

16 February 2011

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Dear Madam

**Review of Medicines Act 1968: informal consultation on issues relating to the PLR regime and homeopathy**

We welcome this consultation and have the following comments.

## Definition of a homeopathic product

This is a profoundly important issue here that has not been adequately dealt with.

The definition of a homeopathic product given in the consultation is taken from the European Directive 2001/83/EC, Article 1:

5. Homeopathic medicinal product:

Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles.

This abdicates responsibility for what constitutes a homeopathic product to the various Pharmacopoeia. The Eur. Ph. gives a long definition of 'homoeopathic preparations', but this is mostly a vague description of a manufacturing process and does not specify the minimum dilution required by a product labelled as homeopathic.

The problem that arises from the lack of a clear definition is that the minimum dilution of the mother tincture is unspecified and may be as low as 0.1 (10% or 1X in homeopathic nomenclature) — this may not be a sufficient dilution to guarantee the safety of the product. As an example, see this product ([Cough Elixir Expectorant 100ml Weleda, cached](#)), sold by Helios Homeopathy, that clearly states the homeopathic 'potencies' of some of its ingredients as 1X, 2X and 3X, corresponding to dilutions of 0.1 (10%), 0.01 (1%) and 0.01 (0.1%). Depending on the mother tincture, there may be serious safety concerns with these dilutions, exposing the public to unnecessary risk.

We also note that there are several products that have been issued HR licences by the MHRA that have dilutions as low as 0.01 (1% or 2X in homeopathic nomenclature).

We urge you to clearly define what constitutes a homeopathic product, making safety a priority.

## Product Licences of Right (PLRs)

We note that all PLRs that were issued to *medicinal* products were either revoked or granted full product licences by the early 1990s. We further note that PLRs for homeopathic and other products still exist, but that you propose that all such PLRs are revoked in April 2013. We also note these products are allowed to have indications, including those for serious medical conditions.

We do not believe that there is any justification for treating homeopathic products any differently to any other product that makes claims to alleviate, treat or cure any medical condition and find it regrettable that special privileges have been awarded to homeopathic products for thirty years. In the interests of protecting the public from misleading claims and allowing them to make fully informed choices, such privileges should be revoked.

We therefore welcome the move to revoke all such PLRs, but urge you to revoke them as soon as possible and not wait a further two years.

It is also regrettable that homeopathic products — whether licenced under the PLR scheme, the simplified scheme or the National Rules Scheme — have been given the imprimatur of being licensed by the MHRA, thus misleading the public into thinking they are medicinal products, when there is no evidence to support that assertion.

We note the options available to manufacturers of these homeopathic products once the PLRs are revoked. We note that you propose to transfer these products to another licence category but you ‘propose not to charge the normal fees that would otherwise be payable for licensing applications under the NRS or the simplified scheme’.

We believe this is not justified and the full costs that would be charged for a new application should be charged so that the burden of the cost is borne by the manufacturer and not subsidised by the MHRA or the public.

We understand there are up to 500 such PLRs and that if the manufacturers applied for a licence under the simplified scheme for all of these, the total loss of income to the MHRA would be in the order of £250,000 to £500,000. If licences for the NRS were applied for, the MHRA would lose up to £700,000 by waiving the usual fees.

We believe that this loss of income to the MHRA is not justified.

We welcome the proposal to revoke all PLRs for Bach flower products and urge that this be done as soon as possible to limit further misleading of the public into thinking they are authorised, legitimate and efficacious medicinal products, when, in fact, there is no robust scientific evidence that they are efficacious for any medical condition.

We urge you to revoke all PLRs for anthroposophic products.

We believe that all products that make medicinal claims should be treated equally and no special privileges given to homeopathic products and other products that do not meet the requirements for efficacy or safety.

## Information for patients under the national rules scheme

The House of Commons Science and Technology Sub-Committee evidence check meetings discussed the labelling of homeopathic products and the MHRA’s labelling requirements under both the simplified scheme and the NRS were highlighted. The Committee’s report (at paragraphs 136 to 141) also discussed the labelling under both schemes. The Government’s response (at paragraph 44) admitted that those concerns raised ‘wider issues about the labelling of homeopathic products’.

