Assisting the Patient Who Uses Homeopathic Medicines

The strong growth in natural products has led to an increasing number of homeopathic medicine departments in pharmacies across the country. Because there is still much controversy and misunderstanding by patients surrounding homeopathic medicine, U.S. Pharmacist *asked Andy Bormeth, R.Ph., president of the American Association of Homeopathic Pharmacists (AAHP), which represents the homeopathic drug industry and works as a liaison with FDA, state boards of pharmacy and pharmacy organizations, to discuss how pharmacists can best assist patients who use homeopathic medicines, the role homeopathy plays in healthcare, and to answer some basic questions regarding homeopathy.*

Who uses homeopathic medicines?

The typical consumer using homeopathic medicines is well-educated, health-conscious, female, and environmentally concerned. Roughly 40% of these consumers shop in a typical pharmacy (chain or independent) and are comfortable selecting a natural product, including homeopathy. They are driving the growth of natural products in the pharmacy market, which has been tracked at up to 40% annually.[1] Consumers shop for these natural products as they would any other OTC medicine, looking for an effective and safe product to help them with their health conditions.

Why do consumers use homeopathic medicines?

Consumers purchase homeopathic medicines because they perceive them to be natural and effective. Many consumers are dissatisfied with the side effects of conventional, Western medicines. They seek the benefits of a natural product, and they are disillusioned with the current medical system (believing that it is an insurance dominated HMO system, where decision making is dictated by cost concerns). These customers typically do the research to make their own decisions, and are willing to pay for unreimbursed complementary, alternative medicines (CAMs).

Homeopathic medicines are different from herbal remedies. Homeopathic medicines are typically used to treat most OTC therapeutic categories. They should be placed in those OTC categories because that is where patients look—not in some special alternative therapy section. Homeopathy is typically much safer than other OTC medicines, especially for children. Homeopathic medicines are easy to use, as the symptoms targeted by the product are listed on the package. Eighty percent of homeopathic medicines are available in consumer-oriented packages, which clearly explain the product and its uses. There have been several meta-analyses performed on hundreds of homeopathic clinical studies that indicate that the homeopathic medicines are, in fact, effective.[2,3]

How are homeopathic medicines regulated?

Homeopathic products are classified as drugs within the meaning of the Food, Drug, and Cosmetic Act as amended,[4] and are regulated as drug products (medicines) by the Food and Drug Administration. They may be either prescription or nonprescription products. The FDA does not regulate homeopathic drugs in precisely the same way as other drugs. Although homeopathic medicines are subject to the same regulations for manufacturing, marketing and sales as their conventional, Western counterparts, premarket approvals of homeopathic medicines are subject to the monograph process of the Homeopathic Pharmacopoeia of the United States (HPUS), rather than the IND/NDA process at FDA. As a result, FDA developed a Compliance Policy Guide (CPG 400.400 "Conditions Under Which Homeopathic Med-

Table 1

Differences Between Homeopathic Agents and Herbal Dietary Supplements

	Homeopathic Agents	Herbals
Legal status	Drug	Dietary supplement (under foods)
Standardization	HPUS (official compendium)	USP (less than 10)
Processing	Drug GMPs*	Food GMPs proposed
Claims	Indications for OTC symptom relief as per FDA OTC monographs	Structure/function (how it supports body function or general well-being)
Active Principle	Plant (80+%), mineral (15%), animal product, other (<5%)	Plant
Side Effect Potential	Very low	Moderate

**Good Manufacturing Practices (see 21 CFR, Parts 210 & 211).*

covery and advancement of the principles of homeopathy. He quit his medical practice and through translating medical texts and studying some of the then current theories, identified three main principles of homeopathy;

1. The Law of Similars ("like cures like")

Substances that cause certain symptoms in a healthy person can be used to relieve those same symptoms in someone suffering from them. For example, exposure to red onion (*Allium cepa*) causes runny and watery nose and eyes. In homeopathic form, a microdose of *Allium cepa* is used to relieve cold or hay fever symptoms of runny and watery nose and eyes.

2. The Minimum Dose

Homeopathic substances can be attenuated (tapered) to render them stronger as the potency increases, at the same time that the original substance is diluted. The result is a microdose of medicine, which triggers a healing response in the body.

3. The Treatment of Symptoms or Symptom Complexes, Instead of Disease States

Homeopathy views the body in a holistic manner, understanding each individual has unique characteristics—physical, mental, emotional—and unique responses to illness. Thus, each person's own set of symptoms guides the practitioner to the correct medicine.

Where can I find out more about homeopathic medicines?

The American Association of Homeopathic Pharmacists (AAHP) was founded in 1923 to represent the interests of homeopathic manufacturers, marketers, and pharmacists to regulatory agencies and other associations. The diverse association has continued to add retail pharmacists to its membership, as the industry has grown over the last decade. Pharmacist CE programs are available, as well as courses in the Compliance through Education programs and a monthly newsletter. AAHP sponsors a week-long CE program "Homeopathy for Pharmacists" in conjunction with the National Center for Homeopathy at Johns Hopkins University in Baltimore each June. Individual enrollments for pharmacists are $100 annually.

AAHP can be reached at 1-800-478-0421 or www.homeopathicpharmacy.org.

