Homeopathy and the consolidation of UK medicines legislation

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Section Science and Environment

UK medicines legislation (including for homeopathy) is being consolidated. The law is not being changed. The consolidation will happen through the *Human Medical Regulations 2012*, which were due to come into force in July 2012. They will be laid under the negative resolution procedure.

Some homeopathic practitioners are concerned that following the consolidation the law will be enforced. They believe that this could constrain some homeopathic practices. They are seeking a change in UK law.

It is not clear that the requested change in the law is possible at the UK level. Such changes might have to be negotiated at EU level.

In 2010 the Science and Technology Select Committee examined Government policy on homeopathy. It found that homeopathic products are placebos, it questioned whether their use in the NHS was ethical and it called for changes to their regulation. The report received vociferous support and opposition from a number of groups.

The Government responded that it agreed with "many" of the Committees conclusions, but it rejected substantive changes to regulation or policy.

Contents

1 The proposals

The current regime for the regulation of homeopathic medicinal products is summarised on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

UK medicines legislation (including for homeopathy) is being consolidated. The proposals do not change the law. This MHRA explained that:

> The current body of UK medicines legislation comprises the Medicines Act 1968 and approximately 200 statutory instruments. It has developed piecemeal since the Medicines Act 1968 came into force some 40 years ago and is fragmented, complex and often difficult to follow.[1]

The MHRA consultation document explained that "the project will bring the existing legislation into one set of regulations, and simplify and clarify the way provisions are drafted" and that "this will in turn reduce net burdens for users: it will save time and costs for business, civil society organisations and the public sector in understanding and applying the law, and reduce the likelihood of costly legal cases arising from different interpretations of the law".[2]

The consolidation project has been ongoing since January 2009 and the MHRA has carried out an extensive consultation process on both general concepts and specific issues (see here for details of all related consultations). Most recently, the MHRA held a consultation on the draft consolidated regulations. This ran for 12 weeks from 25 October 2011 to 17 January 2012. The draft consolidated regulations, the *Human Medicines Regulations 2012*, are published on the MHRA website. This will be delegated legislation and will therefore be laid before Parliament as a statutory instrument.

The MHRA states that the current timetable is for the consolidated legislation to come into force in July 2012.[3]

2 Homeopath concerns

The proposals do not change the law. Some homeopaths are concerned that the future enforcement of the existing law could lead to restrictions on the future sale of homeopathic products, particularly over the internet and telephone. Supporters are using this opportunity to seek a change in the law. Neal's Yard Remedies said:

> If Section 10 is not changed or amended, and is enforced in the future, access to unlicensed homoeopathic remedies will be restricted to receiving them in person from a specialist pharmacy with expertise in homoeopathy. This would be unworkable as far as patient choice and access is concerned for the 10% of the population that use homoeopathy in the UK

[1] Project to consolidate and review UK medicines legislation, MHRA website, viewed 12 June 2012
[2] ibid
[3] ibid

> Whilst this consolidation could be classed as a routine review/consultation of the law and would leave policy unaltered, this is precisely the problem. By not amending Section 10 it may create difficulties with future access to homoeopathic remedies.[4]

The British Homeopathic Association and Homeopathy Action Trust are encouraging users of homeopathic medicinal products to contact their MPs to express their concerns.[5]

3 Counter arguments

Some anti-homeopathy and science bloggers have responded to the concerns raised by homeopaths. For example, the Quackometer website, which has outspoken views on evidence in healthcare and is very critical of homeopathy, has provided its own analysis of the implications for homeopathy. This can be seen here.

The Nightingale Collaboration recently called for homeopathic remedies to be subject to the same regulation as other products that make health claims:

> 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.[6]

4 Is it possible to change the law at UK level?

Directive 2001/83/EC states that no medicinal product can be placed on the market unless it has a marketing authorisation.[7] Unauthorised medicines can only be supplied when "**formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility**".[8]

This may mean that EU law would have to be changed to allow unauthorised homeopathic medicines to be available over the telephone or internet.

However, a detailed consideration of the legal implications is needed to give a definitive answer to this question. The MHRA said:

> There would need to be detailed consideration of the policy and legal implications of any reforms to homeopathy provisions, including full consultation with interested parties. This would not be possible within the timescales of the consolidation initiative.[9]

5 Why has the law not been enforced in the past?

The MHRA stated:

> The MHRA is obliged to investigate any complaint concerned with the manufacture and supply of medicines for human use. Each case will be considered on its individual merits, set in the wider context of the MHRA's role in the protection of public health.[10]

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[4] Homoeopathy under threat – why no change isn't good enough, NYR Natural News, viewed 12 June 2012
[5] Write to your MP!, British Homeopathic Association, viewed 12 June 2012
[6] Review of Medicines Act 1968: informal consultation on issues relating to the PLR regime and homeopathy, The Nightingale Collaboration, viewed 12 June 2012
[7] Court of Justice of the European Union, Press release 36/12, 29 March 2012
[8] DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 6 November 2001
[9] MHRA, personal correspondence, 22 June 2012

