

# Homeopathic and Herbal Products Advice for Pharmacists

## Key Points

- There is no evidence to support the clinical efficacy of homeopathic products beyond a placebo effect, and no scientific or pharmacological basis for homeopathy.
- Pharmacists selling homeopathic products must be competent to do so and be able to discuss with patients the lack of evidence for the efficacy of homeopathic products and their formulation.
- Pharmacists should ensure, wherever possible, that patients do not stop taking their prescribed conventional medication when they take a homeopathic product.
- The MHRA does not currently require homeopathic products to demonstrate efficacy for the purpose of licensing.
- The RPSGB believes that homeopathic products should only be used for the treatment of minor, self-limiting conditions, and must never be used for the treatment of serious medical conditions.
- Pharmacists should be aware that patients requesting homeopathic products may have serious underlying undiagnosed medical conditions that would require referral to another healthcare professional.
- Pharmacists should not knowingly sell homeopathic products for serious medical conditions. However, it is recognised people will self select homeopathic products from open display often without consulting a pharmacist.
- Pharmacists can help people understand the difference between homeopathy and herbal products.
- RPSGB does not endorse homeopathy as a form of treatment.

## Introduction

Homeopathy is a topic that invokes strongly held views both for and against its benefits. Recent media coverage of homeopathy has meant that the RPSGB's views on homeopathy have come under scrutiny, as has the sale of homeopathic products from pharmacies. The RPSGB is currently reviewing its policy on homeopathy. The present document is intended to outline the Society's position with regard to homeopathy, and to inform pharmacists of how to deal with patient requests for homeopathic products.

## Evidence for homeopathy

The RPSGB recently reviewed the evidence surrounding the efficacy of homeopathy and concluded that there was no evidence from randomised controlled trials for the efficacy of homeopathy over placebo, and no scientific or pharmacological basis for homeopathy. These views were presented in the Society's written and oral submissions to the House of Commons Science and Technology Select Committee for its evidence check on homeopathy in November 2009.

**Given the lack of clinical and scientific evidence to support homeopathy, the RPSGB does not endorse homeopathy as a form of treatment.**

## **Code of Ethics**

The RPSGB recognises that patients do have a choice in the healthcare treatments they use and that homeopathy is one of many complementary therapies available.

**While the RPSGB provides, within its Code of Ethics and the Professional Standards and Guidance for the Sale and Supply of Medicines, standards of practice for those pharmacists involved in homeopathy, this should not be viewed as an endorsement of homeopathy as a form of treatment by RPSGB.**

The RPSGB recognises that homeopathic products are on sale from pharmacies and that patients may ask pharmacists for advice on the suitability of homeopathic products. The current Code of Ethics for Pharmacists and Pharmacy Technicians and Professional Standards and Guidance for the Sale and Supply of Medicines requires that pharmacists are competent in any area in which they offer advice on treatment or medicines. For pharmacists selling or supplying homeopathic products, this means they must ensure any stock is obtained from a reputable source, only recommending a product where they are satisfied of its safety and quality, and when asked, assist patients in making informed decisions about homeopathic products by providing the necessary and relevant information, particularly the lack of clinical evidence to support the efficacy of homeopathic products.

## **Sale of homeopathic products**

The RPSGB believes that the best person for an individual to talk to about a health issue that concerns them is a registered health professional such as a pharmacist.

The RPSGB recognises that homeopathic products can be obtained from pharmacies and from other unregulated outlets where patients can make self-selection purchases. In such cases there would be no requirement for a pharmacist to provide additional information to the patient.

However, if a patient approaches a pharmacist for advice on homeopathy, the pharmacist should be able to advise on the lack of evidence on the efficacy of homeopathic products, discuss the formulation and composition of the product, and provide other pertinent advice. Importantly, pharmacists will be in a position to discuss healthcare options and be able to identify any more serious underlying medical conditions and, if required, refer the patient to another healthcare professional. Pharmacists should also ensure that patients do not stop taking their prescribed medication if they take a homeopathic product.

