

## CERTIFIED HOMEOPATHIC ONLINE COURSE - SESSION 5:

- **Regulations**

### Regulation of Homeopathic Treatment

Homeopathic remedies are prepared according to the guidelines of the *Homeopathic Pharmacopeia of the United States (HPUS)*, which was written into law in the Federal Food, Drug, and Cosmetic Act in 1938. Homeopathic remedies are regulated in the same manner as nonprescription, over-the-counter (OTC) drugs. However, because homeopathic products contain little or no active ingredients, they do not have to undergo the same safety and efficacy testing as prescription and new OTC drugs.



The U.S. Food and Drug Administration (FDA) does require that homeopathic remedies meet certain legal standards for strength, purity, and packaging. The labels on the remedies must include at least one major indication (i.e., medical problem to be treated), a list of ingredients, the dilution, and safety instructions. In addition, if a homeopathic remedy claims to treat a serious disease such as cancer, it needs to be sold by prescription. Only products for self-limiting conditions (minor health problems like a cold or headache that go away on their own) can be sold without a prescription.

### The Regulation of Homeopathic Medicines

Since June 9, 1990, a number of changes in status of homeopathic remedies have taken place. Numerous remedies that were once sold as Over-The-Counter have moved to prescription status. This is due to the publication of the FDA Compliance Policy Guide 7132.15 "Conditions Under Which Homeopathic Drugs May Be Marketed," and the Homœopathic Pharmacopœia of the United States (HPUS). These documents form the basis for the regulation of homeopathic drugs in the United States.

On June 9, 1988 the first installment of the new edition of the HPUS (now called the Homœopathic Pharmacopœia Revision Service or HPRS) was published. On the same date, FDA's Compliance Policy Guide relating to the marketing of homeopathic medicines was published. Both documents had two year phase in dates, thus they became "effective" in June, 1990. The fact of the matter is that most manufacturers had phased in the provisions of both prior to that date.

### The Compliance Policy Guide

For many years (from 1938-1988) homeopathic drugs were sold in a regulatory vacuum. FDA action was based on institutional understanding and informal agreements between agency officials and industry members. This caused the FDA to regulate in an unpredictable manner that made the homeopathic industry unsafe from a regulatory and investment standpoint; and the practice of homeopathy open to the whims of local regulators. During the period, the FDA viewed all homeopathic remedies as prescription drugs. From 1982-1988, the industry, professional and consumer members of the community through the American Homeopathic Pharmacists Association (AHPA) worked with the FDA in the development of a regulatory framework called a Compliance Policy Guide (CPG). Although the community didn't get every provision that it sought, it is argued that the community obtained about 80% of its requests. The new CPG strengthened the definition of the homeopathic drug, set forth

guidelines for the prescription and nonprescription drugs and made clear packaging and labeling guidelines.

## Rx and Homeopathic Medicines

The most important element was that the CPG established that homeopathic drugs could be OTC; setting guidelines for an OTC homeopathic drug by saying that an OTC homeopathic was a homeopathic drug claimed for a self limiting condition which did not require medical diagnosis or monitoring and was non-toxic. Further, such drugs, whether sold on an active or reactive basis, needed to be fully labeled with at least one indication for use (and a package insert if Rx.) At one time, the industry was required to drop all Latin labeling but was able to get the regulation rescinded. The industry was not pleased with these restrictions, but they were better than the worst case scenario of all homeopathic drugs having the status of prescription products.



## Official and Non-Official Homeopathic Medicines

One could appreciate the FDA's actions from their vantage point of safety and efficacy. There was one other thing that FDA demanded. That was that the new Pharmacopoeia be "cleaned up" within the guidelines. Any drug included in the HPRS would be considered "official" and those not included in the HPRS would be "non-official." According to the understanding, any official drug could be sold without any further documentation being by the manufacturer.

