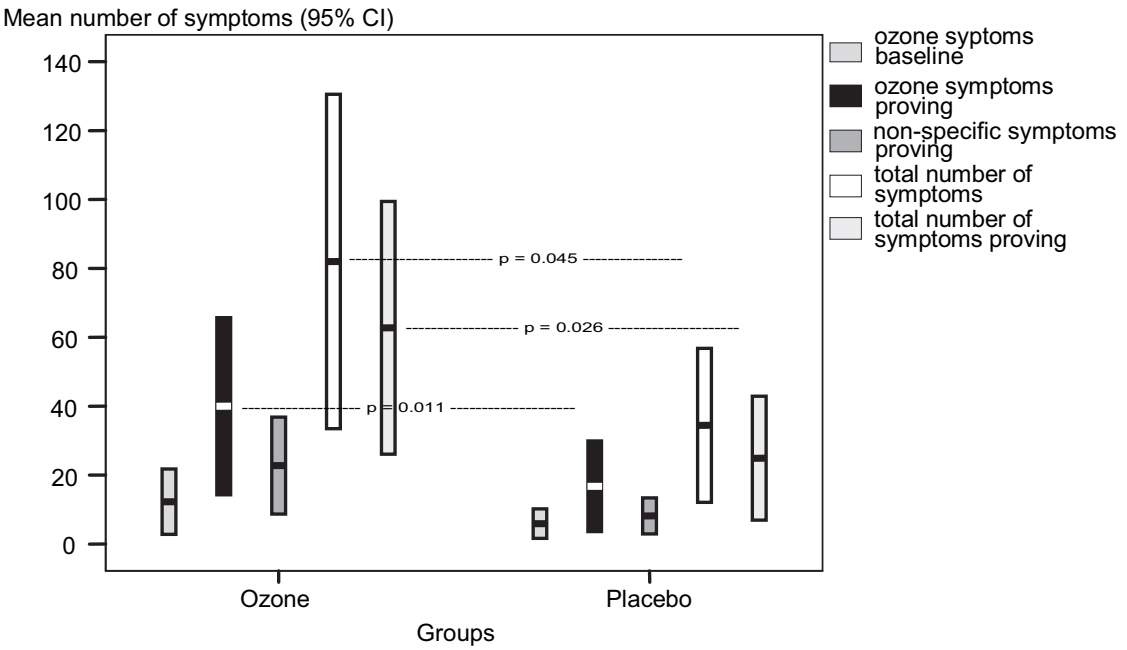


4.2.6 What can also be seen is that significantly more Calendula symptoms were experienced by participants who had taken Ferr. mur. compared with those taking placebo (effect size d = 1.75), and that a sizeable number of Ferr. mur. symptoms were also observed in the Calendula group. While this effect might also be due to the fact that Ferrum muriaticum is a little known substance and hence difficult to identify, the observation that Calendula symptoms were more frequent in the Ferrum mur group is difficult to reconcile with the assumption that these effects are artifacts.

4.3 *Two Parallel Replication Studies*

4.3.1 Following on from these observations Walach et al conducted a study with two arms, placebo vs. homeopathy, another one with three arms, comparing placebo to two different remedies with one of the remedies being common to both studies. The remedies chosen from a predefined list of 20 remedies, in this case newly proven ones; Ozone and Iridium, with Ozone being the one common to both studies. When both studies were combined, a clear significant difference for symptoms typical for Ozone during the treatment period emerged (Figure 3).

4.3.2 Figure 3—Combination of Two Studies Testing Ozone vs. Placebo.[31] Significantly More Symptoms Typical for Ozone During the Experimental Phase in the Group Taking Ozone than in the Group Taking Placebo



5. The Way Forward

5.1 Walach *et al* believe they have proven the case that this new methodology of re-proving homeopathic remedies can now tease out at least partially the specificity of homeopathic remedies *vis-à-vis* placebo in a rigorous experimental design, where other recent approaches have failed.[32–35] While HPTs can be conducted this way, one should avoid the direct replication of any study by using the same types of remedies. A way forward would be to test different remedies, perhaps in several studies with more than two arms that have one or two remedies in common. Then a decision could be made, after the fact and at random, which arms to discard and which to combine. By the combination of changing remedies each time a study is conducted and combining different studies, it might be possible to produce enough single studies with significant outcome testifying to the specificity of symptoms and thus avoiding the observed decline effect.[36] This methodology has only one purpose: to discover whether known homeopathic substances are able to produce symptoms in healthy volunteers that are different from those elicited by placebo. Its pre-supposition has been mentioned: it can only be used if the medication in question is known.

5.2 To the novice and the outside observer it should also be clear that the proving methodology of homeopaths for the purpose of discovering new remedies is different from the author's in several respects, as a rule: they very often do not have symmetrical control groups, ie only few persons, though randomised and mostly double-blinded, receive placebo,[9,24,37] and very often symptoms appearing in the control group are also counted as remedy symptoms, if they fulfil the typical criteria for a symptom defined by Bayr and Stübler[38].

5.3 There is surely a common core to the proving methodology: the careful observation of changes by experienced provers who ingest a potentised substance unknown to them. The symptoms are noted in a diary and verified with a supervisor on a daily basis. Little has changed in principle since this methodology was invented.[39] The only thing we have become suspicious about is how powerful placebos are, and that there are likely a lot of specific symptoms to be observed even under placebo. Everyone still adhering to a classical pharmacological model when investigating homeopathy will have difficulty explaining this conundrum. Homeopathic provings are difficult to investigate but as we begin to understand the process, our methodology improves as it becomes more informed.

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Declaration of Interests

Professor George Lewith is a homeopathic practitioner and a researcher.

Professor Harald Walach is a researcher and has no conflict of interest.

November 2009

Memorandum submitted by the Leeds Institute of Diagnostics and Therapeutics, University of Leeds (HO 15)

1. In addressing the questions posed in relation to the Government's use of evidence in policy-making regarding homeopathy; (1) *What is the policy?* (2) *On what evidence is the policy based?* it is important to recognise that clinical evidence is characterised by its incremental and sometimes less than perfect nature. Many clinical decisions are made on the balance of probabilities suggested by the evidence, rather than clear, unequivocal evidence to support particular decisions. Scientific evidence is supplemented by clinical experience and knowledge when clinical decisions are made in practice. Evidence used for policy-making is no different in that it too can only represent the best information available at a particular time, and equally must be balanced against other types of evidence, including economic and ethical considerations.

1. The proposed "evidence check" for homeopathy should therefore be undertaken within the context of our wider understanding of the nature and value of evidence in other clinical spheres.

2. In particular, it is important to have a clear framework for assessing the existing evidence which takes into account the gradations of certainty that are apparent in any systematic review of the literature. One such framework would be that provided by the British Medical Journal's "Best Health" project. http://besthealth.bmj.com This Web-based project aims to inform patients and practitioners of the extent and certainty of existing scientific evidence for particular treatments and conditions. The following is extracted from this website;

2.1. *Best Health* looks at medical research that is published in journals all over the world. It does this by using *Clinical Evidence*, a collection of the best research evidence for doctors. *Clinical Evidence* gives doctors and other health care workers a good, up-to-date summary of what's known and what isn't about treating a wide range of clinical conditions. It's published by the BMJ Publishing Group.

2.2. *Clinical Evidence* looks at all the evidence and decides how well treatments work, whether the research is good enough and how serious the side effects are. Sometimes no one knows for certain whether a treatment works because the research that's been done isn't good enough. Or it could be that not enough research has been done.

2.3. *Best Health* adds to the *Clinical Evidence* research. It makes the evidence easy to read. It also enables patients to see the same research evidence that doctors see. *Clinical Evidence* gives doctors and other health care workers a good up-to-date summary of what's known and what isn't about treating a wide range of clinical conditions. It's published by the BMJ Publishing Group.

2.4. We follow a strict process to develop each topic on *Best Health*. Here are the key steps:

2.4.1. *Step 1: Selecting a topic*

2.4.2. *Best Health* covers serious, long-lasting illnesses that affect many people in the UK. It also looks at more minor conditions that affect a lot of people, such as coughs and colds. We are guided by national health statistics, doctors and patient groups. The conditions we look at have been included in *Clinical Evidence*.

2.4.3. *Step 2: Asking the right questions*

2.4.4. We cover the treatment options for each condition and give background information to explain the condition itself. *Best Health* works with the *Clinical Evidence* team, an international team of doctors, and patient groups to find out what matters most to doctors and patients. They might ask questions such as: What does the research say about exercise helping people with heart failure? What are the side effects of treatments for childhood asthma?

2.4.5. *Step 3: Finding the evidence*

2.4.6. All our information is based on research evidence and high-quality medical papers. Here is how we gather this evidence:

2.4.7. Information about treatments—This information in *Best Health* is based on *Clinical Evidence.* To answer each question about a treatment, the *Clinical Evidence* medical information specialists do a thorough search for studies that measure how well treatments work. First the information specialists look for the best types of studies (called systematic reviews) and other good-quality studies called randomised controlled trials. If there are none of these studies, the information specialists look for other studies and say how much they can be relied on and what problems there are with the research.

2.4.8. Once the research has been collected, the information specialists weigh up the evidence and take out the studies that aren't good enough. They do this using a method developed by experts in how research is carried out.1 2 .This thorough research helps us find out which treatments work best for a condition, and also why certain treatments work. If you would like to read more about how we search for and select studies, see the *Clinical Evidence* website (http://clinicalevidence.bmj.com).

2.4.9. Information about conditions—The information that we provide to explain medical conditions is based on high-quality original medical papers and textbooks chosen by our information specialists. On each page of the site, you will find the details of the sources of information we have used.

2.4.10. *Step 4: Making sense of the evidence*

2.4.11. The research evidence for each treatment is studied and summarised by a doctor who is an important expert in a particular specialty. Each topic is then checked by at least three more doctors. Then, a leading expert provides advice on how doctors can use this research evidence. We ask people with the condition to tell us what they think the important questions are about their condition and treatments.

2.4.12. A team of experienced medical writers makes sure this evidence can easily be understood by the general public and writes the extra information that explains each condition.

2.4.13. Deciding which treatments work—We group treatments into categories according to how good the evidence is that they work. We use slightly different language to describe the categories than you'll find in *Clinical Evidence*, but the treatments are grouped in the same way. Here is an explanation of what each category means:

Category	*What it means*
Treatments that work	There's clear evidence from randomised controlled trials that the treatment works. Also, the evidence shows that the chance of problems is small compared with the benefits.
Treatments that are likely to work	There is some evidence that the treatment works. But we can't be as certain that the treatment works as we can for those listed under "Treatments that work".
Treatments that work, but whose harms may outweigh benefits	There's some good evidence that the treatment works. But there's also good evidence that it can have serious side effects. Doctors and patients need to weigh up the benefits and risks according to what each person needs and wants.
Treatments that need further study	We don't know if the treatment is effective because there is either too little research to tell or the quality of the research is not good enough.
Treatments that are unlikely to work	There is evidence that the treatments probably don't work. But we can't be as certain that the treatments don't work as we can for the ones in the group "Treatments that are likely to be ineffective or harmful".
Treatments that are likely to be ineffective or harmful	Clear evidence shows the treatments don't work or will be harmful.

2.5. *Step 5: Presenting the answers*

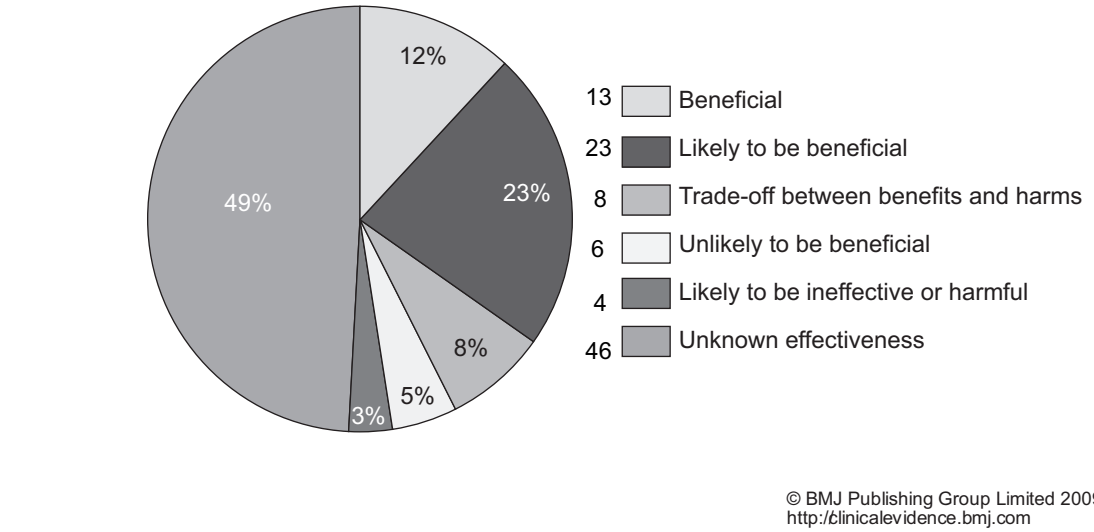
All the information on *Best Health* is edited by a team of editors and checked by our doctors. The information about drugs has been reviewed by a team of qualified pharmacists working in association with PharmacyHealthLink. PharmacyHealthLink is a leading national charity that works to improve the health of the public through the expertise of pharmacists and their staff.

2.6. *Sources for the information on this page:*

Sackett DL, *et al*. Clinical epidemiology: a basic science for clinical medicine. Little, Brown and Co, Boston, USA; 1991.

Jadad A. Randomised controlled trials. In: Assessing the quality of RCTs: why, what, how and by whom? London, UK; 1998.

3. Using this framework, the BMJ group have assessed 2,500 commonly used treatments and their summarised findings are shown in the figure below.



4. Again, it seems appropriate that the committee's deliberations regarding the evidence relating to homeopathy are conducted with reference to the larger picture regarding the imperfect and emerging evidence base informing policy for commonly provided treatments within the NHS.

5. While evidence-based policy is a laudable goal, something to be strived for, it can only happen in the prevailing climate of imperfect and emerging knowledge. If, as seems likely, an unacceptable gap is identified between the level of reported use of homeopathy and the evidence available to help inform the public or the NHS of its value, the most objective and ethical way forward would be to support the generation of high quality research findings to close this gap. The current structures of the NIHR are adequate to facilitate this.

6. The above recommendations for further research echo those made in relation to homeopathy in the GO-Science Review of the Department of Health:

> *"[…]. Flagship trials should be run in the most promising areas, chosen on plausibility, and patient demand. […] The Health Technology Assessment Programme provided a framework that should be as applicable to research on homeopathy as to any other therapy."*

GO-Science Review of the Department of Health, Annex 1 (2008). Government Office for Science: Department for Innovation, Universities and Skills; Paragraph 3.16.

7. Declaration of Interest

The author of this submission, Professor Katharine Thomas, is an academic researcher at the University of Leeds; she is not a homeopathic practitioner, and has no financial interest in the provision of homeopathy.

Katharine Thomas BA (Hons) MA
Professor of Complementary and Alternative Medicine Research
Leeds Institute of Diagnostics and Therapeutics
University of Leeds

November 2009

Memorandum submitted by Anne Waters (HO 17)

1. With very little time to prepare this submission, I would like to make the following points.

2. I would like to register my regret and concern that the amount of time allowed for this consultation is so severely limited. You call for evidence on 20 October and want submissions by 6 November. This is unreasonable

3. I would like to draw your attention to the following research, by Nobel Prize winning virologist, Professor Luc Montagnier

4. In a recent paper, Prof Montagnier, and his team report the results of a series of rigorous experiments investigating the electromagnetic (EM) properties of highly-diluted biological samples.

5. The abstract of this research in part asserts, "A novel property of DNA is described: the capacity of some bacterial DNA sequences to induce electromagnetic waves at high aqueous dilutions. It appears to be a resonance phenomenon triggered by the ambient electromagnetic background of very low frequency waves."

6. Although homeopathy is not mentioned anywhere in the article, the researchers used aqueous solutions that were agitated and serially diluted (the researchers note that the solutions were "strongly agitated" and that this step was "critical for the generation of signals")

7. This is exactly the way that homeopathic remedies are prepared.

8. The researchers found that pathogenic bacteria and viruses show a distinct Electro Magnetic signature at dilutions ranging from 10(–5) to 10(–12) (that is 10 to the negative 5th power to 10 to the negative 12th power…corresponding to 5X to 12X) and that small DNA fragments (responsible for pathogenicity) were solely accountable for the EM signal.

9. The researchers also noted that one experiment found significant effects from dilutions as high as 10(–18) (to the negative 18th power, equivalent to 18X). The EM signature changed with dilution levels but was unaffected by the initial concentration and remained even after the remaining DNA fragments were destroyed by chemical agents.

10. Of additional interest was the researchers' observation that they observed the SAME results whether their initial concentration of cells were just 10 or one part in 1,000,000,000.

11. The researchers also detected the same electromagnetic signals in the plasma and in the DNA extracted from the plasma of patients suffering from Alzheimer, Parkinson disease, multiple sclerosis, and rheumatoid arthritis.

12. The researchers also quote Italian physicist, E. Del Guidice, (the same scientist who Benveniste cited), for positing that water molecules can form long polymers of dipoles associated by hydrogen bonds and that electromagnetic radiations that the emit enable them to avoid decay.

13. With this initial paper Prof Montagnier and his team have started a very promising line of enquiry, which has direct relevance to homeopathy as they continue to investigate the characteristic physico-chemical properties found in high-dilutions of biological material.

14. Reference: Luc Montagnier, Jamal Aissa, Stéphane Ferris, Jean-Luc Montagnier, Claude Lavallee, Electromagnetic Signals Are Produced by Aqueous Nanostructures Derived from Bacterial DNA Sequences. Interdiscip Sci Comput Life Sci (2009) 1: 81-90.

15. http://www.springerlink.com/content/0557v31188m3766x/fulltext.pdf

16. Are you aware that cutting edge science is now recognizing that our current understanding of DNA is flawed, and that in his book *The Biology of Belief* Bruce H Lipton, PhD. (published by Hay House, Inc. ISBN: 978-1-4019-2311-2) states on page 55 that

17. "because receptors can read energy fields, the notion that only physical molecules can impact cell physiology is outmoded. **Biological behavior can be controlled by invisible forces** including thought, as well as it can be controlled by physical molecules like penicillin, **a fact that provides the scientific under-pinning for pharmaceutical-free energy medicine."** (my bold).

18. Please look at the work of French immunologist Jacques Benveniste on the memory of water. (1988) This work was inappropriately discredited a month after publication in the journal Nature, but current scientific knowledge now accepts that much of what Benveniste said was in fact right.

19. Evidence based medicine is about integrating individual clinical expertise and the best external evidence. The individual clinical expertise of homeopaths is dismissed as anecdotal, and so invalidated. This is unfair, inappropriate, and prejudicial. Patients own reports of benefit are ignored. There is no will to fund further research, because those who control the funding are unable to think outside the box of their own personal experience.

20. Good science relies on scientist who can think outside the box, and yet, good science is dismissed, because those who control the press, the policy and the decisions are those who have a vested interest in control, profit and outcome.

21. There is no profit in homeopathy.

22. There is no control, when the public make decisions that they consider to be in their own best interests, but are against the accepted methodology, or the limited wisdom of the day.

23. Science is very good at saying "we used to think, but now we know" This is evident in the way many pharmaceutical drugs have been licensed and then later withdrawn. It is evident in physics, chemistry, and biology. Please do not approach an energy medicine such as homeopathy with a paradigm that is inappropriate.

Anne Waters MA (SEN)
Lakeland College of Homeopathy

November 2009

Memorandum submitted by the European Committee for Homeopathic Medicine in Europe (HO 18)

THE USE OF HOMEOPATHIC MEDICINE IN EUROPE: ITS LICENSING AND REGULATION.

1. Introduction

1.1 Over the past 30–40 years homeopathy has benefited from growing demand both from doctors and from the public in the majority of the European countries. According to a survey by European Commission order in 1996 three Europeans out of four know about homeopathy and of these about 30% use it for their health care. In the European Union there are approximately 50,000 physicians who have taken a training course in homeopathy. Many more doctors in Europe prescribe homeopathic medicines without any homeopathic training: approximately 25–40 % of the GPs from time to time, 6–8 % of them on a more regular basis.

1.2 Among the different forms of Complementary and Alternative Medicine (CAM), in particular homeopathy has a form of legal recognition in certain European countries, an organisational structure at European level, self-regulatory mechanisms, and a certain level of scientific credibility. Homeopathy is being increasingly recognised as a potential asset to European health care. Resolutions on CAM have been adopted by the European Parliament and the Council of Europe, EU Directives oblige the Member States to register homeopathic medicinal products, and homeopathic medicinal products are being included in the European Pharmacopoeia.

Earlier this year the Swiss people in a national referendum voted in favour of a constitutional article for complementary medicine. Switzerland is the first country in Europe to set out in the constitution, authority for the state and constituent states (cantons) to take complementary medicine into consideration in the public health service. On this constitutional basis, parliament and the authorities have to admit doctors trained in anthroposophic medicine, homeopathy, neural therapy, herbal medicine and Traditional Chinese Medicine into the obligatory public health insurance system, and create national diplomas for CAM therapists without a full medical education.

2. Homeopathy and the European Union

2.1 The European Parliament has taken the position that homeopathy—as well as other branches of non-conventional medicine-, should be recognised. Its resolution of 29 May 1997 (A4-0075/97) called on the European Commission

(a) to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees;

(b) to carry out a thorough study into the safety, effectiveness, area of application and the complementary or alternative nature of all non-conventional medicines and to draw up a comparative study of the various national legal models to which non-conventional medical practitioners are subject;

(c) to make, in formulating European legislation on non-conventional forms of medicine, a clear distinction between non-conventional medicines which are "complementary" in nature and those which are "alternative" medicines in the sense that they replace conventional medicine;

and calls on the Council of Ministers after completion of the preliminary work referred to above (at b.) to encourage the development of research programmes in the field of non-conventional medicines covering the individual and holistic approach, the preventive role and the specific characteristics of the non-conventional medical disciplines; Parliament undertakes to do likewise.

2.2 As to homeopathy in veterinary medicine, the first steps of recognition have been made. In July 1999 Council Regulation 1804/1999/EC was adopted, supplementing Regulation 2092/91/EEC by establishing rules on organic production and agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production. This Regulation stipulates that, when animals become sick or injured, they should be treated immediately by giving preference to homeopathic or herbal medicinal products and by limiting to a strict minimum the use of chemically-synthesised allopathic medicinal products in order to guarantee the integrity of organic production for consumers.

2.3 All EU Member States are obliged to register homeopathic medicines pursuant to Directive 2001/82/EC (veterinary use) and 2001/83/EC (human use)—amended by Directive 2004/28/EC and Directive 2004/27/EC respectively—on the Community Code relating to medicinal products. Homeopathic

medicines are prepared in accordance with a homeopathic manufacturing procedure described in the official pharmacopoeias currently used in the Member States,—the French, German, and increasingly, the European Pharmacopoeia.

3. Homeopathy and the Council of Europe

In 1999 the Council of Europe, in its Resolution 1206 (1999) on non-conventional medicine (=Complementary and Alternative Medicine) called on "member states to promote official recognition of these forms of medicine in medical faculties and to encourage hospitals to use them". In addition, the Council stated that "appropriate courses should be offered in universities to train allopathic doctors in alternative and complementary forms of treatment", and that "the best guarantee for patients lies in a properly trained profession, which is aware of its limitations, has a system of ethics and self-regulation and is also subject to outside control".

4. Homeopathy and National Statutory Regulations

4.1 Homeopathy is recognised by law as a distinct medical therapy in Belgium (1999), Bulgaria (2005), Hungary (1997), Latvia (1997), Portugal (2003), Romania (1981), and Slovenia (2007). In some countries where the government has delegated the tasks of authorisation, registration and supervision of medical practitioners to the national medical associations, statutory regulation has been introduced by the national medical associations, ie in Austria, Germany, Romania and Switzerland. In Lithuania it was the national institute of medico-legal affairs that regulated homeopathy. The national medical associations in France and Italy have recognised homeopathy as a distinct medical therapy and called on the government to provide the necessary legislation.

4.2 In Latvia the medical council/chamber has recognised homeopathy as a medical specialty. In the following countries as an additional qualification: Austria, Germany, Hungary, Latvia, Lithuania (almost a subspecialty), Romania, Switzerland (subspecialty for GPs, paediatricians and internists).

5. Homeopathy Teaching at Universities

5.1 Familiarisation courses about homeopathy are provided in the medical undergraduate curriculum as a part of a course on Complementary and Alternative Medicine in Hungary (one university), Italy and the Netherlands; as a separate subject in Bulgaria, Germany and Romania. These familiarisation courses are optional for medical students in Germany, Hungary (one university), Italy, the Netherlands and Switzerland (some universities), obligatory in Latvia and Romania.

Postgraduate training courses in homeopathy for doctors are provided at universities in Bulgaria, Germany, France, Italy, Lithuania and Spain, in other countries at private teaching centres.

5.2 A lectureship specifically for homeopathy exists only in the Netherlands (Amsterdam), a professorial chair of CAM including homeopathy in Hungary (Pécs) and Switzerland (Bern).

6. Homeopathy Provision in Hospitals

Several hospitals in continental Europe, in their out-patient departments, currently provide homeopathic treatment by physicians, ie in Austria (seven), France (two), Germany (five), Spain (two), Italy (some).

Dr Ton Nicolai, President of the European Committee for Homeopathy

November 2009

Memorandum submitted by Professor Vincent Marks (HO 19)

Government Policy on Licensing of Homeopathic Products

1. Homeopathic products have no place in a society and more especially a National Health Service that aims to protect people from unnecessary harm arising whether due to ignorance or misfeance. Homeopathy has no justification for continuing to exist in a world where medical practice is a craft that relies upon the basic sciences of anatomy, physiology, pathology, pharmacology and psychology and demands evidence of efficacy.

2. Homeopathy has none of these attributes and whilst it may have been justified because when inaugurated because it fullfilled one of the prime maximes of medical practice namely, "First do no harm.." which was in sharp contrast to much of orthodox medical practice at the time, it no longer is so.

3. Homeopathy produces harm, in my experience and in numerous published reports,not by commission but by omission, and by the denial of access to remedies of proven benefit. Licensing homeopathic remedies gives them a credibility they do not deserve or warrant from either a pragmatic or philosophical point of view.

Government Policy on the Funding of Homeopathy Through the NHS

4. Evidence based medical practice should not have to compete for funds with what can legitimately be described as a cult practice based upon nothing than unsubstantiated dogma.

5. This has repeatedly been shown, through fair trials, to provide no benefits beyond those achievable by diligent use of the placebo effect whose adantages cannot be used to full effect by practioners of modern medicine.

6. Registered Medical Practioners are ethically bound to explain to their patients the scientific basis of treatments they recommend and both the desirable and undesirable consequences of it.

The Evidence Base on Homeopathic Products and Services

7. I am not aware of any genuine evidence base for homeopathy whose philosophy flies in the face of all known physical, chemical and biological science.

8. The proposition that "like cures like" was a preposterous proposition based on nothing more profound than the imagination of its author.

9. Properly conducted randomised controlled clinical trials of homeopathy (fair trials) have not established any benefit greater than can be achieved by placebo therapy and that cannot be explained by chance.

10. Claims that animals respond to homeopathy do not withstand scrutiny but are often attested to as pragmatic evidence for the efficacy of homeopathy in spite of its implausibility.

Vincent Marks, MA, DM,FRCPath, FRCP (Edin & Lond)

November 2009

Memorandum submitted by Dr Jean Monro and Dr Peter Julu (HO 20)

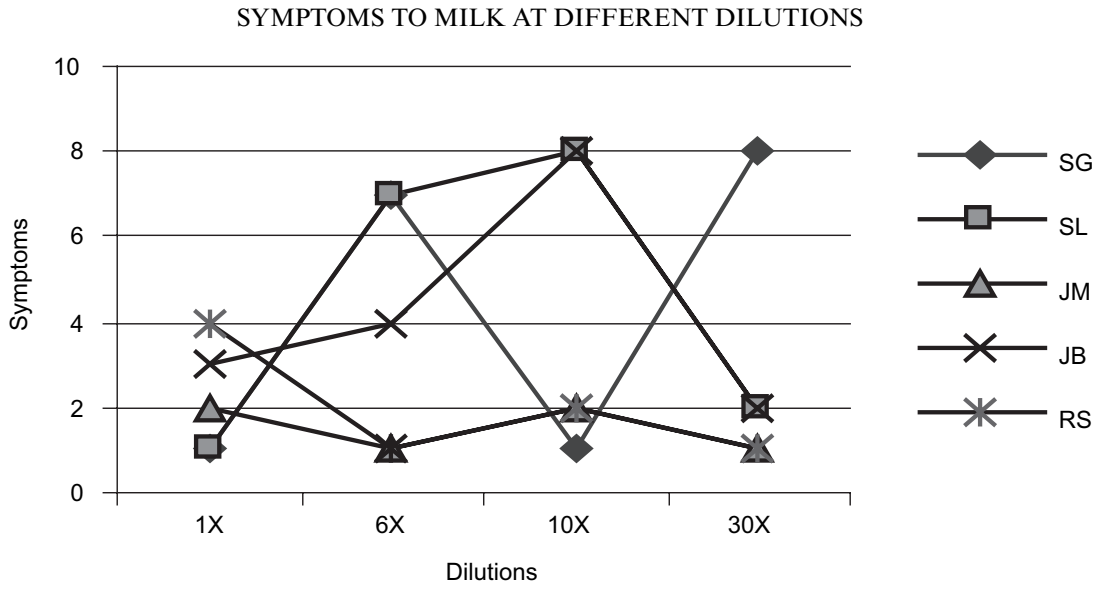
Summary of the Main Points being Made:

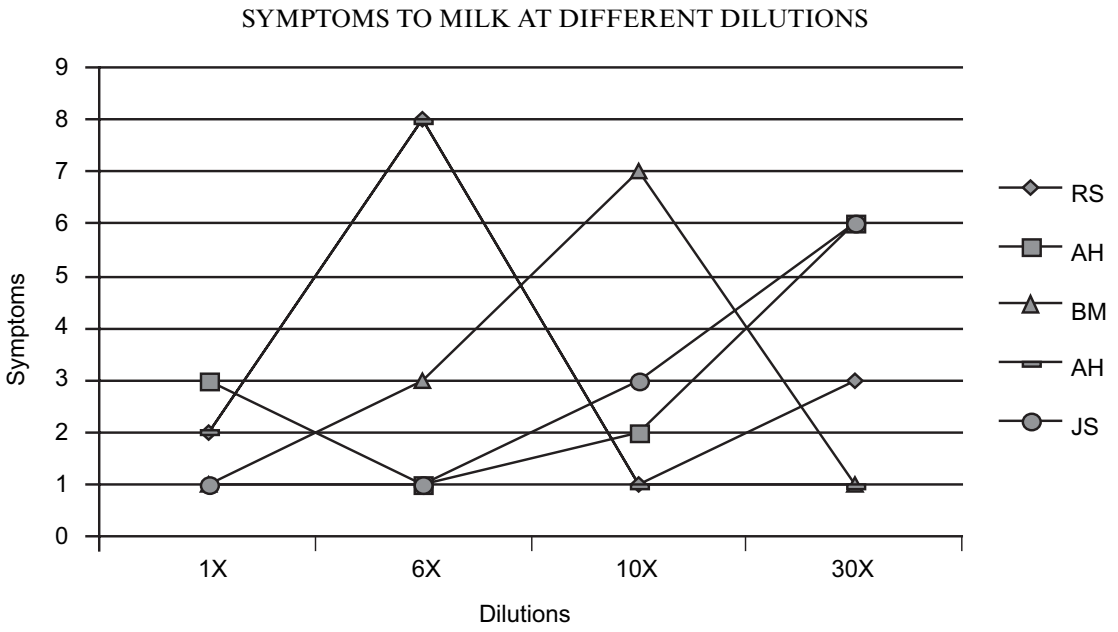
1. Homoeopathic dilutions resemble dilutions of antigens made for low-dose immunotherapy.
2. Allergy is evinced by autonomic changes which are physiologically demonstrable and measurable using the NeuroScope.
3. Low-dose immunotherapy can reverse dysautonomia. This has been demonstrated before and after depictions of physiological abnormalities.
4. Homoeopathic dilutions have been shown to mirror the provocation and nullification of symptoms in different dilutions which are evinced by low-dose immunotherapy dilutions.
5. The lymphocyte sensitivity test is described. It shows sensitivity of lymphocyte membranes when exposed to agents to which the patient is sensitive.
6. Low-dose immunotherapy can stabilise lymphocyte membranes and abort abnormal cell membrane responses, hence controlling symptoms of sensitivity.
7. The findings described have been published, in the first instance, in a peer-reviewed publication and, subsequently as presented to the Joint International Neurogastroenterology and Motility Conference held in Chicago in August 2009.
8. Ongoing studies and observations corroborating these findings have been undertaken and are in the process of being collated.
9. There is clear, scientific evidence of the mode of action of sensitivities, allergies through the autonomic nervous system, which is the neural pathway of allergy and its control through low-dose immunotherapy.
10. As low-dose immunotherapy and homoeopathy are showing parallel effects, the findings in relation to low-dose immunotherapy are relevant to homoeopathy.