6 Science and Technology Committee—Evidence Check 2: Homeopathy

In 2010 the Science and Technology Select Committee published *Evidence Check 2: Homeopathy*. The Committee reviewed Government policy on homeopathy. It concluded that homeopathy does not work beyond a placebo effect:

> …the evidence base shows that homeopathy is not efficacious (that is, it does not work beyond the placebo effect) and that explanations for why homeopathy would work are scientifically implausible.[11]

It called on changes to the regulation of homeopathy to make it clear that, in its view, homeopathic products are placebos. It was concerned that prescribing such products on the NHS might be unethical and that licensing such products provided "spurious medical legitimacy" to them:[12]

> By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, 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.[13]

It went on to recommend that the NHS withdraw funding for homeopathy and that the MHRA should not allow homeopathic medicines to make medical claims without evidence of efficacy.[14]

6.1 Responses to the Committee report

Sense About Science, a science and evidence charity, described the report as "detailed". It urged the Government to accept the report findings.[15] It provided a critique of homeopathic practices here.

The British Homeopathic Association (BHA) was highly critical of the report, calling it "biased", "riddled with poor process" and stating that it had failed to acknowledge some of the evidence supporting homeopathy.[16] The BHA provided a critique of the report and its findings here.

6.2 The Government response

The Government responded to the report saying that "we agree with many of the Committee's conclusions and recommendations". It went on that the Government Chief

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[10] MHRA, personal correspondence, 22 June 2012

[11] MPS URGE GOVERNMENT TO WITHDRAW NHS FUNDING AND MHRA LICENSING OF HOMEOPATHY, Science and Technology Committee, Evidence Check 2: Homeopathy, viewed 12 June 2012

[12] MPS URGE GOVERNMENT TO WITHDRAW NHS FUNDING AND MHRA LICENSING OF HOMEOPATHY, Science and Technology Committee, Evidence Check 2: Homeopathy, viewed 12 June 2012

[13] Evidence check 2: Homeopathy, Science and Technology Committee, HC 45, 8 February 2012

[14] MPS URGE GOVERNMENT TO WITHDRAW NHS FUNDING AND MHRA LICENSING OF HOMEOPATHY, Science and Technology Committee, Evidence Check 2: Homeopathy, viewed 12 June 2012

[15] Evidence check: homeopathy, Sense About Science, viewed 20 June 2012

[16] The Science & Technology Select Committee Evidence Check on Homeopathy, British Homeopathic Association, viewed 20 June 2012

Scientific Adviser had advised that "the evidence of efficacy and the scientific basis of homeopathy is highly questionable".[17]

However, it said that the use of homeopathy in the NHS would remain with "local NHS and clinicians":

> …our continued position on the use of homeopathy within the NHS is that the local NHS and clinicians, rather than Whitehall, are best placed to make decisions on what treatment is appropriate for their patients - including complementary or alternative treatments such as homeopathy - and provide accordingly for those treatments.[18]

It was concerned about changing the regulation of these products, saying that this could have a negative impact on "consumer choice" and risk "unregulated, poor quality and potentially unsafe products" entering the market "to satisfy consumer demand".[19] The full Government response can be found here.

The BHA welcomed the Government's response as protecting consumer choice:

> I am pleased to see that the government's response embraces patients' right to make informed choices about healthcare,' notes British Homeopathic Association Chief Executive, Cristal Sumner. 'This response makes it quite clear that this choice includes complementary medicine and homeopathy more particularly, which is a welcome affirmation to all current and potential patients across the UK.'[20]

Sense about Science was critical of the Government's response, calling it "perverse" at "a time when PCTs are reviewing expenditure on ineffective treatments":

> The Government has ignored the Committee's detailed consideration of the licensing of homeopathic products as medicines. It has acknowledged that "there will be an assumption that if the NHS is offering homeopathic treatments then they will be efficacious" and that homeopathic products can be licensed with no requirement for evidence that they treat any condition at all. However, the Government has put forward a weak point about 'patient choice' instead of considering what to do about these problems. At a time when PCTs are reviewing expenditure on ineffective treatments, this is perverse. We urge them to go back and give proper consideration to this part of the Committee's report. In the meantime, we recommend a warning on the label of homeopathic products telling people that the product is licensed without any evidence that it works.[21]

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[17] Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy', Department of Health, 26 July 2010, Cm 7914

[18] Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy', Department of Health, 26 July 2010, Cm 7914

[19] Government Response to the Science and Technology Committee report 'Evidence Check 2: Homeopathy', Department of Health, 26 July 2010, Cm 7914

[20] Government response confirms place of homeopathy in the NHS, British Homeopathic Association, viewed 20 June 2012

[21] Evidence check: homeopathy, Sense About Science, viewed 20 June 2012