Non-official drugs would require the manufacturer to produce a proving or sufficient clinical data for the FDA to make a determination as to whether the drug was in fact homeopathic. FDA still reserves the right to revise their criteria for what determines a homeopathic drug. The construct of an official and non-official drug is one that certainly benefits the community, although FDA has expressed a lack of comfort with the idea. The result was a new focus on the HPRS.

## The Role of the HPCUS

The HPUS is "written" by a group of pharmacists, physicians and lay people who meet 3-6 times a year to review monographs (information about specific drugs) and pharmacy procedures. Currently, there are about 1,350 drugs in the Pharmacopœia, 440 or so are prescription in some potency and 20 or so are Rx. For a drug to be included in the HPUS, it needs to have sufficient clinical data or proving to show efficacy. The process for review is very formal as are the criteria for acceptance. Both *Resonance* and *Homeopathy Today* have published extensively on these topics. All of the Pharmacopœia's activities are published for 90 days for public comment in *Resonance* and *Homeopathy Today*, among others. The decisions are finalized by the HPUS Board of Directors. OTC/Rx status is determined by the criteria outlined in the CPG, effectively toxicity and OTC uses for the products, i.e. a drug needs to be non-toxic and have an OTC indication for it to be classed OTC. The HPRS is a dynamic document, which can change. The changes are published in June and December of each year.



## Licensure

It is important to note that when looking at the distinction between OTC and Rx, one is compelled to look at the "lowest common denominator", that is the consumer in a natural foods store or pharmacy, not a trained homeopath. This has caused some problems as it relates to licensure, as many people who are very competently trained to use homeopathic remedies lack the license to obtain Rx products. The new results of the increased regulation of homeopathy is that, whether we agree with them or not, there are now clearly established guidelines for the manufacturing, marketing and sale of homeopathic medicines. When one considers that OTC homeopathic remedies were technically illegal prior to the Compliance Policy Guide, one can appreciate that the OTC is indeed a mixed blessing. On the one hand, many homeopathic remedies are now able to be sold over the counter without fear. Of course, there are some remedies, which continue to be prescription items. Clearly, this presents little difficulty for the fully licensed medical practitioner. It is the limited licensed practitioner that is most affected by the regulation. Time will tell what the ultimate impact is. Interested individuals should follow the issue closely in the press and feed back their ideas and comments to the HPCUS in Washington as well as their homeopathic pharmacists.

## Research Challenges

Homeopathy is difficult to study using current scientific methods because highly diluted substances (known as ultra-high dilutions or UHDs) cannot be readily measured, making it difficult to design or replicate studies. In addition, homeopathic treatments are highly individualized and there is no uniform prescribing standard for homeopaths. There are hundreds of different homeopathic remedies, which can be prescribed in a variety of different dilutions to treat thousands of symptoms. On the other hand, many aspects of the interactions between the homeopathic practitioner and his or her patients may be quite beneficial, and can be studied more easily.

## Controversies Regarding Homeopathy

Homeopathy is a controversial area of CAM because a number of its key concepts are not consistent with established laws of science (particularly chemistry and physics). Critics think it is implausible that a remedy containing a miniscule amount of an active ingredient (sometimes not a single molecule of the original compound) can have any biological effect—beneficial or otherwise. For these reasons, critics argue that continuing the scientific study of homeopathy is not worthwhile. Others point to observational and anecdotal evidence that homeopathy does work and argue that it should not be rejected just because science has not been able to explain it.



## Side Effects and Risks

Although the side effects and risks of homeopathic treatments are not well researched outside of observational studies, some general points can be made about the safety of these treatments:

- A systematic review found that homeopathic remedies in high dilution, taken under the supervision of trained professionals, are generally considered safe and unlikely to cause severe adverse reactions.