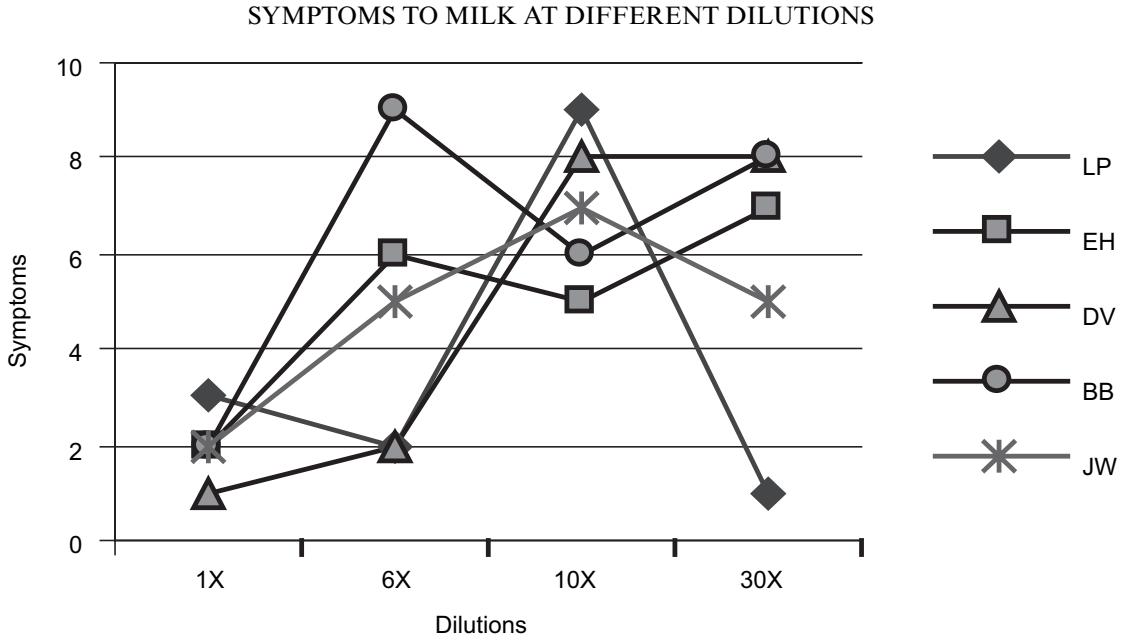
1. In our attempt to investigate the physiological evidence of low-dose immunotherapy, we have carried out several studies which included dilution of antigens, up to homoeopathic concentrations.[36] These produced symptomatic responses at some dilutions and abrogations of responses at others. Selected antigens which suited the individual provoking no symptoms nor increased wheals when injected intradermally, were then used for treating patients with migraine and food allergies. Subsequently, with homoeopathic dilutions provided by Ainsworth Homoeopathic Pharmacy, similar responses were observed of provocation and nullification of symptoms.

[36] Monro JA. Biological effects of neutralising vaccines: the effects of weak electromagnetic fields and the concordance between the two. Proceedings of the International Conference on Electromagnetic Environments and Health in Buildings; 2002 May; London. In: Clements-Croome D, editor. Electromagnetic environments and health in buildings. London: Spon Press; 2004. p.267–80.

2. Below are the graphic representations of the response to homoeopathic concentrations.







3. The text in relation to these graphs is as follows:

Fifteen patients were selected. Each of these patients had been previously diagnosed as being allergic to wheat, milk and egg, both by elimination diet followed by challenge which induced symptoms or observable physiological changes, and by previous skin testing using the provocation/neutralisation method, with allopathic vaccines of 1:5 dilutions. The homoeopathic vaccines were prepared by Ainsworth Homoeopathic Pharmacy in dilutions of 1x, 6x, 10x, 30x.

Patients were exposed to each of these strengths within their vials, and also injected intradermally, with a 0.05 ml wheal being raised. Symptoms were noted and charted. Patients then held the vial and symptoms were noted. Where symptoms occurred, intermediary preparations of vaccines were obtained and charted. Dilutions of antigens below Avogradro's number, viz homoeopathic remedies, behaved in a manner similar to antigens injected sequentially, as in the Miller provocation/neutralisation technique and homoeopathic remedies have a similar pattern of provoking and neutralising symptoms.

4. It was then necessary to further investigate the physiological evidence of low-dose immunotherapy. This was, therefore, designed in the experimental terms of "before and after" evidence. This is an ongoing clinical evaluation, but due to the urgency of this call for evidence, we want to share with you our early results.

5. The first pilot study was carried out and presented to the Joint International Neurogastroenterology and Motility Conference in August 2009 this year, showing very clear physiological responses to low-dose immunotherapy. Autonomic dysfunction was demonstrated and this was corrected by low-dose immunotherapy. We clearly showed that low-dose immunotherapy manipulates the autonomic nervous system and this is the basis for its mechanism of action. For example, we showed that low-dose immunotherapy corrected dysfunction of the sympathetic nervous system in both the splanchnic regions and skeletal muscles (see illustration attached, as presented at the Joint International Neurogastroenterology and Motility Conference 27–30 August 2009).

6. Further evidence of the mechanism of action of the low-dose immunotherapy is biochemical/immunological. The lymphocyte sensitivity assay is a test in which lymphocytes are viewed by confocal microscopy on a slide in which the medium is accessible to the addition of possible agents to which the lymphocytes can react, if they are sensitive. In the medium is a calcium probe which becomes fluorescent blue if the cell wall is breached with calcium. When the person's cells are viewed initially, the amount of calcium in the cell can be calculated by the density of the fluorescent probe. Thereafter, different agents are added to slides and the lymphocyte, if it is sensitive, will allow the ingress of further calcium. This was undertaken before and after the use of low-dose immunotherapy and shows a normalisation of cell membranes as a result of low-dose immunotherapy.

7. These findings are clear scientific evidence of the action of low-dose immunotherapy, and, since low-dose immunotherapy with homoeopathic dilutions has been shown to work similarly, giving parallel clinical results, we have no doubt that this is the mechanism of action of homoeopathic agents.

8. We have, therefore, embarked on the clinical evaluation of the physiological and chemical/immunological mechanisms of homoeopathic dilutions of our antigens.

9. A memorandum was presented to the House of Lords Science and Technology Select Committee on Allergy, Session 2006–07, which was chaired by Baroness Finlay of Llandaff. This described the background of low-dose immunotherapy.

10. Further presentations were offered at a seminar organised by Breakspear Hospital Trust at the House of Commons when we were guests of Michael Penning MP Shadow Health Minister. Information that was presented regarding allergy at that meeting can be made available to the Science and Technology Committee.

Declaration of Interests:

Jean Monro—Director of Breakspear Medical Group Ltd

Peter Julu—Inventor of NeuroScope

November 2009

Memorandum submitted by Dr Sara Eames (HO 22)

THE EVIDENCE FOR HOMEOPATHY AND ITS PROVISION WITHIN THE NHS.

1. *The Faculty of Homeopathy* represents over 1000 healthcare professionals in the UK who choose to incorporate homeopathy into their everyday work. Many of these members have become interested in homeopathy because they have seen patients who have been helped by this therapy when conventional treatments have failed.

2. *What is Homeopathy?*

It is well known that the choice of a homeopathic medicine is made by matching the symptoms of a patient with a substance which is known to cause those particular symptoms when taken in larger doses. What is less widely appreciated however is that the whole homeopathic consultation is a complex process and is an ideal way to practice good medicine. It starts with a careful history taking, involving not only the main problem, but also other current problems, past medical, family and social history and factors about the patient's physiology, interests and concerns. It is mandatory to enquire about the patient's lifestyle and identify those factors inhibiting healing and good health. These can include poor diet and lack of or excessive exercise as well as living in difficult emotional situations. The doctor will work with the patient to identify ways in which these blocks may be removed and only then will a homeopathic medicine be prescribed. It thus becomes obvious that when considering the role of homeopathy in the management of patients it is the whole process rather than just the action of the medicine which is to be considered.

3. *What is Evidence?*

3.1. The concept of evidence is multi-faceted, but in recent years it has become progressively reduced to accepting double blind trials as the gold standard. While these can be useful in assessing the effects of a single intervention on a single symptom or outcome, they are far less suitable when studying the overall effects of a holistic therapy in a complex organism with multiple problems. Notwithstanding this there have been over 100 double blind trials in homeopathy with far more positive than negative outcomes. These are summarised in the submission by my colleague Dr Robert Mathie, on behalf of The British Homeopathic Association.

3.2. There are also many other types of evidence for homeopathy:

Hundreds of thousands of case histories, recording successful cases. (NICE accepts case series as evidence in its review of treatments)

3.3 Outcome studies from the Homeopathic Hospitals, show consistent results in improving not only the presenting symptoms but also overall well-being and in reducing the use of conventional medicine.[1] The majority of patients in these surveys have chronic conditions, and many have multiple pathologies. All have been referred to the hospitals by their GP or hospital consultants and many have not responded to previous conventional treatment. The outcome studies from the hospitals are discussed in greater detail in the submission by my colleague Dr Hugh Neilsen.

3.4. The Department of Health is now advocating the use of patient reported outcome measures (PROMs) as a way of assessing improvements in patients with complex health care needs.
The NHS website requests patient feedback on their hospital experiences and the Royal London Homeopathic Hospital has very positive results.

4. *How Should Evidence be Used in Medicine?*

It is the role of scientists to research and discover new treatments in medicine, but it is the role of the doctor to practice the art of medicine. Pure science and the results of randomised controlled trials (RCTs) are tools in this practice, but should never become the master. A wise physician will use his wisdom and experience to consider a range of treatment options suitable for the individual patient in their particular situation and many conventional doctors find that having homeopathy as an additional tool at their disposal allows them to help more patients in a safe and cost effective way.

5. *The Case for and against Homeopathy.*

5.1 There has been a surprising amount of negative publicity around homeopathy when one considers the tiny proportion of the NHS spending it involves and the fact that it is a remarkably safe therapy which is both popular with and helpful for patients.
There are three main strands to these negative arguments which are the dispute of the evidence from RCTs, the denial of any possibility that an ultra dilute homeopathic medicine can have any action and the publicity given to the few unfortunate cases involving homeopathy where there have been poor outcomes.

5.2 *1. The consideration of the trial results in homeopathy* is fascinating. As stated above in over 100 RCTs there are far more positive than negative results in spite of the fact that in the trials involving classical homeopathy, all trial participants, including those in the placebo group, will have benefited from the homeopathic process as outlined above. This becomes even more compelling in terms of health economics when considering that many of the trial patients will have noticed additional improvements in other health problems which were not recorded as they were not included in the original trial parameters and also that participants suffer from very few, expensive to treat, side effects. All meta-analyses of these trials have been broadly positive,[2,3,4,5] until the last one published by Shang *et al* in the Lancet[6]. Critics of homeopathy have selectively accepted this outcome as the final word in the argument against homeopathy, but it is worth noting that Shang's work did not include many new trials and was merely a different statistical reworking of the old information. Perhaps the most important conclusion from this is that responsible decision makers should not rely on statistics alone!

5.3 It is important to note however that the Shang meta-analysis has been widely criticised for not adhering to even the very basic principles of good meta-analysis as outlined in the QUOROM guidelines.[7]

5.4 Some of the main points of the critique to be aware of include:

Statisticians involved in a meta-analysis should not have prior knowledge of the subject. At least one of the authors of this study had already critiqued homeopathy although this was not declared in the conflict of interests.

Enough information about trial selection must be given for the study to be reproducible, yet the article said nothing about the detailed methodology of trial selection and indeed did not even name the trials which had been involved.
The final conclusions of the study were based on the comparison of only eight homeopathy trials, although over 100 had initially been looked at. There is no clear information about how this reduction was done and this number of eight trials was not pre-stated in the methodology as required by QUOROM. One of the chosen homeopathic trials was not even Medline listed, although most of the published homeopathic trials are.

5.5 At best this is a very poor quality meta-analysis and at worst an example of biased data dredging searching for pre-determined results.

5.6 *2. The possibility of action of ultra-molecular substances* is dismissed as completely implausible by critics of homeopathy, in the face of increasing scientific evidence to the contrary. This evidence has been comprehensively listed and discussed by Dr Peter Fisher in his submission.

5.7 Some of the more intriguing results include the experiments around the concept of hormesis, where a small dose of a toxic substance will stimulate an organism, even though a larger dose will be toxic. There is also an ever growing group of in-vitro experiments from different centres showing the blocking of basophil activity by highly diluted histamine.

5.8 It is also fascinating that both plant and animal experiments show how growth can be stimulated or reduced according to the level of dilution of the substance.

While there is certainly much more to discover about the action of dilute substances, it is no longer scientifically correct to say that they cannot work, with such an increasing body of scientific evidence showing their activity.

5.9 *3. Individual cases of poor outcomes with homeopathic treatment* are obviously to be regretted and may constitute personal tragedy, but they are thankfully rare and usually involve the failure to integrate homeopathy with the best available conventional treatment rather than as an effect of the homeopathic treatment *per se*.

It is somewhat surprising that great emphasis and headlines are given to these individual incidents while many thousands of successfully treated patients are dismissed as mere anecdote.

5.10 There is also a great contrast with the scant publicity given to the side effects of conventional medicine which can produce many serious and expensive to treat complications, but which receive little publicity. The Journal of the American Medical Association (JAMA) has a series of illuminating articles on this subject.

A study at Toronto University published in 1998 found that over two million hospitalised Americans suffered serious adverse drug reactions during the 12 month period of the study and that 100,000 died as a result of these events. The figures do not include accidental overdoses or errors in administration and they account for more deaths than road traffic accidents each year.

5.11 A study at John Hopkins School of Hygiene and Public Health two years later found that iatrogenic disease was the third largest killer in the US behind only cancer and cardiovascular disease. It also showed that the largest sub group of these deaths was caused by non-error adverse effects of medication, larger even than deaths caused by hospital acquired infections.[9]

5.12 It is also important to note that the prescription of multiple conventional drugs concurrently is frequently non-evidence based as little is known about the complicated reactions between them and the effect on patients overall.

6. *The Funding of Homeopathy within the NHS.*

6.1 The two main settings in which homeopathy is used in the NHS are in general practice and at the four homeopathic hospitals.

6.2 There have been a number of reports of outcomes of GPs prescribing for acute problems and they are all low cost prescribing practices. A recent study published by Robinson showed this and how he was able to use the homeopathic medicines within the context of 10 minute consultations with his patients.[10]

6.3 It is interesting that some of the positive trials of specific conditions are of great relevance to commonly occurring problems in general practice and include the treatment of allergies,[11] the reduction in duration of influenza symptoms,[12] and a reduction in the duration and severity of childhood diarrhoea when homeopathy is added to conventional treatment.[13]

6.4 The topic of the Homeopathic Hospitals is discussed in the submission by my colleague Dr Hugh Nielsen, but it is important to stress their unique role and importance within the NHS. They offer an alternative for doctors and their patients when conventional treatments have failed or are contra-indicated and especially when patients suffer from multiple and chronic conditions.

7. Summary.

7.1 Homeopathy is a branch of medicine which has an increasing evidence base, both from clinical studies and basic scientific research, which confirms the clinical outcomes reported by practitioners world-wide for over 200 years. There is naturally always scope for further study as suggested by the House of Lords CAM report in 2000.

7.2 Homeopathy can usefully contribute to care within the NHS both in general practice and the hospital setting. By reducing prescribing costs it will help with the current economic challenges that the health service faces, by reducing not only direct drug costs, but also the number of expensive to treat and sometimes fatal adverse effects of conventional medicine. It is popular with patients and can help with problems that have not responded to conventional treatment including chronic and multiple pathologies.

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Declaration of Interests.

President of the Faculty of Homeopathy and Director of Education and Women's Services at The Royal London Homeopathic Hospital. I have a small private practice.

November 2009

Memorandum submitted by the Society of Homeopaths (HO23)

1. Summary

1.1 The demand for Evidence Based Practice in healthcare has led to a stringent examination of evidence for all types of healthcare interventions. Decisions about what treatments are offered are informed by the "best" evidence available. However, there are many other factors that also inform this decision making process such as cost effectiveness, safety and patient preference. In addition, policy making in health care has to adhere to ethical standards. Government policy in health care, as in all other areas of policy making, cannot be founded upon consideration of evidence in isolation. In this submission the question of efficacy is considered within a broader ethical framework. In particular the issue of decision making in situations where there is debate about efficacy is addressed.

2. About the Society of Homeopaths

2.1 Established in 1978, the Society of Homeopaths is the longest standing registering body for professional homeopaths and is now the largest organisation of its kind in Europe. The Society, with approximately 2,500 current members, represents 65% of all registered homeopaths in the UK.

2.2 The Society has long been committed to the highest standards for homeopathy, having run a voluntary regulatory system for the last 30 years and a course recognition process for the last 15 years. Further, it was the first homeopathy organisation to institute a Code of Ethics & Practice. Members must meet the stringent standards of competence for clinical and administrative practice set by the Society. Consequently our members are trained to very high academic and professional standards. Our members also hold comprehensive insurance.

2.3 The Society is applying to the Health Professions Council (HPC) for the statutory regulation of homeopaths, following a survey in 2006 which showed that 65% of our membership supported statutory regulation. The application coincides with the tenth anniversary of the House of Lords' Select Committee on Science & Technology report into Complementary & Alternative Medicine (session 1999–2000), which categorised homeopathy as a "Group One" therapy along with acupuncture, chiropractic, herbal medicine and osteopathy. This report stated that, "Under The Society of Homeopaths, the non-medical homeopaths have organised themselves well and their professional organisation should mean the transition to statutory regulation does not present too great an upheaval."[1] The move to statutory regulation is seen as a natural step forward for both The Society and the profession, most importantly to offer protection to the public as, under existing laws, someone without training can currently practise as a homeopath.

3. A Framework for Decision Making

3.1 Traditionally the practice of medicine has been subject to many pressures, driven not only by developing scientific knowledge, but also in reaction to social, political and financial forces. For example, Primary Care Trusts, controlling 80% of the NHS budget, respond to the needs of their local communities when making decisions about delivery of health care and health improvements to their local areas. The National Institute for Clinical Excellence (NICE), responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health, outline key principles underlying NICE clinical guidelines that incorporates the following factors:

- designed to promote good health and prevent ill health;
- produced by the people affected by our work, including health and social care professionals, patients and the public;
- based on the best evidence;
- transparent in its development, consistent, reliable and based on a rigorous development process;
- good value for money, weighing up the cost and benefits of treatments; and
- internationally recognised for its excellence.[2]

3.2 Government policy in health care, as in all other areas of policy making, cannot be founded upon consideration of evidence in isolation. For instance, good value for money has to be considered within the context of limited resources. Efficacy plays an important role but cannot be the sole deciding factor. To do otherwise could exclude a large proportion of conventionally accepted treatments currently used within the NHS that do not satisfy the evidence standard.[3]

3.3 In addition, policy making in health care has to adhere to ethical standards. Current thinking in healthcare ethics tends to focus upon the four principles outlined by Beauchamp and Childress[4] as the foundation for ethical professional practice and these will form the point of reference for this submission. The four principles are:

— Respect for autonomy.

— Beneficence.

— Non-maleficence.

— Justice.

The question of efficacy will be considered within a broader ethical framework that also takes into consideration the above four principles

3.4 Hence five questions arise from ethical consideration of the issues to be addressed by the committee:

(a) Is the intervention effective?

(b) Is the autonomy of the patient respected?

(c) Is there a prospect of benefit?

(d) Is there a risk of harm?

(e) Is the principle of justice respected?

4. *Is the intervention effective?*

4.1 The question of efficacy in homeopathy often generates a highly charged debate, particularly in the UK, that has to date not yet been resolved. The following table describes some of the main issues that are often quoted on either side of the debate.

Homeopathy is effective	*Homeopathy is not effective*
Historical and case-based evidence shows the clinical effectiveness.	Historical and case-based evidence is not acceptable as proof of efficacy.
Observational studies (of which there are many) consistently report highly positive effects	Observational studies do not exclude the possibility that homeopathy is no more than placebo
Research methods most highly placed in the evidence hierarchy of Evidence Based Medicine (RCTs and systematic reviews) do not adapt well to complex interventions such as homeopathy	The only way to thoroughly test an intervention is through a placebo controlled, randomised trial
Inherent bias prevents a fair consideration of evidence such that when positive results from RCTs in homeopathy are published they are dismissed.	Bias exists on both sides and results can be manipulated or occur by chance
There is a distinct lack of funding available for research in homeopathy	Research into homeopathy should not be funded as the agents cannot be effective in the dilutions given.

4.2 The above two positions cannot be reconciled on the position of evidence.

If only evidence from RCTs and systematic reviews of RCTs is considered acceptable proof of efficacy, a substantial proportion of interventions currently used within the NHS violates the evidence principle. Estimates vary widely (from 11–70%) as to the exact proportion of interventions that can be evidence-based in this manner.[3] In addition, it is accepted that in some areas of medical practice, for example surgical procedures, most practice is not evidenced through RCT research as RCTs would be unethical to conduct. Hence a major challenge for the evidence-based movement in medicine is that many areas of practice suffer from a paucity of RCT evidence leading to the conclusion that there is "no evidence" for the practice on evidence databases such as Bandolier and The Cochrane Library.

4.3 This demand for RCT evidence also contradicts current World Health Organisation (WHO) policy to promote and stimulate research into and use of traditional medicines.[5] For the WHO, therefore, other types of evidence must carry some value. For example, The Complementary Medicines Evaluation Committee has adopted the following definition of "traditional use" for regulatory purposes:

> "Traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose".[6]

4.4 Typically however the greatest debate in homeopathy centres not on the issue of whether treatment by a homeopath can have positive benefits, but rather it is rooted in the question as to whether or not highly diluted remedies can have an effect. Sceptics variously describe homeopathy as "water", "placebo" or even "the ultimate fake".[7] To accept that homeopathic remedies have an effect would entail revision of much of our basic scientific conception of chemistry and the body.[8] Others point to a growing number of scientists around the world who are investigating possible measurable effects of ultra high dilutions.[9–11] These scientists include well known and respected individuals such as Luc Montagnier, Nobel Prize winner for discovery of the AIDS virus, who recently published a paper describing detection of electromagnetic signals from highly diluted solutions of pathogenic bacteria.[12] In spite of the opinions of many sceptics scientific investigation of this nature is being undertaken suggesting that this remains an unanswered question.

4.5 Philosophers of science might tell us that what we have here is a state of underdetermination. This thesis states that any given body of evidence may support numerous, even contradictory theories, a situation that can be exacerbated when there is disagreement about what constitutes evidence. Scientific theories are inevitably underdetermined by data, such that what counts as good scientific theory depends largely upon other factors: social and political agendas, preferences, biases and whims—not the evidence itself. We can find clear examples of underdetermination in homeopathy. Many people have carried out systematic reviews and meta-analyses of placebo-controlled homeopathy trials in an attempt to answer the question of whether or not homeopathy is more effective than placebo.[13] These studies have been drawing upon the same data sources, published trials of homeopathy, and yet they come up with conflicting and contradictory results. The same data can be used to support either the claim that homeopathy does have an effect over and above placebo and also that it does not have an effect over and above placebo. Both theories are underdetermined by the available data and the data can be used to support either one.

4.6 Hence the question arises, "what happens when agreement cannot be reached about efficacy?" Should a practice continue to be funded or should it be withdrawn? What actually happens in healthcare is that where there is a lack of RCT based evidence decisions are made on the basis of other types of evidence that may include traditional and historical use or advice from experts etc. The treatments are not simply withdrawn. Evaluation of existing practice can act as a crucial indicator in this scenario and results of that evaluation are fundamental for any decision making. These questions need to be asked: "Have the outcomes been measured?" "Is there an indication of benefit?" If the answer is yes then practice should continue but further research might be needed. Decisions about healthcare should not and are not based purely upon the issue of "evidence" in its narrowest sense.

5. *Is autonomy of the patient respected?*

5.1 Respect for autonomy means respecting the capacity of an individual to be self-determining, to make decisions for themselves without undue pressure, coercion or other forms of persuasion. Paternalism occurs when actions of a health care practitioner override or do not seek the wishes of the patient, believing that they are better able to decide what is in the patient's best interests. Respect for autonomy implies that paternalism should be avoided as much as possible such that whether or not the doctor knows best, s/he should respect the patient's own choices and wishes if possible.

> "Giving people more choice is a priority of the modern NHS. This is because research in the UK and overseas has shown that treatments are more effective if patients choose, understand and control their care."[14]

5.2 The United Kingdom is a nation of well-educated individuals who are capable of making decisions about their own healthcare and it is clear that there is much choice available to them. Many studies show that homeopathy is one of the most popular forms of complementary and alternative medicine (CAM) in Europe, being practised in 41 out of 42 European countries.[15] Homeopathy is the most frequently used CAM therapy in five out of 16 surveyed countries in Europe and among the three most frequently used in 11 out of 16 surveyed countries.[16] If people are choosing to use homeopathy then the more information that is available to them to help inform decision making the better.

5.3 The labelling of the most commonly used over the counter homeopathic medications could inform decision making for individuals ensuring responsible usage of these medications. Thus labelling of a limited range of products should be acceptable if it does not contravene other ethical principles.

5.4 Autonomy of patient and patient choice in healthcare must be considered within light of other ethical principles such that welfare is protected.

6. *Is there a prospect of benefit?*

6.1 Results from many studies, including an evaluation of service by practitioners registered with the Society of Homeopaths, show that many patients seek homeopathic treatment for conditions for which there is either no conventional alternative or for whom the conventional treatment is not acceptable.[17] For example many people seek help for conditions such as Chronic Fatigue for which there is no clear conventional treatment. Women for whom Hormone Replacement Therapy is contraindicated might come

with symptoms associated with the menopause. The majority of patients that seek homeopathic treatment have tried conventional approaches first.[18] The provision of homeopathy is therefore meeting the needs of a patient population who are not having those needs met elsewhere.

6.2 The results from numerous large scale observational studies around the globe demonstrate that homeopathic treatment evaluates very well. The largest in the UK to date was conducted at the Bristol Homeopathic Hospital[18]. In this observational study of 6,544 consecutive patients during a six-year period, and over 23,000 consultations, results showed that 70.7 % reported positive health changes, with 50.7 % recording their improvement as better (+2) or much better (+3). Of the 1270 children that were treated 80.5 % had some improvement, and 65.8 % were better (+2) or much better (+3).

6.3 Who decides whether homeopathy is of benefit? Should this be the homeopath, the doctor, the politician, the sceptic? Clearly those patients who seek homeopathic treatment on a regular basis believe that they benefit from this intervention.

7. *Is there a risk of harm?*

7.1 The World Health Organisation acknowledge that, "in general, traditional procedure-based therapies are relatively safe, if they are performed properly by well-trained practitioners"[5] In particular studies show a very good safety record for homeopathy with little risk of harm from the remedies.[19] In contrast the number of adverse drug reactions from conventional medicines reported in 2005 in the UK was 21,234, of which 5% were fatal. The NHS spends £466 million/year treating adverse effects from conventional medicines.[20]

7.2 Risk of harm to the patient in homeopathy arises from poorly qualified or regulated practitioners rather than the practice itself. Registered members of The Society of Homeopaths have met stringent academic requirements, completed a registration process, hold comprehensive insurance and agreed to abide by a Code of Ethics & Practice, providing the general public with a guarantee of safety and competence.[21]

7.3 The best way to ensure patient safety is to continue to offer homeopathy within the NHS and to properly regulate those practitioners who work in private practice.

7.4 It is sometimes stated that patients are put at risk of harm when seeking help from CAM practitioners because this might delay them seeking help from conventional medicine.[22] In practice it is rare for a patient to seek help who has not already tried the conventional approach. In addition it is not uncommon for a homeopath to refer a patient back to their GP. The in-depth method of consultation by a homeopath can reveal signs and symptoms that the GP may not have had time to uncover and hence treatment can act as an extra safety net rather than a potential risk. The Society of Homeopaths has a clear and transparent complaints procedure and registered practitioners have agreed to abide by a strict code of ethics and practice.

8. *Is the principle of justice respected?*

8.1 The principle of justice requires that we do what we can to ensure that costs and benefits are fairly distributed. In the UK homeopathy is mostly delivered in the private sector and therefore not easily accessible to those who cannot afford to pay for treatment. Patient choice here is affected by affordability and those with less money have less choice. However, homeopathic treatment is available via the NHS in some parts of the country such that patient choice for individuals in these locations is increased in this regard.

8.2 In considering the justice of offering homeopathic treatment by the NHS the relative cost of this provision must be weighed against the relative benefits to the patients. In addition the issue of whether the money that is used to provide this service could bring a greater amount of benefit to a greater number of people if used otherwise needs to be considered.

8.3 The total amount that is spent on homeopathy in the NHS is approximately £4 million per year representing just 0.0004% of the total NHS budget.[23] What we have here is a situation where a comparatively small amount of money is being used to generate a very high level of patient satisfaction.

8.4 0.0004% of the total NHS budget is being spent on a service for patients for whom conventional approaches are either not suitable or desirable. The patients choose this service, they feel benefit from the service and there is no evidence of harm resulting from that use. It could be claimed here that adherence to the principle of justice leads to the conclusion that homeopathic provision should be vastly *increased* on the NHS to ensure that benefits are available to all.

9. Recommendations

9.1 When reviewing the evidence for traditional medicines such as homeopathy that consideration be paid to a variety of different types of evidence as recommended by the WHO.[5]

9.2 When reviewing the provision of homeopathy by the NHS due consideration be paid to ethical issues such as patient autonomy, safety, benefit and cost-effectiveness and not simply the notion of evidence in its narrowest sense.

9.3 When considering policy on the licensing of homeopathic products that again due consideration be paid to the ethical concerns described.

Conflict of Interests

The Society of Homeopaths is a registering body for professional homeopaths in the UK.

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November 2009

Supplementary memorandum submitted by the Society of Homeopaths (HO 23a)

RE: EVIDENCE CHECK: HOMEOPATHY, 25 NOVEMBER 2009

I attended the above session this morning and was concerned to hear Dr Evan Harris ask questions of two witnesses that directly related to The Society of Homeopaths, without intervention or challenge from the Chair or opportunity from The Society itself to clarify and defend its position.

For your information, The Society, as the largest body representing professional homeopaths, did ask to give oral evidence to support its written submission but was refused.

Dr Harris asked Dr Fisher "What was your reaction to The Society of Homeopath's symposium that argued that AIDS could be treated homeopathically?"

This symposium on HIV/AIDS (2007) was just that—a symposium—or discussion forum—to look at whether homeopathy had a role to play in the treatment of patients with HIV/AIDS. At no point was the symposium or The Society making claims that homeopathy offered a cure for this terrible disease.

