



## The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006

HealthWatch is a small independent charity (No 1003392) set up in 1990 to promote the proper testing of all forms of treatments, whether "Orthodox" or "Alternative". Patients are entitled to have reliable information about the treatment they are offered - has it been shown to work or not? The Medicines Act 1968, which followed a review of the thalidomide tragedy, required controlled clinical trials to provide scientific evidence of the safety and efficacy of medicines, and applied strict controls on the marketing of medicines and the medical claims made on them. To protect the public the UK's licensing body, the MHRA was set up to **"enhance and safeguard the health of the public by ensuring that medicines and medical devices work~ and are acceptably safe."** Tragically, the **MHRA has now failed to do what it was set up to do.**

From 1<sup>st</sup> 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/BC) but reduce requirements for efficacy, accepting homeopathic '*provings*' as sole evidence of efficacy.

Homeopathic '*provings*' are not in any way a proof of efficacy or safety. They are based on the observation that quinine (for example) when taken in normal dosage may cure malaria, but it can also cause symptoms similar to those caused by malaria. In the 1790s Dr Samuel Hahnemann applied the Hippocratic theory that "like cures like" and reasoned that quinine could cure malaria, but if sufficiently diluted should be free of side effects. Not surprisingly, controlled clinical trials in the 20<sup>th</sup> century have shown that the almost infinitely diluted homeopathic remedies are free from side effects, but unfortunately **do not** cure malaria, or any other disease.

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 known as PLRs). Such claims, however worded, imply that efficacy has been proven, which is simply untrue.

In the past Health Watch has often criticised alternative treatments (as well as orthodox ones) when they made health claims that were untrue or misleading. The response from alternative practitioners has always been that we are mere puppets defending the commercial interests of the pharmaceutical industry. This is untrue, and in the case of the new regulations about homeopathic treatments it is the exact opposite of the truth. The MHRA has accepted homeopathic '*provings*' as evidence of efficacy in order to protect the commercial interests of the homeopathic industry, and with disregard for the truth, or the health interests of the public. It was under no obligation to do so. Under Directive 200 1/83/EC, national governments are permitted to make their own regulations stipulating efficacy requirements and labelling authorisations of homeopathic products.

HealthWatch has no vested interests for or against homeopathy, but a duty to tell the public the -truth about treatments The MHRA has a similar duty,-but their shameful betrayal has been achieved furtively, while Parliament was in recess. The new regulations should be rescinded when parliament reconvenes, and all homeopathic products, including those with PLRs, should be required to submit to the requirements of the Medicines Act 1968 in order to seek authorisation to be marketed as a medicine with indications.

### ***What can we do to reverse the effect of these misleading regulations?***

The way in which the regulations have been presented meant that they have never been debated in Parliament, but if there is sufficient evidence of public concern it would be possible to call for a debate when Parliament convenes on October 9<sup>th</sup>. If you are concerned (as you should be) please go to the "Sense about Science" website at <http://www.senseaboutscience.org.uk/index.php/site/project/106> and sign up to the protest. Please act now, before it is too late. It is the thin edge of a very dangerous wedge if the MHRA is allowed to bow to political or commercial pressure to the detriment of truth and public safety.

Professor John Garrow  
Vice-chairman, Health Watch,  
On behalf of the Committee: 18<sup>th</sup> September 2006