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**ANH Feature**

## **UK homeopathy's Catch-22 moment**

*Professional homeopaths face uncertain future*

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### **KEY POINTS**

1. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is tidying up UK medicines legislation
2. A campaign by representatives of UK homeopathy says that unlicensed homeopathic remedies will become difficult to obtain as a result
3. In fact, the MHRA exercise will not change the legal situation, which severely restricts the provision of unlicensed medicines
4. We recommend that professional homeopaths in the UK regularly access [Malleus Homeopathicum's blog](#)

UK homeopathy could be on the verge of shaking itself apart, prompted by a legislative [tidying-up exercise](#) by the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). How could this have happened? And where does homeopathy stand elsewhere in the European Union (EU)?

### **Campaign by UK homeopathy**

UK homeopathic [professional associations](#) and certain homeopathic pharmacies are working together on a letter-writing campaign to UK Members of Parliament (MPs), in response to the [MHRA's consolidation](#) of UK medicines legislation. The campaign claims that homeopaths and homeopathic pharmacies alike stand

**“Promoting natural and sustainable healthcare through the use of good science and good law”**

to lose their ability to prescribe or supply unlicensed homeopathic medicines to the UK public, once the consolidated legislation is adopted.

### **Homeopathic regulation in the UK: a diluted history**

The legal status of homeopathic remedies is unique among medicinal products in the UK, and we'll need to briefly trace their history since the pivotal 1968 [Medicines Act](#) in order to fully understand what's going on.

When the 1968 Act was enacted in 1971, those homeopathic remedies that were available on the UK market at the time were granted '[Product Licenses of Right](#)' (PLRs). PLR homeopathic products could be sold with a therapeutic indication and were available from high-street pharmacies and health-food shops.

The rules were updated in 1992 with the passing of European Union (EU) [Directive 92/73/EEC](#), which resulted in the [UK's Medicines \(Homoeopathic Medicinal Products for Human Use\) Regulations 1994](#). This legislation set up a so-called 'Simplified Scheme' for homeopathic products, which not only exempts them from the need to prove efficacy via clinical trials but also assumes that safety is a given, bearing in mind the extreme dilutions involved. However, homeopathic products licensed under the Simplified Scheme cannot display therapeutic indications – these are the 50–60 single remedies, such as Arnica, Ignatia and Arsenicum, that are commonly seen in UK high street retailers like Boots.

When the [Human Medicinal Products Directive](#) (HMPD; 2001/83/EC, as amended) became law in 2001 and superseded all previous medicines legislation, homeopathic products officially and for the first time became defined as 'medicines' under the all-encompassing [EU definition of a medicine](#) in Article 1(2). Under the provisions of the HMPD, the UK set up its own [National Rules Scheme](#) (NRS) for homeopathic medicines, which does permit limited therapeutic indications for products registered under it and, like the Simplified Scheme, requires evidence of safety and quality. At this point, however, only one homeopathic medicine has been registered under this scheme, although more are in the pipeline. Products with PLRs, which include tissue salts and several homeopathic formulae, are gradually transitioning over to the NRS system.

Despite all this, it's crucial to our story to understand that the Simplified Scheme and the NRS between them license around 100 products. Unfortunately, the homeopathic Materia Medica consists of thousands of remedies, almost all of which are unlicensed in the UK, although they aren't prescription only medicines.

### **Clear? Good, then we'll begin**

If the history of homeopathic product regulation is long and convoluted, the parallel situation of professional homeopaths – that is, practitioners who have undertaken a course of study but who are not qualified doctors – is relatively simple and consistent. And that's where their troubles lie.

Because – at least according to our reading of the relevant EU and UK law – professional homeopaths have never, legally, had the right to prescribe anything. As far as the law is concerned, they are no different from any other member of the public, and are not considered ‘supplementary prescribers’ in the same way as appropriately qualified nurses or pharmacists. Of course, medical doctors who are also homeopaths can prescribe what they like, licensed or unlicensed. Also – unlike the [statutorily regulated health professions](#), such as osteopaths, chiropractors and, hopefully soon, herbalists – homeopaths are not considered, “*Authorised health-care professionals*” under [Article 5\(1\) of the HMPD](#). This means that they do not have the right to supply unlicensed medicines to patients, following a face-to-face consultation.