Dr Harris also spoke about disciplinary action, including striking off members from a register and referred to the 2006 undercover interviews of several homeopaths by the organisation Sense About Science.

Dr Harris asked Dr Matthie whether any action had been taken against any of the ten practitioners accused of promoting "prophylactic homeopathic anti-malarials in the absence of advice about conventional malarials and bed nets…avoiding being bitten." He continued by asking "Should The Society of Homeopaths take and register someone who prescribes (prophylactics)?"

I would like to advise the Committee that, in actual fact, only one of the practitioners interviewed for this programme was a homeopath registered with The Society and that after significant delay and reluctance on their part, Sense About Science finally released the transcript of the relevant telephone conversation to us for investigation. This was immediately forwarded to our Professional Conduct Department, who reviewed it and concluded that it had not breached The Society's Code of Ethics & Practice.

Whilst Dr Harris is right to be concerned about the advice given to the public concerning homeopathy, it is dangerous to assume that edited material on a television programme constitutes evidence of malpractice. The propensity for trial by media must surely be replaced by an independent adjudication process which assesses all the evidence against a clearly laid out Code of Ethics & Practice?

Of greater concern should surely be the number of homeopaths in the UK who are not registered with any organisation. Currently, there is no requirement for any training at all in order to call oneself a homeopath. This is certainly a cause for concern for The Society and I am sure, for the Select Committee also.

The Society of Homeopaths has a strict Code of Ethics & Practice, which all registered members are required to abide by. The ultimate sanction is removal from the register. Indeed, during the last two years, two members have been removed in this way. However, one of the flaws of this voluntary regulation process is that anyone removed is free to simply transfer to another register.

You will be aware from our submission to the Committee (although this was not mentioned at all during today's session) that The Society is leading the call for the statutory regulation of homeopaths, through its application to The Health Professions Council.

It was therefore encouraging to hear universal support today for greater regulation of homeopaths. I hope, in its summing up, that the committee makes this a formal recommendation for future action by government.

Paula Ross
Chief Executive
The Society of Homeopaths

November 2009

Memorandum submitted by the Complementary Medicine Research Group, University of York (HO24)

ABOUT THE COMPLEMENTARY MEDICINE RESEARCH GROUP, UNIVERSITY OF YORK

The Complementary Medicine Research Group is based within Department of Health Sciences, which in the 2008 Research Assessment Exercise, was rated joint first nationally for health services research. We have a strong track record of conducting clinical evaluations of osteopathy, chiropractic, acupuncture and homeopathy.

We have five primary aims:

1. To establish the clinical, economic and individual impact of complementary therapies for specific conditions.
2. To evaluate the safety of complementary therapies.
3. To develop evaluative methodologies appropriate to complementary medicine.

4. To build capacity for rigorous research into complementary and alternative medicine.
5. To disseminate the results of research in order to inform the public and influence policy and practice.

We have been successful in attracting a range of funding from the National Institute for Health Research (NIHR), including a Career Scientist Award (for Hugh MacPherson at £365,000 from 2007 to 2012), a Research for Patient Benefit Grant (£250,000 from October 2008 to September 2011) and a Programme Grant for Applied Research (£1,300,000 from 2009 to 2014). More information about our projects and publications can be obtained from: https://hsciweb.york.ac.uk/research/public/Group.aspx?ID=4.

The Context

Homeopathy is regarded with scepticism by the establishment yet it is widely used by the general public who often experience it as a useful adjunct to conventional medicinal care. While the plausibility of homeopathy is of concern to many scientists, its widespread use leads those of us who conduct health services research to call for more and better research into the evidence in the interests of the public good. In parallel with the increased public interest in homeopathy is the demand to show evidence of clinical efficacy. While the evidence base is currently patchy for homeopathy, as it is for quite a number of conventional medical interventions, the imperative from the research point of view is to conduct research that reflects the way homeopathy is used, whether as over-the-counter remedies or with a consultation by a homeopath. Such research should build on the current evidence base, which is summarised below.

The Evidence Base

Since the early 1970s, there have been a total of 99 randomised controlled trials investigating homeopathy with over half of those conducted since 2000. The reports of those trials have been published in good quality peer reviewed journals, and the results show a mixed picture.

In 44% (n = 60) the studies report positive findings, where the homeopathy treatment showed statically significant superior effect compared to placebo, and those effects have been replicated by two or more studies in conditions of Childhood diarrhoea (individualized treatment),[1–3] Fibromyalgia,[4,5] Influenza, [6,7] Osteoarthritis, [8,9,10] Seasonal allergic rhinitis, [11,12–21] Sinusitis [22–25] and Vertigo.[26,27]

There have also been positive findings in RCTs investigating: Chronic fatigue syndrome,[28] Premenstrual syndrome, [29] Post-partum bleeding,[30] Sepsis [31] and Stomatitis[32], however, for these conditions conducted between 2001 and 2005, there has been no replication to verify the findings.

In contrast 7% of the RCTs reported negative findings, where the homeopathy was considered to have a worse effect than the placebo, whilst nearly half (49% n = 68) find inconclusive results.

Negative or inconclusive results have been observed for: Anxiety,[33–35] Childhood asthma,[36,37] Insect bites,[38,39] Menopausal symptoms in breast cancer,[41,41] Migraine,[42–44] Muscle soreness,[45–49] Post-operative bruising/haematoma/pain/swelling,[50,51–57] Rheumatoid arthritis,[58–60] Stroke,[61,62] Upper respiratory tract infection (prevention)[63,64] and Warts[65,66].

The most robust evidence presented is from several major systematic reviews of randomised controlled trials. The aim of the systematic review is to assess the quality and rigour of the individual trials that are included, and then compare and contrast the findings of each and comment on the consistency or inconsistency of the findings as a body of work. To date there are eight systematic reviews that provide evidence that the effects of homeopathy are beyond placebo when used as a treatment for childhood diarrhoea, influenza, post-operative ileus, respiratory tract infection and vertigo, and three providing consistent evidence of effectiveness for hay fever and associated pollenitis.

Future Research into Homeopathy

Although there is an increasing body of trials available, the lack of independent confirmation of reported trials and the presence of conflicting results is a major limitation to homeopathy research. Furthermore the general field is bedevilled by the lack of well-designed replicable studies conducted by independent research teams. Two key factors inhibiting current and future homeopathy research are the lack of adequate funding and lack of well-trained homeopaths who are sufficiently qualified and interested in engaging in objective research.

Of those studies that have been conducted, a common finding by systematic reviewers is the poor quality research and weak methodology. Also problematic is the lack of reporting the key components such as allocation concealment after randomisation, pre-specified outcome measures, and the reporting of attrition rates and numbers of participants withdrawing from trials. The influence of indicators of methodological quality on study outcome cannot be underestimated. Linde and colleagues[67] find that studies with higher-quality scores had a tendency to be less positive than those with lower-quality scores. After discarding the lower-quality trials, however, they still found homeopathic treatment to be more effective than placebo.

A common refrain among reviewers is to call for more trials and larger trials. However, it would be more meaningful to consider not only the need for more and larger trials, but for trials of more rigorous quality. Furthermore, we suggest that there should be a greater emphasis on comparisons to conventional treatments. There is a need for to develop pragmatic randomised controlled trials that compare homeopathy to the usual care available for the condition. For placebo controlled trials of homeopathic remedies prescribed by a homeopath, there needs to be a placebo control that adequately emulates the therapeutic relationship.

Reporting of homeopathy trials will be enhanced by the implementation of the recent "RedHot"[68] supplement to the widely adopted CONSORT guidelines. The RedHot recommendations support the inclusion of information on consultations, practitioners, theoretical models, and case analysis strategies. These recommendations were developed as part of our research endeavour at the University of York to facilitate the replication of homeopathy trials and support the development of a more robust evidence base for homeopathy.

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November 2009

Memorandum submitted by Francis Treuherz (HO 25)

1. I am responding to the invitation to submit material to the Science and Technology Committee of the House of Commons on the subject of homeopathy.

2. In relation to the licensing of homeopathic products and the evidence base on homeopathic products and services I wish to make you aware of one of the largest resources of literature about homeopathy. The library collection has well over 8,000 volumes from the beginnings of homeopathy to the present day, in books and journals. This is an invitation to members of the committee to come and study the books in my private library in northwest London. I have one of the largest such collections in the world. There is a catalogue and many of the books are on computer and fully searchable.

3. I am sending to the committee a copy of a book, *Homeopathy: Science or Myth*, by Bill Gray MD. (Berkeley California, 2000, North Atlantic Books). This book is a first rate introduction to homeopathy and the contents are relevant to your interests, including clinical evidence and public policy concerns.

4. I am sending to the committee a copy of a report on homeopathic work in NHS primary care: *Homeopathy in General Practice*, by Francis Treuherz RSHom. (Northampton, 2000, Society of Homeopaths), which I hope is of interest.

November 2009

Memorandum submitted by the Homeopathy Research Institute (HO 26)

SUMMARY

1. In this report I will focus on the evidence base of the action of homeopathic preparations, more specifically on the evidence coming from clinical trials, animal studies, in-vitro studies and physico-chemical experiments.

2. From this evidence several conclusions can be drawn: firstly, the evidence for homeopathy in clinical trials is sufficient to warrant further research; secondly, although the mechanism of action of homeopathy is still unknown experiments on cellular system preclude the hypothesis that placebo effects be solely responsible for the results from clinical trials.

3. In conclusion, although the mechanism of action remains elusive, the results of scientific studies indicate that homeopathy shows physical, biochemical and clinical effects sufficient to classify it as a therapeutic agent in its own right, warranting pursued clinical and fundamental research.

ABOUT THE AUTHOR

4. The author (Dr A Tournier PhD) is a biophysicist with training in: physics (BSc, Imperial College), theoretical physics (Cambridge, part III), the biophysics of water-protein interactions (PhD, Heidelberg) and homeopathy (Diploma, CHE).

5. Dr Tournier is currently actively involved in research as postdoctoral fellow working for Cancer Research UK.

6. Dr Tournier is also the founding director of the Homeopathy Research Institute, a charity dedicated to promoting high-quality research in the field of homeopathy.

Evidence from Clinical Trials

(a) *Evidence from Placebo Randomized Controlled Trials (RCTs)*

7. With over 150 clinical trials in homeopathy to date, there have been four meta-analyses of RCTs of the field.[1–4] All four conclude that the results of the trials cannot be attributed to placebo alone and recommend further research be undertaken in the field.

8. Contrary to this trend, a recent comparative meta-analysis of homeopathic trial vs. equivalent trials from conventional medicine concluded in favor of placebo being the likely explanation behind the results.[5] However, its methodology has since then been heavily criticized and its conclusion deemed unreliable.[6]

(b) *Evidence from pathogenetic trial*

9. Pathogenetic trials (or provings) lie at the heart of homeopathy practice: they are traditionally used to compile and analyze the symptoms reported by healthy individuals when ingesting a specific homeopathic remedies. These symptoms are then used in practice to cure patients with similar symptoms. This is referred to as the "law of similars".

11. Although early pathogenetic trials have been criticized for their lack of scientific rigour,[7] results from recent studies such as Möllinger etal 2009[8] strongly indicate that homeopathic medicines create remedy-specific symptoms in healthy volunteers.

12. While such studies are relatively inexpensive to perform, reproducing and extending such trials could conclusively answer the question "*do homeopathic remedies have a specific clinical effects beyond placebo?*".

Evidence from Animal Studies

(a) *Veterinary research*

10. Although homeopathy is widely used to treat animals relatively little veterinary research has been undertaken so far.[9]

(b) *Animal Models*

11. Animal models have been used to investigate the effects of homeopathy in the context of immunology.[10] With over 36 publications in this field interesting observations have been made of the way homeopathic remedies affect the immune system. Although encouraging results exist in the field the present state of the research does not lead to any definitive conclusion.

12. Researchers in Austria have experimented with homeopathic doses of thyroxin (a thyroid hormone). It was found to have the effect of slowing down their morphogenesis into frogs. The results seem to be reproducible (five labs), more trials need to be performed.[11]

Evidence from In-Vitro Studies

13. In-vitro studies have been used to look at the effect of homeopathy on certain cell lines and cell types. Overall the evidence strongly suggests that homeopathic preparations have an effect on cell lines and on biochemical reactions.[12]

(a) *Basophils degranulation experiments*

14. The basophil degranulation experiment was originally developed in the lab of the last Prof J. Benvenist. In this experiment human cells (basophils) are subjected to homeopathic dilutions of a specific anti-body, which triggers a phenomenon called degranulation in normal circumstances. These experiments, now widely repeated (11 high-quality publications) have reported that homeopathic preparations trigger the degranulation process although none of the original antibody remains in the preparation.[12]

(a) *Cellular systems*

15. In these experiments cells, such as cancer cell lines, and different types of cells are subjected to different homeopathic preparations. Five high-quality publications have reported effects in this field.[12]

(b) *Molecular systems*

16. These experiments measure the effect homeopathic preparation have on enzymatic reaction. The majority of high-quality investigations (7/9) in this field have reported positive results.[12]

Evidence from Physico-Chemical Studies

17. A number of experiments have looked at the physical properties of homeopathically prepared samples.[13]

18. NMR experiments: Five high-quality studies reported results in favour of the presence of a homeopathic effect using Nuclear Magnetic Resonance (NMR) measurements.[13]

19. More than 10 studies have looked investigated the properties of homeopathic preparations using different types of spectroscopic analysis (UV, Raman, IR). Although some studies have reported interesting observations no definitive conclusion can be drawn from the current studies.[13]

20. Another set of experiments investigate the electrical properties of homeopathically prepared samples. Here again, although the interesting results have been reported, due to methological defect, no definitive conclusion can be drawn.[13]

Overall Conclusions and Recommendations

21. Of the four areas of research presented above, human clinical trials and studies on cellular system show strong evidence of the presence of a clinically relevant effect of homeopathic preparations.

22. Many areas of research in homeopathy are not well developed enough to provide strong evidence. However, it is of the opinion of the author that the existing evidence warrants further research.

23. Most of the current criticism of homeopathy hinges upon the fact that no adequate explanation for the phenomenon currently exists. However, it is of the opinion of the author that the present levels of evidence are sufficient to seriously consider the hypothesis that the effect of homeopathic preparations relies on novel states of matter as yet poorly understood.

24. In the present state of ignorance of the physical theory behind the phenomena, the current knowledge is based entirely on meticulously gathered empirical evidence by generations of dedicated homeopaths. Until our theoretical understanding catches up with the empirical knowledge in the field, research in homeopathy will rely heavily on the accumulated knowledge of practising homeopaths.

25. My recommendations are the following:

26. To pursue and ensure the adequate funding of clinical research in homeopathy, making sure the practical experience of practising homeopaths is properly taken into account in designing the research protocols.

27. To foster basic research in homeopathy, recognising homeopathy as a potentially groundbreaking field of research.

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Dr Alexander Tournier

November 2009

Memorandum submitted by the Alliance of Registered Homeopaths (ARH) (HO 27)

1. Declaration of Interests

The Alliance of Registered Homeopaths (ARH) is the second largest registering and regulatory body for the homeopathy profession in the UK. ARH currently has nearly seven hundred qualified homeopaths on its register, and just under four hundred individuals belonging to other membership categories, such as students and subscribers. ARH is set up as a Company Limited by Guarantee, and is a not for profit organisation. We are committed to supporting and promoting a high standard of safe, effective homeopathic practice, and to ensure that quality homeopathy is available to all who wish to use it. Other ARH functions include:

— raising public awareness of the potential of homeopathic treatment;

— encouraging a high standard of education for homeopaths;

— supporting the ongoing professional development of our members;

— encouraging co-operation between our members and other healthcare professionals, for the benefit of patients;

— engaging in research, publishing and other activities that enhance our understanding of homeopathy; and

— acting as an information base for the general public.

2. ARH has based our regulatory criteria on the UK National Occupational Standards for Homeopathy (NOS), and we were active participants in the recent revision of the NOS's, as overseen by Skills for Health, earlier this year.

3. Brief Overview of Homeopathy in the UK

It is estimated that there are well over 3,000 practising homeopaths in the UK, of whom 2,500 are registered with a professional body. Homeopathy is one of the most frequently sought complementary therapies, with at least 20% of patients choosing homeopathy as their treatment option each year. Access to homeopathic treatment via the NHS is limited. There are now just four homeopathic hospitals in the UK, and a number of Primary Care Trusts (PCTs) have withdrawn funding for homeopathy altogether, or will only refer a patient to one of the 400 GP's trained in homeopathy. Patients who choose to consult with a registered homeopath, or want to avoid long waiting lists, have to fund their own treatment. Many patients seek homeopathic treatment because conventional medicine has little to offer them, or they are suffering from adverse reactions resulting from a conventional intervention. Although homeopathy is often sought as a last resort when other treatment options have failed, outcomes are consistently positive, with an average of 70% of patients reporting an improvement of their symptoms following treatment.[1,2,3]

4. Recently, there has been a campaign demanding the withdrawal of funding for homeopathy via the NHS altogether, on the grounds that homeopathy is nothing more than placebo. This assertion by homeopathy's detractors represents a selective interpretation of the growing evidence base that exists, which in reality shows homeopathy to offer an effective, safe, and l cost healthcare intervention. Furthermore, to withdraw homeopathy from NHS provision would deny patients the right of choice, a fundamental component of the concept of patient centred healthcare delivery, as outlined in the Department of Health (DoH) White Paper "*Our health, our care, our say: a new direction for community services*".[4]

5. Cost Effectiveness

There have been a number of studies that demonstrate the cost effectiveness of homeopathy, but the constraints of time and word allocation only allow for a brief mention of two relatively recent examples. The Bristol Homeopathic Hospital conducted an outcome survey of over 6,500 individual patients, spanning 6 years from 1997–2003, and representing over 23,000 consultations. Two papers resulted from the analysis compiled by Dr David Spence and his colleagues, one focusing on patient outcomes,[1] and the other on cost efficiency.[5] Patients suffering from a broad range of chronic conditions including asthma, rheumatoid arthritis, depression, irritable bowel syndrome and chronic fatigue syndrome, were treated with homeopathy. An average of 70% of the patients surveyed experienced a significant improvement in their overall health following homeopathic treatment, and this was delivered at a fraction of the cost normally associated with providing conventional interventions for a similar range of conditions.

6. A cost evaluation of the treatment of respiratory disorders, was undertaken in the Campo di Marte Hospital, Tuscany, Italy, from 1998–2003.[6] The cost of conventional drug treatment given to a group of patients suffering from asthma and recurring respiratory disorders, was monitored for one year prior the introduction of homeopathic treatment, then compared to the conventional drug costs incurred over a two year period, following the introduction of homeopathic treatment. The analysis shows a reduction in drug costs specific to respiratory disorders of over 46%, and a reduction of general drug costs of over 42% in the patient group given homeopathy. Overall patient wellbeing also improved significantly, a fact which undoubtedly contributed to the reduction in drug requirements. For the patient group suffering from asthma specifically, conventional drug costs were *reduced* by 71% during the first year of homeopathic treatment, compared to the group receiving only conventional medication, whose drug requirements resulted in a 12% *increase* in overall costs. According to a recent news release from Asthma UK, dated 21 October 2009, the treatment of asthma in the UK costs an estimated £1 billion per year. The Italian study shows a cost saving on conventional drugs ranging from between 42% to 71% over a two year period. This makes the long term implications for delivering effective, cost efficient treatment of asthma with homeopathy, highly significant. A different facet of the cost effectiveness of homeopathy will be touched on later, in relation to the prevention of infectious diseases.

7. Gathering evidence

There are three principal ways in which evidence is normally gathered:

— the randomised, double blind, placebo controlled trial (RCT);

— outcomes based evidence, which can either be clinically sourced, or patient generated in the form of a "measure yourself medical outcome profile" (MYMOP); and

— empirical evidence, which is data acquired through direct observation, usually under controlled circumstances, where results are reported according to previously agreed protocols. There may be some overlap with outcomes based evidence.

8. The RCT

RCT's were originally developed as an appraisal tool, and were intended to support and augment evidence acquired through other, more observation based means. A number of scientists consider RCTs to represent a gold standard for determining the efficacy of a therapeutic intervention. However, RCTs have several inherent fundamental flaws. They are designed to support/enhance a particular outcome. The results they produce can, either intentionally or unintentionally, be interpreted to reflect the required outcomes. RCT protocols are founded on a number of broad generalisations and assumptions, making it difficult to take into account the reactions of each individual participant. Because homeopathy is a system of medicine in which individualisation is key to a successful prescription, gathering evidence via RCTs presents a significant challenge. However, a number of RCTs looking for quantitative evidence to support the efficacy of homeopathy, have been undertaken. In 1997, a meta analysis of data extracted from 89 clinical trials was published in The Lancet,[7] and concluded that the results showed the beneficial action of homeopathy could not be attributed to the placebo affect alone. Two subsequent reviews, analysing trials from the same data set, corroborated this conclusion,[8,9] though less strikingly than the original systematic review. This highlights a problem associated with meta analyses in general, which is that the quality of the reviews under consideration determines the usefulness of the information extracted via systematic analysis. Another problem may arise when (as mentioned earlier) the researcher selects the reviews to be analysed, via criteria likely to influence the outcome. Undoubtedly there is a valuable place for the RCT within scientific research, providing its limitations are fully acknowledged when interpreting the resulting data.

9. Outcomes Based Evidence

A number of outcomes based trials have provided positive information relating to the efficacy of homeopathy as a treatment option, and their scope is broad ranging. The Bristol Homeopathic Hospital Survey[1] is one well documented example already referenced. Another high profile study, this time considering homeopathy alongside other CAM therapies, was run as a year long pilot study in Northern Ireland, starting in February 2007. Its primary purpose was to evaluate how CAM could be effectively utilised in collaboration with conventional interventions provided by the NHS. The full report was published in May 2008,[10] and the results are very interesting. An in depth evaluation of the report entitled *Northern Ireland CAM Study*, by Heidi Stevenson,[11,12] concludes that the pilot was highly successful in achieving its goal; a demonstration of how CAM modalities could be integrated into the NHS, to the benefit of both patients and health care providers alike. As an aside, it also produced significant information giving credence to the efficacy of CAM modalities, with homeopathy showing excellent results for the treatment of mental/emotional problems. The study provides convincing evidence regarding the efficacy of CAM provision, which highlights the need for further research to be undertaken in this area. Given the severe financial constraints currently faced by the NHS, and the additional burden placed on already stretched NHS resources by an increasingly ageing population, the question to consider is "*how can the NHS afford not to fully utilise CAM provision in the services it offers*"?

10. A research project undertaken by Nigel Hargreaves in 2003, in partnership with NORCAS, a charity offering support to individuals with alcohol related problems, offered homeopathy and counselling to clients over a six month period.[13,14] Clients were given six in depth consultations with the homeopath, and their treatment was supported by regular sessions with their counsellor in between appointments. Outcomes where measured using MYMOPS, combined with feedback provided by the counsellors involved. Although the study was small, the results were very encouraging. Participants who completed the course reported that alcohol now affected their lives an average of 64% less than before commencing treatment. An additional benefit from treatment with homeopathy was a reduction averaging 68% in their use of conventional medication, such as anti depressants, sleeping pills and anti-psychotic drugs. This reduction would probably have increased if the study could have been extended further, because a number of drugs have a lengthy withdrawal period. Unfortunately lack of funding did not allow for any follow ups to take place. However, setting up and undertaking the study provided a useful foundation upon which to build for future initiatives. The study, which ran on a budget of just £5,000, also demonstrated that useful research into homeopathy does not necessarily have to cost large sums of money.

11. The North Kirklees PCT Homeopathy Service,[15] was a small scale pilot project which took place from April 2001 until March 2003. Two registered homeopaths worked in collaboration with a GP homeopath to offer a homeopathy service to patients in the North Kirklees Primary Care Group. Initially, patients participating in the study were offered six consultations with a homeopath. 287 patients were referred for homeopathy treatment, with the largest number suffering from anxiety and depression, with the next most common complaint being "female" problems. Again, MYMOPS were used to gather information. About 19% of patients did not complete the homeopathy course, but those who participated to the end of the project gave overwhelmingly positive feedback. 93% of participants said they would recommend the service to their friends. GPs within the PCG were also asked to provide feedback re the study, and although only just over half of the GPs asked actually responded, 76% of respondees said they wanted the service to continue, and 40% believed it should be a priority for funding.

12. Empirical Evidence

Empirical evidence represents the collective experience of countless individuals. It is information gathered primarily via observation over an extended period of time, which is then recorded, collated and used to increase and further develop knowledge within a particular field. Empiricism lies at the foundation of most of the scientific knowledge we take for granted today. Homeopathic literature is full of examples of the efficacy of homeopathy. One spectacular example is chronicled in the ARH's Journal, Homeopathy in Practice,[16] and describes an incident which took place in Kenya in 2005. A man in a feverish condition, and clearly in a great deal of pain, presented with a seriously swollen hand. The flesh across the bridge of his hand had been eaten away, and his fingers were in danger of falling off. Apparently he had been "bitten" by something some two weeks earlier. The homeopath prescribed for him, and took a photograph of the patient's suppurating hand. The patient then left to return to his remote village, somewhere in the bush. Some months later, the patient returned. He just wanted to say "thank-you" to the homeopath. His hand was back to normal, apart from a tiny hole just below his third finger, which was still oozing a small amount of pus. The homeopath gave him a new prescription and took another photograph, after which the patient left for the long trek home. The full case study, complete with photos, is included with this submission as appendix one.

13. It is worth noting that there are homeopaths all over the world, working in remote and sometimes hostile environments, treating life threatening conditions on a daily basis. These are places where homeopathy is the only healthcare option available. These are circumstances where the efficacy of homeopathy is constantly demonstrated, not in a laboratory, or as the result of a RCT purposely constructed to prove some hypothesis, but where it matters most, which is helping to relieve the suffering of countless human beings.

14. Homeopathy and Epidemics

Extensive medical records exist, recording the efficacy of homeopathy in the treatment of epidemics. For example, homeopathy's success at treating the Spanish flu outbreak of 1918 is well documented, especially in the US. The medical records of hospitals across the country consistently show a mortality rate of above 28% in sufferers treated allopathically, as opposed to a mortality rate of just over 1% of those treated with homeopathy. A more detailed account of homeopathy's efficacy in treating the Spanish flu outbreak in the US, is documented in a report to the Journal of the American Institute of Homeopathy, entitled "*Homeopathy in Influenza—A Chorus of Fifty in Harmony*".[17]

15. In 2008, a groundbreaking research study was conducted in Cuba, where homeopathy was used to prevent an outbreak of leptospirosis in 2.4 million people during the hurricane season. The results of this remarkable experiment, yet to be published in full, were first presented at a conference in Havana in December 2008. The Finlay Institute, a Cuban based research institute, responsible for the production of allopathic vaccines, is also involved in the research and development of homeopathic products. They were responsible for the manufacture of a homeopathic *Leptospira* nosode, which was rapidly made available to populations in the three areas most affected by the hurricanes. The result was that following the intervention, a dramatic decrease in mortality was observed, with confirmed cases of Leptospirosis at lower levels than

normally expected. Furthermore, there were no fatalities in hospitalized cases. This compared to several thousand confirmed cases of Leptospirosis in previous years, including some fatalities, even in populations where the allopathic vaccine had been used. Another remarkable feature of this study was its cost efficiency. The Leptospirosis nosode programme had been delivered at a total cost of around US$200,00, whereas a "normal" vaccination programme, which would only be delivered to the most "at risk" population, would be expected to cost in the region of US$3,000,000. The implications of these findings to third world countries, struggling to provide effective health interventions at a price they can afford, are massive. The Finlay Institute is planning to undertake a new study on a similar scale, using a homeopathic nosode of the H1N1 swine flu virus on large cohorts of the Cuban population. The results should prove to be very interesting. An overview of the Leptospirosis study is included with this submission, as appendix two.[18]

16. *Homeopathy and Chronic Disease*

Homeopathy has a long history of bringing relief and improved wellbeing to patients suffering from chronic diseases. A number of Indian homeopaths have written extensively about their experience of working with chronic diseases, and as many consultations in India take place within the clinical setting of a hospital, extensive records of medical diagnosis and response to treatment exist, to substantiate claims of successful treatment. Dr AU Ramakrishnan is well known within homeopathic circles, for his success in treating cancer. His book, *A Homeopathic Approach to Cancer*,[19] synthesis his experience of treating over 5,000 patients suffering from cancer, and is generally regarded as an invaluable reference source for homeopaths in practice worldwide.

17. *Homeopathy and Animal Health*

Homeopathy can be of considerable benefit to animal health. Animals are crucial to human existence, forming an important part of the food chain Animal health and human health are inextricably linked. It is harder to cite the placebo affect when observing an animal's response to appropriate homeopathic treatment. Critics often claim that restoration to health results from the intention to heal the animal. This hypotheses doesn't explain how mastitis in cattle for example, can be controlled by placing drops of a selected remedy in the drinking water accessed by the entire herd. Also, if an inappropriate remedy is prescribed, the best intentions in the world will not achieve a curative result. Homeopathy can be highly effective in the treatment of animals, yet surprisingly there are only about 250 vets trained in homeopathy in the UK, and of those, only a few treat farm animals. This restricts the choices available to livestock farmers, which can have particularly serious implications for organic farmers. It potentially limits the availability of chemical/hormone free meat available within the food chain, which in turn impacts upon the health and wellbeing of humans. As a result, an increasing number of livestock farmers are learning to use homeopathy themselves to successfully treat straight forward, acute situations. ARH has published a journal solely dedicated to exploring the potential of homeopathy in animal health,[20] a copy of which is included with this submission (will be posted separately) as appendix four.

18. In Conclusion

This submission has been an attempt to demonstrate the breadth and range of available evidence which shows homeopathy to offer safe, effective healthcare. The set word limit and tight time frame has precluded a more in depth submission. ARH would like to ask the House of Commons Science and Technology Committee to recommend that an investment of funding and resources is made, in order to gather more evidence of homeopathy in practice, and undertake new research. Every practising homeopath has a wealth of valuable information contained within their case studies. The establishment of simple protocols appropriate for undertaking a clinical audit, combined with the provision of means to systematically collate and analyse data, would be relatively inexpensive to oversee, and would reveal a wealth of information to further enhance our knowledge and understanding of homeopathy. Many ARH registered practitioners would be more than willing to participate in evidence gathering studies, provided they were offered basic guidance and support. Currently, the annual NHS budget stands at around £110 billion, and increasing patient demands are stretching available resources to breaking point. The inclusion of homeopathy in health care delivery could do much to enhance patient wellbeing, at the same time as significantly reducing overall costs to the NHS.

Karin Mont, on behalf of the Alliance of Registered Homeopaths

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November 2009

Memorandum submitted by the Arthritis Research Campaign (HO 28)

EXECUTIVE SUMMARY

1.0 *Brief introduction to the organisation and the submitter*

1.1 The mission of the Arthritis Research Campaign is to improve the lives of people with arthritis by: funding high quality research into the cause, treatment and cure of arthritic conditions, translating the outcomes of research to benefit patients, educating health professionals and providing information to the general public. The charity was founded in 1936 and is the fourth largest medical research charity in the UK and the only charity in the UK solely dedicated to investigating arthritis in all its forms. The charity invests an average of £30 million pounds every year in research, education and training.

1.2 The Arthritis Research Campaign does not receive any government or statutory funding and is therefore totally dependent on voluntary donations. Fundraising in the community is organised through a combination of voluntary fundraising branches, paid staff and charity shops. The charity has no conflict of interests to declare.

1.3 Professor Alan Silman, the Medical Director of Arthritis Research Campaign, makes this submission on behalf of the charity. In addition to his remit of developing and directing the research strategy for the Arthritis Research Campaign, he covers the charity's educational role which ranges from patient information to ensuring training for all health professionals. Prior to joining the charity in 2007 he was the director of the Epidemiology Unit in Manchester and had research interests in several areas of rheumatology. He has published over 500 original articles and several books, including being one of the five joint editors of the major international reference work *"Rheumatology"*. He serves on several national and international committees which include, among others, membership of the Expert Advisory Group to the MHRA and Chair of the Op Telic Health Review Board, the MoD committee responsible for overseeing research on the health of servicemen and women in Iraq and Afghanistan.