Resources

The National Center for Homeopathy (NCH)
1-703-548-7790 and www.homeopathic.org

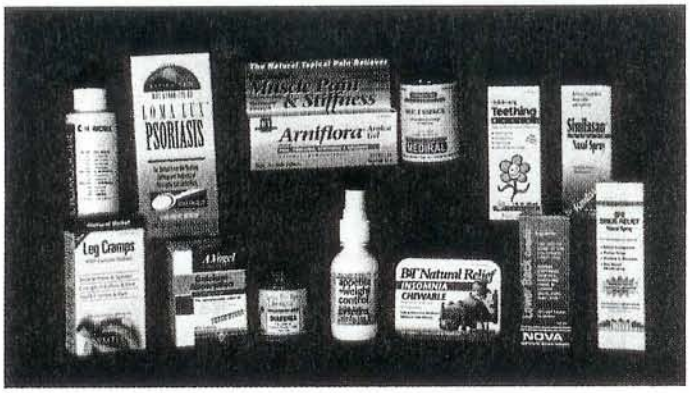
The Council on Homeopathic Education (CHE)
1-518-392-7975 and www.chedu.org

The American Institute of Homeopathy (AIH)
1-888-445-9988

Homeopathic Pharmacopeia Convention of the United States (HPCUS)
www.hpcus.com

REFERENCES

1. SPINscan Homeopathic Data, 12 months ending October 1999.
2. Linde K et al. Are the clinical effects of homeopathy placebo effects? Lancet (350) 9081, Sept. 1997:834–843.
3. Kleijnen J et al. Clinical trials on homeopathy. Brit Med J (302): 316–323.
4. Federal Food, Drug, and Cosmetic Act of 1938, as amended by the FDA Modernization Act of 1997; www.fda.gov/opacom/laws/fdcact/fdcact.html.
5. FDA. Compliance Policy guide (CPG) 7132.15, Conditions Under Which Homeopathic Medicines May Be Marketed. Rockville, MD. 1988. Section 400.400 of the U.S. FDA Compliance Policy Guide manual.
6. Homeopathic Pharmacopoeia Convention of the U.S. Homeopathic Pharmacopoeia of the U.S./Revision Service (HPUS/RS). Washington, DC 2000.
7. Dietary Supplement Health and Education Act of 1994, Public Law 103–417, 103rd Congress; www.fda.gov/opacom/laws/dshea.html.



Homeopathic medicines, some of which are shown above, are available in consumer-oriented packages, which clearly explain the products and their uses.

icines May Be Marketed),[5] which gives specific regulatory guidance for the marketing of homeopathic drugs. The CPG states:

Nonprescription homeopathic drug products may be sold only for self-limiting conditions recognizable by consumers...labeling must adequately instruct consumers in the product's safe use.

Just as for products that meet the requirements of the USP and NF, a product's compliance with the HPUS alone does not establish that it has been shown by appropriate means to be safe, effective and not misbranded for its intended use. However, as discussed below, measures are in place to assure that only safe, effective, and properly branded homeopathic drugs are marketed in the United States.

What is the Homeopathic Pharmacopoeia of the United States/Revision Service (HPUS/RS)[6]?

Homeopathic medicines have official compendial status in the United States. Royal Copeland, M.D., a homeopathic physician and U.S. senator from New York, was the principal author of the federal Food Drug and Cosmetic Act of 1938. Copeland understood the need for a separate homeopathic compendium, the HPUS, due to the differences between homeopathic and Western medicine. Since that time, the HPUS/RS has the same official status as the USP/NF. If a drug appears in both pharmacopoeias, it is subject to the requirements of the USP unless it is distinctly marketed, labeled and offered for sale as a homeopathic drug. It would then be subject to HPUS/RS requirements.

The HPUS/RS was first published in 1897 and is currently updated through a Revision Service. The Revision Service is published by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), a private, not-for-profit organization developed exclusively for charitable, educational and scientific activities. The HPCUS membership includes pharmacists, physicians, biochemists, botanists and other professionals. The HPCUS has several committees to guide the future direction of homeopathic medicine.

For a drug to be accepted for inclusion in the HPUS, the HPCUS must determine its safety and efficacy. The drug must be manufactured according to HPUS/RS requirements. An extensive review of all the available documentation by several committees of the Convention is necessary before a new monograph is accepted for publication. The HPCUS then decides at which dilution level the agent should be classified: OTC or prescription. A vast majority of homeopathic medicines marketed in the United States are nonprescription products, thus confirming their safety.

How are homeopathic medicines different from herbal remedies?

Many pharmacists associate homeopathy with herbal and nutritional supplements, which are regulated by the Dietary Supplement and Health Education Act (DSHEA).[7] But key differences exist between homeopathic drugs and dietary supplements. Over-the-counter homeopathic medicines must have a drug claim on the product label for self-limiting, self-diagnosable conditions. This is in contrast to dietary supplements, for which only a structure/function claim can be made. In other words, dietary supplements may not make claims for the diagnosis, relief, cure or mitigation of symptoms of a given condition or illness. Homeopathic medicines are regulated in the same sense as any other drug; therefore, OTC homeopathic medicines must have a therapeutic indication on their label and make claims for symptomatic relief. **TABLE 1** distinguishes homeopathic agents from herbal dietary supplements.

What is homeopathy and what are homeopathic medicines?

Although the precise mechanism of action of homeopathic drugs is not well understood, homeopathy is a 200-year-old system of medicine based on the observation that the body has the potential to heal itself. It uses natural substances, specially prepared, to stimulate the body towards homeostasis. This is in direct contrast to the typical Western approach of suppressing the symptoms.

This system of medicine was first postulated by a pioneer in medicine, disillusioned at that time with the current medical system available (e.g., blood letting, high-dose heavy metals, etc.). Dr. Samuel Hahnemann (1755–1843) is credited with the dis-