- Liquid homeopathic remedies may contain alcohol. The FDA allows higher levels of alcohol in these remedies than it allows in conventional drugs. However, no adverse effects from alcohol levels have been reported to the FDA.
- Homeopaths expect some of their patients to experience homeopathic aggravation (a temporary worsening of existing symptoms after taking a homeopathic prescription). Researchers have not found much evidence of this reaction in clinical studies; however, research on homeopathic aggravations is scarce.
- Homeopathic remedies are not known to interfere with conventional drugs.

## Licensing

There are currently no uniform licensing or professional standards for the practice of homeopathy in the United States; the licensing of homeopaths varies from state to state. Usually, a homeopathic practitioner is licensed in a medical profession, such as conventional or osteopathic medicine. Homeopathy is also part of the medical education for naturopathy.

Licensure as a homeopathic physician is available only to medical doctors and doctors of osteopathic medicine in Arizona, Connecticut, and Nevada. Arizona and Nevada also license homeopathic assistants, who are allowed to perform medical services under the supervision of a homeopathic physician. Some states explicitly include homeopathy within the scope of practice of chiropractic, naturopathy, physical therapy, dentistry, nursing, and veterinary medicine.

## If You Are Thinking About Using Homeopathy

- Do not use homeopathy as a replacement for proven conventional care or to postpone seeing a doctor about a medical problem.
- Look for published research studies on homeopathy for the health condition you are interested in.
- If you are considering using homeopathy and decide to seek treatment from a homeopath, ask about the training and experience of the practitioner you are considering.
- Women who are pregnant or nursing, or people who are thinking of using homeopathy to treat a child, should consult their health care provider.
- Tell all your health care providers about any complementary and alternative practices you use. Give them a full picture of all you do to manage your health. This will ensure coordinated and safe care.



## Does Medical Insurance Usually Cover Homeopathy?

Insurance companies are more likely to cover homeopathy when the person providing the service is a licensed health care professional, such as an MD or DO who also practices homeopathy.

## Have any Side Effects or Complications Been Reported From the Use of Homeopathy?



The FDA has learned of a few reports of illness associated with the use of homeopathic remedies. However, the FDA reviewed these reports and decided that the remedies were not likely to be the cause, because of the high dilutions.

Here is some general information that has been reported about risks and side effects in homeopathy:

- Homeopathic medicines in high dilutions, taken under the supervision of trained professionals, are considered safe and unlikely to cause severe adverse reactions.
- Some patients report feeling worse for a brief period of time after starting homeopathic remedies. Homeopaths interpret this as the body temporarily stimulating symptoms while it makes an effort to restore health.
- Liquid homeopathic remedies can contain alcohol and are permitted to have higher levels of alcohol than conventional drugs for adults. This may be of concern to some consumers. However, no adverse effects from the alcohol levels have been reported either to the FDA or in the scientific literature.
- Homeopathic remedies are not known to interfere with conventional drugs; however, if you are considering using homeopathic remedies, you should discuss this with your health care provider. If you have more than one provider, discuss it with each one.

As with all medicinal products, a person taking a homeopathic remedy is best advised to:

- Contact his health care provider if his symptoms continue unimproved for more than 5 days.
- Keep the remedy out of the reach of children.
- Consult a health care provider before using the product if the user is a woman who is pregnant or nursing a baby.

## What has Scientific Research Found out About Whether Homeopathy Works?

This section summarizes results from (1) individual clinical trials (research studies in people) and (2) broad analyses of groups of clinical trials.

The results of individual, controlled clinical trials of homeopathy have been contradictory. In some trials, homeopathy appeared to be no more helpful than a placebo; in other studies, some benefits were seen that the researchers believed were greater than one would expect from a placebo.

Systematic reviews and meta-analyses take a broader look at collections of a set of results from clinical trials. In sum, systematic reviews have not found homeopathy to be a definitively proven treatment for any medical condition. Two groups of authors found some positive evidence in the groups of studies they examined, and they did not find this evidence

to be explainable completely as placebo effects (a third group found 1 out of 16 trials to have some added effect relative to placebo). Each author or group of authors criticized the quality of evidence in the studies. Examples of problems they noted include weaknesses in design and/or reporting, choice of measuring techniques, small numbers of participants, and difficulties in replicating results. A common theme in the reviews of homeopathy trials is that because of these problems and others, it is difficult or impossible to draw firm conclusions about whether homeopathy is effective for any single clinical condition.

