

**Patrons:**

The Baroness Greenfield, OBE  
Professor Tom Kirkwood  
Lord Taverne  
Lord Walton of Detchant

**HealthWatch**  
for treatment that works



## **Review of Medicines Act 1968: Informal consultation on issues relating to the product licences of right (PLR) regime and homeopathy**

### **Response**

HealthWatch is a long-established charity which support evidence-based medicine. It is not in any way related to the similarly named organisation recently launched by the Department of Health. Our comments set out here refer to the numbered points in the consultation document.

#### Point 9

While the MHRA is not legally required to regulate homeopathic products in the same way as real medicines, there are other responsibilities and obligations. The MHRA states:

*“The MHRA’s mission is to enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.”*

This is an obligation to Britain, not to the EU. The MHRA may have been granted a certain flexibility by the EU, but that does not dilute its responsibilities to British consumers, as laid down in its mission statement.

#### Point 15

Bach flower remedies have no evidence of efficacy. They are placebos. But they do make medicinal claims. Regulating them as food supplements raises serious issues. Firstly, the European Food Standards Agency (EFSA) is currently evaluating several thousand claims for nutritional ingredients. To enable regulation of Bach flower remedies under the Food Standards Regulations, the actual ingredients would need to be identified. But these products do not contain anything other than water and dilute brandy. It would therefore be impossible to evaluate the claims. Secondly, the EFSA is taking years to evaluate claims, so it will be many years before any claim for Bach flower remedies (assuming some sort of ingredient is claimed to be present) were to be evaluated. During this time consumers will continue to be misled by the labelling claims on these products. This proposal looks very much like the MHRA wishing to avoid doing its job.

#### Point 16

Of course, anyone can invent a new “system of medicine” by imagining all sorts of mechanisms and remedies. Indeed the `special clinical need' that requires an imaginary remedy would be rather difficult to define. It would not be possible for the MHRA to keep up with the creativity of those who prefer imagination to science, and one can appreciate the desire to avoid a regulatory role. However by far the simplest approach would be to regulate anyone making a medicinal claim in the

same way, ie to provide evidence of efficacy, safety and quality.

#### Point 17

This does not really provide a proposal. Again the simplest approach is to require evidence of efficacy.

#### Point 18

What the MHRA asserts is “given” is not given at all. The MHRA is required by its mission statement to demand evidence of efficacy whatever the nature of the product making a medicinal claim. The NRS should therefore be abolished.

#### Point 19

It is quite bizarre to see the MHRA discussing anthroposophical medicine as if it were a valid profession. Yet again, the import of this section is that the MHRA does not wish to regulate those whose practices are not evidence-based.

#### Point 20

This is redundant. The MHRA does not need to create any more schemes, it just needs to regulate all medicinal claims in exactly the same way.

#### Point 21

There is no dialogue to have with homeopathy companies, other than that they should provide the same evidence as anyone else who makes a medicinal claim.

#### Point 23

It was disingenuous of the government to suggest that the public will not expect regulatory endorsement of a labelling claim. Consumers know what the MHRA regulates, and that it ensures “that medicines work”. The public will assume that a licence issued by the MHRA is an endorsement of efficacy.

#### Points 25 and 26

The “nature of homeopathy” is that it is a placebo. The government agrees with that, the MHRA agrees, and all qualified experts in therapeutics agree. Why is it so difficult to tell consumers this? A more honest label would say:

*“Warning: There is no evidence that this product has any beneficial effects”*

For dilutions in excess of  $10^{23}$ , the label should state:

*“This product does not contain any active ingredients”*.

Points 27 to 33

It is difficult to see the relevance of the NOP scheme to homeopathy. Virtually all homeopathic products do not contain any active ingredients, so preparing them could not be described as “mix and assembly”. Ultra-dilution is not mixing. Homeopathic stocks may or may not contain general sales list items (there is no limit to the substances that homeopaths will try to dilute, such as light beams from Venus, and the Berlin Wall).

### **Further Comments**

It is not clear why the MHRA finds it necessary to treat with the utmost respect practices that do not rely on scientific evidence. Homeopathy has been so thoroughly discredited that its lack of efficacy is beyond debate by informed people. All relevant parties in this matter agree that it does not work, except for those with vested interests. In consultation MLX312 the MHRA admitted that homeopathy does not work, by stating that it “had difficulty in demonstrating effectiveness in clinical trials”. Despite this admission, and objections voiced in the responses to MLX312, the NRS was pushed through Parliament without debate, resulting in a huge outcry from scientific organisations.

If public consultations are to mean anything, they must not be seen as window dressing by government. This consultation will receive the usual high volume of spurious material from homeopaths and their commercial organisations. The MHRA must take into account not simply the volume of responses, but their scientific value. This debate is primarily about evidence. The public is not interested in the economic impacts on homeopaths and homeopathy companies; people *are* interested in what treatments will help them, and homeopathy does nothing more than placebo. If there is tacit agreement within the MHRA that selling a placebo is acceptable, that is a serious matter that is contrary to its mission statement.

We do not propose that homeopathic products be banned. We simply require that accurate information be given to the paying public, upon which they can make their own purchasing decisions.

In conclusion, our recommendations are:

1. The National Rules Scheme should be phased out.
2. All homeopathy products should be regulated as medicines if they make medicinal claims.
3. While the NRS is being phased out, labelling should be changed to make it clear that homeopathic products are placebos. All indications should be removed immediately.
4. Other medicinal claims such those of anthroposophical medicine must not be hived off to essentially unregulated domains, but should be regulated in the same way as real medicines.

President: Nick Ross

Chairman: Dr James May

Secretary: Professor David Bender

For further information please contact Professor John Garrow, 01923 710665, [johngarrow@aol.com](mailto:johngarrow@aol.com)

Issued by Les Rose, 01722 322945, [lesrose@ntlworld.com](mailto:lesrose@ntlworld.com), on 16<sup>th</sup> February 2011.