

Sense About Science Statement
on Evidence-Based Medicine and
The Medicines for Human Use
(National Rules for Homeopathic
Products) Regulations 2006

The charity Sense About Science has published a statement on its website to support its arguments criticising the recent legislation allowing over-the-counter homeopathic medicines to carry labelling giving indications of use.

The Faculty of Homeopathy and British Homeopathic Association dispute the claims made in this statement arguing that they are biased and unscientific.

Our response to their statement follows...

1. Sense About Science claim:

evidence-based medicine has been a major public gain of the 20th century

Response:

- As described by Professor David Sackett in *Teaching and Practising Evidence Based Medicine* (<http://www.cche.net/usersguides/ebm.asp>), evidence-based medicine is the use of the best available evidence from research to inform the value-based decision making of individual patients who look to clinicians to give them guidance. However, this laudable goal is frequently subverted for very unscientific reasons, and EBM is claimed as a reason to abandon treatments that are valued and desired by patients or to dismiss treatments that a particular lobby group just doesn't like.
- Evidence-based medicine is vitally necessary to protect the public from dangerous new drugs (as clearly demonstrated by the recent Northwick Park drug trial that nearly killed 6 healthy volunteers). However, it failed thousands of patients in the case of Vioxx which was estimated by a study published in *The Lancet* in 2005 to have caused between 88,000 and 140,000 extra cases of serious coronary heart disease in the US and which has been withdrawn from the market.
- Equally, the evidence base for many conventional medical treatments is still extremely weak. According to a *British Medical Journal* clinical evidence review of 2,404 conventional treatments, only 15% were rated as beneficial, 22% as likely to be beneficial, 7% as trade off between benefits and harms, 5% as unlikely to be beneficial, 4% as likely to be ineffective or harmful and 47% of unknown effectiveness. <http://www.clinicalevidence.com/ceweb/about/knowledge.jsp>

2. Sense About Science claim:

homeopathy is not evidence-based medicine

Response:

- This is a completely untrue statement. A substantial body of evidence exists despite the chronic underfunding of research.
- The effectiveness of homeopathy in many conditions is supported by randomised clinical trials including:
 - > childhood diarrhoea, hay fever, post-operative ileus and osteoarthritis (meta-analyses of specific medical conditions with positive conclusions);
 - > asthma, fibromyalgia, influenza, glue ear, side-effects of radio- or chemo-therapy, sprains, upper respiratory tract infections and vertigo (at least 2 positive RCTs);
 - > anxiety, ADHD, CFS, IBS, migraine, PMS, seborrheic dermatitis and tissue trauma (a single RCT with positive results).
- The study published by *The Lancet* in August 2005 claiming that homeopathy is no more than a placebo was biased and set out to prove a negative by a process of clever statistical manipulation. Its conclusions were based on only 8 trials out of a possible 110. Had the trials included in the final 8 been different, the conclusion would have come out in favour of homeopathy.
- A six-year study at Bristol Homeopathic Hospital (part of United Bristol Healthcare NHS Trust), one of five NHS homeopathic hospitals in the UK, shows that over 70% of follow-up patients with chronic diseases reported positive health changes after homeopathic treatment. Over 6,500 consecutive patients took part in the study, published in the *Journal of Alternative and Complementary Medicine*.

All the patients were referred by their GP or hospital specialist and many had tried conventional treatment first without success.

Condition	% patients showing clinical improvement
Asthma (under-16s)	89%
Chronic fatigue syndrome	72%
Crohns disease/ulcerative colitis	76%
Depression	71%
Eczema (under-16s)	82%
Headache/migraine	74%
IBS	71%
Menopausal syndrome	77%
Rheumatoid arthritis	70%

3. Sense About Science claim:

the new regulations on homeopathic products compromise standards of evidence and clear labelling

Response:

- The new regulations merely clear up an existing anomaly and bring the UK into line with other countries. Many conventional OTC medicines do not have proven standards of evidence. For example:

British National Formulary edition 51 March 2006 p172:

"Expectorants are claimed to promote expulsion of bronchial secretions but there is no evidence that any drug can specifically facilitate expectoration. The assumption that sub-emetic doses of expectorants such as ammonium chloride, ipecachuanha and squill promote expectoration is a myth. However, a simple expectorant mixture may serve a useful placebo function and has the advantage of being inexpensive.

Demulcent cough preparations contain soothing substances such as syrup or glycerol and some patients believe that such preparations relieve a dry irritating cough. Preparations such as simple linctus have the advantage of being harmless and inexpensive.

Compound preparations are on sale to the public for the treatment of cough and colds; the rationale for some is dubious"

Sudafed Expectorant is allowed to claim: "clears chesty coughs". If homeopathic medicines were not to be allowed to give indications in future, there would be serious implications for a wide range of other over-the-counter preparations currently on sale. Clearly, there is a precedent for the licensing of medicines on the basis of quality, safety and effectiveness rather than efficacy.

4. Sense About Science claim:

the policy change is damaging to patients' best interests

Response:

- The legislation only covers a limited range of acute, self-limiting conditions such as nausea, headache, coughs and colds, minor skin conditions etc. It aims to help the public make informed choices when purchasing over-the-counter preparations based on widely documented traditional use going back 200 years. This includes but is not limited to provings. The legislation brings homeopathic medicines into line with the 2005 legislation on the "traditional use" of herbal medicines. The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 allow a herbal product with 30 years' traditional use to include indications "based on information obtained from its long-standing use and experience".
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=595
- Homeopathic medicines are safe and have never killed anyone, unlike many newly developed drugs for which strict testing is justifiably required
- The legislation supports patient choice and allows patients to make their own decisions.

5. Sense About Science claim:

evidence-based medicine is essential to public health; the growth of the homeopathic industry does not contribute to public health

Response:

- The homeopathic approach is appreciated and valued by patients. Studies from the NHS homeopathic hospitals show that homeopathy helps patients for whom conventional treatment has either failed or has unacceptable side effects. Evidence-based medicine must take into account what happens in the real world to real patients, not just in clinical trials.
- The argument made by Sense About Science that taking homeopathic medicines may delay the patient getting a proper diagnosis from their GP applies equally to a wide range of conventional over-the-counter treatments.

6. Sense About Science claim:

rules for the regulation of medicines should not allow homeopathic products to make unsubstantiated health claims

Response:

- 200 years of bibliographic evidence, provings and traditional use are not “unsubstantiated health claims”.
- A proving is a qualitative research study observing and recording the experience of a group of healthy subjects who experimentally take a particular drug. Contemporary qualitative narrative-based research methods are becoming increasingly popular in conventional medicine but are very similar to the techniques used in provings.
- There are many precedents for the licensing of medicines on the basis of quality, safety and effectiveness rather than efficacy.