2.0 *Factual information*

2.1 *Some facts on arthritis:* more than six million people in the UK have painful osteoarthritis in one or both knees. Prevalence increases with age with one in five adults aged 50–59 to almost one in every two adults aged 80 + having painful osteoarthritis in one or both knees.[1] It is thought that over 10 million people in the UK have a form of arthritis. The Arthritis Research Campaign is currently re-evaluating the prevalence of arthritis in the UK and hopes to publish the results by the end of 2009. In terms of the cost of arthritis, research has shown that 10 million working days were lost in 2006–07 due to musculoskeletal conditions, second only to stress, depression and anxiety.[2] The cost to the UK of musculoskeletal conditions is £5.7billion annually[3] and arthritis is the most common condition for which people receive Disability Living Allowance.[37][4]

2.2 *Arthritis and alternative treatments:* over 60% of people with arthritis or other aches and pains use some form of complementary and alternative medicine[5]—and claim different things work for them. Under this broad heading are included care from alternative practitioners such as chiropractic and osteopathy as well as the use of over the counter herbal and other ingested agents. Overall 46% of the UK population use complementary medicines at some point in their lives spending over £450 million per year.[6] People with arthritis and musculoskeletal conditions, whose symptoms are often chronic, are particularly attracted to try such medicines and therefore need guidance to help them decide if such treatments may or may not be suitable for their arthritis and associated rheumatic conditions.

2.3 *An evidence-based approach to homeopathy:* in February 2009, the Arthritis Research Campaign published the first evidence-based report on the use of homeopathy and complementary medicines in arthritis using evidence from randomised controlled trials. A second report is underway on the use of complementary practitioners. A section within this report, written by the Arthritis Research Campaign in conjunction with national experts, is dedicated to homeopathy, which is defined by the Society of Homeopaths in England as "treating like with like" and based on an observation that symptoms of an illness are identical to those experienced by a healthy person treated for that illness. Homeopathic remedies are produced by a sequence of dilutions of an active substance causing similar symptoms in the belief that this will reduce the likelihood of harm.[7] The report is a summary of existing published studies which indicates whether or not there is scientific evidence to support the clinical effectiveness and safety of certain named products for people with arthritis. The report also considered issues such as biological plausibility and ease of obtaining the treatments.

2.4 *A simple way of communicating the information to the general public:* the Arthritis Research Campaign score medicines according to their effectiveness with one indicating that there is no evidence that the compound works and five indicating that the compound is effective. It also grades the medicines according to safety, providing traffic light classifications for each.

2.4.1 Based on the evidence available from clinical trials with other supporting information, the Arthritis Research Campaign categorised each medicine into one of five categories:

1. There is, overall, no evidence to suggest that the compound works or only a little evidence which is outweighed by much stronger evidence that it does not work.

2. There is only a little evidence to suggest the compound might work. The evidence from studies in this category often come from only a single study which has reported positive results and there are therefore important doubts about whether it works.

3. There is some promising evidence to suggest that the compound works. The evidence will be from more than one study. However there may also be some studies showing that it does not work. For a compound in this category however we are still uncertain whether it works or not.

4. There is some consistency to the evidence, which will come from more than one study, to suggest that the compound works. Although there are still doubts from the evidence that it works, on balance we feel that it is more likely to be effective than not.

5. There is consistent evidence across several studies to suggest that this compound is effective.

2.4.2 The research also included a categorisation of all compounds according to their safety profile. For many compounds it was not easy to do this because there was relatively little information available on safety. Where information was available, it was categorised, assuming that it is taken within the range of recommended doses. Compounds which are safe at the recommended doses may have serious adverse effects when taken at higher doses. Again, it should be emphasised that most conventional medicines have adverse effects, some serious. However, there is generally greater information available on conventional drugs in order to determine the frequency and range of such adverse effects. The categorisation used was:

[37] Disability Living Allowance (DLA) is a benefit for people who are so disabled, they have personal care needs, mobility needs or both. Claimants must be under 65.

Traffic light at Green

Compounds with reported adverse effects which are mainly minor symptoms and infrequent. A classification of Green does not mean that the compound has no reported adverse effects and patients should check in the product information leaflet what these are.

Traffic light at Amber

Compounds with adverse effects reported as common (even if they are mainly minor symptoms) or with more serious adverse effects.

Traffic light at Red

Compounds with serious adverse effects reported. Patients should carefully consider these before deciding whether to take these medicines.

There were some compounds on which there was very little information on adverse effects and it was therefore not possible to classify them. Such examples are therefore indicated by traffic light at Amber together with "No information" written alongside.

2.5 *Conclusion from the review of the evidence:* homeopathic remedies are widely available over-the-counter in pharmacies and health food shops throughout the UK. The mechanism of action of these remedies is not clear. There is no evident safety risk with the use of these remedies, and interactions with other drugs are unlikely. Even though isolated reports have suggested positive effects of homeopathy in the treatment of fibromyalgia, evidence is still not conclusive. Trials which investigated the role of these remedies in osteoarthritis and rheumatoid arthritis yielded inconsistent results.

2.6 *Relationship to Conventional Medicine:* The Arthritis Research Campaign review also made clear that the effectiveness of homeopathic and other complementary medicines needs to be evaluated in part against that of conventional remedies for the same condition. Furthermore, as many patients take both kinds of treatment there is a need to consider interactions both in terms of effectiveness and safety.

3.0 Recommendations

3.1 That the Committee welcomes an evidence-based approach to homeopathy, (as well as other non conventional therapies available over the counter), that can be communicated directly with lay audiences, and that the Committee actively encourages further evidence-based assessments of homeopathic remedies in arthritis as well as other diseases, so that more information is available to assess any real benefits from homeopathy. This is particularly important in chronic, progressive diseases.

3.2 That the Committee considers the straightforward 1–5 categorisation process for efficacy and the traffic light system for safety used in the Arthritis Research Campaign's review described above, for all areas of homeopathy, so that patients can make better informed decisions.

3.3 That the Committee agrees that the efficacy and safety of homeopathic and other complementary medicines available over the counter need be evaluated against the conventional remedies for the same condition as well as potential interactions of other remedies that could be taken at the same time.

4.0 Supplementary Material

Please find attached a pdf of the report, Complementary and alternative medicines for the treatment of Rheumatoid Arthritis, Osteoarthritis and Fibromyalgia, 2009. The report was written national experts in conjunction with the Arthritis Research Campaign.

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November 2009

Memorandum submitted by Dr Hugh J Nielsen (HO 29)

EVIDENCE FOR HOMEOPATHY IN THE NHS

1. Summary

1.1 Each of the homeopathic hospitals on the NHS reported clinical outcomes data from a wide range of medical complaints.[1–5] At each hospital, positive outcomes has been reported by about 70% of follow-up patients overall, pointing out the value of homeopathy to patients and the need for further research initiatives to investigate the positive effects of the homeopathic intervention in particular diagnoses.[6,7]

2. Background

2.1 The United Kingdom's homeopathic hospitals are located in Bristol, Glasgow, Liverpool, and London. The four have been part of the country's National Health Service (NHS) since its inception in 1948, and are staffed by medically qualified practitioners who possess additional training and certification in homeopathy. All units have outpatient services only, except Glasgow Homoeopathic Hospital (GHH), which has an additional in-patient service.

3. Homeopathic Hospitals Outcome Surveys and Other Studies

3.1 An observational study at Bristol Homeopathic Hospital included over 6,500 consecutive patients with over 23,000 attendances in a six-year period (Spence, Thompson & Barron, 2005).[8] 70% of follow-up patients reported improved health, 50% major improvement. The most common diagnostic groups were Dermatology, Neurology, Rheumatology, Gastroenterology, Psychiatry and Ear, Nose & Throat. The best treatment responses were reported in childhood eczema or asthma, and in inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine. The main weakness of this study was the crudeness of the outcome measure; the strength of the work was in its size and comprehensiveness. Further non-randomised research has corroborated such results in childhood eczema (Keil *et al*., 2008)[9] and menopausal syndrome (Bordet *et al*, 2008),[10] for example.

3.2 A 500-patient survey at the RLHH showed that many patients were able to reduce or stop conventional medication following homeopathic treatment (Sharples, van Haselen & Fisher, 2003).[11] The size of the effect varied between diagnoses: for skin complaints, for example, 72% of patients reported being able to stop or reduce their conventional medication. The study also showed that many patients seek homeopathy because of their concerns about the safety of conventional treatment.

3.3 In a pilot study published in 2008, data from 1602 follow-up patient appointments at all five NHS homeopathic hospitals were collected together over a one-month period (Thompson *et al*, 2008).[12] Eczema, chronic fatigue syndrome, menopausal disorder, osteoarthritis and depression were the "top five" most referred conditions. The medical problems referred to the hospitals typically are chronic conditions where available conventional treatments are often not effective. In total, the study identified 235 separate medical complaints treated at the hospitals during one month. Many patients had multiple pathologies. At just their second homeopathic appointment, 34% of follow-up patients overall reported an improvement that affected their daily living. For patients at their sixth appointment, the corresponding improvement rate was 59%. The study showed that reported health benefit may be gained more quickly in some medical conditions than in others. The pilot findings are informing a programme of standard setting for treatment outcomes in the NHS homeopathic hospitals.

3.4 Qualitative research carried out at GHH found that those motivated to seek this form of treatment may achieve an empathy with their homeopathic doctor that can make a positive contribution to the enablement and health change they feel as a result of their appointments (Mercer, Reilly & Watt, 2002; Bikker, Mercer & Reilly, 2005).[13,14] Patients attributed key importance to the length of consultations, the whole-person approach, being treated as an individual, and telling and having their "story" listened to in depth (Mercer & Reilly, 2004).[15]

3.5 An outcome survey carried out at the Liverpool department of homeopathic medicine over a 12 month period in 1999–2000 (Richardson, 2001)[16] 1,100 patients were surveyed; 76.6% reported an improvement in their condition since starting homeopathic treatment and 60.3% regarded their improvement as major. 814 patients were taking conventional treatment for their condition and 424[52%] of these were able to reduce or stop conventional medication. The main conditions treated were osteoarthritis, eczema, chronic fatigue syndrome, asthma, anxiety, headaches, inflammatory arthritis and irritable bowel syndrome.

3.6 A further outcome study was conducted at the same department in Liverpool covering the period 2001–06 (the study is in the final stages of preparation for publication). The study looked at 2,495 patients of whom 72.9% reported an improvement in their condition and 57.3% rated their improvement as major. 1648 patients were taking conventional treatment and 771[46.8%] of those were able to reduce or stop it. The main conditions treated in this study were eczema, osteoarthritis, chronic fatigue syndrome, menopausal symptoms, anxiety, asthma and depression.

3.7 A patient satisfaction survey carried out at the Liverpool department in November 2008 showed that of 132 patients questioned, 115 were very satisfied and 15 were satisfied with the service provided. 98 patients said that they thought homeopathy was helping their condition, 27 were unsure and two said it wasn't helping.

4. Recommendations

4.1 Given the patient outcomes and satisfaction it would be of immense benefit to the NHS and to patients to engage in research in homeopathy and cost effectiveness of homeopathy in the NHS.

4.2 The outcome studies demonstrate that there are specific conditions where homeopathy is particularly useful and is an important element in improving patients' lives.

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November 2009

Memorandum submitted by the Liga Medicorum Homoeopathica Internationalis (LMHI) (HO 31)

THE WORLDWIDE USE OF MEDICAL HOMEOPATHY

1. The Liga Medicorum Homoeopathica Internationalis (LMHI) was founded in Rotterdam, 10 September 1925 and was established under the terms of Swiss civil law with Geneva designated as its registered office.

1.2 The purposes of the association are the development and securing of homeopathy worldwide and the creation of a link among licensed homeopaths with medical diplomas and societies and persons who are interested in homeopathy. The association is exclusively devoted to non-profit activities serving philanthropic benefits.

1.3 The LMHI represents at this moment 70 countries worldwide and has approximately 10.000 members. The LMHI is therefore the worldwide biggest homeopathic medical association representing around 50 homeopathic medical associations worldwide.

2. THE USE OF HOMEOPATHY AROUND THE WORLD

2.1 In many countries all over the world homeopathy has gained official status. It has been officially recognized by the government as a system of medicine or medical specialty in the following countries:

— in Central and South America (Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, Mexico),

— in Asia (India, Pakistan, Sri Lanka) and

— in Europe (Belgium, Bulgaria, Hungary, Lithuania, Portugal, Romania, Russia, United Kingdom).

2.2 In some of these countries homeopathy has been integrated into the national health care systems, namely in:

— Brazil, India, Mexico, Pakistan, Sri Lanka and the United Kingdom.

2.3 In India, Pakistan and Sri Lanka, the legal standing of homeopathy is equivalent to that of conventional western (allopathic) medicine, many practitioners are certified in both homeopathy and allopathic medicine, and the primary care provider for many patients is a homeopathic doctor.

2.4 In India alone there are around 180,000 homeopathic doctors, trained and educated in hundreds of homeopathic medical colleges, recognized and supported by the Indian Government. Thousands of homeopathic hospitals support the Indian health care system.

2.5 There are a few thousand veterinary surgeons in the world who provide homeopathic treatment to pets, food-producing and other animals. The International Association for Veterinary Homeopathy IAVH established minimum training standards and the requirements for teaching programmes, examinations and continuing education. In most EU Member States there are special homeopathic training programmes for veterinarians as well as for dentists and pharmacists.

2.6 Over the past 30–40 years homeopathy has benefited from growing demand both from doctors and from the public in the majority of the European countries. According to a survey by European Commission order three Europeans out of four know about homeopathy and of these about 30% use it for their health care.

2.7 In the European Union there are approximately 40,000 physicians who have taken a training course in homeopathy. Many more doctors in Europe prescribe homeopathic medicines without any homeopathic training: approximately 25–40% of the GPs from time to time, 6–8% of them on a more regular basis.

2.8 Among the different forms of Complementary and Alternative Medicine (CAM), in particular homeopathy has a form of legal recognition in certain European countries, an organisational structure at European level as well as in many other countries in the world , self-regulatory mechanisms, and a level of scientific credibility.

2.9 Homeopathy is being increasingly recognised as a potential asset to European health care and to many other health care systems in the world. Resolutions on CAM (or non-conventional medicine) have been adopted by the European Parliament and the Council of Europe, EU Directives oblige the Member States to register homeopathic medicinal products, and homeopathic medicinal products are being included in the European Pharmacopoeia.

In Hungary (1997) and Lithuania (1999) homeopathy is officially recognized as a regular medical method by the government.

2.10 In 1999 the Belgian Parliament adopted a law with the aim to recognise some CAM modalities, including homeopathy. According to this law homeopathy is considered as an additional qualification (GP with homeopathy, paediatrician with homeopathy etc).

The Portuguese Parliament in 2003 and the Bulgarian Parliament in 2005 adopted similar laws, providing a framework for recognition of individual branches of CAM including homeopathy.

The Italian Parliament is currently discussing legislation that will eventually lead to the recognition of medical qualifications in homeopathy and other branches of CAM.

Several National Medical Associations have recognised homeopathy as a therapeutic medical method.

2.11 In Germany doctors can obtain, after passing an examination, an additional qualification "Homöopathischer Arzt" recognised by the Bundesärztekammer. A similar situation exists in Austria where the additional qualification "Homöopathie" is recognized by the Österreichische Ärztekammer.

The Latvian Medical Association (Latvijas Arstu Biedriba), which regulates and supervises all medical specialties, conferred homeopathy the official status of a clinical specialty in 1995.

2.12 In 1997 the French Medical Association (Ordre National des Médecins) recognised homeopathy as an existing therapeutic medical method and stated that homeopathic education should be installed at Universities, leading to a diploma authorised by the Ordre, and that systematic information on homeopathy should be given within the undergraduate medical curriculum.

2.13 A subspecialty under the term of "certificate of capacity in homeopathy" has been in place in Switzerland since 1998 in collaboration with the Swiss Medical Association FMH, for doctors holding a title of a current specialty such as General Medicine, Internal Medicine or Paediatrics.

2.14 In some countries, such as France, Germany, Poland and Spain, homeopathic education is provided at universities as well as at other training institutes. In France at eight universities (Aix-Marseille, Besançon, Lille, Paris-Bobigny, Bordeaux II, Limoges, Poitiers, and Lyon), in Germany at five universities (Berlin, Düsseldorf, Hannover, Heidelberg, and Freiburg), in Poland at seven universities (Warsaw, Poznan, Krakow, Katowice, Lublin, Gdansk, and Wroclaw), and in Spain at four universities (Barcelona, Murcia, Sevilla and Valladolid).

In all other European countries homeopathy is taught in private training institutes.

2.15 Several hospitals in Europe, in their out-patient departments, currently provide homeopathic treatment by physicians, ie Austria (7), France (2), Germany (5), Spain (2), Italy (some). There are five dedicated public sector homeopathic hospitals in the United Kingdom.

2.16 The LMHI has been also adviser to the World Health Organization (WHO) in regard to several working projects:

WHO Guidelines: Quality for Safety of Homeopathic Medicines

WHO Report Homeopathy: Overview and Analysis of Clinical Research

WHO Guidelines for Homeopathic Education

According to the World Health Organisation WHO, traditional medicine(TM) and complementary and alternative medicine (CAM) account for a major part of the health care provided worldwide. The WHO in 2002 drew up its report "Traditional Medicine Strategy 2002–05", describing its first global strategy on traditional and alternative medicine, which provides a framework for policy to assist countries to regulate traditional or complementary/alternative medicine (TM/CAM) to make its use safer, more accessible to their populations and sustainable.

3. Homeopathy and Scientific Credibility

3.1 Homeopathy is rooted in experiment and careful observation. In fact, the earliest systematic study of the action of medicines in medical history is the homeopathic pathogenetic trial—also called proving. Homeopathic pathogenetic trials are a type of research, in which compounds are tested on healthy human volunteers in order to observe as many effects as possible, at a non-toxic level.

3.2 Over the 200 years of its existence a large amount of documentation particularly case studies has been published on the curative effects of homeopathic medicines. Further, research in homeopathy takes place in the areas of Clinical Research (on patients), and Basic Research (in laboratories).

4. Homeopathy: A Safe Treatment

Homeopathy is safe. Unlike other medication, homeopathic medicines are non-toxic and harmless and do not have any adverse side effects. Patients unable to use conventional prescription drugs due to side effects can often safely use Homeopathic medicines. Homeopathic medicines are natural, prepared from minute amounts of herbs, minerals and animal products. Their quality and safety are assured by the national medicine agencies based eg on European Union legislation and European Pharmacopoeia requirements as well as on the national requirements in other countries of the world.

5. Homeopathy: A Low-Cost Treatment

Homeopathic medicines are much less expensive than conventional prescription drugs, because they are generic, non-patented and non-patentable medicinal substances, produced at low costs. On average, homeopathic medicines cost less than €1 per day in acute conditions and a few cents per day (sometimes a fraction of a cent) in chronic conditions.

The long-term gain has been demonstrated by several research studies. They show that patients who were treated with homeopathy used fewer medications, had better health, fewer days off sick, fewer visits to medical specialists, less time in the hospital than patients of conventional physicians. Moreover, there are no costs associated with complications due to adverse medication effects. In other words, homeopathy may offer significant cost savings to public health bodies, and to the economy more widely.

On account of the just mentioned advantages of an homeopathic treatment (Low-cost, high effectivity and safety) the Government of Thailand recently introduced homeopathy in their health care system providing also—at a university level—a full Homeopathic training for their medical doctors according to the Homeopathic Medical Education Standards from the LMHI.

It remains to mention that some health insurances in Europe offer the reimbursement of homeopathic treatments. In Germany eg, all PRIVATE Insurances reimburse the fees for the consultations with a homeopathic MD, as well as the costs for homeopathic medicines.

Also several PUBLIC Insurances made contracts for reimbursement for the fees for homeopathic consultations with the GERMAN ASSOCIATION OF HOMEOPATHIC MEDICAL DOCTORS. That means all homeopathic doctors being members of this association and having completed the three year long homeopathic training program for medical doctors are able to take part of these contracts and receive an adequate reimbursement for their work.

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November 2009

Memorandum submitted by Dr Clare Relton (HO 32)

Summary

1. This submission proposes that there is clarity in the key terms used in the inquiry: "homeopathy" and "evidence base".

2. "Homeopathy" is a term with multiple meanings which include:

(a) Therapeutic system of homeopathy

(b) Homeopathic products/medicines/remedies/pillules

(c) Homeopathic services/treatment by a homeopath

(d) Principles of homeopathy:

(i) Principle of Similars ("like cures like")

(ii) Principle of Minimum Dose

3. If understanding in this area is to progress, then the precise meaning of the term "Homeopathy" (a, b, c or d), should be stated.

4. Evidence base: there are many different types of evidence. We must be clear as to the nature of a) the evidence called for, b) the evidence cited and c) the evidence that exists.

5. The type of evidence called for to address a question, should match the evidence that is required to address that question, ie does this question require evidence of efficacy, clinical effectiveness, cost effectiveness, acceptability, safety..?

6. Thus each question in this inquiry will require clarification as to:

(a) What aspect of "homeopathy" is being referred to in this question (a,b,c,di,dii)?

(b) What type of evidence is required to answer this question?

(c) Whether the quality and the quantity of the existing evidence is sufficient evidence to yield an answer?

(d) If not, then can this evidence be produced?

Defining "Homeopathy"

7. Medical Subject Headings (MeSH) Terms were developed by the United States National Library of Medicine in order to index articles in Index Medicus and MEDLINE in order to provide a standardised way to describe diseases, symptoms, treatments, drugs etc. http://www.nlm.nih.gov/cgi/mesh/2007/MB_cgi

8. The MeSH term for "Homeopathy"describes it as: *"A system of therapeutics founded by Samuel Hahnemann (1755–1843), based on the Law of Similars where "like cures like". Diseases are treated by highly diluted substances that cause, in healthy persons, symptoms like those of the disease to be treated. The dilutions are repeated so many times that there is less than one molecule per dose and it is suggested that benefit is from the energetic life force of the original substance." (National Library of Medicine, 2007)*. The term "homeopathy" here is used to refer to:

(a) the "system of therapeutics"—Therapeutic System

(b) doses—homeopathic products, medicine, pillules.

in addition to these meanings, the term "homeopathy" is also used to refer to:

(c) Homeopathic services/treatment by a homeopath

(d) One or more of the Principles of homeopathy:

(i) Principle of Similars ("like cures like")

(ii) Principle of Minimum Dose

9. As a consequence of these multiple possible meanings, ambiguity in the use of the term "homeopathy" is common. The term "homeopathy" is often used to denote two or more different meanings in the same conversation or article. Conclusions drawn from research on one aspect of homeopathy (eg homeopathic medicines/products) are then applied to another meaning of the term (eg the therapeutic system of homeopathy). This confounding of meanings is most obvious in systematic reviews of "homeopathy"[1],[2],[3] and reviews of systematic reviews of "homeopathy"[4],[5]. For example, in a review entitled *"A systematic review of systematic reviews of homeopathy"*[4] where the primary evidence reviewed are systematic reviews of trials of homeopathic medicines, the author switches between the following terms: *"homeopath" "homeopathy" "homeopathic medicines" "homeopathy's… two principles"*, resulting in confusion as to what conclusions might possibly refer to.

10. The lack of differentiation between the various possible uses of the term is further perpetuated by "homeopathy" being the only MeSH term available for searching the research evidence of homeopathy. It is of fundamental importance to distinguish between the multiple possible meanings of the term "homeopathy". We propose that the MeSH term "homeopathy" has additional subheadings to help differentiate various aspects of the therapeutic system of "homeopathy": "*homeopathic medicines", "treatment by a homeopath", "the principles of homeopathy" etc* and that these are used in the reporting of research eg "RCT of the efficacy of homeopathic medicine/product for …" or "An observational study of treatment by a homeopath"

Defining "Evidence"

11. Two common types of evidence called for are evidence of efficacy or effectiveness:

(a) Evidence of efficacy is interpreted as meaning that "*the treatment offers therapeutic benefits greater than placebo"*[6]. Evidence of efficacy requires evidence from placebo-controlled randomised controlled trials (RCTs).

(b) "Effectiveness" refers to the extent to which a treatment improves the outcome for patients in practice. Evidence of effectiveness requires pragmatic RCTs (which compare a treatment to treatment as usual rather than to a placebo) and well conducted observational studies of routine clinical practice which uses that treatment.

12. Evidence called for: The editor of the Lancet called for NICE to evaluate "homeopathy"[7]—an offer which was declined by the Department of Health. Professor Born and colleagues called for "*evidence of efficacy"* in their letter to the Director of NHS commissioning, ie, evidence that the treatment offers therapeutic benefits greater than placebo. However is it evidence of efficacy or is it evidence of effectiveness that is required to justify NHS spending?

13. Evidence required: Since 2002 NHS Primary Care Trust commissioners have been required to follow guidance from National Institute for Clinical Excellence[8] (NICE). This guidance is primarily based on clinical and cost effectiveness. Cost effectiveness is calculated by NICE using cost utility analysis which

estimates the ratio between the cost of a health intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiary. From an NHS commissioning perspective the primary question is one of clinical effectiveness and cost effectiveness—benefits and costs—rather than efficacy. Leading Complementary and alternative medicine researchers[9],[10],[11] concur with NICE on the importance of establishing evidence of effectiveness before seeking evidence of efficacy.

14. NHS spending on "homeopathy": With an estimated 120,000 visits to homeopaths in the NHS annually and an NHS expenditure of £3.3 million,[12] what is this £3.3 million being spent on? The total NHS spending on homeopathic medicines (products) does not amount to more than 5% of this total amount, the bulk of the cost of "homeopathy" in the NHS is the cost of homeopathic services—treatment by/consultations with homeopaths and the infrastructure to facilitate this. Thus the evidence required to inform the debate regarding NHS spending on "homeopathy" is largely evidence of the clinical and cost effectiveness of treatment by a homeopath, homeopathic services.

15. Does this evidence exist? The following paragraphs explore the evidence cited, dividing this evidence into two types: experimental and observational.

16. Experimental evidence is derived from situations where subjects have been randomly assigned to one of two or more groups, for instance in a randomised controlled trial (RCT). The experimental evidence base comprises published reports of trials, systematic reviews of RCTs, meta-analyses of RCTs and reviews of systematic reviews.

17. Since 1940, over 150 RCTs of "homeopathy" and 26 systematic reviews of "homeopathy" have been published.[13] The majority of RCTs have compared a homeopathic medicine/product to a placebo—thus providing information on the efficacy of homeopathic medicines/products. Only 14 RCTs compare homeopathic medicine to orthodox treatment and thus provide information on the comparative effectiveness of homeopathic medicines.

18. However the majority of NHS "homeopathy" is delivered by a homeopaths. Van Hootegem[14] in relating the case of a 23 year old woman with chronic fatigue syndrome who was cured with a course of "homeopathic" treatment states: "*the action of the homeopathic medicine was intimately woven with the relationship I had with her as a therapist. It is impossible to separate these two influences"*

19. Thompson and Thompson[15,16] have used qualitative research to identify what might be the "*active ingredients"* of the homeopathic approach. Through a process of direct observation and modelling in a real world context, they attempted to *"identify the components of the intervention and underlying mechanisms by which they will influence outcome".* Six putative active ingredients were identified which might contribute to the effectiveness of homeopathic care: *patient's openness to the mind body connection, consultational empathy, in depth enquiry into bodily complaints, disclosure, the remedy matching process, homeopathic remedies.* Other authors have discussed the difficulties of separating out the effects of the homeopathic medicine from the consultation effects.[17,18]

20. I suggest that until there is clarity as to the active ingredients in homeopathic treatment and how such ingredients relate to each other, treatment by a homeopath needs to be viewed as a complex intervention[19] (which includes homeopathic medicines/products). Thus, assessment of the effectiveness of "homeopathy", should not separate out the component parts of treatment by a homeopath—instead "homeopathy" should be assessed as a package of care as it is delivered.

21. Observational evidence: In addition to experimental evidence, there is a large body of observational evidence. The observational evidence base consists of observational studies (of groups of patients) and case studies (single or case series) of treatment by homeopaths. There are 22+ observational studies (12 conducted in the NHS)[20,21,22] which report the outcomes of 15,703 patients receiving treatment by a homeopath. In addition there are several hundred thousand published single case reports[23] the majority of which exist in the "grey" literature (just 507 single case reports/series are available in online databases). This body of literature provides an evidence base as to the clinical effectiveness of treatment by a homeopath (not homeopathic medicines/products *per se*).

22. The research methods used to collect observational data mean that this evidence is vulnerable to substantial biases (regression to the mean, patient selection bias, outcome measurement bias.[20] Individual case studies are often vulnerable to other forms of additional bias: observer bias, recall bias, and analysis assessment bias. Any bias may exaggerate or deflate the true effect of the treatment. Since observational evidence is prone to many types of bias, observational evidence is regarded as weaker than experimental evidence, and has been disregarded in systematic reviews of evidence (though NICE commissioned systematic reviews now include observational evidence).

Recommendations

23. The precise meaning of the term "Homeopathy" should always be stated ie

(a) Therapeutic system of homeopathy

(b) Homeopathic products/medicines/remedies/pillules

(c) Homeopathic services/treatment by a homeopath

(d) Principles of homeopathy:

(i) Principle of Similars ("like cures like")

(ii) Principle of Minimum Dose

24. The type of evidence called for to address a question, should match the evidence that is required to address that question, ie does this question require evidence of efficacy, clinical effectiveness, cost effectiveness, acceptability, safety..?

25. If quality and the quantity of the existing evidence is insufficient to yield an answer, then means to provide this evidence should be sought.

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Memorandum submitted by Homeopathy: Medicine for the 21st Century (H:MC21) (HO 33)

INTRODUCTION

1. Karl Popper stated that:

> … the belief that we can start with pure observation alone, without anything in the nature of a theory, is absurd … Observation is always selective. It needs a chosen object, a definite task, an interest, a point of view, a problem.[1]

Any evidence in the field of health, therefore, should be considered in relation to the "point of view" which provides its context. In particular there is a need to ensure that scientifically valid definitions are used, and a theoretical framework capable of being tested scientifically.

2. A distinction also needs to be drawn between the use of science and technology.[2] The use of modern technology may not mean that a field is scientific, whilst scientific theory may be able to predict results without being wholly capable of explaining the details of how the results are achieved.

THE EMPIRICAL APPROACH

3. The practice of conventional clinical medicine uses technologies derived from scientific fields, but it operates within an empirical one:

> Clinical practice must not be regarded as applied biological medicine, *and it is necessary to adopt the empiricist approach for the solution of clinical problems*.[3]

3.1. *The definition of illness*. Disease categorisation is based on the following approach:

> Doctors have studied millions of sick people, and we must imagine that no two of these were ever completely identical as regards their clinical pictures and the underlying causal mechanisms, but in order to build up a medical science, it was essential to stress the similarities rather than the differences.[4]

Though empirically useful, this is not scientifically sound, because:

3.1.1. Disease definitions change over time as symptomatology and causative processes are better understood. For example, the illness of pneumonia is now categorised as eleven illnesses.[5]

3.1.2. Some diseases are essentially individual, or "idiopathic".[6]

3.1.3. Research and clinical evidence indicate that differences in individuals affect treatment (see 4.3).

3.2. *The definition of effectiveness*. There is no scientifically justified definition, and the "effectiveness" of treatments changes unpredictably.

3.2.1. The "intention to treat" means that "effectiveness" is dependent on what symptomatology is chosen.

3.2.1.1. There is an arbitrary division into "desirable" effects and side effects, despite the fact that the true effect of the drug is the combination of these.