**The RPSGB believes that homeopathic products should only be used for the treatment of minor, self-limiting conditions, and must never be used for the treatment of serious medical conditions.**

## Licensing of homeopathic products

The Medicines and Healthcare Products Regulatory Agency (MHRA) licences homeopathic products that may be sold from pharmacies. For a conventional medicinal product to be licensed by the MHRA, extensive and expensive testing to demonstrate the quality, safety and efficacy of the medicine is required. However, for a homeopathic product, the MHRA only assesses quality and safety; robust evidence for efficacy is not currently required, even for those products that contain indications on the label. It is important to be aware that patients and customers may view the fact that the MHRA are now licensing homeopathic products with indications as formal approval that the products have been tested and shown to be effective, which is not the case.

## Homeopathic and herbal products

Many people confuse homeopathic with herbal products, most probably because homeopathic products are often derived from herbs and are called by their botanical name, e.g. both herbal and homeopathic products prepared using aloe will be called aloe. Further confusion may result from the fact that a single manufacturer may produce both homeopathic and herbal products. A table detailing the main differences between herbal and homeopathic products is given below to provide pharmacists with information to enable them to advise and inform the public of the differences between herbal and homeopathic products.

Homeopaths believe that homeopathy is based on three main principles, namely that like cures like, the minimal dose, and the use of a single medicine. Within the minimum dose principle is embodied the idea that the more dilute a medicine, the more potent it becomes, and that this potentiation requires a series of dilution and succussion (shaking) stages. From a molecular viewpoint, there is no guarantee that a homeopathic product diluted to 24X or 12C (i.e. a  $10^{24}$  dilution) or more would contain a single molecule of the starting material.

Homeopathic products available from community pharmacies are generally 30C dilutions although 6C dilutions are available for certain products (e.g. arnica; chamomilla; sulphur; thuja). A 30C dilution equates to a  $10^{60}$  dilution - well below the level at which any molecules of the starting material would be present. However, a 6C dilution represents a  $10^{12}$  dilution, which means that some molecules of the starting material remain in the product because it has not been diluted to below Avogadro's number.

**It is important to be aware that not all homeopathic products are ultradilute and it is possible for some homeopathic products to contain significant quantities of the starting material e.g. mother tinctures may be taken orally but are more commonly applied topically. However, in licensed products available from most community pharmacies, the starting material will have been considerably diluted.**

Herbal medicine is the use of plant remedies in the treatment of disease, and many currently used conventional medicines have their origins in herbal products and plant materials. Herbal products subscribe to dose-response pharmacology where the biological response varies in direct proportion to the dose or concentration of the product. Herbal products are known to cause adverse effects and to interact with conventional medicines.

The main difference between herbal and homeopathic products is that with herbal products, increasing the dose would be expected to increase the therapeutic effect, while homeopathic practitioners believe that the more a homeopathic product is diluted, the greater effect the product is expected to have. In addition, the dilution and succussion steps involved in the product of a homeopathic product are believed by homeopaths to be critical to the efficacy of the product. Furthermore, due to the different philosophies used in selecting a treatment for a condition, it would be reasonably expected that herbal and homeopathic products could not be used to treat the same condition, although this is not always the case in practice.

### **Definition of some terms used in homeopathy**

**Dilution** – homeopathic dilutions are usually centesimal, where 1 drop is added to 99 drops of diluent, or decimal where 1 drop is added to 9 drops of diluent. Diluents are generally ethanol and water mixtures.

**Potentiation** (also called dynamisation or attenuation) – homeopaths believe that this process increases the power of homeopathic products by successive dilutions and succussions of a mother tincture. Potentiation cannot occur without both dilution and succussion.

**Succussion** - the forceful agitation between each dilution step during the product of the homeopathic product. The number of times a product is succussed after each dilution step of potentiation is not well defined and can range from 20 to 100.

**Mother Tincture** – liquid products obtained following the maceration, incubation, and extraction of plant material, usually with an ethanol/water mixture. Mother tinctures can be given undiluted by the oral or topical routes, but are usually subject to potentiation.

