

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



1. Evidence-based medicine has been a major public gain of the 20th Century
2. Homeopathy is not evidence-based medicine
3. The new regulations on homeopathic products compromise standards of evidence and clear labelling
4. The policy change is damaging to patients' best interests
5. Evidence-based medicine is essential to public health; the growth of the homeopathic industry does not contribute to public health
6. Rules for the regulation of medicines should not allow homeopathic products to make unsubstantiated health claims

1. Evidence-based medicine has been a major public gain of the 20th Century

Evidence-based medicine advocates up-to-date, high quality scientific evidence from healthcare research as the basis for making decisions about the marketing of medicines and their clinical use. The Medicines Act 1968, which followed a review of the thalidomide tragedy, established the importance of:

- Clinical trials and scientific evidence of safety and efficacy of medicines
- Strict controls on the marketing of medicines and the medical claims made on them.
- Clear, honest information about safety and efficacy
- Risk/benefit assessments and reporting of adverse consequences

The importance of these to the public is captured in the mission of the UK's licensing body, the Medicines and Healthcare products Regulatory Agency (MHRA): to “enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.”

2. Homeopathy is not evidence-based medicine

Homeopathy lacks convincing scientific evidence of its clinical efficacy. It also lacks a plausible mechanism for delivering medical benefits – active ingredients are usually so diluted that the chance of the end solution containing one molecule of active ingredient is less than one in a thousand million million million. Homeopaths say that this does not matter because water can ‘remember’ the ingredient, a theory which has found no evidence in 30 years of testing and is contrary to the laws of science.

3. The new regulations on homeopathic products compromise standards of evidence and clear labelling

From 1st September 2006, new regulations have come into force for marketing authorisation of homeopathic products, with the specified aim of removing barriers to the expansion of the homeopathic industry. In recognition of homeopathic products being unable to meet standards of clinical efficacy required under the Medicines Act, these separate rules set out safety requirements (in accordance with Directive 2001/83/EC) but accept, as sole evidence of efficacy, “the results of investigations, commonly known as homeopathic provings, which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance.” (Statutory Instrument 2006 No.1952)

The new regulations also permit new homeopathic products to indicate on the label their intended use for relief of minor conditions or symptoms, as was the case prior to the Medicines Act 1968. For over thirty years it had not been possible to make medicinal claims for new homeopathic products other than those still around from before the Medicines Act (i.e., products with Product Licence of Right, or PLRs). Such claims, however worded, imply efficacy where none has been proven.

4. The policy change is damaging to patients’ best interests

The MHRA’s regard for the expansion of the homeopathic industry (highlighted repeatedly in its impact assessment of these regulations, to the exclusion of medical concerns), its acceptance of homeopathic ‘provings’ as data on efficacy, and its decision to allow labels to carry indications, all damage patients’ interests by lending credibility to the practice of selling remedies that have no evidence of efficacy and which are likely to increase the number of patients who fail to seek appropriate diagnosis and treatment. Health claims made by homeopathy products with MHRA approval will make it more difficult for the NHS to move towards the evidence-based prescribing that NICE was set up to achieve.

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

Evidence-based decisions on medicines, the accountable and dependable nature of regulatory standards, and clear, honest public information about contents and efficacy are, wrongly, being sacrificed for the aim of enabling “the expansion of the homeopathic industry” that is given as the main reason for this legislation by MHRA (2005) in its impact assessment (Section 2.3: Rationale for Government Intervention).

Under Directive 2001/83/EC, national governments are permitted to make their own regulations stipulating efficacy requirements and labelling authorisations of homeopathic products. The new regulations should be rescinded and all homeopathic products, including those with PLRs, should be required either to submit to the requirements of the Medicines Act 1968 in order to seek authorisation to be marketed as a medicine with indications, or to the safety requirements of the Simplified Scheme 1992 if marketed without indications.

6. Rules for the regulation of medicines should not allow homeopathic products to make unsubstantiated health claims

We object to the Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006.

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