## **Are There Scientific Controversies Associated with Homeopathy?**



Yes. Homeopathy is an area of complementary and alternative medicine that has seen high levels of controversy and debate, largely because a number of its key concepts do not follow the laws of science (particularly chemistry and physics).

- It is debated how something that causes illness might also cure it.
- It has been questioned whether a remedy with a very tiny amount (perhaps not even one molecule)

of active ingredient could have a biological effect, beneficial or otherwise.

There has been some research studies published on the use of ultra-high dilutions (UHDs) of substances, diluted to levels compatible with those in homeopathy and shaken hard at each step of dilution. The results are claimed to involve phenomena at the molecular level and beyond, such as the structure of water, and waves and fields. Both laboratory research and clinical trials have been published. There have been mixed results in attempts to replicate them. Reviews have not found UHD results to be definitive or compelling.

There have been some studies that found effects of UHDs on isolated organs, plants, and animals. There has been controversy and debate about these findings as well.

- Effects in homeopathy might be due to the placebo or other non-specific effect.
- There are key questions about homeopathy that are yet to be subjected to studies that are well-designed--such as whether it actually works for some of the diseases or medical conditions for which it is used, and if so, how it might work.
- There is a point of view that homeopathy does work, but that modern scientific methods have not yet explained why. The failure of science to provide full explanations for all treatments is not unique to homeopathy.
- Some people feel that if homeopathy appears to be helpful and safe, then scientifically valid explanations or proofs of this alternative system of medicine are not necessary.

## **What Kind of Training do Homeopathic Practitioners Receive?**

In European countries, training in homeopathy is usually pursued either as a primary professional degree completed over 3 to 6 years or as postgraduate training for doctors. In the United States, training in homeopathy is offered through diploma programs, certificate programs, short courses, and correspondence courses. Also, homeopathic training is part of medical education in naturopathy. Most homeopathy in the United States is practiced along with another health care practice for which the practitioner is licensed, such as conventional medicine, naturopathy, chiropractic, dentistry, acupuncture, or veterinary medicine (homeopathy is used to treat animals). Laws about what is required to practice homeopathy vary among states. Three states (Connecticut, Arizona, and Nevada) license medical doctors specifically for homeopathy.



## **What do Homeopathic Practitioners do in Treating Patients?**

Typically, in homeopathy, patients have a lengthy first visit, during which the provider takes an in-depth assessment of the patient. This is used to guide the selection of one or more homeopathic remedies. During follow-up visits, patients report how they are responding to the remedy or remedies, which helps the practitioner make decisions about further treatment.

## CERTIFIED HOMEOPATHY ONLINE COURSE - SESSION 5 – QUESTION & ANSWERS

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY, STATE, ZIP, PC: \_\_\_\_\_

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Please be sure to fill out the information above, complete the test and e-mail or fax it back to us at [iridology@netzero.net](mailto:iridology@netzero.net) or 530-878-1119. We will grade your question & answer session and will let you know if we have any questions or concerns.

1. What is “homeopathic aggravation?”
2. What is a “UHD”?
3. What is a Monograph?
4. Currently, there are about 1,300 drugs in the Pharmacopœia, 420 or so are prescription in some potency and 40 or so are Rx. T/F
5. Homeopathic remedies are prepared according to the guidelines of the *Homeopathic Pharmacopeia of the United States (HPUS)*, which was written into law in the Federal Food, Drug, and Cosmetic Act in \_\_\_\_\_.
6. As with all medicinal products, a person taking a homeopathic remedy is best advised to: