Response to the MHRA informal consultation on Review of the Medicines Act 1968.

D. Colquhoun FRS
Professor of Pharmacology
University College London
Dept of Pharmacology
University College London
Gower Street
London WC1E 6BT

To andreafarmer@mhra.gsi.gov.uk

Quotations are indented.

Introduction

The National Rules Scheme (2006) was subject to huge criticism from over 40 scientific and medical bodies, for allowing misleading labelling. It quite clearly has to be revised if the MHRA is to retain any credibility as a scientifically-based organisation. I consider the MHRA to be a very important body. It states its job thus.

> "We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe."

Likewise The MHRA's press releases say

> "The MHRA is the government agency responsible for 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 judgments to ensure that the benefits to patients and the public justify the risks."

The existence of the word "work" has already been betrayed by the MHRA by its licensing of things that, *by its own admission*, do not work. Still worse, no clear statement is required on the label that they don't work.

This is disjunction between the stated aim of the MHRA and its actual actions is a sad state of affairs. The MHRA is in danger of losing its reputation for sound judgement. This consultation is a welcome sign that the MHRA now realises that its present position is untenable. The proposals to remedy that, sadly don't go far enough.

The consultation document states

> "Our starting point is the Government's response in July 2010 to the report on homeopathy published earlier in that year by the House of Commons Science and Technology Select Committee."

House of Commons Science and Technology Select Committee

I shall start by quoting relevant bits of that report
http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf

> "It is unacceptable for the MHRA to license placebo products—in this case sugar pills—conferring upon them some of the status of medicines. Even if medical claims on labels are prohibited, the MHRA's licensing itself lends direct credibility to a product. Licensing paves the way for retail in pharmacies and consequently the patient's view of the credibility of homeopathy may be further enhanced. We conclude that it is time to break this chain and, as the licensing regimes operated by the MHRA fail the Evidence Check, the MHRA should withdraw its discrete licensing schemes for homeopathic products."

> "We welcome the Government's acknowledgement that there is no credible evidence of efficacy for homeopathy, which is an evidence-based view. However, the Government's view has not translated into evidence-based policies."

> "We were concerned, however, that in introducing the National Rules Scheme in 2006, the MHRA chose not to take a rigorous, evidence-based approach to licensing of homeopathic products. The MHRA's justification for introducing a scheme permitting products to make medical indications—that the product labelling was stringently tested to ensure patients would understand the purpose of the product—was not evidence-based."

> "the Government should not endorse the use of placebo treatments, including homeopathy. Homeopathy should not be funded on the NHS and the MHRA should stop licensing homeopathic products."

> "We are concerned that homeopathic products were, and continued to be, exempted from the requirement for evidence of efficacy and have been allowed to continue holding Product Licences of Right. We recommend that no PLRs for homeopathic products are renewed beyond 2013. (Paragraph 121)"

> "We conclude that the MHRA should seek evidence of efficacy to the same standard for all the products examined for licensing which make medical claims and we recommend that the MHRA remove all references to

> homeopathic provings from its guidance other than to make it clear that they are not evidence of efficacy. (Paragraph 128)"
>
> "We consider that the MHRA's consultation, which led to the introduction of the NRS, was flawed and we remain unconvinced that the NRS was designed with a public health rationale. (Paragraph 135)".
>
> **"**We fail to see why the label test design should be acceptable to the MHRA given that, first, it considers that homeopathic products have no effect beyond placebo and, second, Arnica Montana 30C contains no active ingredient and there is no scientific evidence that it has been demonstrated to be efficacious. We conclude that the user testing of the Arnica Montana 30C label was poorly designed with parts of the test actively misleading participants. In our view the MHRA's testing of the public's understanding of the labelling of homeopathic products is defective. (Paragraph 140)".
>
> **"**If the MHRA is to continue to regulate the labelling of homeopathic products, which we do not support, we recommend that the tests are redesigned to ensure and demonstrate through user testing that participants clearly understand that the products contain no active ingredients and are unsupported by evidence of efficacy, and the labelling should not mention symptoms, unless the same standard of evidence of efficacy used to assess conventional medicines has been met. (Paragraph 141)."