With that in mind we make recommendations for the labelling of homeopathic products under the simplified scheme as well as the NRS.

## *Simplified scheme*

The current required wording is:

Homeopathic medicinal product without approved therapeutic indications

The MHRA have admitted that this wording has not been tested for understanding by the general public.

It is clear to us that this technical wording is very likely to mislead the public because it will not be fully understood. We believe it is misleading for several reasons:

### 1. Homeopathic products are not medicinal

We believe the general public understand 'medicinal' to mean something that treats, alleviates or cures a medical condition<sup>1</sup>. Since there is no good evidence that any homeopathic product is efficacious for any medical condition, we believe it is highly misleading to call homeopathic products 'medicines' and doing so misleads the public. This exploits their lack of experience or knowledge and may delay or dissuade people, particularly the gullible or vulnerable, possibly with serious medical conditions from seeking proper and possibly urgently needed medical advice and treatment. It also abuses the trust of members of the public in the regulation of medicinal products and undermines the MHRA's standing.

### 2. Few will understand 'without approved therapeutic indications'

This is technical jargon that many members of the public will not understand. It is not clear that these words are intended to mean that the manufacturers are not allowed to make claims that these products are effective for any medical condition. We therefore believe the current words are highly misleading and should be replaced with words that properly convey the intended meaning.

We strongly recommend that an organisation such as the [Plain English Campaign](#) are consulted so that the intended meaning can be made clear to the general public.

## *National Rules Scheme*

The current required wording is:

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

### 1. Homeopathic products are not medicinal

We believe the general public understand 'medicinal' to mean something that treats, alleviates or cures a medical condition<sup>1</sup>. Since there is no good evidence that any homeopathic product is efficacious for any medical condition, we believe it is highly misleading to call homeopathic products 'medicines' and doing so misleads the public. This exploits their lack of experience or knowledge and may delay or dissuade people, particularly the gullible or vulnerable, possibly with serious medical conditions from seeking proper and possibly urgently needed medical advice and treatment. It also abuses the trust of members of the public in the regulation of medicinal products and undermines the MHRA's standing.

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<sup>1</sup> For example, see Chambers Dictionary:

<http://www.chambersharrap.co.uk/chambers/features/chref/chref.py/main?query=medicinal&title=21st>

2. The words 'homeopathic tradition' are misleading

This gives the impression that homeopathy is simply another medical tradition that is in some way an alternative to conventional or evidence-based medicine. We would expect such claims from a homeopath, but it is highly misleading when endorsed by the MHRA.

3. The words 'for the symptomatic relief of...'

This is technical jargon that many members of the public will not understand. We believe the public will understand this to mean that the homeopathic product is efficacious in the relief of the symptoms associated with the listed medical conditions. However, since there is no good evidence that any homeopathic product is efficacious for any medical condition, we believe it is highly misleading.

We note that you are proposing changes to this wording:

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

We believe this does not address our concerns given above and, indeed, adds to their misleading nature.

The main issue is that adding the word 'quality' may lead the public into thinking that these products are efficacious.

So that the public are fully protected and have all the information they require with which to make a fully informed choice about the products they buy and the medicines they take to alleviate a medical condition, the wording must change to something that is absolutely clear and which contains no jargon or technical terms.

In light of this, we suggest that the warning is completely revised so that the customer is completely clear that there is no good evidence that the product will work and that the purported mechanism of action is highly implausible, if not impossible.

We strongly recommend that an organisation such as the [Plain English Campaign](#) are consulted so that the meaning can be made clear to the general public.

### Summary of recommendations

- To protect the public, homeopathic products should be properly defined.
- All PLRs should be revoked at the earliest opportunity.
- The normal fees for the transfer of PLRs to other licence categories should be charged to the manufacturers, saving the MHRA some £250,000 to £700,000.
- The warning labels on all homeopathic products should be revised so that the public have the information necessary to make fully informed choices.

If you require any further information, please do not hesitate to contact me.

Yours

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Alan Hennes

*Director*