At least since the UK Medicines Act became law, professional homeopaths have acted in tandem with homeopathic pharmacies in order to fulfil the individual needs of their patients, in the following manner. A patient has a consultation with a homeopath, who decides which remedy the patient needs and then either contacts the pharmacy to post the appropriate remedy, or gives the remedy details to the patient for them to collect from the pharmacy. Last but definitely not least, the third route involves either the homeopath or the patient visiting a homeopathic pharmacy in person to obtain the remedy.

### **Turning a blind eye**

This arrangement has worked well for a long time, but unfortunately contains a significant flaw. Homeopaths have no prescribing rights, and [Section 10 of the 1968 Medicines Act](#) allows registered pharmacists to prepare unlicensed medicines only after a face-to-face consultation, with the patient, on the pharmacy premises – posting those medicines is not mentioned. Therefore, every time a professional homeopath or a homeopathic pharmacy provides a patient with an unlicensed homeopathic remedy via any route other than a face-to-face consultation with a registered pharmacist, they are acting outside the law. The pharmacies are not even legally permitted to provide unlicensed homeopathic medicines to professional homeopaths on behalf of their patients because, as we noted earlier, professional homeopaths have no prescribing rights. Providing unlicensed remedies in response to a prescription written by a homeopathic doctor is a different matter. An answer to a recent UK Parliamentary question appears to [support our interpretation of the law](#).

To put it bluntly, it appears that the current arrangement has only worked so well for so long because the MHRA has turned a blind eye to this uncomfortable fact.

### **An inconvenient truth**

Which brings us back to the letter-writing campaign by representatives of UK homeopathy. On the one hand, it suggests that the MHRA’s review of legislation will result in changes to the prescribing rights of homeopaths and homeopathic pharmacies; however, the MHRA has no power to create legislation, so any rewording of the newly simplified legislation should not change how the law actually works in practice. On

the other hand, the campaign does not make clear the past, current and ongoing legal status of professional homeopaths and homeopathic pharmacies, as outlined above.

Furthermore, while it may be true that the average registered pharmacist has no homeopathic training, and that it will be difficult or impossible for most patients to visit one of the five homeopathic pharmacies in the UK, none of this is due to a consolidation of UK medicines legislation. Neither will consolidation ban homeopathic pharmacies from posting remedies in response to patient need, nor will it clamp down on convenient and accurate Internet ordering. Similarly, it may well be true that the MHRA has failed to engage effectively with representatives of UK homeopathy, but the hard fact is that these activities have never been sanctioned under UK law.

### **The campaign for exemption**

As a solution, the UK homeopaths' representatives propose the [addition of a clause to Section 10](#) of the 1968 Medicines Act, which is referred to directly in the [proposed consolidated legislation](#). According to the most [recent campaign update](#), the new clause would amend Section 10 (4a), *"So that it does not apply to homeopathic medicines dispensed at dilutions of 6X or above"*.

This concept is similar to a solution proposed by Steve Gordon, General Secretary of the [European Central Council of Homeopaths](#). Under his proposal, all homeopathic remedies from all source materials at dilutions of 12C and above would legally be exempt from licensing, since they are too dilute to pose any risk to the consumer. At dilutions of below 12C, the concept of the ['first safe dilution'](#) would kick in, and this would differ according to the substance upon which the remedy is based. Chamomile, for example, would have a very different first safe dilution from *Arnica* or arsenic, and low potency dilutions of each remedy would be licensed as appropriate.

The UK campaign has also asked the MHRA for its opinion on whether section j512 of the [proposed consolidated legislation](#), entitled 'Exemptions for medicinal products at high dilution', represents a sufficient legal sidestep. The MHRA has yet to respond.

### **The European perspective**

There are distinct parallels between the UK and the wider European situation, as well as obvious differences. Compared with the UK, homeopathy is far more established and more widely accepted in many European countries. As Dr Ton Nicolai, President of the [European Committee for Homeopathy](#), points out, *"In many EU countries, notably Italy, Spain, Germany, Austria, Switzerland and the eastern European countries, homeopathy is far more embedded in the local culture, even though it's only medical doctors who are allowed to prescribe unlicensed homeopathic medicines. That's the case in most of Europe,*

*in fact: only Finland, Sweden, Norway, Switzerland and Germany allow professional homeopaths to practise legally. Germany gets round that one by licensing the majority of the homeopathic Materia Medica!"*

Steve Gordon emphasised that confusion among regulators is one of the overriding common features of European homeopathy. *"The EU Directives have attempted to harmonise the situation across Europe, and this legislation is supported by the big European homeopathic manufacturers. But the unharmonised way the new regulations are being interpreted and implemented in many countries is making it more difficult and expensive for the manufacturing companies to make their products. It's a bit of a nightmare for everyone."*

### **A misdirected campaign?**

Whatever happens, even bearing in mind that it began in March 2012, the letter-writing campaign hasn't long to have the desired effect, since the consolidated legislation is [due to come into force in July](#) this year.