The Government's Response

The response from the Government to the SciTech report was political rather than scientific. It is unfortunate, to put it mildly, that the Government chose to overrule advice from its own Chief Scientific Adviser.

> "The Government Chief Scientific Adviser has discussed the Department of Health policy on homeopathy with lead officials, and understands the reasons for the policy decision. However, he still has concerns about how this policy is communicated to the public. There naturally will be an assumption that if the NHS is offering homeopathic treatments then they will be efficacious, whereas the overriding reason for NHS provision is that homeopathy is available to provide patient choice."

However the last paragraph of the response does place a clear commitment by the Government to make it absolutely clear that homeopathic pills don't work, and the responsibility for that action lies with the MHRA.

Sadly, the proposals in the draft consultation document fall far short of what the government clearly requested.

> "**In order for the public to make informed choices, it is therefore vitally important that the scientific evidence base for homeopathy is clearly explained and available**. He will therefore engage further with the Department of Health to ensure communication to the public is addressed. His position remains that the evidence of efficacy and the scientific basis of homeopathy is highly questionable. "

The consultation document.

Paragraph 11 lays out the possible regulation schemes.

Since the MHRA has recognised that there is no credible evidence for the efficacy of homeopathic or anthroposophical 'medicines' it is hard to see why the last option was included. It is not at present credible that *any* could be given conventional marketing authorisation.

Para 12

It is very gratifying that the MHRA regards PLRs as temporary, and intends, at last, to end them.

Para 15

I agree that it makes no sense to regulate "Bach flower Remedies" as medicines, so I agree with the proposal to remove them. This paragraph omits two important points.

(1) It makes equally little sense to allow "Bach flower Remedies" to be described as food supplements. They clearly have no nutritional value and descriptions that are so obviously inaccurate bring the law into disrepute.

(2) However they are regulated, it is important that they should not be allowed to make false claims (which they regularly do).

(3) Most important for this consultation, it makes no more sense to regulate homeopathy as medicine than it does to treat "Bach flower Remedies" as medicines. Arguably it makes even less sense. At least flower remedies contain something that could possibly have an effect. I see no reason why they should be treated differently (apart from the size of the industry that sells them, something that should not influence the MHRA)

Para 19

Anthroposophic medicines do not need to be distinguished as a special class. To do so implies that the government and the MHRA ascribe some special significance to the teachings of Rudolf Steiner, who, whether or not he was racist, as certainly about as far from being a scientist as it is possible to get. If the Anthroposophic medicines are homeopathic they should be treated like any other homeopathic product. If they are herbal, they should be treated like any other herbal product.

Para 21

This paragraph underlines a paradox that seems to be present in much of the MHRA's thinking about alternative medicine. The MHRA must make up its mind whether it is on the side of the manufacturers or on the side of the public. In my view it is not the job of the MHRA to defend industries, especially industries that are widely regarded as profiting from products that don't work. The MHRA must be firmly on the side of providing the public with accurate information. At the moment, this seems not to be the case, but there is now a chance to remedy that.

Paras 21 – 24

It is good that the MHRA has at last recognised that the labelling allowed under the NRS was grossly misleading. It's hard to understand why it has taken the MHRA to realise this, given the number of people and the number of scientific bodies that pointed it out at the time it was introduced, but better late than never.

Paras 25 and 26

These say

> "We propose the following more explicit form of wording should be used, on the outer packaging and patient information leaflet:
>
> > *"A homeopathic medicinal product licensed only on the basis of safety, quality and use within the homeopathic tradition*"
>
> 26. Information about indications would read:
>
> > *"A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of……""*

Sad to say these proposals to remedy the labelling problem are wholly inadequate. They are almost as deceptive as the originals. These labels don't come anywhere near to fulfilling the requirement in the government's response which said

In order for the public to make informed choices, it is therefore vitally important that the scientific evidence base for homeopathy is clearly explained and available

Why, oh why, cannot the MHRA bring itself to simply tell the truth? It seems to be so stifled by some perversion of political correctness that it is unable to do what it must know is right.