## Differences between Herbal and Homeopathic Products

	<b>Herbal Products</b>	<b>Homeopathic Products</b>
What are they made from?	Naturally occurring plants, parts of plants or extracts of plants	Often plants but may be from mineral, animal or even synthetic material.
Do they contain active ingredients?	Often contain mixtures of many chemical compounds obtained from the plant although precise compositions can be variable due to the natural source.	Generally the starting material is diluted so that few or no molecules of the starting material remain in the product. Some products are administered orally and topically that do contain measurable amounts of the starting material.
How is the product made?	Herbal products are prepared using either extracts of the herbal material or through use of the crude drug itself.	Homeopaths believe that serial dilution and succussion (shaking) steps are critical in ensuring the efficacy of the product. They believe that the more succussion that takes place through the dilution steps, the more energy is imparted and the more efficacious the product
How are products selected?	In a manner similar to other medicines, herbal products are selected according to the range of symptoms they are known to treat. They are often used to restore, correct or modify a physiological function.	Homeopaths believe in the three principles of homeopathy, one of which is that like should be treated with like. For example, they believe that a substance that causes vomiting in high doses may be used to treat vomiting using a very dilute product.
How is a particular product selected?	Based on the symptoms presented, a product is selected taking account of the known pharmacological activity of the herbal product.	Homeopathic practitioners adopt a holistic approach where a detailed patient consultation takes place prior to a suitable product being recommended. The self selection of homeopathic products may be based on their traditional use in homeopathy.
How does the dose affect the efficacy of the product?	Increasing the dose will increase the effect and/or increase the risk of adverse effects.	Due to extensive dilution, homeopathy usually involves the administration of no, or an incredibly small amount, of the starting material. Homeopaths believe that the greater the dilution of a product the more potent and efficacious it becomes.
Are the products safe?	Although they are obtained from natural	Generally considered by homeopaths to be non-toxic and safe for

	<b>Herbal Products</b>	<b>Homeopathic Products</b>
	sources, they are not without unwanted effects and cannot be regarded as "safe". The active substance in many prescription medicines is obtained or derived from plant sources.	administration to adults and children, particularly at high dilution. It is important to note that some homeopathic products are not ultra-dilute and may contain discernable amounts of the starting material.  <b>See footnote below for advice on low dilution products.</b>
Are there any side effects?	May produce side effects.	Side effects have not been reported in the scientific literature for high dilution products. Homeopaths believe homeopathic products can cause aggravations (exacerbations or worsening of symptoms). May cause reactions in lactose intolerant patients.  <b>See footnote below for advice on low dilution products.</b>
Will they interact with prescription or other medicines?	Can interact with prescription and other conventional medicines.	No evidence of interactions between high dilution products and conventional medicines  <b>See footnote below for advice on low dilution products.</b>
Are they safe in pregnancy and when breastfeeding?	Certain herbal ingredients should be avoided or used with caution in pregnancy and while breastfeeding.	Considered by homeopaths to be suitable for use during pregnancy and while breastfeeding, but ideally under the guidance of a suitably qualified homeopath. However it is important that patients inform healthcare professionals if they are taking a homeopathic product during pregnancy and while breastfeeding, even if it is a highly diluted product.  <b>See footnote below for advice on low dilution products.</b>
Should I inform other healthcare professionals	Patients should inform healthcare professionals if they are taking herbal products.	Although homeopaths believe this is not necessary, it is important that patients inform healthcare professionals if they are taking a

	<b>Herbal Products</b>	<b>Homeopathic Products</b>
if I am taking these products?		homeopathic product, even if it is highly diluted.  <b>See footnote below for advice on low dilution products.</b>
Labelling	The label or packaging will indicate it is a “herbal medicinal product”.	Will include the words “homeopathic medicinal product” on the label.
Is it known how they work?	The effects of the active ingredients in a herbal product can be shown to have pharmacological actions.	There is no sound pharmacological or scientific basis to explain the activity of homeopathic products claimed by homeopaths.
What is the evidence to support the efficacy of these products?	There is scientific evidence to support the efficacy of a limited number of herbal products in specific conditions; however, for many herbal products, efficacy has not been formally evaluated.	There is no scientific or clinical evidence to support the efficacy of homeopathic products, although anecdotal reports of their effectiveness have been published, particularly when used as part of individualised homeopathic treatment by a homeopathic practitioner.

**Footnote**

Mother tinctures or homeopathic products of low dilution will contain measurable amounts of active materials. For those homeopathic products, it is more appropriate to use the guidance given for herbal products.