3.2.1.2. Changing the "intention to treat" changes the definition of "desirable" effects and side effects, and so changes the "effectiveness", as in the case of Viagra.[7]

3.2.1.3. The severity of side effects in clinical practice can lead to the withdrawal of a treatment shown to be "effective" in trials.

3.2.2. The time-scale of trials may be insufficient for establishing the effects of a treatment.

3.2.2.1. Effects which lie outside the time-frame will only be identified from clinical practice.

3.2.2.2. The "effectiveness" of drugs can be redefined as a result of experience in clinical practice, as in the case of Aspirin.[8]

3.3. *Theory of health and disease*. The absence of a theory means that processes of change in health cannot be distinguished from each other, such as:

3.3.1. The "natural course" of the disease from a course affected by treatment.[9]

3.3.2. The effect of a "placebo" from that of a curative agent.

3.3.3. Improvement in one part of the body cannot be readily and systematically related to symptomatology in other parts of the body.

Evidence-based Medicine

4. In the face of these problems, medical practitioners have devloped the system of evidence-based medicine (EBM). This involves three elements, none of which is sufficient by itself as a basis for successful medical practice (our emphases):

> Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.
>
> Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.[10]

4.1. *Care of the individual*. The purpose of medicine is successful treatment of the individual, so evidence of what is successful in individual cases is essential. One method of acquiring this information is outcome studies, but these cannot provide information enabling the development of new treatments.

4.2. *Clinical expertise*. Practitioners can acquire experience which enables them to assess the differerent effects of treatments across a range of individuals, and to target treatments based on that experience. The problem is that this knowledge is rarely quantified, let alone rigorously quantified, and therefore it is liable to be subjective.

4.3. *External clinical evidence*. Evidence about treatments gathered from RCTs can offer some degree of objectivity about treatments, but it cannot provide reliable information about the appropriateness of a specific treatment to a particular individual. Thus:

> There was still no guarantee that a treatment that had succeeded during a set of trials would cure a particular patient …[11]

As a result RCTs alone cannot enable medicine to fulfil its primary purpose. RCTs are also dependent on a scientific framework if they are to produce valid results.

4.3.1. RCTs can successfully produce reliable evidence of the harmful effects of a treatment because:

4.3.1.1. A scientifically valid definition of outcome is simply the increase in morbid effects or mortality rates.

4.3.1.2. Issues of homogeneity and generalisability are irrelevant since everyone is affected by harmful interventions, with only the extent and rapidity of harm being individual.

4.3.2. Evidence from RCTs cannot prove effectiveness because:

4.3.2.1. Curative processes are fundamentally individual, and so tests which generate statistical likelihoods of success are not valid in an individual case (see 4.3).

4.3.2.2. There is no scientific definition of effectiveness (see 3.2ff.).

4.3.2.3. A scientifically valid definition of effectiveness is complex, as it needs to take into account all the outcomes of treatment and over a significant time-scale.

4.3.2.4. The mismatch between the definitions of diseases and their actual appearance in individuals leads to a conflict between "homogeneity" and "generalisability" (see 3.1ff.).

4.3.3. Since RCTs gather evidence in the absence of a scientific theory, the evidence cannot be checked against predictions based on a consistent theoretical framework, but only against other evidence gathered in the same flawed conditions.

Consequences of Evidence without Theory

5. Using an approach which is not based on a scientific framework, but which attempts to balance different sources of unreliable evidence in order to develop more reliable solutions, means that there can be no certainty as to whether the correct balance has been achieved. In addition, none of the three aspects has scientific validity in its own right, and any tendency towards dominance of one aspect over the others will

render the approach valueless. This is a growing tendency among opponents of homeopathy who insist on giving undue (even exclusive) weight to RCTs over other sources of evidence.[12,13,14] As a general attitude this would lead to:

5.1. A tendency for practitioners to ignore and fail to report adverse reactions in clinical practice on the grounds that there is nothing in the trial literature.

5.2. A tendency for long-term effects to go unidentified, including increases in chronic illness (as in the analogous case of cigarettes and lung cancer). There are indications that this is occurring:

> The cost of the National Health Service nearly trebled from 1951 to 1975 (at 1950 prices); both the consultation rate in general practice and the hospital admission rate rose, and the waiting lists became longer and longer.

In Denmark the experience was the same…

Obviously this growth has many aspects, but it must be admitted that it is difficult to register the beneficial effect in the available health statistics. The average expected life-span has not changed much, and hospital waiting lists have not been eliminated.[15]

5.3. Additional NHS personnel and financial costs of managing the adverse reactions.

5.4. Additional cost of research into new treatments for new illnesses.

5.5. Lost work days, and consequent costs for employers and the economy.

5.6. Potential increases in disability pension costs.

5.7. Deaths, entraining emotional trauma and other costs.

Homeopathy

6. There are further issues which mean that it is particularly inappropriate to apply this evidence-oriented process to homeopathy.

Definition of what is to be treated.

7. Homeopathy uses a scientifically valid definition of disease.

7.1. The understanding of what is to be treated is based on the actual signs and symptoms of the individual in their totality.[16]

7.2. The understanding of what is to be treated takes into account the chronological relationships of conditions in the individual.[17]

7.3. Homeopathy organises this information on the basis of general principles, distinguishing the relative importance of the signs and symptoms on the basis of:

7.3.1. Severity and pain, which indicate urgent need in all systems of medicine;

7.3.2. Peculiarities, which indicate the individual curative reaction and so the specific remedy needed;[18]

7.3.3. Location;[19]

7.3.4. Chronology.[20]

Testing of remedies.

8. Homeopathy recognises that as no two unique substances can have identical effects on the human organism, so each must be tested for its pattern of action.[21] As a result:

8.1. Homeopathy was the first medical system to gather as complete evidence as possible of the action of each substance on the human body.[22]

8.2. Homeopathy was the first medical system to test substances on healthy people prior to their use, in order to avoid the distortions inevitable in tests on sick people.[23,24]

8.3. Homeopathy was the first medical system to seek to identify those peculiarities of the effects of each substance which enable one to be distinguished from another.[25]

Application of remedies.

9. With full information about what is to be treated and about the available medicines, there are only three theoretical possibilities for relating one to the other:

9.1. If there is no relationship between the bodies of information, then there is no possibility of a science of medicine.

9.2. The bodies of information can have no consistent relationship as opposites, because some conditions have no opposite, but are either present or absent (for example, a cough, pain, delusions). Again there is no possibility of a science of medicine.

9.3. Relating the bodies of information on the basis of similarity is possible, and so makes a science of medicine theoretically possible. This theoretical position is evidenced in practice, as in the case of cinchona (and its derivative quinine) which has been used for hundreds of years in the treatment of malaria even though the symptoms of quinine poisoning (cinchonism) closely resemble those of malaria.[26]

Homeopathy uses a scientific approach to treatment.

10. On this basis homeopathy uses a scientifically valid approach, and confirmation can be seen in that:

10.1. Homeopathy was developed using the scientific method, employing experiment and observation to test and articulate its theoretical framework. This can even be seen in the inaccurate and incomplete descriptions of opponents of homeopathy.[27]

10.2. Homeopathy was the first medical system to recognise the importance of micro-organisms in disease, some 60 years before Koch identified the cholera bacterium.[28]

10.3. Homeopathy was the first medical system to recognise that these micro-organsms could evolve, some 30 years before Darwin published *On the Origin of Species*.[29]

10.4. Homeopaths promoted hospital hygiene, some 50 years before Florence Nightingale.[30]

10.5. Homeopaths promoted public hygeine before the start of the nineteenth century,[31,32] and the medical historian Simon Szreter has identified this as the primary factor in disease reduction at the end of that century.[33]

10.6. Homeopathy was the first medical system to identify a role for biophysics.[34]

10.7. The principles of homeopathy are capable of being tested scientifically, as there is a consistent theory linking selection of a treatment and analysis of the results of treatment. Furthermore:

10.7.1. The general principles are derived from clinical experience (see 7.3ff.).

10.7.2. Individuality is incorporated into the theory (see 7.1 and 7.3.2).

10.7.3. It is possible to determine what is treatable at a given point in time (see 7.3.4).

10.7.4. The results of treatment, even in individual cases, can be measured against the general principles (known as Hering's "Law of Cure"), offering a scientific definition of effectiveness.[35]

10.7.5. Different outcomes can be distinguished from each other, and an objective assessment of effectiveness obtained.[36]

11. It is possible to produce evidence for the effectiveness of homeopathy, but the mechanisms which have been used offer conflicting results.

Randomised Controlled Trials.

12. Homeopathic principles can provide a scientific basis for RCTs to test effectiveness because:

12.1. Homeopathy can consistently define the conditions being treated.

12.2. Homeopathy can consistently define expected outcomes.

12.3. There is no problem with individuality in homeopathic treatment, and so no conflict between homogeneity and generalisability.

13. However, if a homeopathic RCT does not conform to the integrated whole of homeopathic principles, it will produce inaccurate results.[37]

13.1. There are at least eleven factors which can affect the results of the trial, and even reduce the therapeutic intervention to a placebo intervention.[38] These include:

13.1.1. Inappropriate definitions of what is being treated.

13.1.2. Inappropriate definitions of outcome.

13.1.3. Inappropriate timescales.

13.2. In practice RCTs produce ambiguous results. Moreover, positive trials are accused of being "implausible",[39] a "stitch-up",[40] too small, or insufficiently rigorous, where rigour' refers to adherence to an evidence-oriented trial structure rather than to scientific adherence to homeopathic principles.[41]

Meta-analyses.

14. Because meta-analyses are based on clinical trials, and because they tend to use the same approach to rigour, they offer no improvement in terms of evidence.

14.1. The Linde analysis (1997) was reworked (1999) as a result of criticism based on the demands of evidence-oriented rigour.[42]

14.2. The Shang analysis (2005) also defined the rigour of the trials they selected without reference to homeopathic principles.[43]

14.3. These analyses show that a significant degree of subjectivity is introduced into the research process using this method.[44]

15. In practice meta-analyses also produce ambigiuous results, but the arguments usually focus on the selection criteria.[45,46,47,48]

Outcome studies.

16. Outcome studies of homeopathy present very different results from RCTs.

16.1. The Get Well UK study in Northern Ireland showed health improvements in 84% of patients with GP correlation for 65% of patients.[49]

16.2. The Bristol Homeopathic Hospital study showed positive change in 70.7% of patients, with 50.7% recording their improvement as better (+2) or much better (+3).[50]

17. Outcome studies also measure "effectiveness" in a different area of the EBM model.

17.1. They assess the effect of "care of the individual" and of "clinical expertise" (see 6ff.).

17.2. They do not constrain the treatment process, and so do not affect the scientific integrity of this process.

17.3. Their results can be compared with the general tendency in the population to recover (or not) from such conditions.

18. Typically outcome studies show that substantial numbers of patients derive benefit from homeopathic treatment, and often to a substantial degree.

Clinical practice.

19. Both historical and present-day evidence of homeopathy in clinical practice reflects the results seen in outcome studies.

19.1. A typical example is

> a cholera epidemic in London in 1854, when patients at the London Homoeopathic Hospital had a survival rate of 84 per cent, compared to just 47 per cent for patients receiving more conventional treatment at the nearby Middlesex Hospital.[51]

A mortality rate of 16% (at the homeopathic hospital) is unachievable without medical intervention, whilst 53% (at the conventional hospital) is typical without treatment.[52,53]

19.2. A number of similar cases have been compared.[54]

19.3. Homeopathy has also recently been used as a prophyactic for *leptospirosis* in over 2 million people in Cuba, dramatically reducing infection and mortality rates.[55]

Conclusion

20. Conventional medicine relies on an model known as Evidence Based Medicine which balances bodies of evidence in order to minimise the risks of harm. Within this model no form of evidence can provide a definitive statement of effectiveness. Attempts to limit the approach used and allow one form of evidence to dominate will defeat the object of this model. The model is an implicit (and often explicit) recognition of the fact that medicine has no underlying scientific theory.

21. Homeopathy has an underlying scientific theory. This theory is consistent with observed facts, it has led to analyses decades in advance of other medical practice, and it has a strong body of evidence of successful practice. On this basis it is entirely inappropriate to use the EBM model to assess its practice, let alone a single element of that approach. Instead it should be tested by relating its clinical practice to the predictions of its theory, as would be the case in any other field of science. Homeopathy requires a Science Based Medicine model.

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H:MC21 is a charity which promotes homeopathy.

November 2009

Memorandum submitted by the European Central Council of Homeopaths (HO 35)

Introduction to ECCH: The European Central Council of Homeopaths was established in 1990 and is the professional platform representing the homeopathy profession in Europe. Among its 27 national professional associations in 23 countries it counts three members in the UK, the Alliance of Registered Homeopaths, the Homeopathic Medical Association and the Society of Homeopaths.

1. *Government policy on licensing of homeopathic products*

1.1 Homeopathic Medicinal Products (HMPs) are available over the counter (OTC) and on prescription in all EU Member States. They are an increasingly important part of the European pharmaceutical market.[1]

1.2 HMPs are subject to the provisions of EU Directives on pharmaceutical products for human use[2,3]. As a member of the European Union, the UK is bound by the provisions of these directives to regulate HMPs on the UK market.

1.3 The idea that because HMPs are diluted they are safe and do not require regulation is a naïve misconception. HMPs are derived from a wide range of mineral, plant, zoological and microbial products, many of which are potentially toxic in their raw state. While the homeopathic manufacturing process known as "potentisation" renders all HMPs safe and of no toxic risk once a certain dilution level has been passed, the fact that some source materials are of potential risk during the early part of the manufacturing process means manufacturers' premises and processes have to be strictly regulated according to standard Good Manufacturing Practice (GMP) in order that there is no risk to workers in the premises or risk of toxic material remaining in the final product placed on the market.

1.4 Normal licensing policy for placing a pharmaceutical product on the market requires evidence of quality safety and efficacy. Homeopathic treatment using single HMPs is normally individualised according to the whole symptom picture of each patient suffering any diagnosed condition. Consequently, to prove efficacy for any single HMP for any particular condition as is normally required for conventional pharmaceuticals is extremely difficult. The current licensing policy of only requiring proof of safety and quality for single HMPs as outlined in Article 14 of the EU directive 2001/83/EC therefore makes pragmatic sense, particularly given the low-risk non-toxic state of HMPs once potentised. Evidence for the range of symptoms that each single HMP is capable of addressing is available through the extensive "homeopathic materia medica" that is available for single HMPs.

1.5 Complex HMPs and any other HMPs for which manufacturers wish to make therapeutic claims should be subject to the normal requirements for evidence of proof of efficacy as for conventional pharmaceuticals as detailed in Article 16 of EU directive 2001/83/EC.

1.6 Within the EU the UK Medicines and Healthcare products Regulatory Agency (MHRA) is perceived by homeopathy stakeholders, and other national licensing authorities, to have a proportionate and pragmatic approach to the licensing of HMPs. We consider it essential that the MHRA should continue to administer the regulation of HMPs within the UK in the present manner, not least as an example of best practice for other EU agencies.

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3. Directive 2001/83/EC on the Community code relating to medicinal products for human use

2. Government Policy on the Funding of Homeopathy through the NHS

2.1 Homeopathy has been funded through the NHS from its inception in 1948. Throughout that time the cost of homeopathic treatment has been an extremely small percentage of the NHS's overall budget. Yet, when emerging evidence from recent studies into the provision of homeopathy in the NHS is taken into account, the benefit to patients who've had homeopathic treatment would seem to be substantial and worthy of more consideration than it has received up until now.

2.2 Whether provided by GPs themselves, through GPs delegating patients for treatment by homeopathic practitioners or through referral to homeopathic doctors in the outpatient units of the homeopathic hospitals there is a range of evidence in existence showing that homeopathy provided through the NHS is effective, highly appreciated by patients and capable of improving patients health overall.[1,2]. There is also evidence from outside the UK that homeopathy provided in general practice has short and long-term benefits on patients' health. A large German cohort study showed sustained improvement in patients' health over an eight-year period[3].

2.3 GPs are the recognised gatekeepers to NHS services and it is they who should continue to decide whether to refer patients for homeopathic treatment. They make their decisions on the basis of perceived patient need, within the constraints of their practice budget and, hopefully, in consultation with their patients. The element of therapeutic choice is an important priority in current NHS policy and the maintenance of homeopathy as a viable treatment option for patents and GPs is an important example of this principle being maintained and developed. There are a range of "effectiveness gaps" involving conditions where conventional approaches are either relatively ineffective or simply do not exist and where homeopathy has been shown to be effective.[4–13]

2.4 The National Institute for Health and Clinical Excellence (NICE) recently published guidance on the treatment of low back pain that recommended consideration among other interventions of the use of acupuncture and manipulative therapies.[14] This landmark recommendation was based on the fact that conventional medicine has a limited potential for intervention in this condition and there is a *range of evidence, including but not totally reliant on RCTs,* to support the use of the therapies such as acupuncture, osteopathy and chiropractic as effective interventions before considering more drug and surgical intervention. This pragmatic approach to the evaluation of evidence is one we consider should be applied to the consideration of homeopathic treatment where the *range evidence* available, including RCTs, presents a far more convincing case for its use than the simplistic criteria of whether sufficient RCTs alone exist to support it.[15]

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3. The Evidence Base on Homeopathic Products and Services

3.1 *The evidence for the therapeutic action of homeopathic products*

The central controversy surrounding HMPs, and the one that has dogged homeopathy for two hundred years, relates to whether (a) HMPs have an action and (b) what the nature of that action is. Mathematically HMPs potentised above a level of dilution synonymous with Avogadro's Number do not contain any molecules of the source material of the medicine ie they are not having a molecular action in the way conventional pharmaceuticals do. Yet potentised HMPs above this dilution are commonly used with apparent effect in homeopathic practice and have been used in research trials that have produced results indicating a positive action. Furthermore, there is an accumulating body of evidence from a variety of research areas within and outwith homeopathy that high dilutions of source materials appear to have a measurable effect.[1–14] While we may therefore actually be approaching a point where it can be established that potentised medicines have an action, the mechanism of action may take a little longer to elucidate.

3.2 *The efficacy of homeopathic treatment*

The efficacy of homeopathy has been considered through a large number of clinical trials of varying methodological quality. The overall results of these trials have been evaluated in a number of literature reviews and meta-analyses.[15–22] Seven out of eight of these reviews/analyses found results in favour of homeopath. The eighth study which did not find an effect in favour of homeopathy, Shang *et al*,[22] has since been severely criticised by scientists and researchers around the world for its poor methodology. The authors first claimed that their conclusions were based on 110 homeopathy trials compared to 110 trials of conventional medicine. It was subsequently shown that they had based their conclusions on just eight homeopathy trials compared with six conventional trials only. When re-analysing the data of this study, researchers found that homeopathy had a significant effect beyond placebo, and the conclusions drawn by the original authors were highly influenced by one single trial.[23] Moreover, the researchers found that the overall quality of homeopathy trials was significantly higher than in the conventional trials.[24] (Note: It is interesting to note that a number of critics of homeopathy have particularly referred to the Shang trial to support their position, where, if they had they taken a more objective viewpoint they should have spotted these methodological faults themselves.)

3.3 *The effectiveness of homeopathic treatment*

The effectiveness of homeopathy has been considered in a number of observational studies, including a six year study of over 6,500 patients treated in a University Hospital Outpatient clinic in the UK, with over 23,000 consultations, where over 70% of patients reported positive health changes, and more than 80% of 1,270 children experienced an improvement.[25] In another study of almost 4,000 patients treated by 103 primary care practitioners, 97 % suffered from chronic complaints lasting an average of 8.8 years.[26] Significant improvement in most complaints was recorded, as well as improvement in patients' quality of life.

3.4 *The cost-effectiveness of homeopathy*

The issue of the cost-effectiveness of homeopathic treatment can be addressed through comparing the direct costs of the treatment itself with conventional treatments and through calculating savings in potential future other care. A number of studies have demonstrated the cost effectiveness of homeopathy. There is enough evidence from these studies to show that homeopathy does offer potential real cost savings in spending on conventional medicines, referrals to consultants and GP consultation time.[27–37]

3.5 *The safety of homeopathy*

Homeopathy is a safe treatment.[40] The potentisation (serial dilution and succussion) of HMPs means that beyond four dilution stages of 1:10 their source materials are rendered safe without risk of toxic side effects to patients. This is recognised by the EU directive 2004/27/EC that permits simple registration for single HMPS diluted one part in 10,000 or more. The only possible toxic risk would come from the use of certain source materials in tinctures and dilutions below one part in 10,000 or from poor manufacturing procedures leaving toxic residues in potentised medicines.

The other element of safety relates to the appropriate education and professional regulation of those who practise homeopathy. As with all healthcare professions, the education and regulation of those practising homeopathy should convey a clear awareness of the boundaries of competence and responsibility surrounding their practice. Anyone offering any form healthcare must be appropriately educated and submit to professional regulation through registration with a recognised professional association.

3.6 *The use of homeopathy*

Homeopathy is practised throughout Europe.[41] Homeopathy is the most frequently used CAM therapy in five out of 14 countries in Europe, and one of three CAM therapies most frequently used in 11 out of 14 countries.[42,43] According to the World Health Organization homeopathy is practised worldwide and it is provided within national healthcare systems in several countries.[44,45]

As an example a poll carried out in Norway in 2001 showed that 52% of the population were of the opinion that homeopathy should be a part of the public health service there.[46] Half of all Norwegian nurses think homeopathy should have a place within the public health service[47] and half of all medical doctors are willing to recommend patients to a homeopath.[48]

3.7 *Meeting the costs of homeopathic treatment*

Expenses for CAM therapies including homeopathy are currently reimbursed through the national healthcare service in eight countries in Europe. Expenses are reimbursed through private insurance companies in 12 countries.[49]

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49. Reimbursement of Expenses for Homeopathic Treatment in Europe, An ECCH Report, European Central Council of Homeopaths April 2008

Stephen Gordon
General Secretary
European Central Council of Homeopaths

November 2009

Memorandum submitted by Judith Ford (HO 38)

I am emphatically enthusiastic about homeopathic products and have taken them since 1982.

I was given the wrong thyroid medication which nearly killed me and caused me to have cancer and heart operations in the nineties.

I am now receiving the correct thyroid medication and vitamins and minerals and strong homeopathic medication. From an homeopathic vet who treats humans as their animals thrive.

Homeopathy does work and has kept me alive these thirty years.

Please consider homeopathy as it is inexpensive and efficacious to the patients whereas allopathy kills its patients.

November 2009

Memorandum submitted by the Prince's Foundation for Integrated Health (HO 41)

INTRODUCTION

1. The Prince's Foundation for Integrated Health was founded in 1993 at the personal initiative of HRH The Prince of Wales to promote integrated healthcare for all. HRH remains its President but has no direct involvement in the Foundation's day to day operations. It is a registered Charity and has no commercial, financial or other vested interests in complementary or alternative products or services.

2. Integrated healthcare encompasses two concepts. First, it means treating patients as whole human beings with bodies, minds and spirit, and understanding that whatever affects one part affects all three. Secondly, it is about integrating those complementary and traditional modalities which have evidence of clinical effectiveness with conventional healthcare, providing that is in the patient's best interests. The Foundation does not suggest that is necessarily the case for all medical conditions or for all patients.

3. The Foundation is clinically led by a group of Fellows and Clinical Leads. They include medical scientists and scientists from related fields together with practising clinicians from a number of healthcare professions including medicine, pharmacy, nursing and physiotherapy. Some Fellows are also researchers and practitioners of complementary medicine. This document reflects their advice.

4. The Foundation's interest in homeopathy is focused on the question of clinical and cost effectiveness: whether or not it provides any benefit to patients and, if can be established that it does, for which conditions and which patient groups at what cost.

Government Policy on Licensing Homeopathic Products

5. The licensing of homeopathic products in the UK is governed by the Medicines Act (1968) and by European legislation, in particular EU Directive (2001/83/EC)/

6. The task of implementation is carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) for whose expertise the Foundation has the highest respect. Currently the rules provide two ways in which homeopathic products may be registered. The Simplified Scheme in which no medical claims or indications for the product are permitted although the safety and quality of the product must be demonstrated. The National Rules Scheme, introduced in 2006, does allow homeopathic medicinal products to be registered with indications for the relief or treatment of minor and self-limiting conditions, with full information on safety and quality together with appropriate product labelling and product literature. In accordance with current pharmaceutical legislation, evidence must be provided that the product is used as a homeopathic treatment for the indications identified.

7. The Foundation has complete confidence in the judgement of the MHRA as to the benefits for public information and safety of the current system.

The Evidence Base

8. Homeopathy is a system of medicine, developed in Germany in the late eighteenth century, that is based on the idea that "like treats like": a substance taken in small quantities will cure the symptoms it would cause in large quantities. In homeopathy, the idea of the small quantity has resulted in extreme dilutions of the substance. In some homeopathic products, not even a single molecule of the original substance remains in the diluted medicine prescribed to the patient. These concepts are not supported by modern science and, indeed, run counter to it.

9. Unlike much pharmaceutically based conventional medicine, treatment is individualised so that patients presenting with the same diagnosis may be prescribed different medicines depending on their personal histories, diet, and other factors. Homeopathy rejects the notion that mind and body are separate (a concept that was also developed in the eighteenth century) and insists that there is continual interaction between them. In this at least, modern science would tend to agree.

10. Homeopathy is highly controversial. From our current understanding of the physical and biological sciences, any specific mechanism of action based on extreme dilution is implausible and regarded as unsupportable by the majority of scientists working in this field, although a small number disagree. The evidence from randomised controlled trials (RTCs) is less than convincing.

11. Nevertheless, there is some evidence of clinical effectiveness of the whole homeopathic package: that is, the consultation and the medicine combined. As a consequence the Foundation finds it difficult to dismiss the experience of patients who say they have benefited from homeopathic treatment. Providing it is delivered by trained and statutorily regulated health professionals such as doctors, homeopathy is safe and low cost. However, there are anxieties about the safety of practice by unregulated, non-medically trained homeopaths.

NHS Funding of Homeopathy

12. Homeopathy is one of a number of complementary therapies that are provided by the NHS as an adjunct to treatment in palliative care and for a range of chronic, benign conditions. A significant number of patients report that they benefit from homeopathy. However there is a need for controlled research studies to establish:

- whether and what benefit is provided;
- the extent of that benefit, if any;
- how the risk/benefit evaluates against conventional medical interventions; and
- the mechanism of action that produces benefit, if any.

13. It would then be for the National Institute of Clinical Excellence (NICE) to evaluate the evidence and reach a decision as to whether the NHS should continue to fund homeopathy treatments.

In Conclusion

14. The Foundation wholeheartedly supports evidence based practice (and, indeed, practice based evidence). That should include evidence, where possible, of the efficacy of a treatment as well as evidence of its clinical and cost effectiveness and safety.

15. We are mindful that many patients who are treated with homeopathy are those for whom no effective evidence based disease specific treatment is available. That may be because no such treatment exists or is provided by the NHS for their condition, for example fibromyalgia and some forms of arthritis, or because the recommended treatment is contra-indicated, for example, the patient is a pregnant woman or there is a risk of drug interactions in cases of multiple morbidities. The health service should not abandon these patients but rather support research into how to improve their management.

EVIDENCE CHECK: HOMEOPATHY

The Prince's Foundation for Integrated Health is grateful to the Committee for the opportunity to provide the attached submission for its Evidence Check into homeopathy.

The Committee may be interested to know of two publications from the USA Institute of Medicine (IoM) that may relate to its discussion of homeopathy and, in particular, to the Foundation's evidence:

— *Initial National Priorities for Comparative Effectiveness Research* was published 30 June 2009. The US Congress has committed £1.1 billion dollars for comparative effectiveness research (CER) and tasked the IoM to recommend national priorities for research questions to be addressed.

— *Integrative Medicine and the Health of the Public* was released 4 November 2009 and provides a summary of the IoM/Bravewell Collaborative summit on integrative medicine, held in February this year. This included thorough discussion of evidence for integrative medicine.

November 2009

Memorandum submitted by the Science Council (HO42)

1. The Science Council welcomes the House of Commons Science and Technology Committee's scrutiny of Government policy and the emphasis the Committee continues to place on the need for a strongly evidence-based approach to policy.

2. The Science Council was established by Royal Charter in 2003 with the object to advance science and its applications for public benefit. It is a membership organisation for learned and professional bodies across science and its applications and works with them to represent this sector to government and others. The Science Council also promotes the profession of scientist through the Chartered Scientist designation and the development of codes of practice. In addition the Science Council supports a range of activities to increase awareness of the role of both science and scientists in society.

3. The Science Council has agreed a definition of science as follows:

> *Science is the pursuit of knowledge and understanding of the natural and social world following a systematic methodology based on evidence.*

4. Scientific methodology includes data collected through objective observation or measurement; testing hypotheses through experiment and benchmarking; deduction and induction to establish general rules or conclusions drawn from data, examples or evidence; critical analysis of evidence; critical exposure to scrutiny, peer review and assessment leading to verification, testing and repetition.

5. The Science Council is far from clear that current Government policy relating to homeopathy is based on evidence that meets such systematic criteria.

November 2009

Memorandum submitted by Jackie Rowe (HO 43)

I have been passionate about homoeopathy since the early 80's, and I am now aged 58. Homoeopathy has kept me out of my overstretched GP's surgery a good while. I rarely see him, having successfully used homoeopathy for various illnesses including chronic backache, the menopause and flu/cold viruses.

My daughter however, was being treated by her GP for asthma. Improvement was minimal. Therefore, I took her to my homoeopath who gave an excellent remedy. Please do consider homoeopathy without delay.

November 2009

Memorandum submitted by the Advertising Standards Authority (ASA) (HO 44)

1. INTRODUCTION

1.1. The Advertising Standards Authority (ASA) is grateful for the opportunity to provide evidence to the Science and Technology Select Committee review into homeopathy. The ASA is happy for this submission to be published and to give evidence, if called.

1.2. The ASA is the UK self-regulatory body for ensuring that all advertisements, wherever they appear, are legal, decent, honest and truthful.

2. Executive Summary

2.1. The protection of consumers is at the heart of the ASA's work. The rules we administer aim to ensure high standards in advertising, by ensuring that advertisements do not mislead, harm or offend.

2.2. This response provides

— A summary of the UK advertising self-regulatory system.

— Details on how the ASA regulates advertisements for homeopathy.

2.3. Relevant rules, guidance for non-broadcast advertisers, and summaries of two recent rulings are included in full in the Annexes.

2.4. We do not have any recommendations for the Science and Technology Select Committee in this area. There are robust regulations in place for advertising and the low level of complaints indicates that there is no great consumer concern in this area.

3. Advertising Self-Regulation in the UK

3.1. More detailed information about the ASA can be found on our website www.asa.org.uk. The website also contains a searchable database of all our adjudications from the past five years.

3.2. The ASA is the UK body responsible for regulating advertising in all media. It does this by enforcing the UK Advertising Codes, which are written and maintained by two industry bodies, the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP).

3.3. The ASA accepts complaints from the public and industry about ads that seem to have breached those Codes. It also conducts other activities such as providing training and advice, and proactively monitoring ads in order to keep advertising standards high.

3.4. The system is based on a concordat between advertisers, agencies and the media that each will act in support of the highest standards in advertising. Compliance with the Codes and ASA adjudications is binding on all advertisers. It is not a voluntary system.

3.5. The system is entirely funded by industry, through a levy of 0.1% on display advertising space and airtime and 0.2% on Royal Mail Mailsort contracts. The levies are collected by two arm-length funding bodies, the Advertising Standards Board of Finance (Asbof) and the Broadcast Advertising Standards Board of Finance (Basbof).[38] Last year the ASA was awarded £8 million to run the system.

3.6. The system is both self-regulatory (for non-broadcast advertising eg press, poster, cinema, online) and co-regulatory (for TV and radio advertising).

3.7. The Codes sit within a legal framework, which means that, where appropriate, they reflect the standards required in law, eg the Consumer Protection for Unfair Trading Regulations 2008 (CPRs) for misleading advertising. The Codes also contain additional protections that are not required under law eg rules related to taste and decency and social responsibility.