Nothing indicates more clearly the ludicrous state of the NRS than the label approved for Arnica 30C pills.

http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con049307.pdf

The approved label says

> "ACTIVE INGREDIENT
>
> Each pill contains 30C Arnica Montana
>
> Also contains: lactose and sucrose"

The MHRA *must* decide whether or not it believes Avogadro's number or not.

How many people in the general public realise the "Each pill contains 30C Arnica Montana" means that the "pills contain no Arnica whatsoever"? The very mention of the words "active ingredient" will suggest to most people that there is an active ingredient when there is not. This wording alone is both dishonest and deceptive.

The rest of the label consists largely of make-believe too.

> "If you are pregnant or breastfeeding consult your doctor before use"

What is your doctor meant to advise you about the dangers of taking a few mg of sugar when you are pregnant?

> "If you take too much of the product (overdose) speak to a doctor / pharmacist and take this label with you."

Unless the MHRA has disavowed Avogadro's number, an overdose is impossible. To allow a label like this makes the MHRA a laughing stock.

Paras 27 – 33

I agree entirely with the proposal to end the "non-orthodox practitioner scheme".

What should be done?

(1) It is absolutely unacceptable for the MHRA to give any sort of license to placebos. If, despite common sense, they do so, the products must be clearly labelled as placebos.

(2) No exception to the usual Trading Standards laws should be allowed. Normally it would be absolutely illegal to sell a product labelled Arnica that actually contains no Arnica whatsoever. At present an exception is made for homeopathic products. I can see no justification for that exception to continue to exist. It should vanish with the PLR. Indeed legally it might vanish when the PLR goes and that would leave the manufacturer open to prosecution by Trading Standards for mislabelling. It is even possible that the MHRA could be prosecuted for condoning misleading labelling.

It is contrary to reason and it is potentially dangerous to patients if they are deceived about the contents of what they are buying.

Labels should tell the truth in plain language. For example they should say

> "This product contains no Arnica"
>
> "There is no evidence that it works for any condition, other than as a placebo"

Presumably the MHRA does not disagree with either of these statements, so why is is the MHRA so unwilling to tell the patients? It is totally baffling. Cigarettes are now labelled clearly and simply. Why not homeopathic pills too?

In my view, it would be more honest, and a great deal cheaper, if the MHRA were to treat homeopathy in the same way that is proposed for "Bach Flower Remedies". **To attempt to regulate as a medicine something that contains no medicine can lead only to extension of the present ludicrous situation and do yet more harm to the reputation of the MHRA.**

The existing law, if enforced, is quite sufficient to protect the public from exploitation by false health claims. In particular the Cancer Act (1939), and the Consumer Protection Regulations (2008) already make it illegal to make false claims. There is no need to have expensive and deceptive "regulation" by the MHRA too. The only step that is necessary is to ensure that Trading Standards enforce the law. At present they fail spectacularly to put into effect their statutory obligation to enforce the Consumer Protection Regulations (2008). Alternatively the obligation to enforce this law could be transferred to the MHRA, which is better qualified to make the necessary judgements.

The proposals at the end of the consultation document are therefore good with two major exceptions. The proposed change to labelling is utterly deceptive and totally unacceptable. Such nonsense is bound to arise if there is an attempt to regulate as

though it were a medicine things that contain no medicine. The form of regulation that I recommend would be simpler and much cheaper. It would also restore the reputation for honesty of the MHRA and it is very important that public confidence in MHRA should be restored. It must once again live up to its own stated obligation “by ensuring that medicines . . .work”. Since 2006 it has let down the public badly in fulfilling that duty.