



House of Commons
Science and Technology
Committee

Evidence Check 2: Homeopathy

Fourth Report of Session 2009–10

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11.00 on Monday 22 February 2010



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**Evidence Check 2:
Homeopathy**

Fourth Report of Session 2009–10

Report, together with formal minutes, oral and written evidence

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The Science and Technology Committee

The Science and Technology Committee is appointed by the House of Commons to examine the expenditure, administration and policy of the Government Office for Science. Under arrangements agreed by the House on 25 June 2009 the Science and Technology Committee was established on 1 October 2009 with the same membership and Chairman as the former Innovation, Universities, Science and Skills Committee and its proceedings were deemed to have been in respect of the Science and Technology Committee.

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A list of reports from the Committee in this Parliament is included at the back of this volume.

Committee staff

The current staff of the Committee are: Glenn McKee (Clerk); Richard Ward (Second Clerk); Dr Christopher Tyler (Committee Specialist); Xameerah Malik (Committee Specialist); Andy Boyd (Senior Committee Assistant); Camilla Brace (Committee Assistant); Dilys Tonge (Committee Assistant); Melanie Lee (Committee Assistant); Jim Hudson (Committee Support Assistant); and Becky Jones (Media Officer).

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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 illness⁶ 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 services¹¹ 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 database²⁶ 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	
Homeopathy is a placebo	FAIL	EITHER PASS OR 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:

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;

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. Proving is 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.

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 physics⁶⁶ 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-values⁸⁰ 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

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 infections⁸⁴ and rheumatic diseases⁸⁵ 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 homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy 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 Association¹¹² 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 NRS¹⁴⁷ 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:

154 Q 46

155 “Consultation Document MLX 312; Licensing of homeopaths: 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 homeopaths: 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 prophylaxis¹⁷⁷ 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

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
Ian Stewart

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

Noes, 1
Ian Stewart

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

Paul Bennett, Professional Standards Director and Superintendent Pharmacist, Boots, **Tracey Brown**, Managing Director, Sense About Science, **Dr Ben Goldacre**, Doctor and Journalist, **Professor Jayne Lawrence**, Chief Scientific Adviser, Royal Pharmaceutical Society of Great Britain, and **Robert Wilson**, Chairman, British Association of Homeopathic Manufacturers Ev 1

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 Ev 21

Monday 30 November 2009

Professor David Harper CBE, Director General, Health Improvement and Protection, and Chief Scientist, Department of Health, **Mr Mike O'Brien QC, MP**, Minister for Health Services, Department of Health, and **Professor Kent Woods**, Chief Executive, Medicines and Healthcare Products Regulatory Agency Ev 60

List of written evidence

1	Department of Health	Ev 60, 61, 75
2	Dental Practitioners Association	Ev 91
3	Professor David Colquhoun	Ev 91
4	John Boulderstone	Ev 93
5	Dr Lionel R Milgrom	Ev 94
6	Katherine Boulderstone	Ev 100
7	Professor John MacLachlan	Ev 101
8	UK Advisory Committee on Malaria Prevention in UK Travellers	Ev 103
9	Cyril W. Smith	Ev 103
10	Northern Ireland Association of Homeopaths	Ev 110, 115
11	Les Rose	Ev 115
12	Dr Andy Lewis	Ev 117
13	British Homeopathic Association	Ev 37, 53
14	Jean Kinchen	Ev 119
15	Professors Harold Walach and George Lewith	Ev 119
16	Professor Katherine Thomas (Leeds Institute of Diagnostics and Therapeutics)	Ev 126
17	Professor Edzard Ernst	Ev 26, 27, 51
18	Anne Waters	Ev 128
19	European Committee for Homeopathic Medicine in Europe	Ev 130
20	Professor Vincent Marks	Ev 131

21	Dr Jean Munro and Dr Peter Julu	Ev 132
22	Dr Peter Fisher	Ev 21
23	Dr Sara Eames	Ev 135
24	Society of Homeopaths	Ev 138, 143
25	Complementary Medicine Research Group, University of York	Ev 143
26	Francis Treuherz	Ev 148
27	Homeopathy Research Institute	Ev 148
28	Alliance of Registered Homeopaths (ARH)	Ev 151
29	Arthritis Research Campaign	Ev 155
30	Dr Hugh J Nielsen	Ev 158
31	British Association of Homeopathic Manufacturers (BAHM)	Ev 5
32	Liga Medicorum Homoeopathica Internationalis (LMHI)	Ev 160
33	Dr Clare Relton	Ev 162
34	Homeopathy: Medicine for the 21st Century (H:MC21)	Ev 166
35	European Central Council of Homeopaths	Ev 173
36	Sense About Science	Ev 6
37	Royal Pharmaceutical Society of Great Britain	Ev 1
38	Judith Ford	Ev 178
39	NHS West Kent	Ev 34
40	Dr Ben Goldacre	Ev 8
41	Prince's Foundation for Integrated Health	Ev 178
42	Science Council	Ev 180
43	Jackie Rowe	Ev 180
44	Advertising Standards Authority (ASA)	Ev 180, 183
45	National Institute for Clinical Excellence (NICE)	Ev 186, 188
46	David Tredinnick MP, Chairman, Parliamentary Group for Integrated and Complementary Healthcare	Ev 189
47	Irish Health Trade Association	Ev 190
48	Oliver Dowding	Ev 190
49	Maria Jevtics	Ev 191
50	Mary English	Ev 192
51	Sue Young	Ev 192
52	J. A. Wheatley	Ev 193
53	Medicines and Healthcare Products Regulatory Agency (MHRA)	Ev 77, 90
54	Hugh Evans	Ev 193
55	British Medical Association (BMA)	Ev 194
56	Dr Vijay Vaishnav	Ev 194
	Memorandum from Government on Evidence Check	Ev 195

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–j]