



Position paper:

The regulation of homeopathic medicines in the UK

On 1st September 2006, UK regulations came into force which permit homeopathic medicines to carry indications on their labels [1]. Hitherto, only such products on the market before 1971, when the 1968 Medicines Act came into force, could carry such claims under a 'licence of right' (in common with all other medicines at the time). All homeopathic products marketed after 1971 are not allowed to carry indications for the diseases they claim to treat. There are currently about 3,000 homeopathic licences, and it is no surprise that the vast majority are licences of right. This contrasts rather sharply with the situation of orthodox medicines, for which virtually no pre-1971 licences exist today.

The new regulations stem from a desire to resolve this obviously anomalous situation, driven by a European Directive. The Medicines and Healthcare products Regulatory Agency (MHRA), issued a consultation on its proposals in February 2005. Four options were offered. Essentially these were

1. to do nothing
2. to revoke all licences of right
3. to allow efficacy claims based on non-clinical trial data
4. to do the same as (3) but also to review all licences of right on a voluntary basis.

The MHRA states that the consultation responses were in favour of the last option, and this is now embodied in Statutory Instrument 2006 number 1952. The new regulations were laid before Parliament four days before the summer recess, and came into force on 1st September 2006, over five weeks before the new session, giving no opportunity for debate. Interestingly, the MHRA says that there were no strong public health reasons for taking any action, and that the only reason for rejecting the first option was the expectation of agitation by the homeopathy companies.

Although one purpose of the regulations might have been to encourage manufacturers to transfer efficacy claims from serious conditions to minor conditions only, a by-product is to allow such claims without the need to provide any supporting evidence. Instead, the MHRA will accept what it calls "non-scientific data" - its own words. In its explanatory notes, the MHRA admits that homeopathic products "have difficulty in demonstrating efficacy in clinical trials". This is no different from saying "they do not work". Data now acceptable can come from homeopathic "provings". It cannot be over emphasised that "provings" have nothing at all to do with efficacy, and are carried out by giving healthy people undiluted homeopathic stocks. These may be of plant, animal, or mineral origin. The symptoms elicited by this process are imagined to indicate the diseases which the ultra-dilute finished product is able to treat, on the principle of "like cures like". This, the so-called "law of similars", is not supported by any scientific evidence. Indeed, since the new regulations appeared, a meta-analysis has appeared which shows that there is no consistency or reliability for studies of provings published from 1945 to 1994 [2]. Thus the already scientifically invalid basis for the MHRA's proposals is also invalidated by the homeopaths themselves. The other main principle of homeopathy is the "law of infinitesimals", the idea that medicines become more potent the more they are diluted. There is of course no evidence to support this either, and it is in conflict with all that we know about pharmacology, therapeutics, and indeed physics and chemistry themselves.

In addition, the new regulations accept as evidence, proof that the product has been used for the claimed indication "within the homeopathic tradition". Obviously neither this requirement, nor "provings", is anywhere near a definitive test of efficacy. The regulations do not list any other types of evidence as acceptable. Potential sources of data were listed as including homeopathic pharmacopoeiae and materiae medicae, and bibliographies, such that they would be accepted by homeopathic practitioners. In other words, all that is necessary is to convince homeopaths, and it is not necessary to win over anyone with a more scientific view of medicine.

The MHRA prefaced its consultation by stating quite clearly that clinical trial evidence was lacking. Interestingly, not one of the various homeopathy organisations which responded enthusiastically to the consultation even suggested that such a view might not be correct, despite vociferous claims from many homeopaths that clinical trials do show efficacy. It is not too difficult to find such positive trials if one ignores the matter of methodological quality. This might explain why, despite two centuries of use,

the clinical evidence for homeopathy actually gets weaker over time [3]. The key question which any scientist, and the MHRA in particular, should ask is: "After 200 years why are we still arguing about the efficacy of homeopathy?"

The MHRA published a summary of responses to the consultation⁴, but omitted to mention that three medical Royal Colleges strongly criticised homeopathy. The Royal College of Physicians stated that, "it is important that unsubstantiated or false claims of efficacy are absolutely prohibited". The other critical Royal Colleges were those of General Practitioners, and of Physicians (Edinburgh). Certain other groups, such as the National Eczema Society, voiced very similar objections. However the Royal College of Radiologists very warmly supported option (4), while all along mistaking homeopathy for herbal medicine. The Royal College of Nursing was even more enthusiastic, but the response was written by a homeopath. Several other organisations issued critical statements, including the Royal Society, The Academy of Medical Sciences, the Biosciences Federation, the Medical Research Council, and the Royal Society. The British Pharmacological Society (of which the MHRA's chief executive and chairman are both members) said:

"The British Pharmacological Society believes that any claim made for a medicine must be based on evidence, and that it is the duty of the regulatory authorities, in particular the MHRA, to ensure that no claims can be made for the efficacy of any form of medicine unless there is good evidence that the claim is true. Despite many years of investigation, we have no convincing scientific evidence that homeopathic remedies work any better than placebo. Pharmacologists have noted frequently that most homeopathic products are diluted to the extent that they contain no molecule of active ingredient, that is, no medicine, which is highly misleading to consumers who are unlikely to recognise the expression "30C" for example. Furthermore, there are serious concerns, even in cases where they are used for minor ailments, that officially endorsed use of such remedies may put patients at risk of delayed diagnosis. The Society is therefore surprised that the national rules scheme for licensing homeopathic products, which came into force on 1st September (Statutory Instrument 2006 1952), will regard non-scientific data as evidence of efficacy."

By now, readers may be wondering what is driving such a bizarre move. The answer might be found in the MHRA's own Regulatory Impact Assessment [5]. It is stated there that not to act thus would "inhibit the expansion of the homeopathic industry". This is the first time that the MHRA has admitted to a commercial remit. It is not in its mission statement, but this is:

"We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks."

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