

MHRA Consultation on the Review of the Medicines Act 1968

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The MHRA's remit is quite clear. It is to *“enhance and safeguard the health of the public by ensuring that medicine and medical devices work and are acceptably safe”*¹ This provides a very simple and unequivocal test against which to consider regulatory changes and proposals. The MHRA is therefore obligated to use this test.

If a product lacks evidence of efficacy, it should not be the role of the MHRA to suggest that efficacy is present. If the manufacturers of alternative remedies wish to make claims of efficacy, then they may do so subject to the restrictions of the Cancer Act (1939), the Consumer Protection Regulations, Trading Standards policies, the Guidance of the ASA, and such other legislation as may emerge.

However, even where an MHRA label is required (by, for instance, EU legislation), the MHRA itself should not make statements which are untrue, either directly, or by implication.

The appropriate licensing therefore appears to be that described in Para 11, bullet point 2, that of the 'Simplified Scheme'. However, the THR requirement *“registration should however be refused if efficacy is not plausible”*, should, for the sake of consistency, also be applied to the Simplified Scheme.

With regards to Paragraphs 25 and 26, the form of wording required by the MHRA's remit is quite unequivocal. The external packaging can reasonably contain the sentence:

“A homeopathic medicinal product licensed only on the basis of safety, quality and use within the homeopathic tradition”

since this an accurate description of the situation.

However, it is unequivocally wrong for the MHRA to provide indications such as

“A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of ...”

since this statement carries a clear implication that the product **will provide** symptomatic relief. Such a claim should only be made by the manufacturer and/or marketers, who may then be required to justify their claims under other legislation and advertising guidance such as that of the ASA. The 'Simplified Scheme' is the appropriate framework, as amended above.

¹ <http://www.mhra.gov.uk/index.htm>

Equally, it is unequivocally wrong for the MHRA label to state, on a homoeopathic preparation (for example):

“Active Ingredient: Each pill contains 30C Arnica Montana”

There is no active ingredient and the pill contains no *Arnica montana*. The MHRA label should state *“Prepared in accordance with homoeopathic practice. Contains no Arnica montana”*.

Again, it is for the manufacturer and/or marketers to make claims of what it contains as an active ingredient, which can then be tested appropriately. It is not the role of the MHRA to endorse such statements. Indeed such endorsements run directly counter to the MHRA’s remit.

The guidance on overdose should also be removed, since it implies that there is an active ingredient. A statement to the effect that, *“if symptoms persist, you should consult a doctor or pharmacist”* is helpful.

In essence, this is quite a simple matter of integrity: the corporate integrity of the MHRA as a body and of its members as individuals in ensuring *“that medicine and medical devices work”*.

Conflict of Interest Statement

JMcL does not benefit from the manufacture or sale of any homoeopathic, naturopathic or other alternative medicine preparation.