3.8. Notably for homeopathic treatments, the Advertising Codes sit within the strict legal framework that regulates medicines. EC Directive 2001/83/EC (as amended by EC Directive 2004/27/EC) on Medicinal Products For Human Use regulates medicines. Only products that have data to show that they have a medicinal effect can obtain a Marketing Authorisation (from the Medicines and Healthcare products Regulatory Agency or the European Medicines Agency) and only products that hold a marketing authorisation may be advertised as a medicine in the UK and make medicinal claims, in line with the product's Summary of Product Characteristics (SPC).

3.9. The Traditional Herbal Medicinal Products Directive, 2004/24/EC will, by 30 April 2011, allow traditional herbal products to have their traditional use acknowledged in the market place. By 2011all traditional herbal medicinal products must be registered or removed from sale. Such products will be able to advertise their traditional use, but may not make efficacy claims.

3.10. The ASA deals with more than 26,000 complaints per year. Just one complaint can cause the ASA to launch an investigation and remove an advertisement, if the ad is found in breach of the Codes.

3.11. The Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) are the industry committees responsible for writing and maintaining the Advertising Codes.

3.12. CAP writes and updates:

— The British Code of Advertising, Sales Promotion and Direct Marketing ("the CAP Code"), which governs non-broadcast advertising (eg print, poster, cinema, online).

[38] www.asbof.co.uk and www.basbof.co.uk

3.13. BCAP writes and updates:

— The BCAP TV Advertising Standards Code.

— The BCAP Radio Advertising Standards Code.

— The BCAP Code on Text Services.

— The Rules on the Scheduling of Television Advertisements.

3.14. Final adjudications on investigations are decided by the ASA Council and published on the ASA website. The Council's membership incorporates two-thirds members of the public, one-third advertising experts and is independently chaired by the Rt Hon the Lord (Chris) Smith of Finsbury.

3.15. In the event that the ASA upholds a complaint against an advertisement, the advertiser or broadcaster is required to amend, withdraw or schedule the advertisement appropriately.

3.16. Advertisers that breach the Code face financial loss from having an ad campaign pulled and loss of reputation through the publication of upheld adjudications.

3.17. The vast majority of advertisers comply with ASA rulings straightaway. For those advertisers who refuse to comply, industry and other pressures can be brought to bear. For example, pre-vetting can be imposed and direct marketing companies can have benefits such as Royal Mail bulk-mailing discounts removed. In serious and persistent cases of non-compliance advertisers can be referred to the OFT (for misleading advertising) and broadcasters can be referred to Ofcom. Referrals are rarely required.

3.18. The system places a lot of importance on helping advertisers to get their ads right before they are published, through education and pre-publication advice.

3.19. For broadcast advertisements, the broadcasters have set up pre-clearance bodies: Clearcast for TV, and the Radio Advertising Clearance Centre (RACC) for radio. These bodies clear ads before they go on air and are very effective at maintaining high standards. However, pre-clearance does not prevent the ASA from investigating or upholding a complaint about a broadcast advertisement.

3.20. It would be impossible to pre-clear the many millions of non-broadcast advertisements that appear every year in the UK. However, CAP offers pre-publication advice for non-broadcast advertisers through its Copy Advice team and providing comprehensive online guidance.[39]

3.21. The total number of ads about which the ASA receives complaints accounts for less than 1% of all advertising published or broadcast in the UK. The ASA also monitors ads to check levels of compliance and have non-compliant ads removed. Compliance surveys regularly show that the vast majority of advertising is compliant with the Advertising Codes.[40]

3.22. The Advertising Codes can be accessed at http://www.cap.org.uk/The-Codes.aspx

4. Advertising Homeopathic Treatments

4.1. Broadly, the Advertising Codes contain clear rules that state that advertisers must not mislead consumers, by act or omission.

4.2. The Advertising Codes also require advertisers (and broadcasters) to hold substantiation for the claims they make. The substantiation must be robust and capable of withstanding third-party scrutiny. Mandatory information which must be included can be found in the Medicines and Healthcare products Regulatory Agency's (MHRA) Blue Guide, which can be found on the MHRA website: www.mhra.gov.uk.

4.3. As mentioned in 3.8 above products may only make medicinal efficacy claims in advertisements if they hold a Marketing Authorisation. Products registered as a traditional herbal product may advertise their product as having a traditional use, but may not make efficacy claims.

4.4. Advertisements for unauthorised products cannot include medicinal or therapeutic claims or refer to a particular ailment. They may only be advertised on an "availability-only" basis.

4.5. This is in line with requirements of EC Directive 2001/83/EC (as amended by EC Directive 2004/27/EC) on Medicinal Products for Human Use.

4.6. All the rules specifically relating to homeopathic medicines can be found in Annex 1.

4.7. The CAP Copy Advice team offers specific online guidance for homeopathy and this can be found in Annex 2.

[39] The Advice Online section has articles on advertising of therapies, and the full list of all Advice Online articles can be found at: http://www.copyadvice.org.uk/

[40] The high compliance rate is often demonstrated in the various sector-specific surveys undertaken by the ASA. These surveys can be found on the ASA website at http://www.asa.org.uk/asa/research/

5. ASA Action

5.1. The ASA undertakes investigations into advertisements for homeopathy either reactively, as a result of complaints, or proactively, through the ASA monitoring team.

5.2. The investigations we have conducted into advertisements for homeopathy focus on three areas:

— the efficacy claims in advertisements;

— the veracity of the testimonies used; and

— whether an ad is irresponsible if it is likely to dissuade consumers from seeking professional medical advice.

5.3. The ASA has received 54 complaints about 50 advertisements for homeopathy in the last five years, which led to 11 advertisements being formally investigated, all of which were upheld or partly upheld. One investigation is currently ongoing. Summaries of two recent example rulings can be found in Annex 3; however, all rulings can be found on the ASA website: www.asa.org.uk.

5.4. 30 advertisements were either not investigated because there was no problem under the Codes; saw the complaint withdrawn; were referred to CAP for compliance work (this means that we may have had dealings with the claim in the past); or were out of remit (eg the complaint related to packaging).

5.5. A further eight advertisements were dealt with informally. Informal rulings may occur if the ASA has already publicly ruled on the matter (for example with a different advertiser) and if the potential breach is not considered to be materially harmful. This allows for a speedy resolution and compliance with the Advertising Codes. However, we cannot define the cases as breaches as they have received no formal investigation. Advertisers that go through the informal process are named on the ASA website.

5.6. Advertisements for homeopathy represent a very small minority of complaints and investigations. From our complaints and monitoring work, we do not consider that advertisements for such products are of significant concern, particularly in light of the impending formal regulation of all products.

5.7. The ASA is grateful for the opportunity to provide evidence to the Select Committee. If the Committee has any questions arising from this response then please do not hesitate to contact me.

Annexes 1–3 are available on the Advertising Standards Authority's website, www.asa.org.uk:

Annex 1: Relevant Advertising Codes and Homeopathy

Annex 2: CAP Copy Advice (Therapies, Homeopathy and Therapies, General)

Annex 3: Two recent rulings (Homeo Home—25 March 2009 and Darulshafa Shirquia—15 July)

Lynsay Taffe
Communications and Policy Manager

November 2009

Supplementary memorandum submitted by the Advertising Standards Authority (HO 44a)

Annex 1

RELEVANT ADVERTISING CODES AND HOMEOPATHY

The Advertising Codes can be found in full on the CAP website: www.cap.org.uk

CAP Code

3. *Substantiation*

3.1 Before distributing or submitting a marketing communication for publication, marketers must hold documentary evidence to prove all claims, whether direct or implied, that are capable of objective substantiation.

Relevant evidence should be sent without delay if requested by the ASA or CAP. The adequacy of evidence will be judged on whether it supports both the detailed claims and the overall impression created by the marketing communication. The full name and geographical business address of marketers should be provided without delay if requested by the ASA or CAP.

3.2 If there is a significant division of informed opinion about any claims made in a marketing communication they should not be portrayed as generally agreed.

7. *Truthfulness*

7.1 No marketing communication should mislead, or be likely to mislead, by inaccuracy, ambiguity, exaggeration, omission or otherwise.

7.2 Marketing communications must not omit, hide or provide in an unclear, unintelligible, ambiguous or untimely manner material information if that omission or presentation is likely to affect consumers' decisions about whether and how to buy the advertised product, unless the information is obvious from the context. If the advertisement is limited by time or space, the ASA will take into account steps that the advertiser has taken to make that information available to consumers by other means.

50. *Health and Beauty Products and Therapies*

50.1 Medical and scientific claims made about beauty and health-related products should be backed by evidence, where appropriate consisting of trials conducted on people. Where relevant, the rules will also relate to claims for products for animals. Substantiation will be assessed by the ASA on the basis of the available scientific knowledge.

50.3 Marketers should not discourage essential treatment. They should not offer specific advice on, diagnosis of or treatment for serious or prolonged conditions unless it is conducted under the supervision of a doctor or other suitably qualified health professional (eg one subject to regulation by a statutory or recognised medical or health professional body). Accurate and responsible general information about such conditions may, however, be offered.

50.6 Marketers offering individual treatments, particularly those that are physically invasive, may be asked by the media and the ASA to provide full details together with information about those who will supervise and administer them. Where appropriate, practitioners should have relevant and recognised qualifications. Marketers should encourage consumers to take independent medical advice before committing themselves to significant treatments, including those that are physically invasive.

50.11 Medicines must have a marketing authorisation from the MHRA before they are marketed and any claims made for products must conform with the authorisation. Medicinal claims should not be made for unauthorised products. Marketing communications should refer to the MHRA, the authorisation or the EC only if required to do so by the MHRA.

50.19 Homeopathic medicinal products must be registered in the UK. Any product information given in the marketing communication should be confined to what appears on the label. Marketing communications should include a warning to consult a doctor if symptoms persist. Marketing communications for unauthorised products should not make any medicinal or therapeutic claims or refer to any ailment.

RADIO BCAP CODE

The Radio BCAP Code includes principles on substantiation and truthfulness, similar to those in the non-broadcast CAP Code, which can be found online.

4.13 *Homeopathic Medicinal Products*

Advertisements for homeopathic medicines are acceptable, subject to all relevant requirements of EC Council Directive 2001/83/EC (as amended by 2004/27/EC) on medicinal products for human use implemented in the UK by the Medicines (Advertising) Regulations 1994 (as amended).

In particular:

(a) advertisements are only acceptable for products which have been registered in the UK;

(b) product information must be confined to that which appears in Schedule 5 of the Medicines (Advertising) Regulations 1994.
Advertisements may not, therefore, include medicinal or therapeutic claims or refer to a particular ailment; and

(c) advertisements must include wording such as "always read the label" or "always read the leaflet" as appropriate.

TV BCAP CODE

The TV BCAP Code includes principles on substantiation and truthfulness, similar to those in the non-broadcast CAP Code, which can be found online.

8.2.2 *Homeopathic medicinal products*

(a) Only homeopathic medicinal products which are registered in the UK may be advertised.

(b) The only information which may be included is that which is allowed to appear on product labelling. Advertisements may not, therefore, include medicinal or therapeutic claims or refer to a particular ailment.

Note to 8.2.2:

This rule incorporates the requirements of EC Directive 2001/83/EC (as amended by EC Directive 2004/27/EC) on Medicinal Products For Human Use.

Annex 2

CAP COPY ADVICE

Therapies—Homeopathy

This section should be read in conjunction with the entry on "Therapies, General".

This discipline works on the principle of treating like with like, with the active ingredient diluted heavily in water. 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.

In July 2007 the General Media Panel considered the application of Clause 50.6. It concluded that complementary and alternative therapy practitioners offering significant or invasive treatments should encourage consumers to take independent medical advice before committing themselves to the treatment.

Clause 50.19 requires homeopathic medicinal products to be registered in the UK. Marcoms should refer consumers to a doctor if their symptoms persist and should not make medicinal or therapeutic claims for unauthorised products. See "Medicines: Homeopathic Medicines".

Annex 3

TWO RECENT RULINGS

Homeo Home—25 March 2009

Ad

Monitoring staff viewed an ad in Bengali on Channel S for the Homeo Home homeopathic practice. The ad showed a sign for the homeopathic practice; it stated "Dr Chakresh Chakraborty, Homeopathic Consultant".

A man, referred to in on-screen text as "Dr Chakresh Chakraborty", was shown sitting at his desk with a stethoscope. The Bengali voice-over stated "Renowned homeopathic practitioner from Dhaka, Dr. Chakresh Chakraborty" has been treating a lot of new and complex diseases for the last three decades … for asthma, skin disease, sexual diseases, spondilitis, diabetes, hay fever, migraine, infertility, piles, mental stress and various other diseases …

Issue

Monitoring staff challenged whether the ad:

1. gave the impression of professional medical advice;

2. made medical and therapeutic claims for treatments and referred to specific ailments.

Assessment

Upheld

Channel S stated that homeopathic consultants were often referred to as doctors within the Asian community. We considered the ad implied the man providing the treatment was offering professional medical advice because, in the on-screen text and the voice-over, he was referred to as "Dr Chakresh Chakraborty" and also as "Homeopathic Consultant". Also, the ad showed people being offered advice in a setting that looked like a doctor's surgery. We understood that Dr Chakresh Chakraborty was not qualified as a medical doctor and so referring to him as such was misleading. We considered that giving the impression of professional advice was unacceptable in advertisements for products or treatments within the remit of Section 8 of the Code.

Upheld

We considered that the ad implied medical treatments were being offered. Furthermore, the ad referred to specific ailments, contrary to the Code.

The ad breached CAP (Broadcast TV Advertising Standards Code rules 5.1 (Misleading advertising) and 8.1.2 (Impressions of professional advice and support).

8.2.2 (b) (Homeopathic medicinal products).

Action

We concluded that the ad must not be shown again in its present form.

DARULSHAFA SHIRQUIA—15 JULY 2009

Ad

A TV ad, in Urdu, for a herbal practitioner showed a man limping into a clinic. The ad featured scenes of the clinic staff and then showed the same man playing football with a group of boys. The voice-over stated "Darulshafa herbal clinic has been established in the UK for 41 years. Mr Mazhar Rana is a qualified herbalist and has been practising for the past 23 years … All our remedies are prepared using herbs from all over the world and to the finest standards possible. For treatment in good time contact us today". On-screen text throughout the ad gave the contact details for clinics in Bradford, London and Birmingham, as well as a website address. One of the staff members stated "Darulshafa. Renewing traditions, inspiring quality".

Issue

One viewer, a medical doctor, challenged whether the implied claim that the advertiser's herbal remedies could treat and cure medical conditions could be substantiated.

Assessment

Upheld

The ASA considered that the scene of the man limping into the clinic, followed by the scene of the same man playing football, implied that he had a medical condition that had been treated at the clinic. We considered that impression was reinforced by the claim "All our remedies are prepared using herbs from all over the world and to the finest standards possible. For treatment in good time contact us today", which was spoken over the scene of the man playing football, and which we considered suggested that the man had been treated using herbal remedies.

Furthermore, we were concerned that some viewers might consider the man had not only been treated but cured of his medical condition. We considered that, unless allowed by a marketing authorisation, illustrations that implied a cure of any medical condition were unacceptable. We were also concerned that, by offering a treatment or cure for a medical condition, the ad gave the impression that a medical consultation was not necessary for conditions for which qualified medical advice should be sought.

We noted that we had not seen any evidence that showed that the herbal remedies provided by Darulshafa could treat or cure medical conditions or that they held a marketing authorisation, and we therefore concluded that the ad was misleading.

The ad breached CAP (Broadcast) TV Advertising Standards Code rules 5.1.1 (Misleading advertising), 8.2.6 and 8.2.9 (Medicinal products and treatments).

Action

The ad must not appear again in its current form.

November 2009

Memorandum submitted by the National Institute for Health and Clinical Excellence (NICE) (HO 45)

I am writing to provide written evidence in answer to the following questions:

1. Why don't NICE provide guidance/evaluation on homeopathy?
2. Has there ever been an interest in NICE evaluating homeopathy? If so, why was this not approved?

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

NICE produces guidance in three areas of health:

- public health—guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector;
- health technologies (including technology appraisals)—guidance on the use of new and existing medicines, treatments and procedures within the NHS; and
- clinical practice—guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Topics for guidance development are referred to NICE by the Secretary of State for Health, in line with national priorities established for the NHS—for example; policy importance (ie whether the topic falls within a government priority area) and whether there is inappropriate variation in practice across the country. Once a topic has been referred, the development of the subsequent advice is entirely the responsibility of NICE.

There are two specific NICE guidance processes relevant here:

- Technology Appraisals—recommendations on the use of new and existing medicines and treatments within the NHS. NICE is asked to look at particular drugs and devices when the availability of the drug or device varies across the country. This may be because of different local prescribing or funding policies, or because there is confusion or uncertainty over its value.
- Clinical guidelines—recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

Technology Appraisals

NICE does not produce blanket guidance on the use of "groups" of therapies, whether complementary and alternative medicines (CAM) or not. To date NICE has not been asked to develop specific guidance on the use of individual complementary therapies. If the Secretary of State for Health referred this topic to us for guidance development, we would develop this guidance. We have not been asked to, and have not turned down a request to evaluate CAM therapies.

Clinical Guidelines

Where the evidence exists, we have considered CAM therapies, including homeopathy, alongside other conventional treatments in a number of our clinical guidelines. NICE has already made recommendations on where complementary therapies do and don't add benefit in relation to specific conditions, including multiple sclerosis, antenatal care, palliative care and most recently, low back pain. A summary of these recommendations is at Appendix 1. Because these guidelines are based on a specific disease or condition, we would not use this process to look at CAM therapies as a whole. We would evaluate, based on available evidence, which specific therapies may be of benefit.

APPENDIX 1

SUMMARY OF NICE CLINICAL GUIDELINES WHERE, BASED ON EVIDENCE, NICE HAS MADE RECOMMENDATIONS ON THE USE OF CAM THERAPIES

Antenatal Care

- Few complementary therapies have been established as being safe and effective during pregnancy.
- The following interventions appear to be effective in reducing morning sickness:
  - Ginger; and
  - P6 acupressure.

Multiple Sclerosis

- There is some evidence to suggest that the following items might be of benefit, although there is insufficient evidence to give more flexible recommendations:
  - Reflexology and massage.
  - Fish oils.
  - Magnetic field therapy.
  - Neural therapy.
  - Massage plus body work.
  - T'ai chi.
  - Multi-modal therapy.

Dementia

— In the dementia guideline recommendation that for comorbid agitation, interventions tailored to the person's preferences, skills and abilities should be considered. Options to consider include:
  — Aromatherapy.
  — Multisensory stimulation.
  — Therapeutic use of music and/or dancing.
  — Animal-assisted therapy.
  — Massage.

Parkinson's Disease

— Recommending that the Alexander Technique may be offered to benefit people with Parkinson's disease (PD) by helping them to make lifestyle adjustments that affect both the physical nature of the condition and the person's attitude to having PD.

Supportive and Palliative Care

— When organising supportive and palliative care services for people with cancer, commissioners and the NHS and voluntary sector providers should work in partnership across a Cancer Network to decide how to best meet the needs of patients for complementary therapies where there is evidence to support their use. As a minimum, high quality information should be made available to patients about complementary therapies and services. Provider organisation should ensure that any practitioner delivering complementary therapies in NHS settings conforms to policies designed to ensure best practice agreed by the Cancer Network.

Hypertension

— Informing people with hypertension that relaxation therapies can reduce blood pressure and individual patients may wish to pursue these as part of their treatment. However, routine provision by primary care teams is not currently recommended. Examples include: stress management, meditation, cognitive therapies, muscle relaxation and biofeedback.

Depression

— Although there is evidence that St John's Wort may be of benefit in mild or moderate depression, healthcare professionals should not prescribe or advise its use by patients because of uncertainty about appropriate doses, variation in the nature of preparations and potential serious interactions with other drugs (including oral contraceptives, anticoagualnts and anticonvulsants).

Low Back Pain

— Consider offering a course of manual therapy, including spinal manipulation, spinal mobilisation and massage. Treatment may be provided by a range of health professionals including chiropractors, osteopaths, manipulative physiotherapists or doctors who have had specialist training.
— Consider offering a course of acupuncture needling, up to a maximum of 10 sessions over a period of up to 12 weeks.
— Injections of therapeutic substances into the back for non-specific low back pain are not recommended.

Professor Peter Littlejohns
Clinical and Public Health Director

November 2009

Supplementary memorandum submitted by National Institute for Health and Clinical Excellence (NICE) (HO 45a)

[We] haven't approached the Department of Health to ask if we could evaluate homeopathy or expressed an interest in evaluating homeopathy.

Tony Beaman
Communications Executive (Public Affairs)
National Institute for Health and Clinical Excellence

November 2009

Memorandum submitted by David Tredinnick MP, Chairman, Parliamentary Group for Integrated and Complementary Healthcare (HO 46)

We spoke briefly at the end of the Science and Technology Committee's Evidence Check on Homeopathy this morning, which I attended in full. I raised a number of concerns with you and am now writing formally as Chairman of the Parliamentary Group for Integrated and Complementary Healthcare (PGICH), formerly Parliamentary Group for Alternative and Complementary Medicine.

I discussed this morning's proceedings at a special meeting of the PGICH following our AGM this afternoon with Lord Colwyn and Alan Simpson. Lord Colwyn sat on the original House of Lords Science and Technology Committee that looked at Complementary and Alternative Medicine in 2000.

I have the following comments.

1. Witnesses

Only one doctor using homeopathy gave oral evidence, and none are scheduled for Monday. No doctors using homeopathy in a primary care setting have been asked. Dr David Reilly from the Glasgow Homeopathic Hospital is regarded as a leading expert on this subject and should have been called. In addition, the Society of Homeopaths, which was discussed both directly and indirectly as the principal organisation representing non-medical homeopaths, should have had the opportunity to put its views forward. I believe that the Committee should have ensured that all the experts in this field were given the opportunity to give oral evidence.

2. Evidence from Sense about Science

The Managing Director of Sense about Science, an organisation whose actions over a number of years has caused much harm to homeopathy in the UK, was invited to give evidence. The result of this organisation's actions has been the closure of courses, the closure of a very good hospital in Kent and withdrawal of NHS contracts following a letter sent to all PCT Chairmen on headed notepaper purporting to have come from the Department of Health instructing them not to commission homeopathic services. The Minister Gillian Merron said in her response to my adjournment debate on 14 October on Complementary and Alternative Medicine that "The hon. Gentleman raised concerns about a document recommending disinvestment from homeopathy, which was circulated using the NHS logo. I can confirm that our inquiries found no record of the Department having authorised the use of the NHS logo and that those who originated the document were asked not to circulate it any further. They were advised about the use of the logo in future and chief executives of trusts were also informed that the document does not represent Government policy." col 416

Sense about Science is an organisation that does not have anyone on their list of advisors who has any expert knowledge in this field.

3. Science's Paradigms Constantly Change

Robert Wilson referred to the fact that other dilute preparations were now being recognised. It is quite likely that science will in the near future adjust its views to take account of this change, in which case the evidence presented by Sense about Science will be dated. It is the role of scientists to push back the frontiers of current knowledge, not to curtail it.

4. Importance of France, Germany and India

It was clear from the evidence put forward that France and Germany are far more advanced in their inclusion of homeopathy within their respective health systems, as usage is significantly more widespread. In addition, in India, for example, homeopathy can be traced back as early as 1810. The Homeopathic hospitals in Calcutta were famous for the treatment of intractable diseases. The success of controlling epidemics like Cholera helped its acceptance in other parts of the country. During the course of its development in India, it has gained substantial governmental patronage and has a vast infrastructure. It is one of the medical systems recognized by the Government of India. In 2002 a National Policy on Indian Systems of Medicine and Homoeopathy was formulated and in 2003 there was a Department of Ayurveda, Siddha, Unani, Yoga & Naturopathy and Homoeopathy (AYUSH).

On such an important enquiry for the future of homeopathy in the UK the Committee must consider evidence from abroad where that exists.

5. Homeopathy Over the Counter and Prescribed

Much of the discussion this morning was about the use and effectiveness of over the counter remedies in Boots and other chemists. This ignored the fact that qualified homeopaths when consulted prescribe a much wider range of homeopathic remedies and in doses well above the 6c and 30c available in chemists. Regularly they would prescribe in 200c or 1m for a constitutional remedy.

6. Impact of a Negative Report

The Committee should be aware that there are many within the orthodox medical profession and elsewhere in the UK that believe that homeopathy has no place in healthcare provision. These people make concerted efforts to discredit it and stop it from being commissioned. A negative outcome would give ammunition to those who seek to discredit it, and the Committee therefore has a duty to ensure that this Evidence Check is thorough and independent. I would suspect that detractors will have no hesitation in forwarding any report produced by this Committee to PCT Commissioners urging them to no longer commission services based on the findings. Dr Evan Harris already suggested at the session that the report produced by NHS Kent West regarding its decision to close the Tunbridge Wells Homeopathic Hospital be circulated by the Department of Health to all other Health Authorities. This is the type of climate that homeopathy faces in the UK.

You will be aware that there is a huge difference between there being no evidence of efficacy and there not being sufficient evidence to determine efficacy. The Committee needs to look carefully at this.

I urge you to take these points into consideration in your deliberations.

David Tredinnick MP
Chairman
Parliamentary Group for Integrated and Complementary Healthcare

November 2009

Memorandum submitted by Irish Health Trade Association (HO 47)

If I may, I would like to refer you to the website of the *South African Faculty of Homeopathy.* The faculty provides training in homeopathy for medical doctors.

In particular, I would like to refer you to a page of the website titled: *Research in Homeopathy*
http://www.homeopathysouthafrica.co.za/homeopathy_research_evidence.htm

There you will find the following:

1. A debunking of the myth that homeopathy "works" by a placebo effect.
2. A highlighting of some randomized clinical trials and the meta-analyses of these trials that show homeopathy has a positive clinical effect.
3. A presentation of outcome studies, large case series and research that demonstrates high rates of patient satisfaction with homeopathic treatment.
4. A look at the laboratory research and a meta-analysis of these trials that all show that homeopathy has a multitude of effects in laboratory conditions.

There follows a demonstration of how research has shown that homeopathy is:

— Safe.

— Cost-effective and offers an opportunity for resource-conscious health authorities to provide additional health benefits for their populations.

Homeopathy and funding is then examined in a South African context as follows:

— Increasing numbers of patients and medical doctors are using homeopathy.

— More medical doctors are being trained in homeopathy.

— Funders are prepared to pay for homeopathy.

Research that gives encouraging indications as to how homeopathy works is also presented.

Dr Alan G Ruth
Chief Executive Officer
Irish Health Trade Association

November 2009

Memorandum submitted by Oliver Dowding (HO 48)

May I take the opportunity to very briefly explain why homoeopathy should be retained?

It's easy to be cynical, and take the line that you don't think that there is anything in it other than water, or if it's on a pill that it's just a sugar pill. May I respectfully suggest that just because it's beyond our ability to understand the mechanism it doesn't mean that it doesn't exist or doesn't work.

I believe that millions of pounds are being invested in the Large Hadron Collider, and much of the finance will have originated from this country. Commendable though it may be to investigate such things, had one taken the view before the investment began that we didn't know how it worked, or whether it worked, that therefore we weren't going to undertake the investigation, all that money could have been saved.

For 15 years, I treated over 300 dairy cows, and 200 of their offspring, almost entirely using homoeopathic remedies. I had two herdsmen who barely had an exam pass between them. They learned very quickly what to do, when to do it, and which remedy would resolve which problem, using their many years of built-up stockmanship and an occasional education, and some book reading, to understand their animal and match remedy to ailment. We did not cause animals suffering, or have welfare problems, and often came out in the top half of research projects undertaking assessment of efficacy of treatment of illnesses.

Of all the animals we treated, to my knowledge none were pathogenic liars, none were fakes, and in fact, I don't think any of them ever knew what we were treating them with. Had they done so, that would've been a fascinating discovery!

How big a scientific study does one need to undertake to prove the efficacy of the science? I might add that alongside treating this large number of cows I have also seen many people treated very successfully with the same remedies. I recently came across a college lecturer in conventional agriculture, who had constantly teased me about my persistence with homoeopathy, rubbishing it at every opportunity, simply because he couldn't understand it and deemed it to be illogical. After many years with a persistent hacking cough, one of his grown-up children persuaded him to go to a homoeopath, and the ailment literally disappeared within 24 hours. He doesn't know how the mechanism works, but he doesn't care, because it made him better. You don't know how your computer works, but just as many of us don't know how many other things work, of which we are perfectly happy to deploy every day, our lack of knowledge doesn't stop by utilising the product.

The same goes for the mechanism by which many drugs operate, in that we don't know exactly how they work in all cases, but it doesn't stop us using them. Unfortunately, we also don't know why in some cases, the use of conventional medication has unexpected side-effects, or when multiple doses are used they react in a way that we don't expect. That also doesn't stop us using them.

I believe some people consider that the homoeopathic industry has undue influence due to its size. Surely that cannot be the case? If it is, surely we have a right to question the influence of the allopathic drug business? If you care to ask and I'll give you some examples.

I thank you for reading this, and although you may be finished with formal settings, I would be happy to make any submission you like, to ensure your knowledge is complete before you adjudicate.

Oliver Dowding
Shepton Farms Ltd

Memorandum submitted by Maria Jevtics (HO 49)

ENQUIRY RECEIVED BY THE COMMONS INFORMATION OFFICE

1. How were the witnesses selected? What qualification did Dr Ben Goldacre, Paul Bennet and Tracey Brown have to give evidence on a highly academic discipline which take more than four years to learn and understand? The committee was far better informed than some of the witnesses.

2. There was no witness representing consumers who use homeopathy with satisfaction. There is a large number of people who use homeopathy and are satisfied and these people are taxpayers and voters. They have a right to be represented in an enquiry such as this.

3. The issue that a homeopath may miss a serious underlying condition is a valid one, however it is the same across the board of all medical disciplines. Homeopaths are trained to ask certain questions to exclude serious underlying conditions. They arev also bound by their code of ethics to recognise these and refer on to a medical doctor if in doubt. There are many misdiagnoses taking place on a daily basis in every GP surgery and the numbers of people affected or killed by misprescribed pharmaceutical is in the hundred thousands per year.

4. If we need scientific evidence for everything we allow, then we must close churches and temples. There is no scientific evidence that God exists and still we allow priests to promise eternal life and salvation. We allow the church to extract money on a monthly basis from churchgoers all on a scientifically unfounded basis. This is the boggest hoax in human history.

5. Homeopathy is physically harmless and risk-free. It also gives people mental and emotional peace of mind. There is no reason to undermine it with demands for scientific validity when history teaches us that often the science lags behind. Let's not repeat the same mistakes over and over.

Quantum physicas also does not make sense to the untrained mind. I do not expect most of the witnesses or committee members to understand something they simply do not know enough about. Just check whether it is harmful ordangerous. If it is not then what is the problem?

November 2009

Memorandum submitted by Mary English (HO 50)

I have read and watched the Committee Meeting for Evidence Check: Homeopathy.

I would like my (humble) views to be known.

1. I am a qualified Homeopath. I had five years training and hold a Diploma from the School of Homeopathy 2001. I am insured to practice. I work privately in Bath and am supervised by Mabel Smith RSHom. I hold a Certificate in Counselling Concepts from the City of Bath College and am first aid trained. I have eight years experience of working as a volunteer running a Homeopathic Clinic for drug addicts and alcoholics with The Drugs and Homeless Initiative in Bath. I am past Chair of the charity the Homeopathy Action Trust.

2. My first experience of homeopathy was buying an over-the-counter "remedy" called Aconite that the leaflet in Boots (where I bought it) said was good for croup. I bought the remedy because it said it was safe for children.

3. When my baby son (18 months) had his next attack of croup, I used one tablet of Aconite 6c and his attack of early morning wheezy, panicky breathing subsided in minutes and completely went.