Besides, since much of healthcare in the UK is nowadays governed from Brussels, the only genuine legislative routes out of this mess are, as the mysterious blogger at [Malleus Homeopathicum](#) puts it, *"Either a change to EU legislation or a UK opt out of the same EU regulation"*. In other words, writing to MPs won't change much, which is why our campaigns on the [Traditional Herbal Medicinal Products Directive](#) (THMPD) and the [Nutrition and Health Claims Regulation](#) (NHCR) have been directed toward MEPs.

### **The way forward**

We'd urge every professional homeopath in the UK to read every word of every post on [Malleus Homeopathicum's blog](#), apparently set up to educate homeopaths about what's actually going on. He or she is obviously highly clued up about the practice and politics of homeopathy in the UK and the EU, the legislation involved and even how the MHRA operates, and we aren't aware of a better resource for interested UK professional homeopaths – which should be all of them.

To be clear, however, we don't necessarily agree that the situation is as bleak as the blog makes out, since homeopathy operates in a legal grey area that the MHRA has never seriously attempted to clarify. In other words, the status quo may continue regardless of any campaigning. But, given the current strength of the small but vocal skeptic fringe, we wouldn't be surprised to see the MHRA take a more robust attitude toward enforcement once the consolidated legislation is in place.

Malleus Homeopathicum sees the [possible solutions](#) as follows:

- Carry on as before, with the MHRA turning a blind eye
- Register more homeopathic medicines, which should certainly occur in the longer term
- License manufacturers instead of remedies

- No regulation at all – which comes with the comment, *“Frankly, it's completely unworkable. Regulation is desired by the European manufacturers”*
- Statutory regulation of the homeopathy profession, which has taken herbalists nearly 30 years to nearly achieve – [not a viable short-term solution!](#)
- Reclassify homeopathic medicines and sell them as food supplements: *“If homeopaths stop claiming the products are "homeopathic", they stop being regulated as homeopathic medicines...Changes to packaging, labelling, promotional material and websites are all that are required”*

The final point may appear somewhat off-the-wall, but the definition of a homeopathic medicine contained in [Article 1\(5\) of the HMPD](#) certainly seems to support this line of reasoning. However, homeopathic remedies are still caught by the incredibly wide definition of a medicine contained in [Article 1\(2\) of the HMPD](#), so it probably wouldn't work – unless the authorities decide to let homeopaths off the hook by 'fudging' the issue.

### **Catch-22**

As we said at the start of this article, this is a [Catch-22](#) situation for UK homeopathy: do nothing and hope that the long-standing status quo continues, in the knowledge that professional homeopaths and homeopathic pharmacies alike may well be flouting the law; or go public with a last-minute campaign, taking an enormous risk that the true legal situation will become public knowledge and the regulators will be forced to act.

Truly, we hope that we aren't witnessing what Malleus Homeopathicum describes as the [“suicide notes” of UK professional homeopathy](#) (although he/she uses the term 'lay homeopathy'). Whatever happens, though, it's important to keep an eye on the bigger picture and realise that homeopathy, with its rich history going back over 200 years, is a vibrant, frequently effective and enormously popular method of healthcare used right around the world – whatever happens in the UK, it ain't going anywhere in many other EU countries. It would be a tragedy if that eventually becomes cold comfort for the UK's professional homeopaths.

### **Call to action**

- Contact your professional organisation and the homeopathic pharmacies and share our interpretation of the legal situation with them. A new and more effective lobbying strategy may be required and the best place to start is a point of total transparency!  
List of [homeopathic pharmacies](#)

Professional organisations:

[Society of Homeopaths](#)

[Alliance of Registered Homeopaths](#)

[British Homeopathic Association](#)

[Homeopathic Medical Association](#)

Other organisations that may be involved in the campaign:

[Faculty of Homeopathy](#)

[Homeopathy Action Trust](#)

[H:MC21](#)