# Royal Pharmaceutical Society of Great Britain

## Response to the House of Commons Science and Technology Committee

**November 2009**

**Preamble**

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

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

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

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

**Summary of Recommendations:**

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

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

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

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

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

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

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

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

**Response**

**1 Government policy on licensing homeopathic products**

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

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

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

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

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

1.06 Homeopathic provings (i.e. where healthy volunteers are given the potential homeopathic substance to elicit the same symptoms as the illness that is to be treated) can now be used as evidence for medical claims despite the fact

that they do not prove efficacy. Furthermore the homeopathic literature can also be used as evidence for medical claims despite the fact that it may not have been subjected to the same level peer review as more main stream scientific literature. The reliance on such evidence for homeopathic preparations is in stark contrast to the stringent tests that conventional medicines must undergo prior to obtaining a licence.

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

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

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

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

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

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

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

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

## 2 Government policy on funding homeopathy through the NHS

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

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

2.03 Homeopathy involves a holistic approach to the treatment of patients, which requires an assessment of the physical, mental and emotional state of the patient as well as the symptoms they present with. Whether the benefits patients gain when taking homoepathic preparations is due to a counselling effect i.e. someone just giving the time to listen to a patients problems and talk them through as many experts believe (a typical initial homeopathic consultations takes about 45-60 minutes, follow up ones slightly less), a

psychological effect due to the belief by the patient they will get better, or the actual homoeopathic remedy itself, is not clear.

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

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

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

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

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

**3 The evidence on homeopathic products and services**

3.01 Homeopathy has been used in Britain for about 150 years, and has always been available through the NHS since its inception in 1948 although it has gained increasing prominence with the general public over the last twenty years, mainly because it is generally viewed as being safe (being prepared from plant, mineral or animal), not producing serious adverse reactions (other than aggravations, i.e. an initial worsening of symptoms following administration of the homeopathic remedy, or in individuals who have a lactose sensitivity when lactose is used as diluent), and not interacting with conventional medicines. (It is worth commenting that homeopathic and herbal medicines are often confused in the Public's mind.) Despite the longevity of homeopathy no plausible scientific reason has yet been proposed as to why it

should work. Further, as yet no unambiguous clinical trial data has been presented as evidence for the effectiveness of a homeopathic preparation.

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

3.03 Such is the extent of dilution used in homeopathy that even the most concentrated homeopathic preparation generally used (i.e. a 6C preparation) contains only one picogram of homeopathic substance. (Conventional medicines are usually administered in milligram or microgram, ie $10^6$ or $10^3$ higher amounts.) The most commonly used preparation (a 30C preparation) is diluted to such an extent that only one molecule of the homeopathic substance would be present in a sphere the size of the orbit of the planet Neptune. As a consequence of their extreme dilution, most high dilution/potency homeopathic remedies do not contain a single active molecule. The administration of a preparation containing substance at such large dilutions leads to a RPSGB view that such preparations will not produce clinical effects.

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

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

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

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

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

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

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

3) A recent Cochrane review reports preliminary data to support the use of specific homoeopathic preparations to treat adverse effects of cancer treatments. Meta-analyses of homoeopathy RCT's suggest that homoeopathy may also be of some benefit in postoperative ileus and acute pollinosis, and possibly in childhood diarrhoea. (see Footnote).

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

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

5) Arguments regarding the design and methodology used for RCT's are made by both proponents and opponents of homeopathy.

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

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

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

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

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

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