4. This then prompted me to investigate homeopathy and eventually led to me becoming a professional practitioner.

5. If I had not been able to buy the remedy in Boots, I would:

   (a) have had a child with regular breathing difficulties, which would have led to drug therapy and side-effects and dependence on the NHS for treatment; and

   (b) have never trained or qualified in a therapy that has brought health and healing to a vast number of my patients who would otherwise be a drain on NHS resources.

6. I would urge your committee to take into account, along with all the scientific and medical opinions my small voice of happiness with my discovery of a safe, person centered, individual form of health therapy and my willingness to continue to treat the public in a safe, person-centred manner.

Mary English DSH
Homeopath

I am a qualified Homeopath working in private practice in Bath, UK

November 2009

Memorandum submitted by Sue Young (HO 51)

I watched with dismay as the bias against homeopathy was given free reign in your Commission on homeopathy the other day—Can someone please enlighten me how the supposed "placebo effect" is relevant to the following:

Animal studies?

http://avilian.co.uk/2008/08/scientific-research-and-homeopathy-animal-studies/

Plant studies?

http://avilian.co.uk/2008/08/scientific-research-and-homeopathy-plant-studies/

In vitro studies?

http://avilian.co.uk/2008/08/scientific-research-and-homeopathy-in-vitro-and-related-studies/

Physics and chemistry studies?

http://avilian.co.uk/2008/08/scientific-research-and-homeopathy-physics-and-chemistry-studies/

Fungus studies?

http://avilian.co.uk/2009/10/maria-curie-sklodowska-university-in-poland-proves-homeopathy/

DNA studies?

http://avilian.co.uk/2009/09/luc-montagnier-foundation-proves-homeopathy-works/

Charles Darwin's work with drosera?

http://avilian.co.uk/2009/03/charles-darwin-proved-homeopathic-dilutions/

Please also see

http://avilian.co.uk/2008/08/scientific-research-and-homeopathy-meta-analysis/

The latest Shang *et al* meta analysis done in 2005 is very biased, has a very small sample size and does not quote its sources, and turns all the earlier meta analysis, carefully conducted with large sample sizes and which do quote their sources, in favour of homeopathy upside down—this is very poor science and quite obviously malicious.

I do trust you can see the vast economic forces fuelling this auto de fe against homeopathy, which is based on lies, more lies, spin and mistruth.

Sue Young RSHom

November 2009

Memorandum submitted by J A Wheatley (HO 52)

I am a lay member who has been studying and practising homeopathic medicine for some 30 years and have been successful in curing cases the medical profession could do no more for. I would be pleased to give chapter and verse to your enquiry. I am sending a copy of this letter to David Tredinnick MP who I know well. He is my MP and Chairman of the Alternative Medicines Committee in the House as I am sure you will know.

December 2009

Memorandum submitted by Hugh Evans (HO 54)

While looking for another programme on iPlayer, I happened upon the broadcast of your Committee's session of 25 November 2009 on homeopathy, and I hope that I am not too late in submitting some observations as an ordinary member of the public.

First let me declare an interest. For a miserable 18 months, my excellent GP and three expert hospital consultants tried hard, but failed, to cure my worsening balance problem (caused by an inner-ear condition), and a series of prescribed pharmaceutical drugs either had no effect or made me feel even worse. In desperation, having been eventually told that I "would have to live with it", I turned to a homeopath practitioner (registered by a national body). I knew nothing about this form of medicine.

Over the following five months, the homeopath worked hard to narrow down the homeopathic profile of my condition, and after monthly consultations, gave me three tablets which I took at two hourly intervals one Friday afternoon. The problem had gone by the Monday. I have been free from all the balance symptoms ever since, and that was 20 years ago.

My observations for the Committee are:

(a) The Germans and the French are not generally regarded as gullible nations, yet they embrace homeopathy in a very significant way. Their Health Insurance organisations are very supportive of homeopathic medicine, because they see good results at a fraction of the cost of the drugs supplied by pharmaceutical companies. I trust that your Committee is taking evidence from European experts and bodies from outside the UK.

(b) Here in the UK, I and many other, including—I dare say—members of the Royal Family, who do not regard ourselves as cranky or gullible, have benefited from homeopathic remedies, sometimes in a highly dramatic way.

(c) Homeopathic remedies are very cheap (eg I paid around £4.50 for my bottle of 60 Arnica pills which I use for bruising etc and this will last for years). In countries such as India, where money is tight for many people, homeopathy flourishes. I hope that the Committee will take evidence from poor countries such as India.

(d) In the discussion I saw from your Committee session, I did not hear much from the point of view of the patient. I hope, therefore, that your report will include evidence from patients, be they people who have benefited from homeopathy, been harmed by it, or found it a waste of time.

I hope that these observations will be of some interest to you.

Memorandum submitted by the British Medical Association (BMA) (HO 55)

HOMOEPATHIC REMEDIES

I note that the Science and Technology Committee's evidence check on homeopathic remedies is drawing to a conclusion and I thought that the Committee might be interested in the British Medical Association's (BMA) view on this issue. I wanted to inform the Committee that we have long been concerned about the use of complementary and alternative medicines (CAM) and over the last 20 years the BMA's Board of Science has worked extensively to develop BMA policy on CAM.

Our policy development has focussed on the discrete therapies which have established training programmes, criteria of competence, professional standards and the potential for use alongside orthodox medical care. Doctors have a duty to safeguard public health and BMA policy has therefore focused on the principles of good practice in CAM which would safeguard the individual against possible harm to health and maximise the potential benefits of particular CAM methods.

As you may be aware, the popularity of CAM has led to greater demand for CAM on the NHS. This has coincided with changes in healthcare provision which aim to facilitate greater patient choice. Research into the efficacy of CAM however has raised questions about the use of NHS resources for such provision. As such our members would be supportive of a call in the Committee's final report to request that NICE review and report on the cost effectiveness of homoeopathic remedies and for NICE to recommend whether they should continue to be funded by the NHS.

I hope that you find this useful.

Professor Sir Ken Calman
Chair
Board of Science

Memorandum submitted by Dr Vijay Vaishnav (HO 56)

We write this as academicians and homoeopathic practitioners. We have been in the field of homoeopathic education and practice for 25 years in Mumbai (Bombay), India.

It is disheartening to learn about the chaos and furore over homoeopathy in the UK. Questions have been raised in the British Parliament whether homoeopathy is scientific and whether it should be supported and funded by the government.

GOVERNMENT PATRONAGE

In India, homoeopathy has progressed considerably because of the patronage received by it from the Indian government. It was recognized as a system of medicine by an Act of Parliament, and with the formation of the Central Council of Homoeopathy (CCH), homoeopathic education and practice was regulated.

REGULATIONS

The CCH has regulations in place that prescribe the minimum standards of education and training in homoeopathic colleges in India. No person is allowed to practice homoeopathy unless he/she has graduated from a homoeopathic college that is recognized by the CCH. Correspondence courses are not recognized.

TRAINING OF HOMOEOPATHS

The training of a homoeopathic student in India is similar to that of a student being trained in conventional (allopathic) medicine. This means that a student has to enroll in a college for a full-time course of $4\frac{1}{2}$ years (plus a one year compulsory internship) in homeopathy. He is taught the same subjects as his contemporary in the allopathic course—anatomy, physiology, pathology, medicine, surgery, OB-GYN and community medicine. He also has to attend practicals (eg dissections in anatomy, biochemistry in physiology, etc.) as well as clinics in clinical subjects with demonstrations on real patients, and observing as well as assisting in surgeries as well as deliveries in the operation rooms.

Use the Indian Model

This is lacking in most of the countries in the world where homoeopathy is being practiced. The onus is on the British government to regulate the training and practice of homoeopathy in UK. The MPs should study the rules and regulations of the CCH, India, and make use of the experience of this organization to help streamline the practice of homoeopathy in UK and also prove to the world (and themselves!) that it has a scientific basis.

Research in Homoeopathy

The Central Council for Research in Homoeopathy (CCRH), India encourages research and development of homoeopathy in India. It has piloted many research projects to prove the efficacy of homoeopathy. Many new drugs have been proved by the CCRH and lots of scientific papers have been published by it including clinical research done on HIV/AIDS, Bronchial Asthma, Cancers, etc.

The CCH and the CCRH are under the Department of AYUSH (Ayurved, Unani, Siddha, Homoeopathy) of the Ministry of Health and Family Welfare, Government of India. The Department of AYUSH encourages the Central Councils of the various alternative systems of medicines to organize CMEs for practitioners and ROTPs (Re-Orientation Training Programmes) for teachers. It also sanctions funds for research at recognised institutions.

Evidence Based Homoeopathy

We have had success in treating cases with organic lesions and we have published them in various homoeopathic journals. We have also published many of these cases on our web site www.drvaishnav.com. Theses cases with documented evidence in the form of X rays, Ultrasounds, Colour Doppler studies, etc, both before and after treatment, prove that homoeopathy really works. We have published an article in a journal for allopathic doctors on the role of ultrsounds in homoeopathic practice. The article underscores the awareness of a modern homoeopath and the scientific approach to the treatment of his patients.

Dr Vijay Vaishnav MD (Hom)
Professor and ex-Head, Dept of Materia Medica, CMP Homoeopathic Medical College, India

Dr Daxa Vaishnav MD (Hom)
Professor Head, Dept. of OB-GYN, CMP Homoeopathic Medical College, India

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Memorandum from Government on "Evidence Check"

This memorandum was collated by the Government Office for Science in response to the former House of Commons Innovation, Universities, Science and Skills Committee's "Evidence Checks".

The response to the first Evidence Check was received on 28 September 2009. The response to the second Evidence Check was received on 13 November 2009.

Homeopathy

[See Ev 60]

Dyslexia

[See Science and Technology Committee, Second Report of Session 2009–10, Evidence Check 1: Literacy Interventions, HC 44, Ev 101]

Swine Flu Vaccinations

This response was provided by the Department of Health.

Q1 *What is the Government's policy regarding the production of a swine flu vaccine and its distribution to the population?*

Government policy is to purchase vaccine licensed for use in Europe in accordance with the European Directive on Procurement. The vaccine has been produced in Europe.

The Secretary of State for Health announced the priority groups for the swine flu vaccine on 13 August. More than 11 million people in England will be targeted first. The vaccine will initially be prioritised to those groups of people who are at highest risk of severe illness, as well as frontline health and social care workers.

Based on the current delivery forecasts from both manufacturers, we expect to have approximately 55 million doses available by the end of the year—enough for up to about 30 million people to be vaccinated—with more following after that. The vaccine will be delivered in phases as stocks become available. The vaccine may be licensed by early October and this could result in the vaccination programme being rolled out from mid October.

Q2 *What expert scientific and medical advice have been used to steer the Government's policy?*

The Joint Committee on Vaccination and Immunisation (JCVI) reviewed the evidence and advised the Department of Health on these priority groups. This advice was also scrutinised and endorsed by the Scientific Advisory Group for Emergencies (SAGE).

We will continue to take the best independent scientific advice to inform our decisions on the response to swine flu.

The following groups will be prioritised for the swine flu vaccine in this order (numbers given are approximate and are for England only):

1. People aged over six months and under 65 years in current seasonal flu vaccine clinical at-risk groups (about 5 million people).
2. All pregnant women, subject to licensing conditions on trimesters (about 0.5 million people).
3. Household contacts of people with compromised immune systems eg people in regular close contact with patients on treatment for cancer (about 0.5 million people).
4. People aged 65 and over in the current seasonal flu vaccine clinical at-risk groups (about 3.5 million people). This does not include otherwise healthy over 65s, since they appear to have some natural immunity to the virus.

Vaccination of frontline health and social care workers (approximately 2 million people) will begin at the same time as the first at-risk group, and will continue for as long as necessary. This group is at increased risk of infection and of transmitting that infection to susceptible patients. Protecting these people will help the NHS workforce to remain resilient and able to treat sick patients.

Literacy and Numeracy Interventions

[See Science and Technology Committee, Second Report of Session 2009–10, Evidence Check 1: Literacy Interventions, HC 44, Ev 34]

Teaching Pseudoscience at Universities

This response was provided by the Department for Business, Innovation and Skills.

Q1 *What is the Government's interpretation of the term "pseudoscience"?*

The Government does not find it helpful to define pseudoscience. It is committed to policy-making based on scientific evidence. By science we mean all-encompassing knowledge based on scholarship and research which is underpinned by methodologies that build up and test increased understanding about the world and beyond.

Q2 *What is the Government's position on universities that award BSc and MSc in subjects that are pseudoscientific? When recruiting staff, does the Government recognise such qualifications as providing the holder with scientific expertise?*

All universities undertake research and teaching, but HEIs are autonomous institutions and decide the courses or content of the higher education they offer to their students who make informed choices about the curriculum they choose to study. In relation to degrees in specific disciplines, there may be further processes around accreditation and recognition by professional bodies, which may allow some judgements to be made about, for example; the quality of course content, teaching, skills acquired, but this is not for Government to prescribe.

The standards of degrees awarded by HEIs, and the quality of learning opportunities, are subject to independent review by the Quality Assurance Agency (QAA) and external examiners. Since the QAA was established in 1997 its reviews have consistently indicated that quality and standards are being maintained.

Departments have delegated responsibility for recruitment and should have robust processes in place for ensuring that appointments are made on merit. When appointing, departments will look at the skills, experience and qualifications required for the role. For some roles, a particular scientific expertise or qualification might be sought from any range of appropriate disciplines.

Health Checks for Over 40s

This response was provided by the Department of Health.

Q1 *What is the Government's policy on the provision of free health checks for over 40s?*

From 2009–10, the NHS is being asked to implement a uniform and universal vascular risk assessment and management programme called the NHS Health Check programme, for everyone in England between 40 and 74. The proposals for this programme were set out in Putting Prevention First published on 1 April 2008.

Vascular diseases, that is heart disease, stroke, diabetes and kidney disease, are the biggest cause of death in the UK, and the NHS Health Check programme could on average prevent 1,600 heart attacks and strokes and save at least 650 lives each year. The programme could prevent over 4,000 people a year from developing diabetes and detect at least 20,000 cases of diabetes or kidney disease earlier, allowing individuals to be better managed and improve their quality of life.

Vascular disease also makes up approximately a third of the difference in life expectancy between spearhead areas and the rest of England. This programme will help ensure greater focus on the prevention of coronary heart disease, stroke, diabetes and kidney disease, and will help people remain well for longer. Type II diabetes mellitus is a growing public health concern. Its prevalence is increasing and diabetes contributes significantly to overall health inequalities within England. This programme offers a real opportunity to make significant inroads in tackling health inequalities, including socio-economic, ethnic and gender inequalities.

The purpose of an NHS Health Check is to identify an individual's risk of coronary heart disease, stroke, diabetes and kidney disease, for this risk to be communicated in a way that the individual understands, and for that risk to be managed by appropriate follow-up, including being recalled every five years for reassessment.

The check itself involves a standard assessment based on straightforward questions and measurements. These would record basic information such as height, weight, current medication, age, family history, smoking and blood pressure and include a simple blood test for cholesterol and (in some cases) glucose levels. This will be followed up with personalised advice on how to lower that risk and maintain a healthy lifestyle. For those at low risk, this might be no more than general advice on how to stay healthy. Others at moderate risk may be recommended a weight management programme, stop smoking service, or a brief intervention to increase levels of physical activity. Those at high risk might require medication with statins or blood pressure treatment, or an intensive lifestyle management programme for those identified with impaired glucose regulation. A few may need further assessment or tests.

We also expect to identify people who already have a vascular disease where it has so far gone undetected, particularly type 2 diabetes and chronic kidney disease. In such cases patients will benefit from an immediate start on a disease management programme to manage their condition and prevent adverse complications.

Q2 *What evidence (specifically cost-benefit analyses) led to the formulation of this policy? What evidence has been used to support health benefit claims (eg lives saved per year)?*

The NHS Health Check programme is both cost effective and clinically effective.

The approach taken in the programme is based on economic modelling undertaken by the Department of Health (DH) which has used guidance produced by the National Institute of Health and Clinical Evidence (which reviews the clinical and cost effectiveness of interventions in medicine).

The full details of the analysis undertaken by the Department are set out in the Impact Assessment which can be viewed on the DH website (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_090351). It shows the cost of the programme to be £332 million each year and the average annual benefit to be £3,678 million. Based on these figures, the NHS Health Check programme is highly cost effective. (The costs are the costs of the checks and net lifetime costs of interventions given to the cohort of individuals checked in the first 20 years. The benefits are calculated on the basis that each quality adjusted life year a patient enjoys has an estimated social value of £50,000).

Quality-adjusted life years are a measure of how many extra years of life of a reasonable quality a person might gain as a result of treatment.

The modelling also showed that the programme would cost around £3,500 per quality-adjusted life year gained. This is considerably below the £20–30,000 per quality-adjusted life year threshold that NICE uses to assess cost effectiveness and therefore, according to this test, the programme is highly cost effective.

Measuring the Benefits of Publicly-funded Research

This response was provided by the Department for Business, Innovation and Skills.

Q1 *What generic social and economic benefits are derived from funding research with public money?*

Publicly funded excellent research produces new knowledge and understanding, which is a benefit in its own right, but also generates significant economic impact. The Warry Report,[41] drew on the HM Treasury Green Book, to define economic impact as follows:

> "An action or activity has an economic impact when it affects the welfare of consumers, the profits of firms and/or the revenue of government. Economic impacts range from those that are readily quantifiable, in terms of greater wealth, cheaper prices and more revenue, to those less easily quantifiable, such as effects on the environment, public health and quality of life."

[41] *Increasing the economic impact of Research Councils* (2006).

Economic impact is delivered by publicly funded research via many routes, including:

— Creating new businesses.

— Improving the performance of existing businesses.

— Delivering highly skilled people to the labour market.

— Attracting R&D investment from global business.

— Improving public policy and public services.

Q2 *What evidence is there for social and economic benefits? How is this evidence used to determine funding priorities?*

There is extensive evidence of the benefits of publicly funded research. A report that looks at the economic impact of the research base as a whole is produced annually by BIS (formerly by DIUS), and is structured around an Economic Impact Reporting Framework, which portrays the generation of economic impacts at the aggregate economy level.[42] It is wide ranging, and includes sections on the five routes to economic impact bulleted above, as well as others. In 2006 the then DTI published Making the most of UK Research, a collection of case studies of benefits from research.[43]

Each Research Council prepared initial Economic Impact baselines as part of their Delivery Plans published in December 2007, and updated versions were published this year.[44]

The impact of other funding streams has been independently evaluated. The Higher Education Innovation Fund (HEIF) is one such stream,[45] and its impact on knowledge transfer is borne out by the annual Higher Education-Business and Community Interaction (HE-BCI) survey,[46] which shows universities external income rising to record levels of over £2.8 billion per year. The Science Research Infrastructure Fund (SRIF) has been shown to have dramatically improved research infrastructure, and to have wider benefits in terms of researcher productivity and ability to attract other funding.[47] The knowledge transfer performance of Public Sector Research Establishments is also improving, bringing in record levels of external income.[48]

The research community itself also regularly carries out evaluation of the economic impact of research. To pick just a few recent examples, the Russell Group have evaluated the impact of research in their universities,[49] the Wellcome Trust has assessed the economic benefits of medical research,[50] and Oxford Economics have assessed the economic effects of fundamental physics research.[51]

Before allocating the Science and Research Budget, DIUS collected evidence on the activities and performance of all funding lines. All the Research Councils and the Academies provided detailed delivery plans, which set out what future investment would deliver against the overarching objectives. Other key programmes, such as HEIF and SRIF, were subject to independent evaluation.

The following factors were taken into account in determining the Science Budget Allocations to individual Research Councils and Academies:

— a thorough assessment of draft Research Council and Academy Delivery Plans for CSR07;

– the strength of the case for increasing the investment in any particular area of research in CSR07; and

— a full evaluation of the performance of each of the Research Councils and Academies through the SR04 period.

The allocation of the Quality-related Research block grant to Higher Education Institutions by HEFCE has in the past been informed by the results of the Research Assessment Exercise (RAE). HEFCE are currently developing the Research Excellence Framework (REF) to replace the RAE. The REF will for the first time explicitly take account of the impact research makes on the economy and society.

[42] *Economic Impacts of Investment in Research & Innovation, DIUS* (2008).
[43] Available at http://www.dius.gov.uk/~/media/publications/F/file35789
[44] Available at http://www.rcuk.ac.uk/aboutrcuk/deliveryplan.htm
[45] *Evaluation of the effectiveness and role of HEFCE/OSI Third Stream Funding,* PACEC (2009).
[46] *Higher education-business and community interaction (HE-BCI) survey* (2009).
[47] *Science Research Investment Fund: a review of Round 2 and wider benefits, Technopolis Group* (2009).
[48] *Fourth Annual Survey of Knowledge Transfer Activities in Public Sector Research Establishments, Technopolis* (2008).
[49] *The Impact of Research produced by Russell Group Universities, Russell Group* (2009).
[50] *Medical Research: What's it worth?,* Health Economics Research Group at Brunel University, the Office of Health Economics and RAND Europe (2008).
[51] *The economic impact of fundamental physics research on the UK economy,* Oxford Economics (2009).

The Future of GM Technologies

This response was provided by the Department for Environment, Food and Rural Affairs.

Q1 *What is the Government's policy on the development and commercialisation of genetically modified crops?*

The Government confirmed its current Policy on GM crops in a Parliamentary statement in March 2004. Safety is the Governments top priority and as such we follow the science and assess potential GM crops on a case-by-case basis. This is consistent with the existing EU legislation which requires genetically modified organisms to be cleared for trial or commercial release, with decisions based on an assessment of the risk to human health and the environment.

The Government acknowledges that GM crops could offer potential benefits over the longer term. We should keep an open mind, but continue to be led by the science.

Q2 *What evidence and expert advice has been used to determine government policy regarding genetically modified crops?*

The Government receives expert advice on individual applications to release GM crops from the Advisory Committee on Releases to the Environment. It conducts an independent scientific evaluation and advises on the potential risks for human health and the environment.

The Government's broad policy on GM outlined above was informed by the findings of the "GM Dialogue" process that it sponsored in 2003. This had three strands: a public debate run by an independent board; a GM science review led by the then Government Chief Scientist; and a study of the overall costs and benefits of GM crops, undertaken by the Prime Minister's Strategy Unit. Further details can be found on Defra's website http://www.defra.gov.uk/ENVIRONMENT/gm/crops/debate/

Synthetic Biology

This response was provided by the Health and Safety executive.

Q1 *What is the Government's policy on the regulation of synthetic biology?*

The Government recognises that this is a new and exciting field of technology, which has the potential to deliver benefits in areas such as medicine, manufacturing, and the environment. However, there is also a need to identify, anticipate and address any societal issues that might arise from synthetic biology, whilst enabling UK research and industry to harness the technology to develop and deliver benefits for society.

Synthetic biology involves a range of techniques culminating in the insertion of synthetic heritable material into living cells. In many ways this is an extension of existing recombinant DNA technologies. Consequently the Government considers that most applications are likely to fall under existing legislation covering the development and use of genetically modified organisms.

Future work may involve the creation of artificial cells, which would not fall within the scope of existing legislation. Consequently, a minor amendment is being proposed to the definition of GM as part of the development of a single regulatory framework for work with human and animal pathogens and GMOs. This will enable the regulations to cover artificial cells, should the technology develop in that direction. This change will be consulted on prior to the implementation of the new regulatory system.

The Government also recognises that the regulatory system needs to be kept under review to ensure that it is able to deal with the likely development and applications of synthetic biology, including those relating to biosafety, biosecurity and the release of genetically modified organisms into the environment. In doing so, it recognises that lessons should be drawn from the past to help ensure regulations keep pace with, or anticipate, scientific developments.

Q2 *What evidence and expert advice will the Government seek to underpin future regulation? Are current regulations adequate or will a new regulatory framework be required?*

The Government regularly checks the appropriateness of the existing UK GM legislation (GMO deliberate release and GMO contained use regulations) to deal with new technologies, including synthetic biology. Scientific advice on the topic has been sought from scientific advisory committees (Advisory Committee for Releases into the Environment (ACRE), and Scientific Advisory Committee for Genetic Modification (SACGM (CU)), the UK research councils, and other government departments and agencies.

The Government will continue to consult a wide range of stakeholders to ensure that the regulatory system is appropriate, and that the best advice is available to evaluate developments in synthetic biology.

It is widely anticipated that most applications of synthetic biology will start in the laboratory in compliance with the GMO contained use regulations, before a proportion will progress to deliberate release. Activities falling under the GMO contained use regulations contained will require risk assessment and proportionate and appropriate containment.

Deliberate release applications can only be approved once sufficient supporting knowledge and data is available. Defra and HSE are also involved in a working group under the auspices of the European Commission, which is considering the new technologies in light of existing GM definitions and legislation. The working group will report to the EC in October.

UK legislation covering the contained use of genetically modified organisms is under review, with the intention of creating new legislation amalgamating the GM legislation with the contained use of human and animal pathogens. This provides an opportunity to ensure that aspects of synthetic biology that might be outside the scope of current legislation are encompassed in the emerging single regulatory framework. The proposed amendment extends the definition of genetic modification to include the "introduction of genetic material into a cell artificially created for that purpose, where the cell is then capable of replication or of transferring genetic material". It is felt that this amendment will be sufficient to ensure that synthetic biology is fully covered by UK legislation. A full consultation exercise will be carried out before the definition is incorporated into the regulations.

Use of Offender Data

This response was provided by the Ministry of Justice.

Q1 *What is the Government's policy on the use of offender data (eg, employment, access to finance)?*

Whether offender data relating to convictions can be used for most purposes is dependent on whether a conviction is spent or unspent under the Rehabilitation of Offenders Act 1974. The Act serves to help rehabilitate those who have stayed on the right side of the law for a period of time, thereby assisting reformed ex-offenders find jobs, obtain insurance and avoid discrimination.

Until a conviction is spent it may have to be declared for any purpose—for instance when obtaining financial products, seeking employment, or applying for any sort of licence, for instance a licence to sell alcohol or engage in a certain type of business. This is fair as an unspent conviction may indicate a relevant risk, and is a fair consequence of a criminal penalty.

However once a conviction is spent under the Act it is treated—for most purposes—as if it doesn't exist. This reflects the fact that the ex-offender has remained on the right side of the law for a specified period and proven they pose less of a risk in most circumstances.

As the rehabilitation periods differ according to the sentence imposed the period for which a conviction needs to be disclosed is related to the severity of the individual offence.

However there are certain positions—particularly those involving access to children and vulnerable adults, and working in positions of exceptional trust or for the State—where the employer needs to be able to take the most stringent of assessments in order to minimise a genuine risk. For instance those working in the police, looking after children or vulnerable adults, or working with access to highly controlled substances, can potentially cause a much greater level of harm if they do offend. For this reason there are certain purposes where an exception to the Rehabilitation of Offenders Act exists. These are all specified by the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 (as subsequently amended on numerous occasions). Amendments to the order are by means of a Statutory Instrument subject to affirmative procedure.

The government's policy is that those areas listed on this order are deemed sufficiently sensitive that the employer should always be able to see a person's full record, including all spent convictions and cautions, in order to come to a fair judgment on their suitability (and any appropriate safeguards) based on the full available evidence.

But it is equally important to note that having a criminal conviction is not an automatic bar to employment in any of these areas. The government believes that it is important for employers to take a balanced view on the fact that an individual has a criminal conviction, whether spent or unspent, taking into account factors such as how long it is since the offence, the person's age at the time of the offence, the relevance of the offence, and what else is known about the individual's character and conduct before and since.

In order to obtain a Criminal Records Bureau disclosure containing details of spent convictions, it is necessary for the employer to make a declaration that it is for purposes specified in the ROA Exceptions Order. An employer obtaining details of spent convictions by means of a fraudulent statement would be committing an offence.

It is the government's belief that this system—within the framework of the Rehabilitation of Offenders Act 1974 and the Police Act 1997, and fine-tuned by updates to both primary and secondary legislation—helps create a balance between the need to disclose offender data when there is a need to do so for purposes of protecting the public, and the need to enable reformed ex-offenders to put their past behind them at all other times.

Q2 *What evidence is there to support the various ways in which offender data are used?*

Statistical evidence is hard to obtain when one is dealing with subjective decisions. The system can be said to have worked either when an offender gets a job and does not re-offend, or when an offender is prevented from entering a job where they intended to cause harm.

The latter is impossible to prove. There is no proof that an ex-offender would re-offend if placed in a sensitive position, even if their criminal conviction was recent, serious and relevant. In some cases an individual who is barred from a sensitive position may—had he or she been employed in that position—have gone on to commit a serious offence or abuse of trust; in other cases they could have gone on to have a faultless record. It is impossible to produce definitive figures on an event which has not been given the opportunity to happen. However when employers make judgments they have to do so on the basis of a fair risk analysis using their knowledge of the job, the opportunities it affords, and the record of the person applying.

CRB statistics, compiled by MORI, indicated that in 2008, around 18,000 unsuitable people were prevented from working with children and/or vulnerable adults as a direct result of a CRB check, bringing the total to around 98,000 people in the past five years. This, even when assessed with the caveats above, would still indicate that the purpose of the system to bar unsuitable candidates is working.

As there is no control study it is hard to use these statistics as proof of the effectiveness of the current system. However they do provide evidence which supports the way in which offender data is currently used. These statistics indicate that there are those on both sides of the system—employers of sensitive positions and ex-offenders—who have benefited from the system. As long as the decision to share information is balanced in terms of being necessary, eg to protect the public, and proportionate, eg to the risk the offender poses, it can benefit all parties.

As to whether a better balance could be established, improving one or both of these sets of figures—this is certainly something to which the government aspires. The 2002 Home Office report "Breaking the Circle" recommended reforms to the ROA and the government has made a commitment to work on implementing the proposals. And the Vetting and Barring Scheme, established under the Safeguarding Vulnerable Groups Act 2006, will enable a better, fairer and more joined-up approach to vetting those working with children and vulnerable adults. But the fundamentals of the scheme—that once convictions are spent they are only made available to those who have a need to know—are working and will not be changed. The next phase of the scheme commences in October 2009 with a phased implementation of registration under the scheme being introduced between July 2010 and 2015.

Sharing of Information between Police and Probation

Information-sharing between criminal justice agencies is necessary for effective sentencing and the protection of the public. Information about offenders is currently shared between the police, prison and probation services to enable staff to manage offenders effectively, as provided for within the Offender Management Act 2007 (s14). Probation may request information from the police service for a range of reasons to enable the public to be protected, including for the following purposes: for bail information interviews and reports; at the pre-sentence stage, for making appropriate sentence recommendations; to make appropriate placement decisions for unpaid work (community payback) requirements; assessment for licence conditions prior to the release of a prisoner; for informing reports to the Parole Board for considering an offender's parole.

However, this must be within the parameters of relevant legislation and guidance, which are designed to balance the rights of the individual, ie the subject of the information being shared, with the rights of society to be protected from that individual. Therefore, information shared about a person must be both necessary (eg to meet the probation purposes of managing risk of harm) and proportionate (eg to the risk posed by that person). These principles should govern the decision by the police service to share information in the first place and the decision by the probation service over whether to use the information to inform their report.

The National Offender Management Service is in the process of agreeing an information-sharing protocol with the Association of Chief Police Officers to formalise the processes for exchanging information between the police and probation services for the effective management of offenders. The agreement will set out the purpose and principles of information-sharing, along with the legal basis for offender management activity, and the legislation governing the disclosure of personal data. It will provide for and encourage the sharing of information in certain circumstances, but make the legal implications to earlier and more widespread information-sharing clear.

Certain offenders are managed under the Multi Agency Public Protection Arrangements. MAPPA is a process where the Responsible Authority (police, prison and probation services together with a number of Duty to Co-operate Services which include Jobcentre Plus and Housing) work together to manage the identified risks presented by these offenders.

MAPPA applies to:

— sexual offenders who are required to notify the police of their details under the Sexual Offences Act 2003;

— violent offenders as defined by Schedule 15 of the Criminal Justice Act 2003 who are sentenced to 12 months custody or more; and

— those dangerous offenders who have a previous conviction or caution for a violent offence who the Responsible Authority (police, prison and probation services) consider present a risk of serious harm to others.

MAPPA relates to offenders in the community and each MAPPA offender will be assessed to identify the level of multi agency management they require and in every case whether a disclosure regarding the risks the offender presents should be made to another person/organisation to protect others from harm. There is occasions where disclosure will be made to an employer to ensure that the offender is not placed in a situation which would be unsuitable for the risks they pose; for example, a sexual offender working unsupervised with children or vulnerable adults. All decisions regarding disclosure are recorded on the case management system.

Where an offender is actively multi agency managed through MAPPA at level 2 or 3 (this means that a number of agencies are actively working together to share information, identify risks and establish a multi agency risk management plan which can require the commitment of additional resources), the disclosure decision will be formally recorded at the MAPP meeting. Where disclosure is to take place, the details of the information to be disclosed, who to and who by will be recorded in the MAPP meeting minutes and recorded on ViSOR. ViSOR is a database which has been developed to be used by police prison and probation to assist in the management of violent and sexual offenders. It is a confidential system which is used by the police as their primary case management system with sexual offenders. The prison and probation services use it to share information which enhances risk assessments.

R&D Spend and PSREs

This memorandum was prepared by the Government Office for Science.

Public Sector Research Establishments

Public Sector Research Establishments (PSREs) deliver a strategic research capability to the Government that is not readily provided by the market.

As described in Tables 1 and 2, PSREs are affiliated to government departments and to Research Councils. Information is provided on PSREs that have been: privatised (Table 3); privatised in part (Table 4); established as companies limited by guarantee (Table 5); and transferred to universities (Table 6) between 1997 and 2009. This information has been provided to GO-Science by the relevant government departments. Should any additional information be received by GO-Science it will be provided to the Committee.

Departmental R&D budgets

A summary of key science, engineering and technology indicators is available in SET Statistics here: http://www.dius.gov.uk/~/media/publications/4/48-08-I_on.

This includes a historical analysis of the Government departmental funding of science, engineering and technology (SET) activities.

Table 1

CURRENT PSREs AFFILIATED TO GOVERNMENT DEPARTMENTS

Government department	*Number of PSREs*	*PSREs*
Health and Safety Executive	1	— Health and Safety Laboratory (HSL)
Department of Health	1	— Health Protection Agency (HPA)
Department for Culture, Media and Sport	18	— 13 National museums and art galleries [British Museum, Imperial War Museum, National Gallery, National Maritime Museum, National Museums Liverpool, National Museum of Science and Industry, National Portrait Gallery, Natural History Museum, Royal Armouries, Sir John Soane's Museum, Tate Galleries, Victoria and Albert Museum, Wallace Collection] — English Heritage — Sport England — Arts Council England — Museums, Libraries and Archives Council — UK Film Council
Department for Environment, Food and Rural Affairs	6	— Centre for Environment, Fisheries & Aquaculture Science (CEFAS) — Food and Environment Research Agency (FERA) — Marine Fisheries Agency (MFA) — Veterinary Laboratory Agency (VLA) — Veterinary Medicines Directorate (VMD) — Royal Botanic Gardens Kew
Forestry Commission	1	— Forest Research
Ministry of Defence	5	— Atomic Weapons Establishment (AWE) — Defence Analytical Services Agency (DASA) — Defence Science & Technology Laboratory (Dstl) — Hydrographic Office (UKHO) — The Met Office
Department for Business, Innovation and Skills	3	— National Physical Laboratory (NPL)[1] — National Measurement Office (NMO) — United Kingdom Atomic Energy Authority (UKAEA)
Home Office	2	— Forensic Science Service (FSS)[2] — National Policing Improvement Agency (NPIA)
Total	**37**	

[1] The National Physical Laboratory is a Government owned company.
[2] The Forencis Science Service if a Government owned company.

Table 2

CURRENT PSREs AFFILIATED TO RESEARCH COUNCILS

Research Councils	*Number of PSREs*	*PSREs*
Biotechnology and Biological Sciences Research Council BBSRC)	5	— Babraham Institute — Institute for Animal Health (IAH) — Institute of Food Research — John Innes Centre (JIC) — Rothamsted Research
Medical Research Council (MRC)	3	— National Institute for Medical Research (NIMR) — Clinical Sciences Centre (CSC) — Laboratory of Molecular Biology (LMB)
Natural Environment Research Council (NERC)	6	— British Antarctic Survey (BAS) — British Geological Survey (BGS) — Centre for Ecology and Hydrology — National Oceanography Centre Southampton (NOCS) — Proudman Oceanographic Laboratory — Scottish Association of Marine Science (SAMS)
Science and Technology Facilities Council (STFC)	5	— Rutherford Appleton Laboratory (includes Chilbolton) (RAL) — Daresbury Laboratory — UK Astronomy Technology Centre (ATC) — The Isaac Newton Group of Telescopes (ING) — The Joint Astronomy Centre (JAC)
Total	**19**	

Table 3

PSREs PRIVATISED (1997–2009)

Affiliated government department/ Research Council	*PSRE*	*Date privatised*	*Rationale*
Ministry of Agriculture, Fisheries and Food (MAFF)	Agricultural Development and Advisory Service (ADAS)	April 1997	— A prior options review found all of ADAS's R&D functions to be suitable for privatisation. On this basis, ADAS was transferred to the private sector as ADAS Consulting Ltd on 1 April 1997.

Table 4

PSREs PRIVATISED IN PART (1997–2009)

Affiliated government department/ Research Council	*PSRE*	*Date privatised in part*	*Rationale*
Department for Business, Innovation and Skills	UKAEA	September 2009	— UKAEA is an NDPB. Until September 2009 UKAEA conducted three main activities: fusion research; pensions administration; and decommissioning of nuclear facilities (a commercial business). — In September 2009, UKAEA established UKAEA Ltd as a separate limited company, and subsidiary to the NDPB. UKAEA Ltd now conducts all work relating to the decommissioning of nuclear facilities. — The decision to establish UKAEA Ltd was made following a strategic review of the business in 2005 and that establishing a commercial business would produce the optimal value for HMG and make best use of the skills and resources held by the organisation whilst responding to demand in the market place. The resulting sale to the private sector of this commercial part of the organisation was the natural and successful outcome of this strategy. The UKAEA's status as a PSRE remains unchanged as a result of this decision as the activities of UKAEA Ltd are entirely commercial (for profit) and no research is undertaken.

Affiliated government department/ Research Council	*PSRE*	*Date privatised in part*	*Rationale*
Ministry of Defence	Defence Evaluation and Research Agency (DERA)	July 2001	— The Defence Evaluation and Research Agency (DERA), an MOD Trading Fund, was the predecessor organisation to QinetiQ and Dstl. The Strategic Defence Review in 1998 proposed that DERA be subject to a Public Private Partnership in order to "strengthen its ability to continue to provide world class scientific research". This was the first step in the route to privatisation. — In particular, DERA was faced with increasing competition from the civil sector, due to technologies in which the civil sector was dominant becoming increasingly relevant to the MOD, and a declining defence research budget. This meant that without the capital and freedoms that privatisation offered, DERA would decline as a force in technology over the longer term. — Privatisation was intended to improve access to technologies from the civil sector to military application; enhance the opportunity for the exploitation of technology locked up in DERA; introduce private capital into DERA to meet its investment needs; thereby accelerating its development; and provide increased freedoms, such as in its ability to grow commercial business.
Department of Health	Public Health Laboratory Service (PHLS)	March 2005	— The microbiological media supply function of the PHLS was sold to Oxoid Ltd in March 2005 after careful consideration of all the options for ensuring a robust supply of high quality media to the NHS which represented good value for money. The sale to Oxoid was considered to offer the best option on all the criteria applied. — PHLS was disbanded in 2005 (most of its functions having been transferred to the Health Protection Agency Special Health Authority in 2003).

Table 5

PSREs ESTABLISHED AS COMPANIES LIMITED BY GUARANTEE (1997)

Affiliated government department/ Research Council	*Former PSRE*	*Established as a company*	*Rationale*
NERC	Plymouth Marine Laboratory (PML)	April 2002	— Arising from changes in priorities of research funding, NERC conducted a wide ranging review to identify the most appropriate future organisation of all its coastal and marine laboratories which would maximise local opportunities whilst maintaining the excellence of their science. In the case of PML, NERC decided to establish it as an independent company limited by guarantee.
Defra	Horticulture Research International (HRI) (HRI was jointly affiliated to Defra and BBSRC)	April 2004	— Part of HRI, East Malling research station, was established as EMR a company limited by guarantee and registered charity. The remainder was transferred to the University of Warwick (Table 6). — The decision to establish EMR as a company limited by guarantee [with continued charitable status] taken following an independent review, led by Dr Derek Langslow (former Chief Executive of English Nature), and a public consultation exercise. Ministers accepted the review's conclusions that HRI's function continued to be required but that it was unviable as then constituted (five sites dispersed across England) and against a background of declining Defra funding and inadequate industry funding. — The transfer of HRI to the University had been under discussion between the two parties and Defra even before the review and the review team recommended that these discussions should be concluded quickly. The majority of respondents to the public consultation exercise agreed that a merger represented a good opportunity for the future success of HRI as it offered high potential synergy and support for HRI's business development and commercial activities.

Table 6

PSREs TRANSFERRED TO UNIVERSITIES (1997–2009)

Affiliated government department/ Research Council	*Former PSRE*	*Transfer date*	*University*
Defra	Horticulture Research International	April 2004	— Part of HRI (HRI Wellesbourne) was transferred to the University of Warwick.
	(HRI was jointly affiliated to Defra and BBSRC)		— The remainder was established as a company limited by guarantee (Table 5).
BBSRC	Institute of Grassland and Environmental Research (IGER)	April 2008	— The Welsh site transferred to Aberystwyth University. North Wyke Research (formerly part of the IGER) became a component of Rothamsted Research.
BBSRC	The Roslin Institute	April 2008	— University of Edinburgh.

28 September 2009

Brain Gym

This response was provided by the Department for Children, Schools and Families.

Q1 *What is the Government's policy on the use of Brain Gym and the teaching of its underlying theory in schools?*

The Department is aware of "Brain Gym", which is presented as learning readiness activities to help children of all physical, social and learning abilities to develop and practice sensory-motor skills for related learning skills.

The Department does not have a specific policy on the use of Brian Gym. We are unaware of any sufficiently robust or peer-reviewed evaluation of the approaches it promotes, which would allow any clear link between the use of Brain Gym and pupils' learning to be established. We are also aware of a significant body of criticism of the theoretical underpinnings of the programme, set out below.

Overall, Brain Gym has not been evaluated using a robust and appropriate methodology, therefore no conclusions about its effectiveness can be drawn using the existing sources of information.

Q2 What scientific evidence is there that Brain Gym works? Does the Government support the scientific theory behind Brain Gym?

Brain Gym has been criticised as being unscientific in a wide-ranging and authoritative review of research into neuroscience and education.

Peer reviewed scientific studies into Brain Gym have found no significant improvement in general academic skills. Brain Gym's claimed results have been put down to the placebo effect and the general benefits of breaks and exercise. Brain Gym's founder, Paul Dennison, has admitted that many of Brain Gym's claims are not based on good science, but on his "hunches".[52]

In 2008 *Sense About Science* published a briefing document in which thirteen British scientists responded to statements taken from the "Brain Gym guide (Teacher's Edition)". Each of them entirely rejected the statements that were put to them. Brain Gym's scientific content was described as "pseudo-scientific". One of the scientists, Professor of neuroscience Colin Blakemore, said that "there have been a few peer reviewed scientific studies into the methods of Brain Gym, but none of them found a significant improvement in general academic skills. Sense about Science, along with the British Neuroscience Association and the Physiological Society, wrote to every Local Education Authority in Britain to warn them about the program.[53]

In 2007 Dr Keith Hyat of *Western Washington University*[54] wrote a paper in which he analysed the available research into Brain Gym, as well as its theoretical basis. He concluded that Brain Gym is not supported by research, and that its theoretical basis does not stand up. The paper also encouraged teachers to learn how to read and understand research, to avoid teaching material that has no rational basis.

Background notes

Brain Gym is a commercial training program created in the 1970's by Dr Paul Dennison and Gail E Dennison, who "were seeking more effective ways to help children and adults of all physical, social and learning abilities, in particular those identified through the programme as "learning disabled."[55]

The program is based on the premise that all learning begins with movement, and that any learning challenges can be overcome by finding the right movements, to subsequently create new pathways in the brain. It claims that the repetition of certain movements "activates the brain for optimal storage and retrieval of information" and "promotes efficient communication among the many nerve cells and functional centres located throughout the brain and sensory motor system. There are 26 of these exercises, which are designed to "integrate body and mind" in order to improve "concentration, memory, reading, writing, organising, listening, physical coordination, and more.

Educational Kinesiology teaches that brain function is defined in terms of three dimensions: laterality is the ability to co-ordinate the left and right sides of the brain, focus is the ability to co-ordinate the front and back of the brain, and centering is the ability to co-ordinate the top and bottom of the brain. According to

[52] "News in brief". *The Times*. 2008-04-05. http://www.timesonline.co.uk/tol/news/uk/article3671213.ece. Retrieved 2008-09-01. "Paul Dennison, a Californian educator who created the programme, admitted that many claims in his teacher's guide were based on his 'hunches' and were not proper science."

[53] Sense About Science—Brain Gym". Sense About Science. http://www.senseaboutscience.org.uk/index.php/site/project/233/. Retrieved 2008-04-11. "These exercises are being taught with pseudoscientific explanations that undermine science teaching and mislead children about how their bodies work. . . . There have been a few peer reviewed scientific studies into the methods of Brain Gym, but none of them found a significant improvement in general academic skills."

[54] Hyatt, Keith J. (April 2007). "Brain Gym—Building Stronger Brains or Wishful Thinking?" (fee required). Remedial and Special Education (SAGE Publications) 28 (2): 117–124. ISSN 0741-9325. http://rse.sagepub.com/cgi/content/abstract/28/2/117. Retrieved 2008-09-12. "a review of the theoretical foundations of Brain Gym and the associated peer-reviewed research studies failed to support the contentions of the promoters of Brain Gym. Educators are encouraged to become informed consumers of research and to avoid implementing programming for which there is neither a credible theoretical nor a sound research basis.".

[55] Brain Gym—about". The Official Brain Gym Web Site. http://www.braingym.org/about.

Brain Gym, people whose brains are not interconnected properly in the three different dimensions suffer from corresponding deficits; for example, the ability to move and think at the same time is dependent on laterality (left to right co-ordination). The Brain Gym exercises are claimed to work by interconnecting the brain in these three dimensions. Anatomical, physiological and neurological research does not support this model.

Teaching English as an Additional Language

This response was provided by the Department for Children, Schools and Families.

Q1 (a) *How does the Government identify school children who do not speak English as a first language and/or who need additional training in English?*

Identification

From 2007 the School Census included a new Pupil First Language question. This allows schools to record each pupil's first language, rather than simply recording whether or not that language is English.

Pupils who do not speak English as a first language are identified through this census and a pupil's first language is defined as any language other than English that a child was exposed to during early development and continues to be exposed to in the home or community.

If a child was exposed to more than one language (which may include English) during early development, a language other than English should be recorded, irrespective of the child's proficiency in English.

Process

Pupil First Language data is collected from either parents or pupils as part of the school's admissions process and is usually obtained after parents have received confirmation of their child's place at the school. This information is also collected for new pupils arriving during the academic year.

Local Authority Data, Statistics, IT and Ethnic Minority Achievement (EMA) teams within Local Authorities are involved in the data collection process. They work closely in planning and implementing the data collection.

School administrative staff will input the information once this has been collected, but the collection process needs to be led by the school's Senior Management Team (SMT) and supported by specialist EMA staff, who should assist administrative staff in making decisions about how to record replies which cannot be mapped easily to the language code set.

DCSF statisticians use the School Census as a source for the Language variable which aggregates the pupils' language into the following seven main groups:

- English.
- Not known but believed to be English.
- Other than English.
- Not known but believed to be other than English.
- Refused.
- Information not obtained.
- Invalid code.

Q1 (b) *How are children whose first language is not English taught English?*

National Strategies, a DCSF delivery partner have developed guidance with detailed strategies to help teachers support EAL pupils in the acquisition of English. They have focused on creating an inclusive learning culture by developing an inclusive curriculum to support learning and teaching. Pupils with EAL are generally taught in the mainstream class using scaffolding learning strategies and other methods that involve keeping cognitive challenges high. The following National Strategies publications provide guidance and advice on teaching pupils with EAL.

Excellence and Enjoyment: Learning and teaching for bilingual children in the primary years. http://nationalstrategies.standards.dcsf.gov.uk/node/85322

Rationale for planning for children learning English as an additional language http://nationalstrategies.standards.dcsf.gov.uk/node/47481

Q2 *What evidence is used to support the method of identifying and teaching those children who require additional language support?*

Method of identification

The Race Relations (Amendment) Act 2000 places a duty on schools to 'monitor and assess how their policies affect ethnic minority pupils, staff and parents'. Monitoring by ethnicity and language allows schools and Local Authorities (LAs) to compare the performance of different ethnic groups and assess the needs of those who seem to be underachieving.

The collection of first language data can make a major contribution to the planning and implementation of strategies which promote equality, value diversity and support the educational inclusion of all pupils. Good quality language data is also of particular importance where provision for pupils who speak more than one language is involved.

Language data also supports the analysis of pupil attainment at school, local and national level, and assists LAs and schools in their use of ethnic background data, providing valuable complementary information and a means of validating ethnicity data.

Children learning EAL are among the highest and the lowest achieving groups nationally and because of this it is important that schools look at the achievement of children from different ethnic groups who are learning EAL.

Proper analysis and understanding of data will make it possible to gain a better insight into the many and complex issues that may contribute to variations in attainment by different groups of learners.

EAL Pedagogy/Method of teaching

Research shows that language support is best provided within the curriculum wherever possible, as time out of subject lessons for additional language tuition is ultimately likely to cause the learner to fall further behind in the curriculum.

Research over the past two decades into the development of young bilingual learners has resulted in the development of a number of theories and principles that underpin the distinctive pedagogy for children who are learning EAL—children for whom the additional language being learned is also the medium of education. The development of EAL pedagogy has been influenced by social constructivist theories which emphasise the importance of scaffolding learning, and those which highlight the importance of socio-cultural and emotional factors. Children learning EAL will be affected by attitudes towards them, their culture, language, religion and ethnicity.

There has been a great deal of research over the past two decades into the development of young bilinguals—international, national and local including classroom-based action research. This has resulted in the development of important theories, principles and knowledge that have underpinned the development of these materials. The practical ideas, supporting materials and approaches included have been developed and trialled with the support of Local Authorities (LAs) and a large number of schools as part of the Primary National Strategy during 2004–06.

Evidence

Research undertaken has looked at:

- How well children from ethnic minority backgrounds are actually doing in our schools.
- The characteristics of effective schools.
- The language and literacy skills and academic achievement of bilingual learners.

The following extract from an OfSTED publication HMI 250 2001 *Inspecting English as an additional language 5–16* states on page 17 that "Inspection evidence demonstrates that the most effective work is closely linked to the National Curriculum and that withdrawal from the mainstream should be limited with outcomes carefully monitored. In particular, de-contextualised language activities are rarely productive."

The QCA (now known as QCDA) booklet—*A language in Common: Assessing English as an additional language* is a guide for Teachers and headteachers of pupils and students with English as an additional language, LEA support services, and English teachers. It has been developed to support the assessment of pupils of all ages for whom English is an additional language. The guide is intended to help teachers ensure that all their pupils develop as competent and confident speakers and writers of English.

The studies of academics, including those below, have been taken into account when developing the English education system of approach to supporting pupils with EAL.

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Street Lighting, CCTV and Crime

This response was provided by the Home Office.

Street lighting and crime

Q1 *What is the Government's policy on the use of street lighting to reduce crime?*

There is a well established body of evidence to show that the design and layout of places has a significant impact reducing crime and fear of crime. Home Office guidance recommends that designing out crime and designing in community safety should be central to the planning and good design of the built environment and that as part of good design the role lighting can play in reducing crime should be considered.

Further, Home Office guidance also reflects that in any crime reduction programme, street lighting should be considered in co-ordination with other intervention strategies not least because of the role it plays in increasing community pride and informal social control.

The companion guide to Planning Policy Statement 1 "Safer Places, The Planning System and Crime Prevention" (ODPM/Home Office 2004) for example highlights that well-designed public lighting increases the opportunity for surveillance at night and sends out positive messages about the management of an area but that it needs to be sensitive to the needs of residents and users and should provide security without resulting in glare and compromising privacy.

Q2 *On what evidence is the Government basing this policy?*

A systematic review of existing international evidence on the effectiveness of improved street lighting on crime was published in 2008 (review for the Campbell Collaboration, by David Farrington & Brandon Welsh). The review concluded that improved street lighting significantly reduces crime, adding that improved street lighting should be considered as a potential strategy in any crime reduction program in coordination with other intervention strategies, and that depending on the analysis of the crime problem, improved street lighting could often be implemented as a feasible, inexpensive, and effective method of reducing crime.

An earlier (2002) review for the Home Office by the same authors had come to the same conclusions.

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http://www.homeoffice.gov.uk/rds/prgpdfs/fcpu29.pdf

Farrington, D and Welsh, C (2002) Effects of improved street lighting on crime: a systematic review. Home Office Research Study 251. London: Home Office. (addendum added 14.10 03)
http://www.homeoffice.gov.uk/rds/pdfs2/hors251.pdf

Government advice on the planning system and crime prevention including general guidance on the importance of surveillance (overlooking) is set out in the ODPM/Home Office guide: Safer Places the Planning System and Crime Prevention (in particular pp 28–29).
http://www.communities.gov.uk/publications/planningandbuilding/saferplaces

"Safer Places" flags that further more detailed advice is available from the police initiative Secured By Design. Details are available from the website:
http://www.Securedbydesign.com

CCTV and crime

Q1 *What is the Government's policy on the use of CCTV to combat crime?*

The origins of CCTV provision for public space in this country lie in the early 1980s. Since then (and mostly by local authorities) the use of public space community safety CCTV has expanded gradually but significantly and it now plays a key role in crime and anti-social behaviour reduction, public protection, missing person inquiries and serious crime, including terrorism investigations. CCTV has been installed for different reasons in different ways.

CCTV does work and works best when it is used alongside a wider strategy of partnership working between the police, local authorities and local communities to tackle crime in their neighbourhood.

Seeking to make sure that the benefits of CCTV are applied effectively to prevent crime and to deal with those who choose to commit crime, the Government's focus is on better training, improved partnership working and more co-ordinated use of technology.

Recognising the need to strengthen the evidence base and provide strong and compelling narrative on the how well CCTV is working:

— The National Policing Improvement Agency and Cheshire Constabulary by the end of the year (2009) aim to have completed a qualitative analysis of recorded crime data and case files in Cheshire to determine the value of CCTV to investigations.

— By next Spring, establish a library of case studies around the use of CCTV in crime detection with particular focus on major crime, including CT and public-space violence; and, in the same time frame.

— Develop the criteria for assessing the quantitative and qualitative costs and benefits of CCTV. This will enable Government, the police, local authorities and the private sector to assess existing and future investment in CCTV and the contribution that it makes and can make to crime detection, crime reduction and public confidence.

Q2 *On what evidence is the Government basing this policy?*

The most recent and most robust assessment of the international evidence on the impact of CCTV was a 2008 systematic review by academics Brandon Welsh and David Farrington, published by the Campbell Crime and Justice Group. The review was part funded by the Home Office. The review found that CCTV has a modest but statistically significant crime reduction effect; is most effective in reducing crime in car parks; is most effective when targeted at vehicle crimes (largely a function of the successful car park schemes); and is more effective in reducing crime in the UK than in other countries. The review concluded that while the results lend support for the continued use of CCTV to prevent crime in public space, they suggest that it be more narrowly targeted than its present use would indicate.

Other research has shown that CCTV can increase public confidence and there are some high profile case study examples of how CCTV has played an important role in detecting crime and protecting the public: for example, in recent terrorist investigations (including 7/7 and 21/7), and the conviction of Steve Wright for the Ipswich murders.

Research Papers

Campbell Crime and Justice Group
http://db.c2admin.org/doc-pdf/Welsh_CCTV_review.pdf

Home Office, Research, Development and Statistics Department: assessing the impact of CCTV, 2005
http://www.homeoffice.gov.uk/rds/pdfs05/hors292.pdf

Home Office, Research, Development and Statistics Department: The impact of CCTV: fourteen case studies, 2005
http://www.homeoffice.gov.uk/rds/pdfs05/rdsolr1505.pdf

Home Office, Research, Development and Statistics Department: Crime prevention effects of closed circuit television: a systematic review, 2002
http://www.homeoffice.gov.uk/rds/pdfs2/hors252.pdf

Human Provenance Pilot Project

This response was provided by the Home Office.

Q1 *What is the Government's initial analysis of the Human Provenance Pilot Project and plans for this scheme in the future?*

This joint UKBA/SOCA pilot project is aimed at tackling abuse of the asylum system, particularly nationality swapping. The pilot planned to run over three months involves a combination of forensic techniques such as isotopic analysis of hair and nails together and ancestral DNA and will be combined with language analysis and enhanced interviewing to examine whether this can indicate a persons possible origins and recent movements. All testing will be voluntary with the person required to give written consent. During the pilot the data will not be used to support live decision making but rather to examine the viability of the techniques. At the conclusion of this pilot we will review the results, including the underpinning science and the ethical implications of the work. The Forensic Regulator will also be consulted during the period of the 3 month pilot. Only if the evaluation and regulatory review is positive, will UKBA proceed to use the results of future tests to support the decision making process in specific cases.

Another part of this project is aimed at combating child trafficking and child abuse by DNA testing family groups where there is a reasonable suspicion they are not biologically related as claimed. This is in line with new statutory duties to protect vulnerable children. These tests are not subject to the three month review and the results will be used by case owners and the social services.

The project planned to run to July 2010 depending on ongoing evaluation and future funding.

Q2 *What evidence was used to formulate this programme?*

The pilot was based on some preliminary scientific papers in these areas (see attached bibliography) which suggested that a small proof of concept trial was an appropriate next step.

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ROAD SAFETY: BICYCLE HELMETS

This response was provided by the Department for Transport.

Q1 *What is the Government's policy on recommending or requiring the use of bicycle helmets?*

The Department for Transport believes it is sensible for cyclists, and especially children, to protect themselves by wearing a cycle helmet. Our road safety publicity materials and the Highway Code recommend the use of a cycle helmet. We have no plans to make their use compulsory.

Q2 *What evidence on bicycle helmets and safety has the Government considered in formulating its policy?*

A review commissioned by the Department ("Bicycle Helmets—A review of their effectiveness", Road Safety Research Report No 30, available at:- http://www.dft.gov.uk/pgr/roadsafety/research/rsrr/theme1/bicyclehelmetsreviewofeffect4726) concluded that overall there is evidence that bicycle helmets can be effective at reducing the incidence and severity of head, brain and upper facial injuries and that they can be

effective in reducing injury for users of all ages, though particularly for children. The report also concludes that there is some evidence that compulsory helmet wearing may discourage some people from cycling, leading to decreased bicycle use.

However, we believe it would be irresponsible not to promote a product that can reduce injuries and we continue to promote helmet wearing on a voluntary basis, especially by children.

The Department has commissioned a new research project on cyclists' road safety. This will include a new review of cycle helmet effectiveness. We are aiming to complete the review of cycle helmet effectiveness later this year with the publication of the project's final reports in Autumn 2010.

We measure cycle helmet wearing rates periodically, in 1994, 1996, 1999, 2002, 2004, 2006 and most recently 2008. The 2008 wearing rate survey shows that cycle helmet rates on major built up roads have gone up from 30.7% in 2006 to 34.3% and on minor roads have gone up from 13.8% in 2006 to 16.7% in 2008. The wearing rate for children on major built up roads was 17.6% in both 2006 and 2008, while for children on minor roads the rate rose from 9.4% in 2006 to 12.0% in 2008.

Whilst compulsion remains an option that we will review from time to time, at these levels making helmets compulsory would cause enforcement difficulties and without greater public acceptance could have an effect on levels of cycling.

Speed Cameras

This response was provided by the Department for Transport.

Q1 *What is the Government's policy on use of speed cameras?*

The primary objective for speed camera deployment is to reduce deaths and injuries on roads by reducing the level and severity of speeding. The aim is to do this by preventing, detecting and enforcing speed offences, which includes encouraging changed driver behaviour by the use of safety camera activity.

Safety cameras are deployed and operated locally by road safety partnerships as part of their overall road safety remit. They have the freedom to spend the specific road safety grant on cameras or any other locally agreed road safety measure. The Department for Transport's guidance on the use of cameras recommends they are deployed only where there is a history of speed related accidents or where there is community concern about speeding. Cameras should be coloured yellow and co-located with speed limit signs where permitted and practicable with warning signs placed in advance, so that motorists are easily able to comply with the speed limit. However, the police may also carry out covert speed enforcement.

Q2 *What evidence is there that the policy improves road safety?*

Evaluations around the world have shown repeatedly that speed cameras reduce vehicle speeds, accidents, deaths and serious injuries at camera sites. A literature review undertaken by the University of the West of England, published 11 February 2005, failed to find a single published research paper anywhere in the world that found cameras to have negative overall effects.

The independent four-year evaluation report of the National Safety Camera Programme was published on 15 December 2005. It found a 42% reduction in people killed or seriously injured at camera sites across the 38 partnership areas, that means around 1,745 fewer people killed or seriously injured per annum, including over 100 fewer deaths. In addition, there was a 22% reduction in personal injury collisions, which translates into a reduction of 4,230. These evaluations are of the benefits of the cameras over and above the long-term national trend of casualty reductions. However, a proportion of the reduction could be attributable to "regression-to-mean" (this arises because accidents in the period before the installation of a camera may be higher than the long-term average for that location). The report concludes that, even after allowing for this, safety cameras achieve substantial reductions in collisions and casualties.

Evidence suggests that in addition to motorists slowing down in the immediate vicinity of camera sites, they have also been slowing down in the wider area where speed cameras are located. The Department's annual Vehicle Speeds data shows that the proportion of cars exceeding the speed limit on 30mph roads has reduced from almost three quarters in 1996 to just under half in recent years.

Wind Turbine Syndrome

This response was provided from the Department for Environment, Food and Rural Affairs with input from the Department of Energy and Climate Change.

Q1 *Does the Government have a stance on Wind Turbine Syndrome?*

Wind Turbine Syndrome is a name coined by one researcher in the United States who believes that those living close to wind farms can suffer from a variety of symptoms as a result of their proximity to wind farms. It is unclear whether there is widespread support from other professionals for these effects to be formally described as a syndrome. The cause of these effects seems to be the noise (and perceived vibration) that can be generated by wind turbine units. The Government has no formal stance on WTS, but will review its position as and when new evidence emerges.

Q2 *What evidence does the Government consider when assessing the potential health risks of wind turbines to nearby residents?*

With regard to noise, the Government has been aware for many years of the potential noise impact from wind turbines. In the mid 90s, it prepared a report through the Energy Technology Support Unit (ETSU) of the former DTi that described how noise from wind farms should be assessed and what noise criteria should be applied. The current Planning Policy Statement (PPS) 22 on renewable energies also makes reference to this document as does the recently published consultation documents setting out the proposed new National Policy Statements for renewable sources. The ETSU report sets out the method by which the government expects developers and planning authorities to take account of the noise impacts and by implication the noise related health effects of wind farms. The Government has also commissioned research to understand further the impacts of noise from wind farms and how they should be assessed. The evidence arising from that research is being reviewed.

The Government is aware of the possibility of other health affects linked to wind turbines, in particular the risk of photo epilepsy arising from "shadow flicker". PPS22 states how to assess and address shadow flicker advising that if the wind turbines are located in accordance with guidance in PPS22 then the risk of shadow flicker should be avoided.

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